Protocol for innovative personalised model of care for dementia in rural Australia

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Abstract

Objective: Current literature indicate the benefits of non-pharmacological interventions on individual behavioural and psychological symptoms of dementia (BPSD) and mood outcomes. However, these approaches to management of BPSD have not been widely implemented in Australian residential aged care facilities (RACFs), especially in rural settings. This study aims to identify key drivers of personalised care interventions, and co-design and implement a new personalised model of care incorporating principles of the Progressively Lowered Stress Threshold (PLST) model and personalised music activities in five Australian rural RACFs.

Methods and analysis: A quasi-experimental study that compares pre- and post-intervention measures with one- and three-months follow up is being implemented. This study is being conducted in five rural RACFs in South Australia and Queensland. The number of residents with advanced dementia sought for the study will be 15-20 at each site depending on size of facility (total n=60-80; statistical power 0.9). The exception will be the Aboriginal and Torres Strait Islander Mutkin Residential Aged Care which has only 15 residents in total; but it provides an opportunity to trial the study in a different cultural context. Methodological triangulation using both qualitative and quantitative methods will be used to understand the effectiveness of the new model.

Ethics and dissemination: This study is approved by the Southern Adelaide Clinical Human Research Ethics Committee (OFR #: 277.17). Dissemination of the study activities, protocol, and findings will be made public in appropriate platforms, such as academic journals/conferences, and media outlets including the Australian and New Zealand Clinical Trials Registry website.

Introduction

Dementia is a major cause of overall disease burden for Australians aged over 65 years[1], and it has no cure. In long-term aged care facilities, many residents with dementia present challenging behavioural and psychological symptoms of dementia (BPSD) such as agitation.[2] BSPD are complex, stressful, costly aspects of care, and associated with diminished quality of life, and a high workload for care staff.[3-5] Non-pharmacological interventions attract growing attention in caring for people with dementia (PWD), due to limited efficacy of the use of antipsychotic medications.[6,7] However, these interventions are not widely implemented in Australian residential facilities and have limited evidence suggesting their benefits. When individually applied to care for PWD, the PLST model and

music intervention prove effective in managing individual BPSD outcomes.[6] The PLST model incorporating music interventions have not been previously tested in managing individual BPSD outcomes. Harmony in the Bush study (HiB) is an innovative project aimed at developing a personalised model of care for dementia in long-term residential settings, based on co-designing and implementation of the PLST model with integrated music intervention, to managing individual residents' BPSD in five Australian rural residential aged care facilities (RACFs). The project incorporates a longitudinal quasi-experimental design including behaviour measurements, interviews, and focus groups in the five facilities to evaluate effectiveness of the model in different kinds of health services; small, large, public and private. This paper aims to showcase the study design, ethically approved protocol and preliminary findings of this large multi-site study. The findings will result in long-term positive outcomes for PWD, aged care staff and their workplaces, and dementia care in aged care facilities.

Methods

Methodological approach

A twelve-weeks quasi-experimental study comparing pre- and post-intervention measures with one and three-month follow-up is being implemented. Methodological triangulation including qualitative and quantitative methods are being used to evaluate the effectiveness of the PLST and personalised music program.

Design and setting

The study uses a two-year longitudinal quasi-experimental design including behaviours measurements, surveys, interviews and focus groups. The duration covers three phases: initiation (n = 6 months), implementation (n = 12 months; as described in Figure X (the Gantt chart 2)), and evaluation, analyses and results write-up for publication. The research planned activities and their timelines are given in Figure 1 (Gantt chart 1) and described in the following section. The study implements a 12-weeks interventional research program in each of the five participating RACFs in rural South Australia (n = 2) and Far North Queensland (n = 3), Australia. The RACFs were purposely selected and their leaders approached by the investigators and the former expressed interest to participate. In order to reflect the diversity of the participant cohorts, two facilities are privately owned; one is a public funded (state-run centre); and one is a not-for-profit facility. The fifth facility is an Aboriginal Residential and Community Aged care, which is not-for-profit and partly funded by the government. This facility provides an opportunity to trial the study in a different socio-cultural context. All the facilities are geographically widely and rurally spread in South Australia and Far North Queensland.

Participants

Participants involve eligible residents living with dementia in the five RACFs, legal guardians and family members/relatives of the residents, aged care staff, and musicians/artists. In four RACFs, 15-20 residents living with dementia are selected as participants; but in one facility, which has a total of 15 residents, all those living with dementia will be invited to participate. As a result, a total of 60-80 participants will be recruited as participants for the study. Eligible residents must have (1) a diagnosis of dementia within the Diagnostic and Statistical Manual of Mental Health Disorders 5 (American Psychiatric Association, 2013), (2) a Standardized Mini Mental Status Examination (SMMSE)[8] score of less than 24, (3) be ambulant, and (4) display dysfunctional behaviour. The residents cannot meet the inclusion criteria or have a medical condition that affects normative behavioural patterns. All legal guardians and family members/relatives of the eligible, consented residents are recruited as participants. In addition, aged care staff, including senior management

staff, are eligible to participate in this research. One to two musicians/artists are involved in preparation and delivery of group and personalised music programs in each facility.

Residents with dementia: selection and recruitment

Four-six weeks prior to the beginning of the intervention in each facility, senior staff or registered nurses purposefully select all residents with dementia, as previously diagnosed by their (residents') clinicians and recorded in personal care records, as potential participants. Selected residents would be experiencing varying levels of significant cognitive impairment that progressively deteriorates with age or time due to dementia; hence their long-term living in the RACFs. The Letter of Introduction/Invitation, Participants' Information Sheets and Consent Forms (PICFs) and stamped return envelops are posted by aged care administrators to legal guardians and/or any power of attorney appointee of all potential residents living with dementia. All information concerning the study aims and expected outcomes are shared with the participants/legal participants, and residents' family members/relatives. Potential participants are recruited following reception of informed consents to participate in the study by their legal guardians/power of attorney appointees. To recruit participants from the Aboriginal Residential Aged care, the investigators will consult with the community elders and seek their approval to proceed. Only after the elders and family members' approval will the participants be recruited to be involved in the study.

Legal guardians and family members/relatives

Legal guardians/power of attorney appointees and/or family members/relatives are informed and briefed on the study in which selected potential residents are to participate, as previously described under the 'selection and recruitment of residents' section. They voluntarily and willingly consent to their participation. Those who consent to the research participation, on their behalf or of the residents, post back one copy each of the signed consent forms directly to the project officer through the Flinders Rural Health SA Renmark campus address.

Aged care staff

Senior staff or registered nurses from each facility purposefully select all probable residents living with dementia for recruitment and request the aged care administrators to post the the Letter of Introduction/Invitation, Participants' Information Sheets and Consent Forms (PICFs) and stamped return envelops to legal guardians/power of attorney appointees, and family members/relatives of all probable residents. Senior staff or registered nurses at each facility then refer residents with signed consents for participation in the study to the investigators for baseline assessment. Legally authorized senior aged care staff access probable residents' health data and provide only de-identified health information to the project officer (AK) and the Chief Investigator (JG). All the aged care staff are to participate in the education and training program on the theory, use and importance of incorporating principles of the PLST model, and personalised music into individualised care plans for residents living with dementia; and in implementing the individualised care model. Voluntarily consenting aged care staff participate in focus group discussions and interviews, and completion of Caregiver Stress Inventory questionnaires.

Musicians/artists

Six musicians/artists are hired to deliver group music/arts activities to residents participating in the study. These musicians/artists are those whose skills and knowledge best matched the most appropriate and preferred group or individualised music/arts and movement activities by the residents. Additional criteria for selecting and enlisting the musicians/artists include that they must be living and working locally within the area in which the relevant Aged Care facility to participate in is located. This is to ensure the project benefits the local community, and the intervention will be sustainable after the research project completion. The musicians/artists must also have

acquired/will acquire the Criminal Clearance Check for working with the vulnerable people from relevant national or state authorities in Australia.

Study implementation

Stage 1 – Baseline assessments (Week 1)
Chief Investigator (CI), Prue Mellor, supported by a project manager/research fellow visits each engaged facility. Residents are recruited in line with the ethical protocol. De-identified clinical records are reviewed to identify residents with a medical diagnosis of a dementia, ability to mobilise, evidence of BPSD, and to residents with a medical diagnosis that affects normal behaviour; thereby meeting the exclusion criteria. At this point potential participants are assessed against the DSM-5 criteria for the syndromes of mild or major neurocognitive disorders and be screened for cognitive function. Demographic profiles and baseline data are then collected for each of the participants including age, gender, ethnicity, education level, and occupation. Clinical records are accessed to identify prescription/administration of sedatives and psychotropic medications. Having met the inclusion criteria, participants are fitted with an ACTi graph watch to record baseline sleep patterns. During this week each participant is assessed using the Cornell Scale for Depression in Dementia (CSDD) or Kimberley Indigenous Cognitive Assessment-Depression (KICA-Dep), Barthel Index of Activities of Daily Living (ADL), Apathy Evaluation Scale (AES), Cohen-Mansfield Agitation Inventory (CMAI), Standardised Mini Mental State Examination (SMMSE), Kimberley Indigenous Cognitive Assessment (KICA-Cog), Pain Assessment in Advanced Dementia (PAINAD) scale, and Actigraphy ACTi-watch 2.

Stage 2 – Education and Development of the PLST care plans (Week 2 – 4)
CI Mellor conducts staff training workshops focusing on the theory and delivery of the PLST and the use of the measurement instruments listed in stage 1 – Baseline assessment. The PLST intervention entails the introduction of individualised care plans based on the following principles of the PLST theory:

- introduce consistent individualised routines to compensate for conative losses
- organise small group activities to eliminate overwhelming stimuli
- allow residents to set their own sleep/wake cycle to prevent fatigue
- plan activities based on past experiences and practices considering present cognitive and functional abilities
- eliminate misleading stimuli that trigger illusions.

All staff members on duty are responsible for observing and recording the residents' behaviour on each shift. At least two aged care staff in each facility are appointed as change champions by senior managers and trained by PM in the process to ensure sustainability of the research outcomes after the project completion.

Stage 3 – Intervention phase (Week 5 – 12)
Participants are provided with a 4-week intervention firstly based on the PLST + personalised preferred music playlists co-designed program, follow by additional four weeks of integrated small groups music sessions program. For all the five facilities, individualised music forms the basis for the music/art and movement intervention. A key aspect to the success of individualised music is identifying specific music preferences including exact song titles and performers. Thus, we use *The*

Assessment of Personal Music Preference Protocol in the *Evidence-Based Guideline of Individualised Music for persons with Dementia©* (5th edition; Gerdner L.A., 2013) to assist in the process of music selection for each of the participating residents. The individualised music songs are determined after discussion with the resident, the resident's family member or next of kin/legal guardian, and the nursing staff, and produced onto a multimedia MP3 video player for listening at an appropriate time by the resident/s.

Applicable music and arts/movement activities are personalised and dependent on the participants' preferences, and their appropriateness to the participants' capability, participation and response. They can take the forms of music that may involve (1) past preferred music that will be individualised for listening by the participants with dementia and (2) group music and movement/dance, disability arts and creative aging program/s, visual arts mediums, storytelling, basketry/weaving, painting, drawing, screen-printing, knitting, and etching. Music/Arts preferences are determined with the assistance of family members and/or caregivers. Planned music and/or arts and movement activities are tailored to groups' and/or individuals' interest and needs; based on the PLST principles and regularly monitoring responses. The investigator(s) continuously gauge activity and stimulation levels using disturbed and dysfunctional behaviour as a measure and adjust care as necessary.

During the last four weeks (i.e., week 8 – 12) in each facility over the course of 2018, the musicians/artists spend 1-hour session for two days each week alongside participating residents. Each day offers a whole group or individual activity, during which all participants are encouraged to have a hands-on experience sharing and playing with their favourite tracks, mixing, dubbing and exploring possibilities supported by the musicians/artists. The musicians/artists facilitate each music/art and movement session guiding the conversations and musical explorations, posing questions to stimulate group and individual discussion. Aged care workers work together with artists to ensure individuals can engage as fully as possible. The researchers take random and representative photographic, audio, and/or video recordings of some participants during the music/arts and movement activities for use in the project specific-designed web-site showing each case facility activities, and in the presentations to other researchers or general public (in the case of media release and conferences) about this research study. The recordings are made only after a free will and voluntary consent is sought and permitted by the participants. All photographs and videos collected during the research study are de-identified to ensure anonymity of the participants. The Music in Dementia Assessment Scales (MIDAS) is used to assess changes in the wellbeing of a person with dementia participating in the music or arts intervention.

Stage 4: Follow-up and Evaluation

Data collection and measures: This study uses a quasi-experimental study design which compares pre- and post-intervention residents' behaviours measures with one- and three-months follow up, and that includes surveys, interviews and focus groups. Selected assessment tools and their expected outcome measures are described as follow.

- Cohen-Mansfield Agitation Inventory (CMAI)[9], is a validated tool that is being used in this study to assess level of agitation in residents with dementia.

- Standardised Mini Mental State Examination (SMMSE)[8], is used to assess orientation, memory, attention and calculation, language and visual construction in residents. The SMMSE is being administered to assess cognition of all resident participants only at the commencement of the project, before the introduction of the interventions. Kimberley Indigenous Cognitive

Assessment (KICA-Cog) developed by LoGiudice et al.[10], is administered for Indigenous participants.

- The 10 item version of The Barthel Index of Activities of Daily Living (ADL)[11], is being administered to assess ADL of all participants only at the commencement of the project, before the introduction of the interventions.

- Pain Assessment in Advanced Dementia (PAINAD) scale. This frequently used simple five-item observational tool with a range of 0 to 10[12], is administered to assess pain of all participants only at the commencement of the project, before the introduction of the interventions. The five indicators are breathing, vocalization, facial expression, body language, and consolability.

- Actigraphy ACTi-watch, which allows for continuous measurements of sleep/wake activities over days, is being used to record sleep patterns in residents, over continuous 5 days, at baseline and four weeks after the introduction of the PLST intervention. The Actigraphy ACTi-Watch is fitted on the less dominant wrists of the residents.

- Cornell Scale for Depression in Dementia (CSDD)[13], which is used to specifically assess signs and symptoms of a major depression in people with a dementia, and that includes items concerning physical well-being, sleep, appetite and other vegetative symptoms, is being administered at baseline, 4 and 8 weeks after the 8-week intervention trial. The Kimberley Indigenous Cognitive Assessment – Depression (KICA-Dep)[14], a culturally acceptable screening tool for depression among older Indigenous Australians living in remote areas, is alternatively administered for Indigenous participants.

- The Apathy Evaluation Scale – clinician version (AES-C)[15] is being used for assessment of apathy in residents with dementia at baseline and after 8 weeks.

- Music in Dementia Assessment Scale (MiDAS)[16,17], a Visual Analogue Scale measuring levels of Interest, Response, Initiation, Involvement and Enjoyment, is being used to measure residents' outcomes during and after the music/arts and movement activities intervention.

- Caregiver Stress Inventory (CSI)[18], which is a 43-items, self-report tool developed to determine individual staff caregiver stress to incidents (behaviours) that occur in residents with dementia, is used for assessing staff stress levels. Staff stress is defined as the response that individual staff members' experience to incidents that occur in the daily care of persons with dementia. Reponses are self-rated on a seven-point Likert-type scale (1=not stressful, 7=extremely stressful) based on current perceptions of stress. The tool consists of four subscales representing staff stress from aggressive behaviour, inappropriate behaviour, resident safety, and resource deficiency. The tool has recently been used in Australia residential care facilities.[19]

- Medication charts: Medication charts of residents are reviewed for administration of night sedation and psychotropic medication at the baseline and three months post-intervention assess reduction in the use of antipsychotic medications to manage BPSD in residents.

Investigators and staff administer measurements post-intervention for the CMAI, ACTi-watch, PAINAD, MiDAS, CCSD and CSI, and conduct semi-structured interviews and focus group groups post-intervention and at 1 and 3-month follow up. The interviews are conducted with one-on-one consenting participants, who include aged care staff including managers, legal guardians and/or family members, and musicians/artists. The focus groups are conducted with aged care staff. Aged

care staff members on duty are responsible for observing and recording the residents' behaviour on each shift, using the CMAI and/or MiDAS tools.

Data analysis

The study uses a quasi-experimental study design which compares pre- and post-intervention residents' behaviours measures with one- and three-months follow up. Quantitative data will be analysed using the statistical package SPSS. Descriptive data will be checked for outliers and assumptions for parametric analyses. Paired-t test and repeated measures ANOVA will be used to understand difference in baseline and follow-up assessments. Multivariate analyses will investigate the effect of PLST intervention with music/arts component as against PLST intervention without the music component measured using the waiting-list approach. The model will be adjusted for potential confounders. The total number of residents living with dementia across the five participating aged care facilities in this this study is approximately 170-180. Allowing for 10% attrition, the investigators have estimated that 70-80 residents from this cohort can ensure a statistical power of 0.90. This estimation is based on a recent meta-analysis on effect of music therapy on agitation, which reports an overall effect size (Cohen's d) of 0.61 calculated from 12 studies[20], and by adopting an alpha level of 0.05 and employing the algorithm detailed in Senn's book (1993, p.218).[21]

Qualitative data from semi-structured interviews and focus groups will be used thematically analysed to explore institutional culture or implications of the research intervention on staff and organisation, and to triangulate the findings.

Ethics and dissemination

The participant information for the legal guardians/staff are prepared in an acceptable manner, which is clear and understandable for participants of various cultures and background.

Simple informatics were developed to gain consent from dementia participants. The pictures provide clear description of activities to be undertaken as part of project.

All research staff and artists who will have direct contact with participants obtained DCS1 clearance to work with vulnerable people such as children and elderly.

Mutkin aged care facility – The elders meeting and approval and appointment of local Aboriginal project staff

The study is registered with the Australian and New Zealand Clinical Trials Registry (ANZCTR) on 20/2/2018 (Registration No: ACTRN12618000263291p; **http://www.ANZCTR.org.au/ACTRN12618000263291p.aspx**).

Discussion

Non-pharmacological interventions are more effective and less harmful than the antipsychotic drugs in managing individual behavioural and psychological symptoms of dementia and mood outcomes in those living with the syndrome in residential aged care facilities.[6,22,23] However, there is no evidence on the feasibility and efficacy of non-pharmacological interventions in rural Australia. In the present study we investigate the efficacy of an innovative non-pharmacological intervention of a personalised model of care in dementia that incorporates the principles of the Progressively Lowered Stress Threshold model[24], and personalised music activities.[23] The significance of this study includes the ability to evaluate effectiveness of the model in different kinds of health services; small,

large, public and private. The protocol details the processes and techniques for identifying key drivers of personalised care interventions, and co-designing and implementing a new personalised model of care for dementia. The longitudinal quasi-experimental design enables the flexibility and feasibility of the study to be conducted in the complex aged care nursing home environment. Further, methodological triangulation using quantitative and qualitative derived data to understand the effectiveness of the new model will provide in-depth information of the study outcomes. The research team included two research fellows, a registered nurse and a social worker. All behaviour measurements were conducted by a qualified nurse. Interviews and focus groups in the five facilities were conducted by research fellows. The present study combines evidence based behavioural interventions (that is, Progressively Lowered Stress Threshold model with personalised music intervention) to co-design, develop and implement a new model of care for dementia in residential aged care settings. This is important in that the study will reveal robust in-depth research outcomes. Additionally, the study will untangle the complex interactions between aged care organisational culture, staff, residents, residents' relatives/family members, and aged care home environment, which will improve the care outcomes for those residents living with dementia, as well as staff care stressful level, knowledge and job satisfaction. This will result in long-term positive outcomes for people living with dementia, aged care staff and their workplaces, and dementia care in aged care facilities. A limitation of this study is that it is a non-randomised controlled trial, thus the design cannot focus on a more robust test of effectiveness. However, this limitation is offset by using both quantitative and qualitative methods to triangulate the findings.

Disclosure statement

The authors declare no conflicts of interest.

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Presenter

Abraham Kuot is a Research Fellow at Flinders University Rural Health South Australia. He is a molecular biologist, geneticist and a public health researcher with 11 years of experience. He completed his PhD in Medical Research at the Department of Ophthalmology, Flinders University of South Australia in 2015. Currently, Kuot is the project manager for a national research study, funded by the Australian Department of Health and Ageing, called the 'Harmony in the Bush: Co-design of a personalised model of care for dementia in rural residential aged care'. This study is undertaken to identify key drivers of personalised care intervention, and use co-design principles to implement and evaluate a personalised model of care, incorporating music, art and movement interventions for residents with dementia in five rural aged care homes in South Australia and Far North Queensland. Kuot's research interests include healthy ageing and innovative care models for dementia in long-term residential aged care facilities, health services delivery, population health, and rural medical education.