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'PROCUIDA-Dementia' a feasibility Mexican study investigating an optimised person-centred intervention to reduce antipsychotic medication and improve the quality of life of older people living in care homes

Submission date
27/03/2017

Recruitment status
No longer recruiting

Registration date
19/05/2017

Overall study status
Completed

Last Edited
04/04/2022

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
Dementia is a common condition in the aging population. People with dementia have difficulties with mental processes such as memory, language, reasoning and identifying people and objects, which become progressively worse over time. Many people with dementia experience symptoms such as agitation and mood changes, and so may be treated using medications to control this (antipsychotic medications). PROCUIDA-Demencia is a staff training programme looking at reviewing antipsychotic medication and enhancing its prescription to treat stress and distress in dementia. The training involves psychosocial interventions (social activities) to improve the quality of life of people with dementia. The aim of this study is to find out whether these activities are effective at improving mood, behaviour and sense of well-being in residents and staff.

Who can participate?
Care homes with resident patients with dementia, staff members and relatives of residents with dementia.

What does the study involve?
Participating care homes are randomly allocated to one of two groups. In the first group staff deliver the PROCUIDA-Demencia programme to residents. This takes place over 24 weeks during which activities with the residents are organised and have fortnightly online meetings with staff are arranged. The activities involve attending a 45 minute exercise session in the care home, twice a week (this applies depending on shift rota) monitoring the mood and behaviour of residents, and taking part in activities that will involve using dolls, board games, and singing. In the second group, care homes deliver usual care to residents throughout the study period. At

the start of the study and then after 12 and 24 weeks, residents, care home staff and relatives of residents complete a range of questionnaires in order to assess the mood, behaviour and wellbeing of the residents.

What are the possible benefits and risks of participating?
Participants who take part in the programme may benefit from improvemetns to mood and wellbeing. In addition, staff benefit from learning new skills which could improve the quality of care they are able to provide. There are no notable risks involved with participating.

Where is the study run from?
The study is run from Instituto Nacional de Geriatria, Mexican Gob and takes place in eight care homes in Mexico City (Mexico)

When is the study starting and how long is it expected to run for?
June 2016 to March 2018

Who is funding the study?
British Academy (UK)

Who is the main contact?
1. Ms Sara Torres-Castro (public)
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2. Dr Azucena Guzman (scientific)
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Contact information

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Public

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EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1

Study information

Scientific Title
PROCUIDA-Demencia: A feasibility study looking at a staff training PROgramme for Optimal Care aiming to develop person-centred care and review antipsychotic prescription in residents with dementia to improve quality of life in care homes

Acronym
PROCUIDA-Dementia

Study objectives
The aim of this study is to investigate the feasibility of PROCUIDA-Demencia when provided in care homes for older adults affected by Dementia.

Hypothesis:
PROCUIDA-Demencia will provide a vehicle for staff development which will enhance the quantity and quality of care home staff-resident interactions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. School of Health in Social Sciences, University of Edinburgh, Ethics Commeette, 30/08/2016, ref: STAFF068
2. Instituto Nacional de Geriatrìa, Mexico Gob, Ethics Commeette, 12/12/2016, ref: DI-PI-011 /2016

Study design
Randomised controlled mixed methods feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to resquest a participant information sheet

Health condition(s) or problem(s) studied
Dementia

Interventions
Care Homes will be randomly allocated to either receive PROCUIDA-Demencia or Treatment as Usual (TAU) using secure web access to the remote randomisation centre at Instituto Nacional de Geriatria in Mexico.

Intervention group: Four Care Homes in which the staff will receive training PROCUIDA-Demencia in the following three areas:
1. Understanding Challenging Behaviour and Review of Antipsychotic Medication UBER
This consists on addressing the side-effect of antipsychotic medication in Dementia cases and will be conducted by the PROCUIDA-Demencia Team every six weeks. This involves consenting person with Dementia (if able to communicate verbally), and acknowledgement by the medic of the care home and family member.
2. Person-Centred Care Therapy
PCC will be delivered by the Mexican Partner with support from the UK Partner. The core element of this intervention will be the principles taught by Tom Kitwood (1997) in order to prevent ‘malignant psychology’ during care. In addition, two elements will be delivered in the training. Care homes will be encouraged to design their own template for a personalized ‘Life Story Book’ to recollect key elements of the participant’s life. Staff will also be encouraged to implement activities according to the participants’ personal choice.
3. Psychosocial Interventions:
DANCIN sessions will be arranged twice-weekly for 45 minutes, preferably in the afternoon with the aim to deliver a total of 24 sessions in each setting. The intervention will be led by staff comfortable with dancing with residents. Residents who scored high risk for falls in SPPB measure will be invited to participate by observing in a ‘dance-chair’ modality.
Doll Therapy will be applied in line with the PCC intervention only if the participants want to have a doll. Then, it is important that the care staff are aware of the intentions and reasons for using dolls in the care home. Training will emphasize how to avoid responding to older adults in a childlike and demeaning manner when doll therapy is being utilized. Reminiscence Group Therapy will be based on some of the published strategies on reminiscence and group work with people with dementia by Pam Schweitzer and Bruce Errollyn (2008). Time, dates and themes are discussed in each reminiscence session.

Control group: Four Care Homes will receive the training and activities material at the end of the study (at 24 weeks). For each care home, the PI will make monthly phone calls, report any adverse events experienced by the PI and the registration of disease and staff turn-over.

Follow up takes place after 12 and 24 weeks.

Intervention Type
Behavioural

Primary outcome measure
1. Quality of Life is measured by applying the the Quality of Life-Alzheimer's Disease (QoL-AD) questionnaire at baseline, 12 and 24 weeks
2. Cognition is measured by using the Addenbrooke's Cognitive Examination Revised (ACE-R) at baseline, 12 and 24 weeks
3. Behaviour is measured by using the Neuropsychiatry Inventory-Nursing Home (NPI-NH) at baseline, 12 and 24 weeks
4. Burnout is measured using Maslach Burnout Inventory (MBI) at baseline, 12 and 24 weeks
5. Staff attitudes towards people with Dementia is measured by applying using the Approaches to Dementia Questionnaire (ADQ) at baseline, 12 and 24 weeks
6. Care staff's sense of competence is measured by using the Sense of Competence in Dementia Care (SCIDS) questionnaire at baseline, 12 and 24 weeks

Secondary outcome measures
No secondary outcome measures.

Overall study start date
01/06/2016

Completion date
31/03/2018

Eligibility

Key inclusion criteria
Care Home inclusion criteria will include:
1. A 20% of residents suspected with a diagnosis of neurodegenative disease (DSM-V criteria) of mild to mild stages (Clinical Dementia Rating/CDR)
2. Care Homes which are not taking similar training on Psychosocial Interventions or who are currently reviewing Antipsychotic Medication
3. Care Homes with at least one spacious and ventilated room designated for PROCUIDA-Dementia Study activities
4. Care Homes with manager and proprietor willing to be involved in the programme and allow staff to take part in the training
5. Psychologist and GP to support residents in case a crisis
6. Health and safety protocols in place

Residents Inclusion Criteria:
1. Residents living permanently in the care home
2. Dementia diagnosis
3. SPPB screening measure, cut off point 10 to prevent risk of falls
4. Informed consent to take part in the study
5. Participants must speak and understand Spanish, alternative English consent forms will be given if the participant is not Spanish-native speaker
6. Preferably on current antipsychotic medication prescription

Staff Inclusion Criteria:
1. Consent to participate in the PROCUIDA-Dementia study
2. Available to the three day staff training delivered by the PIs to ensure that the interventions are being implemented in the care homes
3. Commitment to support the study whether or not allocated to intervention or control group for 24 weeks. Staff willing to facilitate musical and dancing sessions do not require professional dance/musical experience, but a rhythmic response to music is required.

Relatives Inclusion Criteria:
1. Consent to participate in the PROCUIDA-Dementia activities organised by the care home
2. Consent to participate in the Focus Groups targeting family members at the end of the study
3. Visit at least once a month, in order to witness the staff-resident intervention activities
4. Read/Speak Spanish

Participant type(s)
Mixed

Age group
Other

Sex
Both

Target number of participants
25 participants intervention group and 25 participant control group

Total final enrolment
55

Key exclusion criteria
Care homes:
1. Without dementia patients
2. Without psychologist and GP

Residents:
1. Not able to verbally communicate
2. Without consent/informed consent
3. Risk of falls (score 10 on SPPB)

Staff
1. Without consent/informed consent
2. Agency staff

Date of first enrolment
12/12/2016

Date of final enrolment
12/07/2017

Locations

Countries of recruitment
Mexico

Study participating centre
Instituto Nacional de Geriatria, Mexican Gob
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Sponsor information

Organisation
British Academy

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Sponsor type
Charity

ROR
https://ror.org/0302b4677

Funder(s)

Funder type
Charity

Funder Name
British Academy

Alternative Name(s)
The British Academy

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal and presentation at International Conferences.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Sara Torres Castro (saratorrescastro@gmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/01/2018		Yes	No
Results article		01/03/2022	04/04/2022	Yes	No