

# Pilot trial of an interactive music programme for individuals living with dementia

<b>Submission date</b> 13/07/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 31/08/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Dementia is a syndrome (a group of related symptoms) associated with an ongoing decline of the brain and its abilities. Music interventions have the potential to improve quality of life significantly for individuals living with dementia and their families. However, scientific evidence to support the use of a specific intervention within the health service is currently lacking. This study will test the procedures for a full study of an interactive music programme for individuals living with dementia in hospital wards or care homes, which has recently been developed by Scottish Chamber Orchestra in collaboration with the University of Edinburgh.

### Who can participate?

Patients with a diagnosis of moderate to severe dementia from a hospital ward in Edinburgh, UK

### What does the study involve?

Participants are randomly allocated to one of two groups. One group attends one-hour Interactive Music Workshops, provided by the Scottish Chamber Orchestra and led by an experienced music workshop leader, once a week for eight weeks. Trained musicians perform favourite or familiar music, while participants are encouraged to take part by moving, singing or joining in on instruments, as they wish. The other group attends one-hour Music Listening Workshops, led by an experienced music workshop leader, once a week for eight weeks. In-depth interviews are carried out with carers, health staff and intervention staff (musicians and workshop leader) to assess their views. The aim is to establish how many participants would be needed in a full study for the results to be useful, what proportion of eligible patients are likely to take part, and how acceptable and practical the research procedures and music intervention are from the point of view of those involved.

### What are the possible benefits and risks of participating?

The possible benefits of taking part include positive engagement in a shared musical experience for individuals who have lost the ability to communicate verbally. The possible risks of taking part include any upset caused by a disruption of the normal daily routine, and/or any discomfort in response to the music selected for the workshop. Staff and workshop leaders will monitor any participants' apparent state of ease and behaviour throughout the sessions and take action where necessary to avoid any negative impact.

Where is the study run from?  
NHS Lothian (UK)

When is the study starting and how long is it expected to run for?  
July 2016 to December 2016

Who is funding the study?  
Chief Scientist Office (UK)

Who is the main contact?  
1. Dr Katie Overy  
2. Dr Graeme Wilson  
3. Dr Sheila Rodgers

## Contact information

**Type(s)**  
Scientific

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## **Additional identifiers**

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

CGA/16/8

## **Study information**

**Scientific Title**

Pilot trial of an interactive music intervention for individuals living with moderate to severe dementia

**Acronym**

IMID - Interactive Music in Dementia

**Study objectives**

This pilot study will assess the feasibility of a fully randomised control trial by identifying: rates of eligibility, recruitment and retention; acceptability and practicality of trial procedures for patients, their relatives and staff; effect sizes; intervention and outcome measure protocols.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Scotland A Research Ethics Committee, 05/08/2016, REC ref: 16/SS/0129

**Study design**

Single-centre between-groups comparison with randomised per-patient allocation to group and a nested qualitative study

**Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

Hospital

## **Study type(s)**

Quality of life

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Moderate to severe dementia

## **Interventions**

Participants will be recruited from the same ward and randomly allocated, per-patient, to either group.

Experimental Condition: One-hour Interactive Music Workshops for groups of up to ten patients, provided by the Scottish Chamber Orchestra (SCO) and led by an experienced music workshop leader, once a week for eight weeks. Trained musicians will perform favourite or familiar music, while participants are facilitated and encouraged to take part by moving, singing or joining in on instruments, as they wish.

Control Condition: One-hour Music Listening Workshops, led by an experienced music workshop leader, once a week for eight weeks.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Rate of eligibility for the trial, measured prior to recruitment as a percentage of patients resident on the ward
2. Rate of recruitment, measured after informed consent has been granted for all participants and before the interventions begin, as a percentage of patients who were identified as eligible for the study
3. Rate of retention, measured after the study as a percentage of patients who were originally recruited to the study

## **Secondary outcome measures**

1. Effect sizes of scores of patients on the Cohen-Mansfield Agitation Index (CMAI), measured immediately before, half-way through and two weeks after the music interventions
2. Effect sizes of scores of patients on the Music and Dementia Observation Tool (in-house tool specially designed for this study), measured during each music workshop
3. Post-intervention interview responses from individuals from the care team about their experience of the workshops and any observed impact
4. Post-intervention interview responses from patient relatives about their experience of the workshops and any observed impact

5. Post-intervention interview responses from the musicians and workshops leaders about their experience of the workshops and any observed impact

**Overall study start date**

01/07/2016

**Completion date**

30/12/2016

## **Eligibility**

**Key inclusion criteria**

1. Resident on the same hospital ward
2. Diagnosis of Moderate to Severe Dementia and deemed to lack capacity according to the BMA toolkit, taking into account law in Scotland
3. Informed consent provided by nearest relative, guardian or welfare attorney, or for those without, the appointed IMCA (Independent Mental Capacity Advocate)
4. Aged between 16 and 110 years

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Both

**Target number of participants**

20

**Key exclusion criteria**

1. Significant hearing problems
2. Not able to remain comfortably located in the communal space during the workshop
3. Expected to be discharged and moved to another hospital ward/care home during the intervention
4. Informed consent not provided by nearest relative, guardian or welfare attorney, or for those without, the appointed IMCA (Independent Mental Capacity Advocate)

**Date of first enrolment**

08/08/2016

**Date of final enrolment**

26/08/2016

## **Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**NHS Lothian**

Waverley Gate

2-4 Waterloo Place

Edinburgh

United Kingdom

EH1 3EG

## Sponsor information

**Organisation**

The University of Edinburgh (UK)

**Sponsor details**

The Queen's Medical Research Institute

Edinburgh

Scotland

United Kingdom

EH16 4JT

**Sponsor type**

University/education

**ROR**

<https://ror.org/01nrxf90>

## Funder(s)

**Funder type**

Government

**Funder Name**

Chief Scientist Office

**Alternative Name(s)**

CSO

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

To be confirmed at a later date

**Intention to publish date**

30/12/2017

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No