ISRCTN11001662 https://doi.org/10.1186/ISRCTN11001662

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

Submission date
13/07/2016

Recruitment status
No longer recruiting

Registration date
15/07/2016

Overall study status
Completed

Last Edited
31/08/2017

Condition category
Mental and Behavioural Disorders

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

Contact name
Dr Katie Overy

ORCID ID
http://orcid.org/0000-0002-7271-8439

Contact details
IMHSD
Reid School of Music
Alison House
12 Nicolson Square
The University of Edinburgh
Edinburgh
United Kingdom
EH8 9DF

Type(s)
Scientific

Contact name
Dr Graeme Wilson

Contact details
Reid School of Music
Alison House
12 Nicolson Square
The University of Edinburgh
Edinburgh
United Kingdom
EH8 9DF

Type(s)
Scientific

Contact name
Dr Sheila Rodgers

Contact details
Medical School (Doorway 6)
Teviot Row
Edinburgh
United Kingdom
EH8 9AG

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/01nrxwf90

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?
HRA research summary			28/06/2023	No	No