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Agitated BehavioR of Elderly and Alternative Simple Treatments: Individualized Music – a feasibility and pilot study (the ABrEAST-iM study)

Submission date
21/05/2019

Recruitment status
No longer recruiting

Registration date
25/05/2019

Overall study status
Completed

Last Edited
05/06/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia often manifests with behavioural and psychological symptoms of dementia (BPSD) and is a growing global challenge and public health and care issue. The management of BPSD (e.g., agitation, apathy, withdrawal, depression) usually includes pharmacological treatment (e.g., antipsychotics) that may cause serious side effects and influence the quality of life of persons diagnosed with dementia. Non-pharmacological treatment (e.g., music therapy, social engagement, art therapy such as dancing and painting) are increasingly used promising positive outcomes. Specifically, music is a means of communication or intellectual stimulation and emotions aroused by music can enhance recognition of excerpts and memory consolidation. For example, the documentary “Alive Inside” (http://www.aliveinside.us/#land) shows the impact of personalized music on emotional, physical and cognitive well-being as well as on the self in dementia. The aim of this study is to assess the impact of predetermined individualized music (iM) on older adults over 65 years of age with mild to moderate dementia and living in residential care facilities, and to understand families and staff experiences with iM activities.

Who can participate?
Male and female older adults 65 years of age or older who have lived in residential care facilities for at least one month, have mild to moderate dementia and show BPSD

What does the study involve?
For three days per week and for three sequential weeks (that is, nine sessions in total), residents are asked to listen to music of their preference for 10 minutes per day using a device (e.g., iPod) with headphones. This activity takes place in a private (e.g., their room) or public (e.g., dining room) area of the facility between 10:00 am to 1:00 pm or 2:00 to 5:00 pm, when the resident is available from routine care and programs (e.g., eating, bathing). A research assistant (a member of the research team) is with the resident as s/he listens to the music without interacting with them.

What are the possible benefits and risks of participating?
There may or may not be direct benefits to participants (i.e., residents, families, staff) in this study. It is hoped that the information from this study can be used in the future to benefit other people at the same age of residents. There are no potential or known benefits to residents, except for listening to their favourite music. However, there are benefits to the state of knowledge and broadly to society. Participation in this study may cause some inconvenience to participants including the time to listen to music and to participate in interviews. There are no known or anticipated risks to residents, families or staff by participating in this study.

Where is the study run from?
Three residential care facilities in British Columbia: one in mainland and two in Victoria, BC (Canada)

When is the study starting and how long is it expected to run for?
April 2015 to August 2016

Who is funding the study?
University of Victoria (Canada)

Who is the main contact?
Dr Anastasia Mallidou
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Agitated BehavioR of Elderly and Alternative Simple Treatments: Individualized Music – a feasibility and pilot study (the ABrEAST-iM study)

Acronym
ABrEAST-iM

Study objectives
The purpose of this study was to assess the impact of individualized music (iM) activity on older adults over 65 years of age living in residential care facilities (nursing homes) and to understand families and staff/professional caregivers' experiences of the use of iM activity. The research questions were: "What is the effectiveness of iM activity on the behavioral and psychological symptoms of dementia and on affect of older adults living in residential care facilities with diagnosis of mild to moderate dementia?" and "What are families' and caregivers' experiences of the use of iM activity?"

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/12/2015, 04/01/2016 and 02/02/2016 by the Harmonized Human Research Ethics Board (HREB) that was run as a pilot in BC at the time involving all health authorities and higher education institutions (Research Ethics Board, Department of Evaluation and Research Services, Fraser Health Authority, Suite 400, 13450-102nd Avenue, Surrey BC, V3T 0H1, Canada; Tel: +1 (0) 604 587 4436; Email: Sara.OShaughnessy@fraserhealth.ca), protocol number: BC15-146; approval reference number: FHREB 2015-046/10Dec2015; VIHA file number: BC2015-052 /02Feb2016

Study design
Feasibility and pilot study

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Older adults living in residential care facilities with diagnosis of mild to moderate dementia

Interventions
The predetermined iM activity/intervention was delivered/implemented by an interventionist (i. e., staff or family) in a private area (e.g., resident room) between 10:00 am to 1:00 pm or 2:00 to 5:00 pm, because during those times residents were available and not occupied with routine care and residential care programs (e.g., eating, bathing), for 10 minutes by three days per week over

a period of three sequential weeks (i.e., nine sessions of 10 min each within three weeks = dose of intervention). Residents were asked to listen to music of their preference for 10 min per day using a device (e.g., iPod) with headphones. A research assistant (member of the research team) was with the resident as s/he was listening to the music without interacting with them.

Intervention Type
Behavioural

Primary outcome(s)
1. Affect measured through direct observation of facial expression and body movement using Lawton's Modified Behavior Stream (LMBS), which assesses positive affect (i.e., pleasure, interest, contentment) and negative affect (i.e., sadness, anxiety, anger); observation conducted a) before the iM intervention (for 5 min); b) during (for 10 min); c) immediately after the intervention was complete (for 5 min); and d) 10 min after the intervention was complete (for 5 min). For example, pleasure was noted when the participant smiled, laughed, or showed other outward manifestation of happiness using a 5-point Likert scale (1=never, 2= less than 16 seconds, 3= 17-59 seconds, 4= 1-3 minutes, and 5= more than 3 minutes of the observation time). Also, an option 6= "cannot tell" added for the observer. All affect and behavior measures represent duration (amount of time) and frequency. At the same time, resident behavior (i.e., non-verbal and verbal) was also recorded.
2. Quality of Life (QoL) measured using the Quality of Life–Alzheimer's Disease Scale (QoL-AD) of 13-item (i.e., physical health, energy, mood, living situation, memory, family, marriage, friends, self as a whole, ability to do chores around the house, ability to do things for fun, money, and life as a whole) survey questionnaire with 4-point (1= poor to 4= excellent) Likert response scales through both self (via interview; about 10 min) and proxy (via family or caregiver self-administered survey; about 5 min) ratings for capturing both perspectives; the score ranges from 13 to 52 points. Measured at baseline and follow-up (after three weeks of the intervention).

Key secondary outcome(s))
1. Behavior and psychological symptoms of dementia (BPSD) measured using the Canadian version of the Resident Assessment Inventory Minimum Data Set version 2.0 (RAI-MDS 2.0) and administrative data to capture resident patterns of BPSD: wandering (i.e., E4a), verbally abusive behavior (i.e., E4b), physically abusive behavior (i.e., E4c), socially inappropriate or disruptive behavior (i.e., E4d), and resistance of care (i.e., E4e); and any potential change of them (i.e., E5) at baseline, during the intervention, and follow-up (after three weeks of the intervention).
2. Antipsychotics measured using administrative data (resident charts and nursing records of medications) such as the number, type and dose of medications (e.g., antipsychotics) administered to each resident-participant at baseline, during the intervention, and follow-up (after three weeks of the intervention).
3. Experiences and perceptions of the use of iM intervention recorded via face-to-face, one-on-one semi-structured interviews with family and caregivers in a private space within the facility (e.g., resident room) at baseline and follow-up.

Completion date
20/08/2016

Eligibility

Key inclusion criteria
1. Mild to moderate dementia (i.e., a CPS score 2 to 4) using as a proxy of cognitive capability, the Cognitive Performance Scale (CPS) that is part of the Resident Assessment Instrument

Minimum Data Set 2.0 (RAI-MDS 2.0) (reference period of seven days)
2. Manifested BPSD, when at least two indicators (e.g., resistance to care, abusiveness, aggressive or socially inappropriate behavior) are present in the last assessment as they are monitored in the RAI-MDS section E4 (i.e., a, b, c, d, e) (reference period of seven days)
3. Lived in the residential care home for at least one month (at the start of the study)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Accompanying diagnosis of manic depressive – bipolar disorder or schizophrenia
2. Living in a hospice care program

Date of first enrolment
15/02/2016

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
Canada

Study participating centre
University of Victoria
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Sponsor information

Organisation
University of Victoria

ROR
https://ror.org/04s5mat29

Funder(s)

Funder type
University/education

Funder Name
University of Victoria Internal Research and Creative Project Grant

Alternative Name(s)
UVic, Victoria College, Universitas Victoriensis

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the principal investigator, Dr Anastasia Mallidou (mallidou@uvic.ca). Participants have provided consent for sharing the unidentified data and secondary data analyses for five years after the data completion of the study (until August 2021). No ethical or legal restrictions exist for sharing the data. Also, it is possible to upload the datasets, analyses, and study findings to the institutional repository at the University of Victoria (https://dspace.library.uvic.ca/), after accepting the manuscript for publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		22/05/2019	28/05/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes