ISRCTN86317609 https://doi.org/10.1186/ISRCTN86317609

Music therapy embedded in the life of dementia inpatient care

Submission date
02/04/2025

Recruitment status
No longer recruiting

Registration date
25/04/2025

Overall study status
Completed

Last Edited
17/07/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Distress is common for people with dementia on hospital mental health wards, but music might help. There are lots of reasons why people get distressed. Sometimes it is a result of symptoms like hallucinations, and sometimes it is because the care they receive does not meet their needs. If a person with dementia is so distressed that they behave in a way that puts themselves or others at risk, they may be admitted to a hospital mental health ward. The aim of the hospital stay is to understand and treat their distress, so that they may be discharged with an appropriate support plan. This can take a long time.
There is little research looking at these hospital wards, which can be very different to general hospital wards or care homes. It is hard to care for someone who is very frightened and distressed, and both staff and patients can get hurt (staff experience more physical assaults than prison officers). Calming medications (antipsychotics) are often given to a person with dementia on these wards when distressed. This is a worry because research suggests that these increase the risks of falls and death.
Music therapy has helped lower distress for people with dementia living in care homes and supported staff to understand why someone might be distressed. But we do not know enough about how music therapy can help people with dementia in mental health wards. Our own research on mental health wards found that on the days the therapy took place, there were fewer assaults and staff could see a positive impact on the ward. But not all mental health wards have music therapy. People with dementia and their family members that we spoke to also found music helpful and supported the idea of having this therapy on wards.
In this 18-month project, we will create a music therapy manual for mental health wards together with people with dementia, their families and staff with the aim of reducing distress and assaults.

Who can participate?
People who have stayed, visited family or worked on mental health dementia in the NHS in the last 5 years can take part in an interview or focus group (Stage 1). Two mental health wards in the NHS will be invited to take part and test the music therapy manual for four weeks (Stage 3). Everybody staying, visiting or working on the wards will be able to take part.

What does the study involve?
The study has three stages:
Stage 1. Talking to people with dementia, relatives and staff with experience of mental health wards. This will help us understand how distress and assaults are currently managed and the support people need.
Stage 2. Co-creating a music therapy manual with people with dementia, relatives and staff based on findings from Stage 1.
Stage 3: Testing the music therapy manual over four weeks on two mental health wards, one that already has music therapy and one that has never offered this before.
Once the manual is finished, we will share it with the public and look to test it on more mental health wards for people with dementia.

What are the possible benefits and risks of participating?
If you take part in this study you can help shape the way that music and music therapy are used on NHS mental health dementia wards. If you are staying, visiting or working on a ward where the intervention is tested you will have access to more music therapy delivered by a qualified healthcare professional. They will help work out how music can best be used to reduce distress and improve care experience for everyone on the ward.

Where is the study run from?
The study is led by Anglia Ruskin University and the Cambridgeshire and Peterborough NHS Foundation Trust (UK). Other supporters include Dementia UK, the University of Cambridge and the University of Hull.

When is the study starting and how long is it expected to run for?
June 2023 to February 2025

Who is funding the study?
National Institute for Health and Care Research, Research for Patient Benefit Scheme (UK)

Who is the main contact?
Naomi Thompson, naomi.thompson@aru.ac.uk

Contact information

Type(s)
Scientific, Principal investigator

Contact name
Dr Ming-Hung Hsu

Contact details
Cambridge Institute for Music Therapy Research
Anglia Ruskin University
Cambridge
United Kingdom
CB1 1PT
+44 (0)1223 695401
ming-hung.hsu@aru.ac.uk

Type(s)

Public, Scientific

Contact name
Mrs Naomi Thompson

Contact details
Cambridge Institute for Music Therapy Research
Anglia Ruskin University
Cambridge
United Kingdom
CB1 1PT
+44 (0)1223 695401
naomi.thompson@aru.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323503

Protocol serial number
CPMS 54739

Study information

Scientific Title
MELODIC: co-developing a Music therapy intervention Embedded in the Life Of Dementia Inpatient mental health Care to help manage distress

Acronym
MELODIC

Study objectives
This is a complex intervention development study with an embedded feasibility study. The aims are:

Aim 1: To co-develop a music therapy model (MELODIC) for mental health dementia wards. This will include:
1. A manual outlining music therapy intervention delivery
2. A handbook and resources for ward managers, staff, and relatives

Aim 2: To pilot the MELODIC intervention. This will:
1. Enable refinement of the intervention
2. Determine acceptability with patients, relatives, and staff
3. Assess the feasibility of delivery, including facilitators and barriers to implementation
4. Assess adherence to the intervention
5. Establish cost parameters of delivery
6. Test potential outcome measures to inform the design of a future controlled trial

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 26/07/2023, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 (0)207 104 8283; bradfordleeds.rec@hra.nhs.uk), ref: 23/YH/0155

2. approved 25/09/2023, Faculty of Arts, Humanity and Social Sciences, Anglia Ruskin University (Anglia Ruskin University, Cambridge, CB1 1PT, United Kingdom; +44 (0)1223 698708; julia.johnson@aru.ac.uk), ref: ETH2223-8044

Study design
Complex intervention development study including qualitative exploration, co-design of intervention protocol, and a non-randomized feasibility study

Primary study design
Interventional

Study type(s)
Prevention, Quality of life, Treatment

Health condition(s) or problem(s) studied
Management of distress for people with dementia on NHS mental health wards

Interventions
A co-designed, standardised music therapy protocol (MELODIC) will be developed in the first 8 months of the project. This will be tested and refined through a feasibility study on two wards with differing experience of music therapy. Qualitative and quantitative data will be collected to test the feasibility of the research methods.

Intervention Type
Behavioural

Primary outcome(s)
The feasibility of intervention delivery and the research methods will be measured by:
1. Intervention adherence measured through interventionist diaries completed during the intervention period, collected post-intervention
2. Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 4 months
3. Data completeness for quantitative outcome measures across all four timepoints (4 weeks before, baseline, endpoint, 4 weeks follow-up)
4. Training needs and requirements assessed through interviews conducted post-intervention
5. Costs of intervention delivery calculated post-intervention

Key secondary outcome(s))
1. Initial impact of MELODIC for patients, staff, families and the ward measured by:
1.1. Realist interviews post-intervention
1.2. Patient standardised questionnaires (4 weeks before, baseline, endpoint, 4 weeks follow-up):
1.2.1. Distress measured by the Neuropsychiatric Inventory and the Cohen-Mansfield Agitation

Inventory
1.2.2. Quality of life measured by Quality of Life in Alzheimer's Disease
1.3. Staff standardised questionnaires (4 weeks before, baseline, endpoint, 4 weeks follow-up):
1.3.1. Job satisfaction measured by Job Satisfaction Index
1.3.2. Burnout measured by the Maslach Burnout Inventory
1.3.3. Attitudes of hope and personhood in dementia measured by the Approaches to Dementia Questionnaire
1.4. Family standardised questionnaires (4 weeks before, baseline, endpoint, 4 weeks follow-up):
1.4.1. Attitudes of hope and personhood in dementia measured by Approaches to Dementia Questionnaire
1.4.2. Mental health measured by the General Health Questionnaire
1.5. Ward level outcomes (4 weeks before, 4 weeks during, 4 weeks after intervention): psychotropic medication use; physical assaults, seclusion, mortality, restraint, staff absence, number of bank/agency staff, patient length of stay, discharge destination
2. Refinement of the MELODIC Music therapy intervention protocol

Completion date
01/02/2025

Eligibility

Key inclusion criteria
Inclusion criteria for the qualitative study are:
1. Direct or indirect (through family and close friends) experience of inpatient mental health dementia wards in the last five years to capture current experiences
2. The ward was part of the NHS, with private care excluded
3. The ward came under NHS mental health provision, with wards situated within general health hospitals excluded
4. The ward was for people with dementia (sometimes called organic) only, with wards caring for people with other mental health illnesses and dementia together excluded
5. The participant must be able to speak English
6. No geographical restrictions within the UK

Inclusion criteria for the feasibility study are:
The mental health dementia ward will be purposively sampled. It must meet the above criteria for dementia wards. All patients, staff and families on the ward are eligible to participate.

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
150 years

Sex
All

Total final enrolment
138

Key exclusion criteria
Exclusion criteria related to the setting the participant had experience of:
1. Mental health ward not in the NHS
2. Dementia ward within an acute NHS Trust
3. Dementia ward in community nursing or residential care home

Date of first enrolment
01/10/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridgeshire and Peterborough NHS Foundation Trust
Elizabeth House,
Fulbourn Hospital
Fulbourn
Cambridge
United Kingdom
CB21 5EF

Study participating centre
Humber Teaching NHS Foundation Trust
Trust Hq, Block A, Willerby Hill
Beverley Road
Willerby
Hull
United Kingdom
HU10 6FE

Study participating centre

Avon and Wiltshire Mental Health Partnership NHS Trust
Bath NHS House
Newbridge Hill
Bath
United Kingdom
BA1 3QE

Study participating centre
Black Country Healthcare NHS Foundation Trust Hq
Delta Point
Greets Green Road
West Bromwich
United Kingdom
B70 9PL

Study participating centre
Herefordshire and Worcestershire Health and Care NHS Trust
Unit 2 Kings Court
Charles Hastings Way
Worcester
United Kingdom
WR5 1JR

Study participating centre
Northumbria Healthcare NHS Foundation Trust (headquarters)
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
South West Yorkshire Partnership NHS Foundation Trust
Trust Headquarters
Fieldhead Hospital
Ouchthorpe Lane
Wakefield
United Kingdom
WF1 3SP

Study participating centre

Woodlands Care Centre
Hawkins Road
Cambridge
United Kingdom
CB4 2RD

Sponsor information

Organisation
Anglia Ruskin University

ROR
https://ror.org/0009t4v78

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust

ROR
https://ror.org/040ch0e11

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not publicly available due to their confidential nature, but are available from the corresponding author on reasonable request (cimtr@aru.ac.uk).
The type of data that will be shared: anonymised data. Individual demographic information will not be shared to protect anonymity due to the small dataset. Information on type of participant (staff/patient/family member) will be provided.
Dates of availability: until February 2035.
Whether consent from participants was required and obtained: participant consent for sharing of anonymous data for secondary analysis required and obtained.
Comments on data anonymization: ID numbers will be assigned to all participants.
Any ethical or legal restrictions: ethical approval has been obtained from the Health Research Authority and Anglia Ruskin University.

IPD sharing plan summary

Available on request, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/05/2025	17/07/2025	Yes	No
Results article		16/07/2025	17/07/2025	Yes	No
Protocol article		18/12/2024	03/04/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes