The University Of Sheffield.

Person-centred Use of Music in residents living with dementia and Associated changes in behaviour in care homes (NIHR164000)

The PUMA study

RESEARCH PROTOCOL
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Sheffield Clinical Trials Research Unit (CTRU)

The PUMA Study Protocol

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

Contents

Abbreviations

Definition of terms

AE – Adverse Event
CCC – Confirmation of Capacity and Capability
CDR – Clinical Dementia Rating
CEAC – Cost-Effectiveness Acceptability Curve
CI – Chief Investigator
CLARHRC-YH – Collaboration for Leadership in Applied Health Research and Care Yorkshire & Humber
CONSORT – Consolidated Standards of Reporting Trials
CRF – Case Report Form
CQC – Care Quality Commission
CTRU – Clinical Trials Research Unit
DCCs – Dementia Care Champions
DEEP – Dementia Engagement and Empowerment Project
DMEC – Data Monitoring and Ethics Committee
DMP – Data Management Plan
DRAiSY – Dementia Research Advisory in South Yorkshire
eCRF – Electronic Case Report Form
EQ-HWB – EQ Health and Wellbeing questionnaire
FITS – Focused Intervention Training and Support
GDPR – General Data Protection Regulation
GCP – Good Clinical Practice
HRA – Health Research Authority
HTA – Health Technology Assessment
ICC – Intra-Cluster Correlation Coefficient
ICER – Incremental Cost-Effectiveness Ratio
ICH – International Conference on Harmonisation
INVOLVE – National Advisory Group for Public Involvement in Research (UK)
ISF – Investigator Site File (This forms part of the TMF)
ITT – Intention-to-Treat
MCID – Minimum Clinically Important Difference
MiDAS – Music in Dementia Assessment Scale
MICE – Multiple Imputation by Chained Equations
MLM – Mixed Effects Linear Model
mNCA – Model Non-Commercial Agreement
NHS – National Health Service
NICE – National Institute for Health and Care Excellence
NICHE – Nurturing Innovation in Care Home Excellence
NIHR – National Institute for Health and Care Research
NPI – Neuropsychiatric Inventory
NPI-NH – Neuropsychiatric Inventory – Nursing Home version
NPT – Normalization Process Theory
PI – Principal Investigator
PIS – Participant Information Sheet
PPIE – Patient and Public Involvement and Engagement
PROM – Patient Reported Outcome Measure
PSSRU – Personal Social Services Research Unit
QA – Quality Assurance
QC – Quality Control
QALY – Quality-Adjusted Life Year

QUALID – Quality of Life in Late-Stage Dementia Scale
R&D – Research and Development
RCT – Randomised Controlled Trial
RDN – Research Delivery Network
REC – Research Ethics Committee
REML – Restricted Maximum Likelihood
SAE – Serious Adverse Event
SAP – Statistical Analysis Plan
SD – Standard Deviation
SOP – Standard Operating Procedure
TFA – Theoretical Framework of Acceptability
TIDieR – Template for Intervention Description and Replication
TMF – Trial Master File
TMG – Trial Management Group
TSC – Trial Steering Committee

1. General Information

1.1 Investigator details

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1.4 Role of the Funder

The funder has reviewed the research protocol but will have no role in data collection, analysis, data interpretation, report writing or in the decision to submit the report for publication. The funder has approved the selection of members for oversight committees.

1.5 Protocol Amendments

None

Trial Summary

Study title	Person-centred Use of Music in dementia Associated changed behaviours in care homes (PUMA): a cluster randomised controlled trial
Sponsor	Sheffield Health and Social Care National Health Service Foundation Trust
Funder	This study is funded by the National Institute for Health and Care Research - Health Technology Assessment Programme (NIHR164000)
ISRCTN	To be added
Project start date	01 June 2025
Project end date	30 November 2028.
Aims	• To determine whether a personalised music intervention, delivered through staff training informed by the Focused Intervention Training and Support model, reduces changed behaviours in care home residents with dementia compared to standard practice, as measured by Neuropsychiatric Inventory – Nursing Home version scores over 12 months. • To explore whether the intervention impacts residents' quality of life, wellbeing, and use of health and social care resources.

Trial design	Parallel group, cluster randomised controlled trial with 58 care homes randomised 1:1 to intervention or usual care.
Internal pilot/feasibility criteria	**A 6-month internal pilot to assess feasibility of site set-up and recruitment, based on:** • Number of care homes open and recruited 1st participant • Number of participants recruited • Availability of data to contribute to the primary outcome
Setting	Care homes with and without nursing with residents living with dementia and associated changed behaviours across the United Kingdom. Homes may be dementia-specialist or mixed settings, provided eligible participants meet inclusion criteria.
Participants	**Inclusion Criteria:** • Diagnosis of dementia recorded in care records • Identified by care staff as displaying behavioural care needs (e.g. distress, anxiety, apathy, agitation) • Permanent resident in a care home with 24/7 care provision • Capacity to consent, or availability of a personal/nominated consultee • Involvement of a permanent care staff member supported by management to participate and deliver the intervention **Exclusion Criteria:** • No recorded diagnosis of dementia • No behavioural care needs identified by staff • Known adverse sensitivity to music • In respite or short-term care • Already receiving a formal, structured personalised music intervention as part of their usual care (e.g. an intervention based on the Focused Intervention Training and Support model or equivalent systematic approach that integrates music into care planning and daily practice**)** • Care staff on temporary contracts or expected to leave within 12 months
Intervention & control groups	Intervention: Focused Intervention Training and Support model-based training for staff to integrate personalised music into care planning. Control: usual care which may include varied, non-standardised music use.

Primary outcome(s)	Average total score on the Neuropsychiatric Inventory – Nursing Home version over the 12 months post-baseline.
Secondary outcome(s)	Quality of Life in Late-stage Dementia, EQ Health and Wellbeing questionnaire – proxy reported, Resource-Use Measure, Music in Dementia Assessment Scale, Process Evaluation, Cost-Effectiveness.
Duration of recruitment period and first enrolment date	16 months; expected first enrolment February 2026
Duration of follow-up	12 months per participant
Target sample size	406 participants across 58 care homes
Definition of end of trial	The end of trial is defined as the date of the final follow-up assessment for the last participant. Sites will be closed following data cleaning, and the Research Ethics Committee will be notified accordingly.

2. Introduction

2.1 Background

Around 70% of people living in United Kingdom (UK) care homes have dementia or severe memory problems, highlighting the substantial need for residential and nursing care [1]. Around 70% of care home residents experience profound cognitive and communicative decline, along with significant physical and functional impairments. Residents sometimes misunderstand care environments and care staff intentions, resulting in what is often termed ‘distress and unmet need’; this term is preferred by our Participant and Public Involvement and Engagement (PPIE) group and international dementia campaigners instead of the more usual ‘challenging behaviours’ - aggression, agitation, resistance to care labels. Restrictive practices—hands-on interventions/physical restraint—are distressing for residents and carers and are discouraged by the Care Quality Commission (CQC) and Royal College of Nursing (RCN). Antipsychotic medication leads to increased risks of falls, strokes, myocardial infarction, and mortality; National Institute for Health and Care Excellence (NICE) limits its use to situations where alternative methods have failed or where there is risk of harm. There is an urgent need for alternative, non-pharmacological approaches to address distress and unmet need in people living with dementia.

The UK spends £35 billion on dementia care per year. The incidence of antipsychotic prescriptions is 17.4 times as high, and the incidence of falls is twice as high in people with dementia compared to those without, increasing hospitalisations —often attributed to polypharmacy and antipsychotics. Resident dignity and respect are important to care providers. NICE 2019 guidelines list music as a treatment option for distress. Our consultations with care home staff highlighted concerns about medication and physical restraint, alongside positive experiences of using music to reduce agitation and improve the mood of residents and staff. However, most care homes reported uneven use of music based on tacit knowledge, rarely—if ever—incorporating it into care plans. Care home staff were supportive of a trial to systematise the use of music in dementia care homes. Improvement in dementia care is a James Lind Alliance priority;

the National Institute for Health and Care Research (NIHR) and National Health Service (NHS) England identify music in dementia care as a research priority. The International Longevity Centre reported that high-quality music provision was available in only 5% of care homes, highlighting the need for large-scale effectiveness and implementation research. Guidelines do not provide clear and consistent advice on when or how to implement music into dementia care. The literature mostly comprises small studies of diverse interventions, and there is a lack of high-quality, large-scale controlled trials on music-based interventions[2-5]

Music interventions in peer-reviewed literature are heterogeneous, idiosyncratic, and often under-described, and rarely, until recently, addressed cultural sensitivities. Music-based interventions improve neuropsychiatric symptoms in mild dementia, but largely through group interventions with no personalisation—a key mediator of effectiveness and an aspect our PPIE members highlight as important. Randomised controlled trials (RCTs) of personalised music interventions [4] have small sample sizes. Determining a single “best” approach for personalised music delivery in care homes—many of which already have access to music streaming services—is challenging. For this reason, the intervention is deliberately non-prescriptive about the specific music used. Instead, it focuses on providing the supporting framework, training, and processes that enable staff to integrate personalised music effectively into everyday care.

The Focussed Intervention Training and Support (FITS) model [6] is an evidence-based process for the effective training of care home staff. Dementia Care Champions (DCCs) are created who, during protected training time, develop their skills in dementia care and disseminate good practice within their care home. A trial of the FITS approach reported a 40% reduction in antipsychotic prescribing in dementia. FITS is already delivered across a large number of UK care homes. By combining this robust training process with personalised music, we offer an intervention that can be delivered at scale [6].

We ran a search which found seven relevant systematic reviews from 2023 on music in dementia care. These reviews recommend large-scale trials in care homes [2-5] focusing on personalised music [4] for dementia and changed behaviours [2, 4, 5, 7] using consistent outcomes [2-5], and analysing long-term sustainability[2-5]. The PUMA trial addresses these priorities through its cluster randomised design across 58 UK care homes, its focus on residents with dementia and changed behaviours, staff training for personalised music integration, use of validated instruments, and extended follow-up with process evaluation. We use the term 'changed behaviours' as recommended by Alzheimer's Society UK [8] and Dementia Australia [9], avoiding more negative labels.

On 2 February 2024, we searched the WHO International Clinical Trials Registry Platform back to April 2023 (the date of the latest searches run by systematic reviews) and found 13 trials involving music in dementia. There are no recent large-scale, high-quality trials examining music-based interventions for dementia care specifically within the UK care home context. The recently registered trials either focus too narrowly on specific music delivery methods or programmes, rather than on feasible implementation approaches, or do not target dementia and changed behaviours in care homes. Of trials in care home or inpatient settings, none were in the UK, with sample sizes ranging from 2 to 108. In the largest trial, the intervention for nursing home residents included music only as one component among other activities such as aromatherapy, massage, multisensory stimulation, and reminiscence. A recently published feasibility study focused on community-dwelling people, not care home residents, and examined sleep outcomes—not changed behaviours [10].

2.2 Rationale for current study

UK care homes mostly use music on an ad hoc basis, rather than systematically. NICE guidelines recommend music therapy for changed behaviours but lack implementation details. The NHS Long Term Plan prioritises improving dementia care. Existing trials on music interventions for dementia often have methodological limitations or a narrow focus. Only 5% of UK care homes offer quality music therapies, despite managerial support for their adoption.

PUMA will evaluate standardised training of UK care home staff in personalised music therapy, providing Level 1 evidence using rigorous methodology. Findings can inform specialty frameworks and guide the large-scale adoption of best practices across UK care systems. The trial addresses a crucial evidence gap in using music interventions for dementia and changed behaviours, meeting stakeholder demand for affordable non-pharmacological approaches and potentially inspiring nationwide practice change.

The study population comprises care home residents with a diagnosis of dementia and behavioural symptoms such as agitation or distress. The comparator is standard care, which may involve informal or inconsistent use of music, or other approaches such as the FITS model delivered without the personalised music element, and without a structured music implementation process. The intervention is low-risk and non-invasive, with potential benefits including improved behaviour, well-being, and reduced medication use. The study will be conducted in accordance with the protocol and International Conference on Harmonisation Good Clinical Practice (ICH-GCP).

3.Aim and objectives

3.1 Aim

To evaluate whether incorporating a personalised music intervention into care plans, delivered through FITS-informed staff training, reduces distress and changed behaviours in people with dementia compared to standard care.

3.2 Objectives

Primary Objective

To determine whether a personalised music intervention integrated into care planning using the FITS model reduces neuropsychiatric symptoms in care home residents with dementia and changed behaviours, measured by the total score on the Neuropsychiatric Inventory – Nursing Home version (NPI-NH) [11], compared to usual care.

Secondary Objectives

- To evaluate the impact of the intervention on resident quality of life using the Quality of Life in Late-Stage Dementia (QUALID) scale.
- To assess health-related quality of life using the EQ Health and Wellbeing questionnaire proxy reported (EQ-HWB-9-Proxy).
- To capture health and social care resource use using a bespoke resource use survey.
- To assess residents' direct responses to the music intervention using the Music in Dementia Assessment Scale (MiDAS) [12].

- To conduct a process evaluation of the implementation of the FITS-based music intervention.
- To determine the cost-effectiveness of the intervention from a health and social care perspective.

4.Trial Design

A multicentre, pragmatic, parallel group, cluster randomised controlled trial with a 12-month follow-up and within-trial health economic analysis. Clusters are care/nursing homes. The trial aims to recruit 406 participants from 58 care homes across the UK.

The trial will be conducted in 58 care homes with and without nursing in the UK. As far as possible we will ensure diversity in size (less than 20 v 20 more beds), ownership (private v not-for-profit, local authority, and NHS-managed homes), CQC quality ratings (outstanding/good v requires improvement/inadequate), dementia care specialist (Y/N), prior training exposure, and geographic spread, including rural and underserved areas and the devolved administrations. To achieve balance by as many of these characteristics as possible while still achieving our target sample size we will begin by recruiting all eligible homes that express an interest. We will monitor recruitment by each of these characteristics and after recruiting around 20 homes we will begin targeted recruitment targeting and approach homes with characteristics that are underrepresented in our recruitment so far. Homes will be randomly allocated in a 1:1 ratio to intervention or control arms (29 homes per group).

Care home services (both nursing and residential) in the UK are primarily delivered by independent providers. These range from small, single-home businesses (with around 4,000 homes owned and operated by individuals) to large multinational chains owning over 100 homes. The largest six providers account for approximately 11% of care homes and 17% of beds nationally. This variation in provider size and structure has implications for how care homes operate and engage with research.

We plan to approach approximately 300 care homes to participate in the trial. Based on feasibility work and consultation with 10 care home managers, we anticipate that 200 homes will express interest, 100 will receive an initial study visit, and 58 will be recruited into the trial. Across these homes, we expect to approach around 648 residents (approximately 12 per home). We anticipate that 406 residents (average of 7 per home) will consent and be included in the trial.

Our recruitment strategy is supported by research networks including the Nurturing Innovation in Care Home Excellence in Leeds partnership (NICHE-Leeds), and the NIHR Collaboration for Leadership in Applied Health Research and Care Yorkshire and Humber (CLAHRC-YH), as well as sector-facing partnerships such as the National Care Forum. In line with evidence-informed guidance (e.g., On your marks, get set, pause: what care home teams should consider before partnering with a trial research group) [13], we will ensure that care home engagement is tailored, transparent, and responsive to provider needs and context.

A 6-month internal pilot, with clear progression criteria to full trial (see section 8.3), will assess the feasibility of site set-up and recruitment. The internal pilot will include all homes open within the first 6 months after the first home opens. Progression will be assessed by the Trial Steering Committee (TSC) in the month following this period. Pilot data will contribute to the final analysis. If amber criteria are met, a recovery plan will be agreed with the TSC and submitted to the funder.

The primary analysis will be conducted at the participant level, accounting for clustering. Baseline characteristics of homes and residents will be summarised to assess balance across arms. Usual care, including any ad-hoc use of music, will be recorded systematically throughout the trial using a standardised documentation tool.

The study will run over 42 months, including 8 months for set-up, 16 months for recruitment, 12 months for follow-up, and 6 months for data cleaning, analysis, and reporting.

4.1 Blinding

Outcome assessments will be conducted by independent assessors from research delivery network (RDN) Agile team or NHS Trust research staff depending on what is agreed during set-up discussions with each care home. Blinding of participants and care home staff is not feasible due to the nature of the intervention, which involves integrating music into personalised care plans, and the need to time assessments appropriately and extract process data from care home records.

The trial statistician will remain blind until the Statistical Analysis Plan (SAP) has been signed off. To reduce bias, a cluster randomisation process by care home will be used after eligibility, consent, and baseline data collection. Randomisation and allocation will be conducted remotely by the lead statistician at the Sheffield Clinical Trials Research Unit (CTRU), with the trial statistician remaining blind to group allocation (details of how this will be achieved are in Randomisation and Allocation). Group allocation will be communicated to homes by the trial manager or delegate.

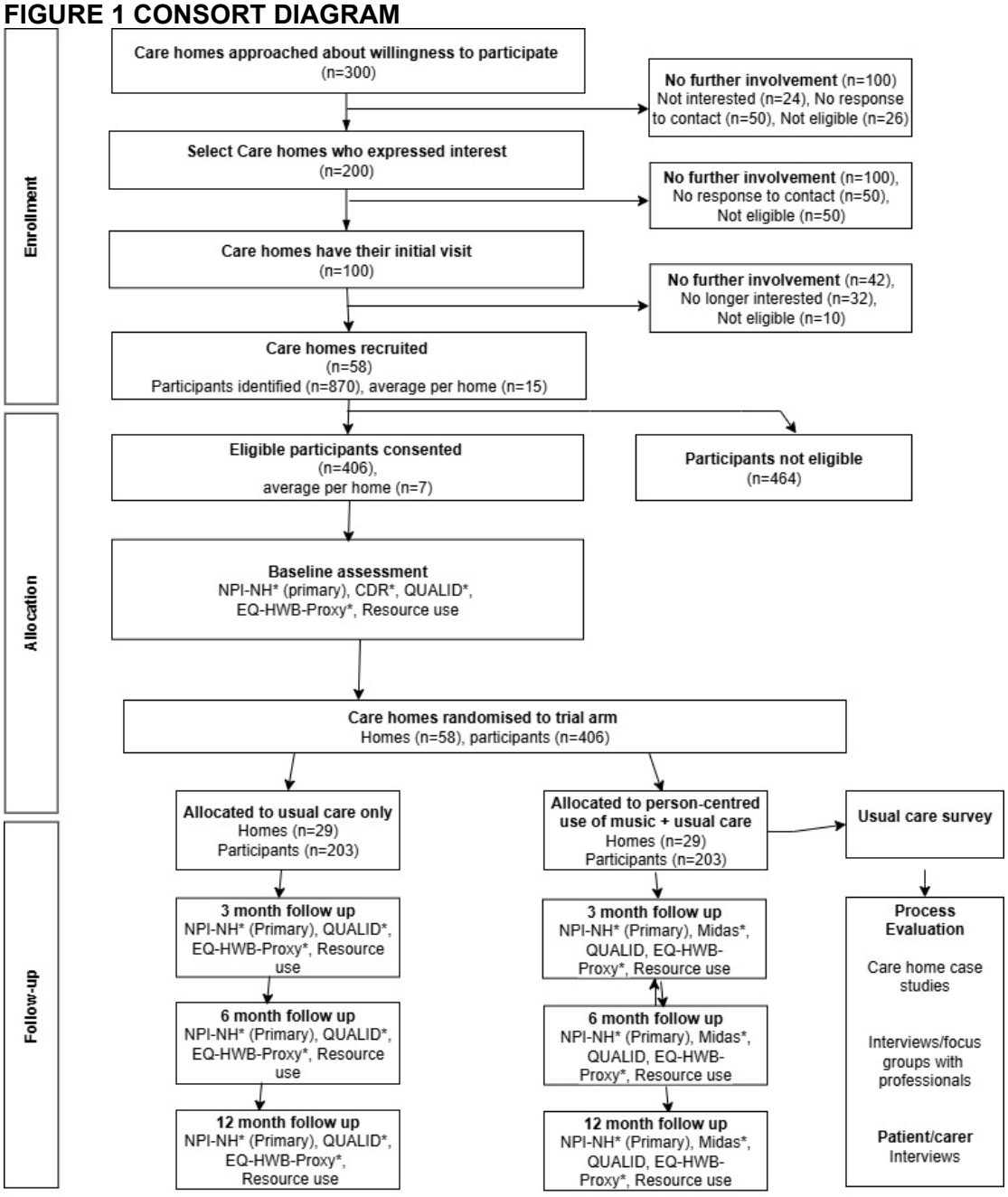
4.2 Unblinding

Not applicable – this is an open-label cluster-randomised study. Allocation is known to participating care homes and care staff following randomisation. As the intervention involves integrating music into care planning, blinding of participants and staff is not feasible.

Wherever possible, follow-up outcome assessors (whether care home staff or delegated research delivery personnel (e.g. RDN Agile team or NHS Trust research staff)) will remain blinded to allocation. However, we acknowledge that inadvertent unblinding may occur (e.g. staff referring to the intervention during assessments). If this happens, the assessor will record the incident in the trial database, and a replacement assessor may be allocated for subsequent visits where feasible. The frequency and circumstances of unblinding events will be monitored and reported to the Trial Management Group (TMG).

All processes relating to allocation and data confidentiality will be managed in accordance with CTRU standard operating procedure (SOP) ST009 and documented within the Trial Master File (TMF).

FIGURE 1 CONSORT DIAGRAM



*NPI-NH - Neuro-Psychiatric Inventory for Nursing Homes, *CDR - Clinical Dementia Rating scale, *QUALID - Quality of Life in late stage Dementia, *EQ-HWB-Proxy - EQ Health and wellbeing measure, *Midas - Music in Dementia Assessment Scale,

5. Selection of care homes and participants

5.1 Selection of care home

Inclusion:
Care homes will be purposively selected based on the following:

- Provide residential and/or nursing care for adults, including people with dementia.
- Located in the UK.
- Willing and able to participate in trial procedures, including cluster randomisation, training, and intervention delivery.
- At least 12 eligible residents (target of 15).
- Management commitment, including appointing a senior staff member as research lead.
- Involvement of at least two permanent care staff members who have consented to take part, is supported by management, and will act as a study champion to assist with training and intervention delivery.

Exclusion:
Care homes will be excluded if:

- Judged by the trial team to lack capacity to participate in research at the time of approach. This may include care homes experiencing staffing shortages, organisational instability, or those currently under review by the CQC due to concerns about the quality of care.
- Currently involved in other dementia studies that may conflict with delivery or evaluation.

A purposive sampling strategy will be used to ensure diversity across key factors, including care home type (residential vs nursing), size, ownership model (e.g. private, charity, local authority), populations served (e.g. people with advanced dementia, or mixed needs), type of care provided (e.g. dementia specialist, end-of-life care), CQC quality ratings, previous dementia-specific training (e.g. FITS), experience with personalised music or similar interventions, and geographic location, including rural and underserved areas.

Recruitment will be supported through collaboration with research networks and care sector organisations, including RDN Agile, NICHE-Leeds, CLAHRC-YH, and the National Care Forum. Care homes rated as providing inadequate quality will be excluded from the trial due to ethical and safety concerns, operational instability, potential issues with data quality and reliability, challenges in obtaining informed consent and engagement, and risks to the study's reputation and participant recruitment.

Care home managers will be contacted via email and phone by the research team and provided with information about the study aims, selection rationale, and participation requirements. Those interested will attend an in-person or online meeting to explore involvement in more detail. Managers will be encouraged to consider how the study fits with their organisational priorities and capacity before formally agreeing to take part [13]. Written consent will be obtained from the care home, and a research lead will be appointed within each home to facilitate the study.

The research lead, typically the care home manager or a senior staff member, will coordinate resident and staff identification, training, and data collection activities. They will receive training and guidance on study procedures, eligibility and consent

processes, and intervention delivery (where applicable). Ongoing support will be provided by the research team throughout the trial to maintain engagement and fidelity.

5.2 Selection of participants

Inclusion Criteria:
Residents must meet all of the following criteria to be eligible for participation:

- Formal diagnosis of dementia as recorded in the resident's care home records (e.g. GP summary, hospital correspondence, or other medical documentation available in the care home).
- A resident that care staff identify as presenting with a behavioural care need (for example distress, anxiety, apathy, agitation)
- Permanent residency in a care home, with continuous care provision (24 hours a day, 365 days a year).
- Capacity to consent, or a designated consultee providing an opinion on participation.
- Involvement of a permanent care staff member at least two permanent care staff members who consent to participation and act as champions, supported by their manager to undergo training and deliver the intervention.

Exclusion Criteria:
Residents will be excluded if any of the following apply:

- Absence of a known diagnosis of dementia recorded in care records.
- Residents that care staff do not identify as presenting with any behavioural care need (for example distress, anxiety, apathy, agitation)
- Known sensitivity to music that is especially upsetting.
- Currently in respite or short-term care.
- Already receiving a formal, structured personalised music intervention as part of their usual care (e.g. an intervention based on the FITS model or equivalent systematic approach that integrates music into care planning and daily practice)
- Care staff members on temporary contracts or anticipated to leave within the next 12 months

5.3 Participant identification

Potential participants will be identified by the care home manager and/or an identified research lead at each participating care home. The care home manager or the research lead will apply the eligibility criteria objectively to all residents, without consideration of known or assumed responsiveness to music, to minimise selection bias. A total of 58 care homes will be recruited, with approximately 648 residents approached (an average of 12 residents per home). We anticipate that around 406 participants (approximately 7 per home) will consent and be enrolled in the trial.

To monitor potential recruitment bias, each site will maintain a simple record of residents considered for inclusion. This record will note whether residents met the eligibility criteria and, where possible, broad reasons for non-recruitment (for example, declining participation or lack of capacity). No detailed screening data will be collected. This approach will allow the study team to monitor recruitment processes and assess the representativeness of the sample, while minimising burden on care homes and maintaining privacy.

Information about the study will be provided to potential participants in an accessible format by care home staff. Interested residents or their advocates will receive an information sheet and be invited to contact one of the care home staff. Subsequently, care home staff or a research team member (e.g. a Clinical Trials Assistant from the community mental health trust) will discuss the study in detail, answer any questions, and allow sufficient time for informed decision-making, with options for in-person, phone, or video consultations as required.

In recruiting care homes and residents and planning training sessions we will seek to minimise the gap between participant's baseline data collection and the start of FITS training for their home. This is to increase the chances of the training having started when we collect the first set of outcomes data at 3 months post-randomisation. As training is conducted for cohorts of 4 to 6 homes at the same time and approximately 50% of homes will be allocated to control, gaps that are longer than 3 months will be unavoidable in some cases but will not preclude the training being provided

5.4 Informed consent process

Eligibility will be confirmed by care home staff, the care home manager, or a delegated research lead. Overall responsibility for confirming eligibility will sit with the care home manager or designated research lead, as recorded on the delegation log.

Informed consent (or consultee declaration) will be obtained by trained and delegated care home staff, supported by an Agile Research Nurse or member of the Agile Research Delivery Team. Consent or consultee declaration will only be taken by individuals who are suitably qualified, having received GCP training and study-specific training on the trial protocol, including the consent and consultee process. This ensures adherence to legal and ethical requirements when working with participants who may lack capacity. This process will ideally take place in person at the care home once a potentially eligible resident is identified.

Potential participants or their representatives will be given accessible study information and the full Participant Information Sheet (PIS). A minimum of 7 days will be allowed for consideration, with additional time if needed. They will have the opportunity to ask questions and may take materials away to support informed decision-making.

Capacity to provide informed consent will be assessed by trained staff using the framework set out in the Mental Capacity Act framework [14]. Residents assessed as having capacity will provide written informed consent. For those lacking capacity, the care home team will liaise with the care home manager to identify a suitable personal consultee (e.g. a family member or close friend) [14]. If a personal consultee is unavailable, a nominated consultee (e.g. a professional involved in the resident's care but independent of the trial) may be approached. If the consultee believes that participation aligns with the resident's wishes, values, or best interests, they will complete a Consultee Declaration Form.

Consent or consultee declaration will include agreement to take part in trial assessments, access care records, and participate in any relevant ancillary sub-studies. Participant-facing materials will be co-developed with our PPIE panel to ensure accessibility and relevance.

Written consent will also be obtained from care home staff involved in implementing the intervention (e.g. developing music care plans) or taking part in qualitative interviews. Staff participation will be agreed in discussion with care home management, with staff provided with clear information about the nature of their

involvement, the time commitment required, and their right to decline without consequence. For those who agree, written informed consent will be taken prior to training or data collection activities. Staff engagement will be monitored as part of the process evaluation to understand levels of participation, barriers and facilitators to involvement, and implications for implementation at scale.

5.5 Co-enrolment guidelines

Participants may take part in other observational or qualitative research studies during their involvement in this study, provided that participation does not place undue burden on them or interfere with the objectives or delivery of this study.

Co-enrolment in other interventional studies, including RCTs, is not permitted to avoid potential confounding effects on outcomes and ensure participant safety and data integrity.

Sites should inform the CTRU if a participant is currently involved in, or is being considered for, another study. The CI and CTRU will assess any proposed co-enrolment in observational or qualitative studies on a case-by-case basis, taking into account the nature and timing of the other study, the participant's capacity to take part in both, and any possible impact on this study.

6. Randomisation and enrolment

A total of 58 care homes will be randomly allocated in a 1:1 ratio to either the intervention group (FITS-informed personalised music intervention) or the control group (usual care).

Cluster randomisation will occur once a care home has been confirmed as eligible, and has provided organisational consent, and once participants' consents have been obtained and participants' baseline data have been collected. The randomisation list will be created remotely by the trial statistician at the Sheffield CTRU, at the start of the trial before any homes have been recruited. For example, the first 4 entries on the list might be Treatment, Control, Control, Treatment. The list will then be provided to the trial manager or a delegated team member who will use the list to inform the care home of their group allocation by phone and followed up with written communication. In the hypothetical example above for example the first home to be recruited will be allocated Treatment the second and third would be allocated Control and so on. The trial statisticians will remain blind to group allocation and the order in which homes are recruited until the SAP has been signed off. We will use simple randomisation using random block sizes. Randomisation will take place prior to the start of any intervention-related training or activities.

Due to the nature of the intervention, blinding of care home staff is not feasible. Outcome assessments will be conducted either by care home staff or delegated research delivery personnel (e.g. RDN Agile team or NHS Trust research staff) depending on arrangements agreed during site set-up. Wherever possible, those conducting follow-up outcome assessments will remain blinded to allocation; however, we acknowledge that inadvertent unblinding may occur (e.g. if staff refer to the intervention during assessments). To minimise bias, standardised procedures will be followed for all assessments. Group allocation will be documented at the site and centrally maintained by the CTRU. Participants (or their consultees) will be informed of their care home's allocation following randomisation.

7. Trial treatment

7.1 Participants randomised to the Person-centred Use of Music in dementia-associated behaviours in care homes (PUMA) intervention plus usual care

The intervention is reported in line with the Template for Intervention Description and Replication (TIDieR) framework [15] for reporting complex interventions). *(Name)* Person-centred Use of Music in dementia Associated changes in behaviours in care homes (PUMA). *(Why)* The aim is to support staff in embedding meaningful, personally significant music into routine care as a non-pharmacological strategy for managing distress and enhancing wellbeing. The intervention seeks to reduce distress behaviours and enhance mood, engagement, and connection, in line with evidence supporting music-based interventions in dementia care [3]. *(What)* Participants allocated to the intervention arm will receive person-centred music integrated into individualised care plans, *(Who provides it)* delivered by trained care home staff, *(How)* face-to-face, *(Where)* in the care home. The intervention is delivered within the framework of the FITS model and draws upon Cohen-Mansfield's Comprehensive Process Model of Engagement of Persons with Dementia [16].

(*How well - Planned)* Care home staff will be trained to develop skills in person-centred [17, 18], and the use of music as an active therapeutic stimulus. *(Tailoring)* The principles of life story work and strength-based approaches are embedded within the FITS-informed framework and will underpin how staff integrate personalised music into care, rather than being delivered as standalone training modules.

(*How well - Planned)* Training will be delivered across three online sessions (each 3 hours), spaced a minimum of two weeks apart:

- **Session 1** introduces person-centred music, the rationale for its use, and reflection on current practice.
- **Session 2** develops practical skills, assigns staff to work with individual residents, and initiates music preference exploration.
- **Session 3** provides a forum for feedback, review of music care planning, troubleshooting, and final reflection.

Across all sessions, the content will reflect the principles of person-centred dementia care, including drawing on residents' life histories and strengths to inform personalised music choices and integration into care plans *(Tailoring)*. Training is delivered by facilitators with teaching qualifications and experience in dementia care. All trainers will hold a minimum Level 2 health/social care qualification and at least one year of dementia care experience [6]. Where applicable, trainers will also hold a teaching or training qualification. Lived experience experts (e.g. family carers) co-deliver sessions, contributing practical insights [3]

Care staff are guided to develop personalised music plans for participating residents, based on a structured exploration of:

- Music preferences (genres, artists, songs, eras) [11]
- Personal history, cultural background, and individual triggers [19]
- Reactions to different types of music (using observational methods) [6]
- Delivery methods tailored to ability and context (e.g. headphones, speakers, live singing) [11]

Music will be used both passively (listening) and actively (engaging), as appropriate to resident needs. Notes on music effectiveness, context, and behavioural impact will be recorded in the care plan. Residents' booklets will document music choices and family input. Staff will be encouraged to explore a variety of music delivery methods (including free and low-cost digital tools, voice, or live music), with training on access options scaled to the home's resources [19, 20].

All participating staff will sign confidentiality agreements confirming that training materials, which remain the intellectual property of the study team, will not be copied or shared externally.

(How well - Planned) A dedicated budget is allocated for repeat training to mitigate staff turnover. Graduates of the training will be designated as DCCs within their homes, supporting sustainability and career development.

(When and how much; Tailoring) The timing, frequency ("dose"), and content of music delivery will be tailored to each individual, based on their care plan and observed responses [3, 11, 16].

(How well - Planned) Dose and reach of the intervention will be monitored through documentation in resident care plans and review of staff records, allowing assessment of how often and for how long music is used, and with how many residents.

Effectiveness will be reviewed using the MiDAS observational tool [3, 12] at predefined sampling points.

Quality of care plans will be reviewed by trainers at Session 3 and scored based on completeness, specificity of music strategies, and evidence of care team engagement.

7.1.1 Criteria for discontinuation or modification of the intervention

There are no predefined criteria for discontinuation of the music intervention. However, if a resident shows signs of discomfort or distress linked to the use of music, care staff will cease the intervention immediately in accordance with standard safeguarding procedures. If a resident or their consultee requests withdrawal from the study or cessation of music use, this will be respected. Adjustments to music selection and delivery method will be made as part of ongoing tailoring based on resident preferences and wellbeing.

7.1.2 Concomitant care and permitted interventions

All usual care practices, including the use of medication, behavioural support strategies, and recreational activities, will continue as normal in both arms of the study. There are no prohibited interventions during the trial. The flexible design allows care homes to maintain their standard care routines, ensuring external validity and relevance to real-world settings. Any additional music-related initiatives will be documented, including access to commercial music providers or involvement in external music therapy.

7.1.3 Intervention fidelity and quality assurance

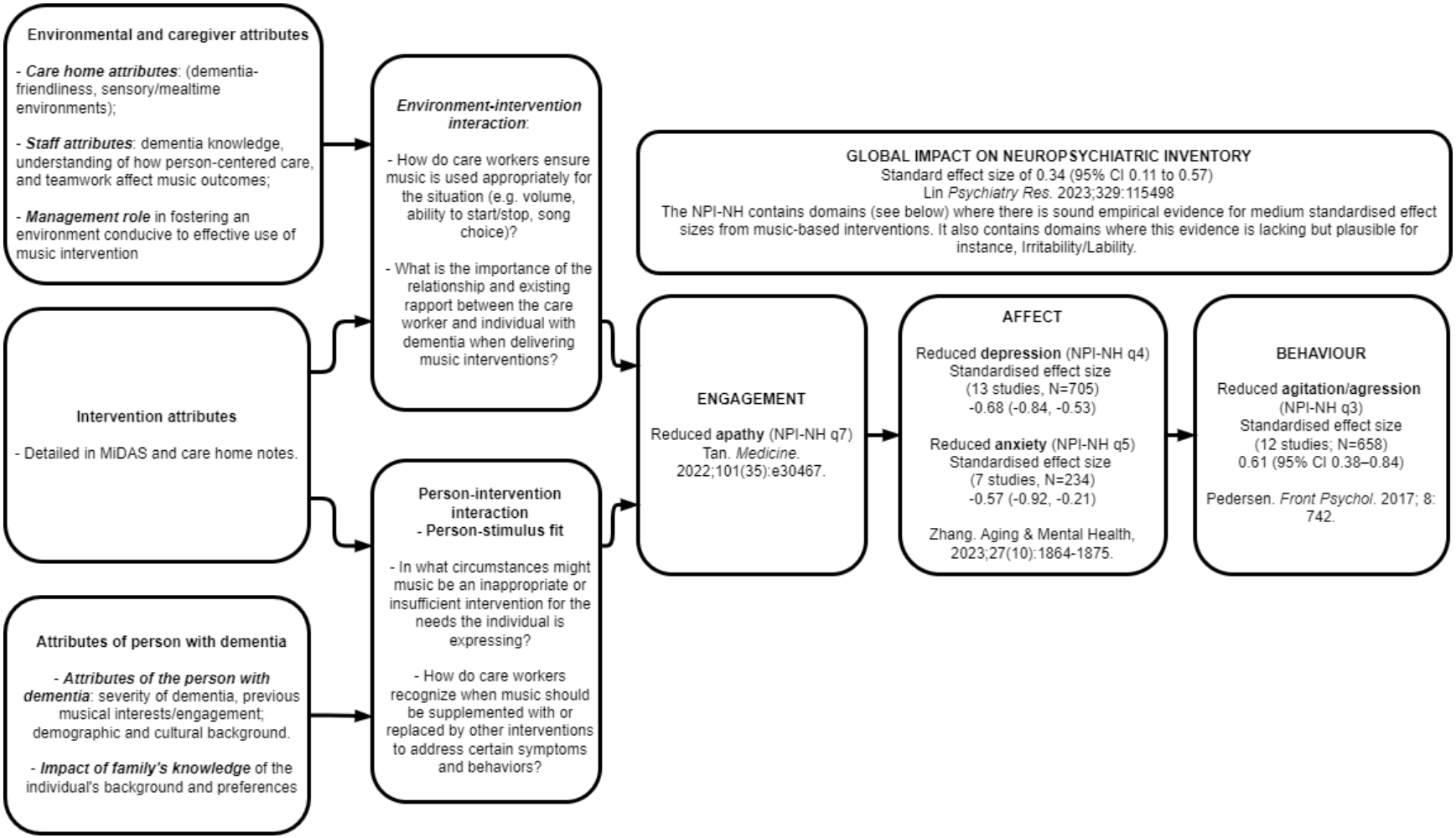
Intervention fidelity will be assessed through:

- Review of care plans by trainers at Session 3
- Completion of care home implementation checklists

- Resident-level tracking of music usage and impact via MiDAS
- Staff interviews and process evaluation measures

Deviations from the intervention protocol will be documented and explored through the process evaluation.

Figure 2. PUMA logic model based on the Comprehensive Process Model of Engagement of Persons with Dementia



7.2 Participants randomised to Control Group (Usual Care)

Usual care in UK care homes is variable and depends on factors such as home type (Care homes with and without nursing), ownership model, size, funding, and management practices. Common elements include collaborative care planning involving residents and, where appropriate, family members, with regular review by senior staff such as registered nurses or care managers.

While the CQC recommends gathering biographical information to inform person-centred care and reduce distress, the implementation of this guidance varies widely. Many homes employ activity or wellbeing coordinators who typically deliver group-based sessions not routinely integrated into care planning. Music, where used, is generally offered in an ad hoc and group-based manner, with limited personalisation or documentation in care records.

In control homes, care will continue as usual, without any additional training or structured support. At site set-up, the research team will reinforce the importance of maintaining current care practices to preserve the integrity of the comparator condition.

To monitor and describe standard care practices across both intervention and control homes, a bespoke usual care survey will be conducted at three timepoints: before, during, and after the intervention period. Data collected will include use of music or streaming services, availability of music-related hardware, and prior staff exposure to dementia-related training such as FITS or equivalent programmes.

8. Outcomes

8.1 Primary outcome/endpoint

The primary outcome is the average score on the Nursing Home version of the NPI-NH measured at 3-, 6-, and 12-months post randomisation. The NPI-NH assesses neuropsychiatric symptoms such as agitation, aggression, psychosis, and other changed behaviours, which are key targets for non-pharmacological interventions in dementia care.

The Neuropsychiatric Inventory (NPI) is widely used in dementia research and recommended as a core clinical outcome by expert guidelines. It reliably and validly captures behaviours that are likely to respond to personalised music therapy and is sensitive to treatment effects in large-scale trials. Use of the NPI aligns with the study's aims to improve behavioural and emotional wellbeing, and it is both feasible for use in care homes and acceptable to stakeholders consulted during trial development [2, 4, 21, 22].

8.2 Secondary outcomes/endpoints

1. The following secondary outcomes will be assessed at baseline, 3, 6, and 12 months unless otherwise specified:
2. MiDAS: Intervention arm only. Captures resident responses to personalised music use.
3. QUALID: Proxy-rated measure of quality of life.
4. EQ-HWB-Proxy: Measures health-related quality of life using proxy respondents.
5. Resource-use Measure: Captures health and social care resource use.
6. Antipsychotic medication use: Tracked through resident medication records at each follow-up timepoint.

8.3 Table 1: Outcome Assessment schedule

Outcome	Baseline	3 months	6 months	12 months
Demographics	✓			
Clinical Dementia Rating Scale (CDR) (if required for subgrouping)	✓			
NPI-NH	✓	✓	✓	✓
MiDAS (Intervention arm only)	✓	✓	✓	✓
QUALID	✓	✓	✓	✓
EQ-HWB-Proxy	✓	✓	✓	✓
Resource-Use Measure	✓	✓	✓	✓
Antipsychotic medication use	✓	✓	✓	✓

8.4 Internal pilot outcomes

An internal pilot will be conducted during the first 6 months of recruitment to assess the feasibility of recruitment and data collection procedures. This internal pilot phase will evaluate site set-up, participant recruitment, and the availability of data points required to contribute to the primary outcome. Progression criteria are defined below.

Table 2: Internal pilot progression criteria assessed after 6 months of recruitment

Criteria	Red: Consider ending study if ≥2 met	Amber: Proceed with remediation and TSC agreement	Green: Proceed

Number of homes open / recruited 1st participant (pilot target: 34)	<60% (n<13)	≥60% (n≥13)	100% (n=22)
Number of participants recruited (pilot target: 222)	<60% (n<82)	≥60% (n≥82)	100% (n=138)
Availability of data points to contribute to primary outcome	<60%	60–70%	>70%

Recruitment and retention data will be reviewed at the end of the internal pilot. If any amber criteria are met, a recovery plan will be developed and agreed with the TSC and submitted to the funder. Sites consulted during study planning indicated strong willingness to participate, and an average of 7 residents per home are expected to be recruited based on feasibility data

9. Assessments and procedures

Outcome, baseline, and follow-up data will be collected at the care home site by appropriately trained personnel. This may include designated care home staff or delegated research delivery staff (e.g. from the RDN Agile team or NHS Trust research teams), depending on arrangements agreed during site set-up and the capacity and experience of each home. The research team will work with each site to confirm responsibilities, provide tailored training, and offer ongoing support to ensure protocol compliance and data quality.

SOPs will be followed, and all individuals involved in data collection will receive training from the central research team (Sheffield CTRU) on the study instruments, administration procedures, and data entry processes. To promote consistency, where possible, the same individual (e.g. care home staff member) will complete proxy-reported measures at each timepoint for a given participant.

Data will be collected at baseline, 3 months, 6 months, and 12 months post randomisation. All patient reported outcome measures (PROMs) will be completed via structured interviews with a proxy respondent (typically a care home staff member familiar with the resident, or a family member or friend if appropriate). Proxy reporting is necessary due to the cognitive impairment of residents with dementia.

All data will be stored securely in the Sheffield CTRU database. Paper forms will be stored separately and securely for no more than 3 months post-trial; research data will be retained for a minimum of 20 years.

Data will be input remotely into the Sheffield CTRU bespoke trial database where possible. Paper based forms with unique pseudonymised participant IDs will be sent by registered post to the CTRU and responses manually entered into the database by CTRU staff. Data will be managed by Sheffield CTRU, in accordance with the UK Data Protection Act.

Instruments and Justification

- **CDR**: A structured interview-based measure assessing cognitive and functional performance across six domains (memory, orientation, judgment and problem solving, community affairs, home and hobbies, personal care). Administered at baseline only. The CDR is a validated and widely used measure of dementia severity, with strong inter-rater reliability, test–retest reliability, and concurrent validity with other cognitive and functional assessments [23-25].

- **NPI-NH** [2]: Primary outcome. A validated proxy measure of neuropsychiatric symptoms in dementia across 10 behavioural domains (e.g. agitation, hallucinations). Each scored 0–12 (frequency × severity). Total score: 0–120; lower scores indicate fewer or less severe symptoms. Recommended as a core outcome by international guidelines.

- **QUALID** [26]: A validated proxy measure assessing 11 behaviours over the past week. Scores range from 11 to 55; lower scores indicate better quality of life.

- **EQ-HWB-Proxy** [27]: An alternative to EQ-5D, designed for populations with cognitive impairment. Captures health and wellbeing across a broader range of domains. Proxy-reported.

- **MiDAS** [28]: Intervention group only. Not an outcome but a tool to guide and tailor music intervention. Six-item visual analogue scale rated before and after music sessions, assessing interest, engagement, and affect.

- **Resource-Use Measure**: Captures health and social care services used to inform economic evaluation. Based on established resource use measure formats, tailored for use in care home settings.

- **Medication Review**: Care home staff (or delegated personnel) will extract antipsychotic medication data from care home records. Information on medication name, dosage, timing, and changes will be entered into the case report forms (CRFs). A binary (yes/no) and continuous measure (extent of reduction) will be calculated.

PROMs will not be used to guide immediate clinical care and will not be shared with care teams unless clinically necessary. Missing data will be minimised through standardised training, monitoring, and support. The importance of PROMs will be emphasised during consent. Strategies to maintain continuity in proxy respondents across timepoints will be implemented.

9.1 Study Assessments Schedule

Data will be collected by care home staff or delegated research delivery personnel (e.g. RDN Agile team or NHS Trust research staff), depending on the availability and capacity of each care home. This will be agreed on a site-by-site basis. Staff responsible for data collection will receive training from the research team to ensure consistency and quality. Where possible, the same individual will complete assessments across time points for each resident. Table 3 outlines the study assessment schedule.

Table 3: Study Assessment Schedule

Assessment	**Screening**	**Baseline**	**3 Months**	**6 Months**	**12 Months**
Consent	x				
CDR		X			
Demographic Characteristics		X			
Medications		X	x	x	x
NPI-NH		X	x	x	x

MiDAS (Intervention only)		X	x	x	x
QUALID		X	x	x	x
EQ-HWB-Proxy		X	x	x	x
Resource-Use Measure		X	x	x	x

9.2 Procedures for Assessing Efficacy

The primary efficacy outcome is the average post-baseline score on the NPI-NH, assessed at 3-, 6-, and 12-months post-baseline. The treatment effect will be calculated as the difference in means between intervention and control groups, adjusting for baseline NPI-NH scores.

Based on findings from the EPIC trial and meta-analyses of music-based interventions, we assume a standard deviation (SD) of 14 and have defined a target difference of 4 points on the NPI-NH as the minimum clinically important difference (MCID) [29]. This equates to an effect size of 0.29, consistent with prior evidence of meaningful change in neuropsychiatric symptoms in similar populations.

9.3 Procedures for Assessing Safety

The intervention comprises low-risk, non-pharmacological, person-centred music activities. Therefore, no adverse events (AEs) are anticipated. However, staff will be asked to record and report any unintended consequences, such as increased agitation following music sessions. These will be reviewed by the research team and, where relevant, the TMG and Data Monitoring & Ethics Committee (DMEC).

Changes to antipsychotic medication, which may indicate either benefit or risk, will be documented and monitored as a secondary safety-related outcome.

9.4 Participant Withdrawals and Loss of Capacity

Participants, or their consultees where appropriate, may withdraw from the study at any time without providing a reason. Withdrawal decisions will be documented using a dedicated study withdrawal CRF, which records the date of withdrawal, the level of participation being discontinued, and any reason offered. Participants will be encouraged to continue contributing data, even if they no longer receive the intervention, in order to support robust outcome evaluation and uphold the integrity of the trial.

To accommodate individual preferences and varying levels of burden, participants may choose to reduce their level of involvement in the study without fully withdrawing. Options for continued participation include: (1) ceasing the intervention while continuing with follow-up assessments; (2) stopping both intervention and assessments, while permitting use of routinely collected care data; or (3) withdrawing from all aspects of the study, in which case no further data will be collected. These

options will be explained in the PIS and discussed at the time of any withdrawal decision.

If a participant with capacity at enrolment is found to have experienced a change in mental capacity during the study (i.e. when the research team becomes aware of this change), their continued involvement will be reviewed on a case-by-case basis. In accordance with the Mental Capacity Act framework, a personal or nominated consultee will be approached to provide agreement for the participant to remain in the study. If no suitable consultee can be identified or agreement is not provided, no further data will be collected, although any data already collected will be retained and included in the final analysis unless otherwise requested.

Care home staff members participating as proxy respondents or as part of intervention delivery (e.g. DCC) may also withdraw at any time. If a staff member acting as a proxy respondent withdraws before the study concludes, a suitable replacement will be identified and supported by the study team to ensure continuity in data collection wherever possible.

Participants who are hospitalised or transferred to another care setting will not be automatically withdrawn from the trial. Continued data collection will be pursued wherever feasible, subject to the participant's or consultee's agreement, including the use of proxy completion or routine records. Routinely collected care home data may also be retained and used for the primary and safety analyses where prior agreement has been given.

Participants will not be replaced after randomisation. However, excessive withdrawal may compromise trial power and data completeness. Sites will be encouraged to explain the value of ongoing data contribution during consent discussions and throughout the trial. The Sheffield CTRU and CI reserve the right to close a study site with appropriate notice should a site become unable to continue due to capacity, feasibility, or concerns about compliance with the protocol.

For the purposes of reporting and final data analysis, the end of the trial is defined as the date on which the final participant completes their final (12-month) follow-up assessment. The Sponsor and Research Ethics Committee (REC) will be notified when the study has ended, in line with HRA and Sponsor requirements.

9.5 Loss to follow-up

Participants will be considered lost to follow-up if no outcome data—specifically the NPI-NH, QUALID, or EQ-HWB—can be collected at both the 6- and 12-month follow-up timepoints, and all reasonable attempts to contact the care home or the participant's consultee have been unsuccessful. Before confirming this status, the study team will attempt contact on at least two occasions over a four-week period, using the care home as the primary point of contact. Where feasible, the participant's consultee or legal representative may also be contacted **via the care home** to facilitate continued data collection or to confirm reasons for discontinuation.

Where outcome data are missing due to illness, death, or care home transition, the reason for loss will be recorded in the CRF, where known. If a participant dies during the course of follow-up, the date and cause of death (where available) will be documented from care home records or communicated via a consultee or legal representative. Any outcome data collected prior to death will be retained and included in the final trial analysis.

In accordance with the intention-to-treat principle, participants who discontinue or deviate from the intervention protocol will remain in the study for the purposes of follow-up and outcome data collection. This will include continued collection of NPI-NH scores, quality of life data (QUALID), proxy wellbeing (EQ-HWB), and where applicable, MiDAS scores and care home-level contextual data such as activity logs or usual care survey responses.

Formal linkage with external national registries, such as the NHS Spine or Office for National Statistics mortality register, is not planned due to the nature of the population and constraints around consent for data linkage.

10. Safety Reporting

A proportionate, plausibility-based approach will be used, consistent with recent recommendations for behaviour-change interventions (BCIs). This limits collection to events plausibly linked to the intervention while maintaining full serious adverse event (SAE) reporting in accordance with ICH-GCP and sponsor requirements. Evidence indicates that BCIs can cause harms, and that unfocused AE collection can be inefficient and miss relevant harms; selective, transparent procedures are recommended.

10.1 Definitions

For this trial, the overarching category of “harm” will be used. Harm is defined as any behavioural, psychological, or physical event plausibly related to personalised music use, whether or not it meets the ICH-GCP definition of a SAE.
AE: Any untoward occurrence in a participant to whom an intervention has been administered. Only AEs plausibly related to personalised music will be recorded.
SAE: Any occurrence that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is otherwise considered medically significant by the investigator. In this trial, SAEs will only be recorded if plausibly related to personalised music [30].

Operational definition of a music-related harm: record a harm only if all of the following apply: (i) music was being used intentionally to comfort, soothe, or engage; (ii) new or worsened distress began during music or within ~2 hours; and (iii) staff, relatives, friends or participants themselves judge music as a plausible contributor based on timing, nature of response, and knowledge of the person. “New or worsened distress” includes agitation (e.g. pacing, resisting care, shouting), anxiety (fear/tenseness), crying indicative of distress, sudden withdrawal, overstimulation/irritability, physical risk (e.g. unsafe movement/fall during music), or disruption to others.

10.2 Recording and reporting

Scope.

- **Serious harms plausibly related to personalised music:** record and report (see 10.4).
- **Non-serious harms plausibly related to personalised music:** record and report [31].

- **SAEs unrelated to personalised music:** not recorded or reported.
- **Control arm:** no harms will be collected.
- **Events unrelated to personalised music (including routine distress, comorbidities, or care activities):** not recorded.

Assessment.
Severity (mild, moderate, severe) and relatedness (related/possibly related/unrelated to personalised music) will be assessed by delegated site staff using clinical judgement, experience and contextual prompts (e.g. timing, plausibility, alternative explanations) [31].

Follow-up.
Study-related harms will be followed until resolution, stabilisation, or a final outcome can be recorded.

10.3 Study specific exemptions

To minimise burden and avoid background noise in a population with frequent unrelated events, the following will not be routinely recorded as harms unless plausibly related to personalised music or unusually severe: routine/non-serious distress consistent with the resident's usual presentation; distress clearly attributable to non-music care activities (e.g. personal care/mealtime routines); common, expected events of ageing/comorbidity without a plausible music link. This implements a selective, proportionate strategy for BCI trials [30].

10.4 Notification procedure

Sites must notify Sheffield CTRU of all serious harms plausibly related to personalised music within 24 hours of awareness, using the study harm reporting form. If the PI is unavailable, a delegated investigator will submit. Provide event details (onset, course, outcome), relevant medical history, and concomitant medications where applicable. The Chief Investigator (CI) (or delegate) will assess causality and expectedness

Causality will be judged as:

- **Unrelated:** No temporal or plausible relationship to personalised music.
- **Possibly related:** Temporal relationship present and a plausible link cannot be ruled out.
- **Related:** Clear temporal relationship with no alternative explanation judged more likely.

Expectedness will be judged against the trial protocol and the music intervention evidence base:

- **Expected:** Harms consistent with anticipated reactions to personalised music (e.g. agitation, overstimulation, withdrawal).
- **Unexpected:** Harms not consistent with anticipated reactions or not previously documented in the literature.

Any harm assessed as serious, related, and unexpected will be reported to the Research Ethics Committee (REC) within 15 days, in line with sponsor requirements.

10.5 CTRU responsibilities

The Sponsor delegates to Sheffield CTRU responsibility for reporting serious, related, and unexpected harms to regulatory authorities and the REC, as appropriate, and for informing investigators/co-applicants of any emerging safety concerns.

10.6 Harm reporting oversight

The DMEC and TSC will receive summaries of all recorded harms at intervals defined in their charters. Data will be reviewed for patterns suggesting undue risk (e.g. repeated distress with particular music contexts). The approach and any adaptations will be transparently documented per best-practice recommendations for BCI harms monitoring [31].

11. Statistics

11.1 Sample size

The sample size for the PUMA trial is based on detecting a clinically meaningful difference in the primary outcome, the total score on the NPI-NH. The NPI-NH is a validated, proxy-completed tool assessing behavioural and psychological symptoms in people with dementia; the total score is the sum of 10 behavioural domains, ranging from 0 (absence of symptoms) to 120 (maximum severity).

We aim to detect a between-group difference of 4 points on the average post-baseline NPI-NH score (collected at 3, 6, and 12 months), which represents a standardised effect size of 0.29. This target effect size is supported by two meta-analyses of non-pharmacological interventions using the NPI, which reported standardised mean differences of 0.23 and 0.34, respectively [2, 4]. A 4-point difference is considered clinically important based on expert consensus and consistency with comparable studies.

NPI-NH outcome data from the EPIC cluster RCT (50 care homes, n=726 residents with dementia) reported mean baseline scores of 12.2 (SD 13.1) and 10.4 (SD 11.2) at 6 months, supporting the assumption of a standard deviation of 14 points for the PUMA trial. A compound symmetry correlation of 0.60 between repeated measures was assumed [32]. Using these assumptions and 90% power with a two-sided 5% significance level, an individually randomised design would require 194 participants (97 per arm).

The PUMA trial will use a parallel-group, cluster randomised, superiority repeated-measures design, with outcome assessments at 3-, 6-, and 12-months post-baseline. To account for clustering, we assume an average of 5 residents per care home, a standard deviation in cluster size of 4.25, and an intra-cluster correlation coefficient (ICC) of 0.06, yielding a design effect of 1.457. This results in a required sample of 284 residents across 58 care homes [29, 32].

To allow for 30% attrition over the 12-month follow-up, the recruitment target is 406 residents across a minimum of 58 care homes (approximately 7 residents per care home).

11.2 Statistical Analysis

All analyses for the PUMA trial will follow the principles of intention-to-treat (ITT) and will be conducted in accordance with the Consolidated Standards of Reporting Trials

(CONSORT) guidelines for cluster randomised controlled trials [33]. The primary analysis population will include all randomised care home residents according to the group to which their care home was allocated, regardless of adherence to the allocated intervention. A separate per-protocol population may be defined for exploratory analyses, but the primary conclusions will be based on the ITT analysis.

The primary estimand of interest is the participant-average treatment effect, defined as the difference in mean NPI-NH scores (averaged over 3-, 6-, and 12-month post-enrolment assessments) between residents allocated to the intervention (person-centred music plus usual care) and those allocated to usual care alone. This estimand is defined using a treatment policy strategy to handle all intercurrent events, meaning that outcome data will be analysed regardless of treatment adherence, switching, or the use of concomitant therapies. For intercurrent events due to death, a “while alive” strategy will be employed, whereby residents contribute data up until their death, with no imputation beyond this point.

The primary statistical analysis will compare the mean post-baseline total NPI-NH score between the intervention and control groups using a three-level linear mixed-effects model. This model will include fixed effects for treatment group, time point (categorical), treatment-by-time interaction, baseline NPI-NH score, and pre-specified covariates including age, ethnicity, and dementia severity. Random intercepts will be fitted for care home (level 3) and participant (level 2), with repeated outcome measures (level 1) nested within participants. Restricted maximum likelihood estimation (REML) will be used to estimate model parameters, and an exchangeable correlation structure will be assumed for the random effects. Both adjusted and unadjusted estimates of the treatment effect, along with 95% confidence intervals, will be presented. This model accommodates data from participants with partially missing follow-up data and ensures appropriate handling of clustering and repeated measures.

For residents with missing NPI-NH scores at all three post-baseline time points who are known to be alive during the relevant time period, we will implement multiple imputation using chained equations (MICE), where appropriate, to account for data missing at random. Sensitivity analyses will be conducted using alternative correlation structures in the mixed model (e.g. unstructured or independent), and the treatment effects from these models will be compared visually to assess robustness. If there is evidence that data may be missing not at random, further sensitivity analyses using appropriate statistical methods will be conducted.

Secondary outcomes—including the QUALID, EQ-HWB-Proxy, and resource use measures—will be analysed using similar three-level linear mixed-effects models, adjusted for baseline values and relevant covariates. Outcomes will be modelled at each post-baseline time point. Analyses of binary or categorical outcomes will use mixed-effects logistic or multinomial models, as appropriate.

AEs and SAEs will be reported descriptively. AEs and SAEs will be tabulated by treatment arm, showing the number and percentage of residents with one or more events, along with event counts and classification. SAEs are defined as events that result in death, are life-threatening, require hospitalisation or prolongation of existing hospitalisation, result in persistent or significant disability or incapacity, or cause congenital anomaly or birth defect.

Exploratory analyses will include tests for subgroup-treatment interactions using the primary outcome model. Subgroups of interest include care homes with prior exposure to the FITS model, dementia specialisation status, and staff characteristics such as

seniority or training level. Subgroup analyses will be considered exploratory and hypothesis-generating, regardless of statistical significance in the main effect.

No formal interim analyses or stopping guidelines are planned. However, recruitment and safety will be monitored by the DMEC based on periodic reports from the CTRU. Full statistical details, including definitions of analysis populations and planned sensitivity analyses, will be provided in a separate SAP to be finalised before completion of data collection.

12. Nested mixed methods process evaluation

A nested mixed methods process evaluation will be conducted alongside the main trial to investigate the implementation, contextual factors, and mechanisms of impact of the person-centred music intervention. The process evaluation will be guided by Normalization Process Theory (NPT) [34] and the Cohen-Mansfield Comprehensive Process Model of Engagement [16]. This evaluation will address three core research questions [35]: (1) What is implemented? (2) How does context affect implementation and outcomes? and (3) How did the intervention produce effects?

To assess implementation fidelity, dose, and resident responses to the music intervention, data will be collected using an adapted version of the MiDAS [12] at multiple timepoints across the 29 intervention care homes. MiDAS data will be collected by care home staff, with theoretical integrity of the adapted measure assured by co-applicant and MiDAS developer OM, in collaboration with process evaluators and dementia care experts. Additional implementation data will be gathered from care notes documenting music use and resident reactions. These data will be collected by designated care home staff or delegated research delivery staff (e.g. from the RDN agile team or NHS Trust research teams), depending on arrangements agreed during site set-up and the capacity and experience of each home. The approach used will be monitored to ensure consistency of data collection across sites.

A bespoke usual care survey will be completed at intervention and control homes, at three timepoints, before, during and after the active period of the trial, to understand streaming services, hardware, and staff exposure to FITS and other training. This approach to monitoring policy change is often used by Sheffield CTRU in trials [36] and has been cited as exemplary by the US National Institutes of Health [37].

To explore how context shapes implementation and outcomes, 10 of the 29 intervention homes will be selected for in-depth case study analysis. Homes will be purposively sampled for maximum variation based on CQC ratings, exposure to FITS, size, location, and resident characteristics. Within each selected home, multiple data sources will be triangulated. These include: (1) structured NPT-based surveys [38] completed by Dementia Care Champions; (2) longitudinal MiDAS scores; and (3) semi-structured interviews with care home managers, staff, residents, and family members.

In each participating care home, potentially suitable resident–family/carer/representative dyads will be identified and initially approached by care home staff or delegated research delivery personnel (e.g. RDN Agile team or NHS Trust research staff). Staff will provide brief information about the study and seek permission for the research team to make contact; no personal details will be shared without prior agreement. Residents who have mental capacity to consent will be asked if they are happy for the research team to contact them directly. Where it is believed that a resident lacks mental capacity, an appropriate personal consultee will be identified and approached in the first instance by care home staff, and subject to the consultee's agreement their contact details will then be shared with the research team.

The research team will then follow up to provide the full information sheet, answer questions, and take informed consent or consultee declaration. As the interviews are dyadic, both the resident (via consent or consultee declaration) and the family/carer/representative participant will be asked to provide consent before participation. Participation is entirely voluntary.

Up to 20 interviews with staff and 20 dyadic interviews with residents and family carers will be conducted to explore implementation experiences, perceived impacts, and contextual facilitators or barriers to intervention delivery and engagement. NPT constructs will guide data collection and analysis for staff, while the Theoretical Framework of Acceptability (TFA) will be applied to resident and family data.

Qualitative data will be analysed using framework analysis, structured by the NPT and TFA domains and the intervention's logic model. Integrated data tables (joint displays) will be used to examine contextual influences on intervention outcomes within and across care homes.

To explore mechanisms of impact, MiDAS scores, qualitative data, care notes, and trial outcome data will be synthesised. This will enable examination of how music engagement, delivery, and contextual variation may have contributed to observed changes in resident outcomes. Findings from the process evaluation will inform interpretation of trial results, guide refinements to the intervention, and support planning for future implementation and scale-up in care home settings.

As the data collection for the process evaluation is integrated with the main study procedures, specific details of data sources and timings are included throughout the protocol and referenced in study-specific guidance where necessary.

13. Health economic analysis

A within-trial economic evaluation will be conducted to assess the cost-effectiveness of the person-centred music intervention compared with usual care in care homes for people living with dementia. The evaluation will adopt a health and social care perspective over a 12-month follow-up period conducted on an intention-to-treat basis. The primary economic outcome will be the incremental cost per quality-adjusted life year (QALY) gained [39].

QALYs will be calculated using the area-under-the-curve method, with utility values derived from the EQ-HWB-9-Proxy. This instrument was selected following careful consideration of alternatives due to concerns regarding the sensitivity of the EQ-5D in populations with dementia. Psychometric analysis will assess the validity and responsiveness of the EQ-HWB-9-Proxy against the NPI-NH and QUALID to evaluate its suitability for the trial population [40-42].

Resource use data will be collected from care home records via a bespoke Resource Use Measure integrated into an electronic case report form (eCRF). Resource-use documentation will be completed on site using tablets by trained care home staff. Unit costs will be drawn from standard published sources, including NHS Reference Costs, the Personal Social Services Research Unit (PSSRU) Unit Costs of Health and Social Care, and the British National Formulary.

Economic analyses will be conducted following the final database lock. Prior to this, a bespoke eCRF proforma will be developed to support consistent and complete data collection across all sites, and appropriate unit costs and sources will be identified and agreed. The primary analysis of costs and outcomes will use the same statistical

methods as for the primary outcomes, such as using a three-level mixed-effects linear model (MLM) to account for clustering at the care home level and repeated measures within participants [43]. The model specifications will also align with those used in the primary statistical analysis. As MLMs are robust to missing-at-random data, alternative missing data methods (e.g. multiple imputation) will only be employed if data are suspected to be missing-not-at-random.

Uncertainty in the estimates of incremental costs and QALYs will be explored through probabilistic sensitivity analysis. A two-stage bootstrap with shrinkage correction will be used to produce bias-corrected confidence intervals that account for clustering. Incremental cost-effectiveness ratios (ICERs), cost-effectiveness acceptability curves (CEACs), and cost-effectiveness planes will be generated [43-45]. Sensitivity analyses will assess the impact of variation in key input parameters, such as unit costs and resource use assumptions.

14. Trial supervision

The PUMA trial will be led by the Chief Investigator (CI) in coordination with the co-applicants and Sheffield CTRU. The Sponsor for the trial is Sheffield Health and Social Care NHS Foundation Trust. Sheffield CTRU will be responsible for trial management and will establish a collaboration agreement with the Sponsor to cover governance, safety reporting, and data management oversight.

A dedicated Trial Manager based at Sheffield CTRU will coordinate the day-to-day operational aspects of the trial and will be supervised by the CI and senior CTRU staff. The Trial Manager will liaise regularly with the study team and provide ongoing reports to oversight committees. CTRU will also provide support in the areas of data management, randomisation, trial monitoring, statistical analysis, health economics, quality assurance (QA), and reporting and dissemination of results.

The trial will be governed by three committees in accordance with Sheffield CTRU SOPs: the TMG, the TSC, and the DMEC.

Sites may be closed with appropriate notice by the Sponsor or CTRU in the event of serious protocol non-compliance, inadequate recruitment, or other concerns. The end of the trial will be defined as the date of final data collection for the final participant at the final site.

14.1 Trial Steering Committee

An independent TSC will provide overarching supervision of the trial. The TSC will include an independent Chair, a public and patient representative, and independent experts in dementia care, social care, trial methodology, statistics, and health economics.

The responsibilities of the TSC include monitoring trial conduct and progress, reviewing the protocol and SAP, advising on any proposed amendments, and considering recommendations from the DMEC. The TSC will meet at regular intervals and has the authority to recommend protocol modifications or early termination of the trial in response to concerns about safety, feasibility, or ethics, or following recommendations from the DMEC.

14.2 Data Monitoring and Ethics Committee

An independent DMEC will be established including at least three independent members, including a statistician, a clinician with expertise in dementia care, and another independent member with experience in care home research or trial methodology.

The DMEC will review reports provided by the CTRU on trial progress, safety data, and critical outcome data. The DMEC will meet at regular intervals, as defined by the DMEC charter, and meetings will comprise an open session to which members of the study team may attend, followed by a closed session with independent members only and to which unblinded data will be available.

The DMEC will advise the TSC on whether the trial should continue as planned or be modified or stopped for safety or efficacy reasons. A DMEC charter will outline the full remit, responsibilities, and meeting schedule. No formal interim efficacy analyses are planned; if required, this will be covered in an ethics amendment and detailed in the SAP.

14.3 Trial Management Group

The TMG will oversee the operational delivery of the trial. Chaired by the CI, the TMG will include co-applicants, the Sheffield CTRU trial team (including the Trial Manager, data managers, statisticians, and health economists), and representatives from the PPIE team, who will attend as appropriate depending on the stage of the study.

The TMG will meet regularly to review the day-to-day running of the trial, address implementation issues, and ensure alignment with protocol timelines and objectives. It will receive reports from the TSC and DMEC and will be responsible for reviewing key trial metrics, including timelines from site initiation to group randomisation. The group will also monitor recruitment processes and identify whether any changes are needed to improve trial delivery. Any significant issues or necessary changes will be escalated to the TSC and DMEC as appropriate.

15. Data handling and record keeping

Resident and consultee confidentiality will be maintained throughout the trial in accordance with Sheffield CTRU SOPs, the UK Policy Framework for Health and Social Care Research, the General Data Protection Regulation (GDPR), and NHS Trust policies at Sheffield Health and Social Care NHS Foundation Trust and the University of Sheffield, who will act as joint Data Controllers.

Data management will be provided by the University of Sheffield CTRU who adhere to their own SOPs relating to all aspects of data management including data protection and archiving. A separate data management plan (DMP) will detail data management activities for the study in accordance with SOP (Shef/CTRU/DM009).

Each participating resident will be assigned a unique trial identification number to support pseudonymity. This identifier will appear on all source data worksheets (shadow CRFs) and trial documentation and will link all of the clinical information held about them on the study database. It will also be used in all correspondence between CTRU and participating centres. Where residents lack capacity to provide informed consent, agreement for participation will be sought from an appropriate consultee in line with the Mental Capacity Act framework.

Data will be collected by trained care home staff or local research delivery teams (e.g. RDN Agile team or NHS Trust research and development (R&D) staff), depending on local arrangements agreed with each site. Data will be recorded remotely via remote data capture into the study database or using paper-based source data worksheets. Remote data capture will be via the CTRU's secure bespoke database (Prospect). Paper forms will be returned by registered post and manually entered into the database by CTRU staff.

All study data will be securely stored at Sheffield CTRU with access restricted to authorised personnel. Anonymised research data will be archived for a minimum of 20 years, in line with sponsor policy, the Records Management Code of Practice for Health and Social Care (2021), GCP, and NIHR guidance.

The care home manager or a delegated staff at each site will maintain comprehensive and accurate source documents to record all relevant study information regarding each participant. The CTRU will provide worksheets (shadow CRFs) to allow the site staff to check what is required for a visit. The worksheets do not need to be completed if alternative source documentation is provided. However, they must be completed for data points where source documentation is not collected elsewhere and where completed the worksheets must accurately reflect the database as they form part of the source data. The source data for the trial will comprise care home records (e.g. medication administration logs, behavioural observations) and completed CRFs. The care home manager (or a delegated staff) will ensure proper documentation and retention of essential records in compliance with GCP.

15.1 Archiving

All data held by Sheffield CTRU will be archived in accordance with CTRU SOP PM012 (Archiving). Paper and electronic documents will be retained securely for a minimum of 20 years following trial completion, in line with the sponsor's policy (Sheffield Health and Social Care NHS Foundation Trust), GCP, and national guidance.

Archived materials will be logged on a dedicated archive register, which will also track any access or retrieval by named individuals. Electronic data will be transferred to a secure 'archive' area of the CTRU's protected server infrastructure for long-term retention.

At site level, archiving of local trial documentation (including site files, consent forms, and relevant source records) will be discussed and agreed with each care home during study set-up, and the agreed arrangements will be recorded. Where a site is unable to commit to maintaining secure archiving facilities for the full 20-year retention period, essential documents will be transferred to Sheffield CTRU at study close-out. CTRU will then assume responsibility for long-term archiving in accordance with sponsor policy, GCP, and applicable national legal and regulatory requirements. This approach ensures flexibility while removing the need for care homes to maintain long-term archiving facilities where this is not feasible.

16. Data access and quality assurance

Direct access to source data/documents (including care home records, observation notes, and electronic data capture) will be granted to authorised representatives from Sheffield CTRU (e.g. study manager, data managers, senior researchers), the study Sponsor, and regulatory authorities to permit trial-related monitoring, audits, and inspections. Data management and QA procedures will be implemented in accordance

with CTRU SOPs, including SOP QA001 (Site Monitoring) and SOP DM009 (Data Management Plan).

All study data will be entered into an eCRF hosted on Sheffield CTRU's secure, in-house data management system. Access to Prospect is controlled by usernames and encrypted passwords, with encrypted SSL/TLS data transmission, and a comprehensive privilege management feature will be used to ensure that users have access to only the minimum amount of data required to complete their tasks. The database will incorporate validation rules and quality control (QC) checks to ensure completeness and accuracy of entered data. Discrepancy reports will be generated to highlight missing or inconsistent data for resolution.

All paper records (e.g. consent forms) will be securely stored in accordance with GDPR and the Data Protection Act (2018) and subsequently archived. Pseudoanonymised data will be held on secure CTRU servers on behalf of the study Sponsor and may be retained for future research subject to appropriate approvals. Access to trial data after study completion will be strictly controlled and managed in line with CTRU SOP DM015 (Data Sharing).

16.1 Site assessment

In this trial, the term 'site' refers to care homes participating in the PUMA trial. All participating sites must be able to comply with study protocol requirements, the UK Policy Framework for Health and Social Care Research, and procedures for outcome data collection and music intervention delivery.

Site staff, including delegated research delivery staff, must be appropriately trained and qualified to undertake trial activities. All site staff will be documented on the site delegation log, with up-to-date CVs held in the Investigator Site File (ISF). Prior to activation, each site's capability to conduct the study will be assessed by CTRU and agreed with the sponsor. Site initiation visits will be conducted either face-to-face or remotely and will include training of care home staff in data collection, consent processes, and delivery of the intervention.

16.2 Risk assessment

A detailed risk assessment has been conducted by Sheffield CTRU in accordance with SOP QA004 (Risk Assessment). The level and frequency of monitoring (central and/or on-site) will be proportionate to this assessment and described in the Site Monitoring Plan (SMP). Risks specific to research in care home environments (e.g. staff turnover, documentation practices) will be reviewed throughout the trial.

16.3 Reporting serious breaches and non-compliances

A "serious breach" is defined as one which is likely to affect, to a significant degree, the safety or integrity of participants, or the scientific value of the study. The Sponsor will be notified immediately upon identification of a potential serious breach. The Sponsor will notify the REC within 7 calendar days of confirmation, in line with regulatory requirements.

All serious breaches and protocol non-compliances must be reported to CTRU within 24 hours of site staff becoming aware, in accordance with SOP PM011 (Protocol and GCP Non-Compliances and Serious Breaches). The process for identifying and reporting non-compliances will be discussed with sites during initiation and outlined in the SMP.

16.4 On-site monitoring

On-site and remote monitoring will be conducted as specified in the Site Monitoring Plan and in accordance with SOP QA001 (Site Monitoring). The purpose of monitoring is to ensure participant safety, protocol compliance, and data integrity.

A site initiation visit (in person or remote) will occur prior to each site's recruitment start date. During this visit, the Monitor will review the study protocol, regulatory requirements, and documentation with site staff. Ongoing site monitoring visits (approximately two per care home) will review consent documentation, CRFs, and local records to confirm:

1. Data are authentic, accurate, and complete.
2. Participant safety and rights are protected.
3. The study is being conducted according to the protocol, GCP, and applicable regulations.

16.5 Central monitoring

In addition to on-site visits, central monitoring will be undertaken throughout the trial. CTRU staff will routinely review submitted data to identify missing values, inconsistencies, or protocol deviations. The consent process will be centrally monitored, and sites will be asked to securely transfer redacted consent forms via NHS.net or encrypted channels. This process will be clearly explained to participants during consent discussions.

Central monitoring will also review recruitment rates, data completeness, and intervention adherence to identify emerging issues and enable timely corrective action.

17. Publication

Results from the PUMA trial will be disseminated through publication in peer-reviewed academic journals and presentation at clinical and scientific conferences. A final report will be submitted to the funder NIHR Health Technology Assessment (HTA), project reference NIHR164000) and made publicly available via their website. Trial results will also be posted to a publicly accessible trial registry within 12 months of completion, in line with NIHR and research transparency requirements.

A Publication and Dissemination Plan will guide all communication activities. This will include plain language summaries co-produced with PPIE contributors, shared with participating care homes, residents (where appropriate), family members, and consultees.

Dissemination activities will follow the Knowledge to Action framework [46] and include targeted engagement with care providers, social care networks, and national bodies. Channels will include social media, media releases, blogs, podcasts (e.g. NIHR Dementia Researcher), and conference presentations (e.g. UK Dementia Congress, British Society of Gerontology, Alzheimer Europe). Materials and resources for care home staff will be promoted through networks such as Skills for Care.

Full details, including authorship criteria, will be set out in the trial's Publication and Dissemination Plan and reporting will be undertaken in accordance with CTRU SOP PM014: *Planning for and Reporting the End of the Study* (v5.0)**.**

18. Finance

The PUMA study (NIHR164000) is funded by the NIHR HTA Programme. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

19. Ethics approval & regulatory compliance

Before initiation of the study at participating sites, the protocol, PIS, and consultee declaration forms will be submitted to the Health Research Authority (HRA) and a REC for review and approval. Any subsequent amendments to the study documents or protocol will also be submitted for approval to the HRA and REC in accordance with national regulatory requirements.

The study will be submitted to local participating NHS Trusts and care provider organisations for confirmation of Capacity and Capability (CCC), in accordance with national research governance processes, prior to any research activity taking place at the site.

Any substantial amendments, including protocol modifications (e.g. changes to eligibility criteria, outcomes, or analysis plans), will be communicated to all participating sites, collaborators, and oversight committees. Sites will be asked for CCC in light of the updated documentation. Where changes affect the information provided to consultees or participants, updated documents will be provided, and re-consent or renewed consultee agreement will be sought as appropriate.

The study will be conducted in accordance with the UK Policy Framework for Health and Social Care Research, GCP, and applicable regulatory guidance.

The end of the study will be defined as the date on which the final participant completes their final (12-month) follow-up assessment. The Sponsor and Research Ethics Committee (REC) will be notified when the study has ended, in line with HRA and Sponsor requirements.

20. Sponsor and site approval

Before initiation of the study at participating sites, the protocol, PIS, and consultee declaration materials will require formal sponsor approval from Sheffield Health and Social Care NHS Foundation Trust.

A site agreement between the Sponsor, participating sites, and Sheffield CTRU will outline the roles and responsibilities of all parties. This agreement must be signed before any research activity or recruitment commences at a site.

21. Trial Organisation and Responsibilities

21.1 Principal Investigators

Each participating site will nominate a local Principal Investigator (PI), typically the care home manager or a senior staff member, with delegated responsibility for the conduct of the study at their site. The PI will sign the model Non-Commercial Agreement (mNCA) and must ensure that all relevant staff are appropriately trained in study procedures, including eligibility screening, obtaining consultee declarations,

intervention delivery, and data collection, in accordance with GCP and the UK Policy Framework.

The PI is responsible for ensuring the study is conducted in compliance with the protocol and regulatory approvals, maintaining oversight of site activity, and liaising with the CTRU Trial Manager on operational matters. Where a suitable PI cannot be identified within the care home, the role may be fulfilled by a delegated individual from the supporting NHS Trust or research delivery team.

21.2 Sheffield Clinical Trials Research Unit (CTRU)

The Sheffield CTRU at the University of Sheffield will coordinate the trial in accordance with CTRU SOPs, the principles of GCP, and the UK Policy Framework for Health and Social Care Research (2017). CTRU responsibilities will include protocol development, CRF design, randomisation, database development and provision, statistical analysis, and development of the site monitoring and data management plans.
CTRU will support submission to the main Research Ethics Committee (REC), HRA, and care home specific approvals, including CCC. CTRU will oversee care home set-up and will supply each with an electronic ISF once required approvals are in place.
CTRU will be responsible for the day-to-day management of the trial, including trial administration, data management, safety reporting, training and support to care home staff, and monitoring trial conduct. CTRU will work closely with the CI to address operational issues, ensure adherence to the protocol and regulatory requirements, and support the successful delivery of the trial.

22. Patient & Public Involvement (PPI)

PPIE has informed the design of the PUMA trial and will remain integral throughout study delivery, oversight, and dissemination. The approach follows NIHR co-production principles and includes involvement from family carers, people living with dementia, and care home staff. A former carer of two people with dementia (one of whom lived in a care home) was a co-applicant on the study (though they have since withdrawn), we will ensure PPIE representation on the TMG; there is also a co-applicant PPI lead role. Two members of the PPIE community (a carer and a person with lived experience) will be invited to join the TMG. These members will provide input into study oversight and implementation. Where necessary the TMG will be conducted in an accessible, dementia-friendly format, avoiding jargon, and allowing time for processing and participation. Support and tailored induction will be provided by the study team, with accessible notes issued before and after meetings, with additional or alternate meetings if appropriate, to support engagement.

In addition to TMG involvement, a wider PPIE panel of up to seven members (people living with dementia and carers) will meet regularly in an advisory capacity to inform key stages of the study, including development of participant-facing materials, recruitment strategies, interpretation of findings, and dissemination. These meetings will be facilitated by the PPIE Lead and CI, with outcomes fed back to the TMG to ensure recommendations are acted upon where appropriate.

A separate forum for care home staff will also be convened to provide input on design and implementation. This group will include managers, care staff, and activity coordinators from both nursing and residential homes.

We will work closely with the Dementia Research Advisory in South Yorkshire (DRAiSY), a dementia research advice PPIE group, who have agreed to act as a critical friend throughout the trial. Annual visits to the group will be used to share

progress, gain feedback, and troubleshoot any concerns arising around resident or family participation. PPIE contributors will help shape our evaluation of involvement through informal feedback after each meeting and more formal evaluations on an annual basis. We will report on this evaluation at the end of the trial.

PPIE contributors will also sit on the TSC to ensure public perspectives inform governance and oversight. All PPIE contributors will be reimbursed for their time and travel or remote participation costs in line with the National Advisory Group for Public Involvement in Research (UK) (INVOLVE) guidance. Training needs will be met through bespoke support provided by the PPIE Lead.

In dissemination, PPIE contributors will co-produce plain language summaries, infographics, videos and blogs to share findings with residents, families, care home staff and wider stakeholders. A hybrid celebration and dissemination event will be co-designed with PPIE and care home forums, and dissemination will extend to networks including Dementia Engagement and Empowerment Project (DEEP), Alzheimer's Society, Skills for Care, and national care home forums.

23. Indemnity / Compensation / Insurance

The University of Sheffield has in place clinical trials insurance against liabilities for which it may be legally liable, and this cover includes any such liabilities arising out of this clinical study.

Standard NHS indemnity operates in respect of the clinical treatment that is provided.

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