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Caring for people with advanced dementia living in nursing homes

Submission date
03/10/2017

Recruitment status
No longer recruiting

Registration date
04/10/2017

Overall study status
Completed

Last Edited
22/01/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Dementia is a broad category of brain diseases that cause a long-term gradual decrease in the ability to think and remember. The Namaste Care intervention has been designed to improve the quality of dying for people with advanced dementia living in care homes. Namaste Care is a structured care programme and is based on both best practice dementia care and best practice end-of-life care. Namaste Care is based around sensory experience: music, massage, colour, taste and scents, and promotes person-centred care with adaptations made to the programme to reflect the resident's 'life story'. The Namaste Care intervention is delivered in a dedicated space up to twice a day with each session lasting 2 hours. The aim of this study is to assess the feasibility of conducting a larger study of the Namaste Care intervention.

Who can participate?
Permanent nursing home residents with advanced dementia, informal carers and nursing home staff

What does the study involve?
The participating nursing homes are randomly allocated to either the intervention group or the control group. The intervention group deliver Namaste Care and the control group continue to deliver the normal care provided to residents living in the care home. The duration of the intervention is 6 months and the duration of follow-up is also 6 months. The quality of life of the person with dementia and quality of dying are measured.

What are the possible benefits and risks of participating?
Participating in Namaste Care may improve quality of life and sleep for participants with advanced dementia. Nursing home staff who deliver Namaste Care may have increased job satisfaction, and for informal carers the delivery of Namaste Care sessions may provide a helpful and enjoyable way to interact with their family members with dementia. The risks are minimal as activities in the Namaste Care intervention are carried out routinely in nursing homes during the care of residents.

Where is the study run from?
Lancaster University (UK)

When is the study starting and how long is it expected to run for?
January 2017 to November 2018

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
Prof. Katherine Froggatt

Study website
http://www.namastetrial.org.uk

Contact information

Type(s)
Public

Contact name
Prof Katherine Froggatt

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 15/10/11

Study information

Scientific Title
The Namaste Care intervention to improve the quality of dying for people with advanced dementia living in care homes: a feasibility study for a cluster randomised controlled trial

Acronym

Namaste

Study objectives
This feasibility trial is being conducted to ascertain if the trial can be conducted on a larger scale in more nursing homes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Feasibility parallel two-arm multi-centre cluster controlled randomised trial with embedded process and economic evaluation

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Advanced dementia

Interventions
The nursing homes will be randomised to either the intervention arm or the control arm by assigning an ID to each nursing homes and randomly selecting each ID. The random allocation will be carried out by a statistician not otherwise involved in the trial.

Namaste Care is a structured care programme and is based on both best practice dementia care and best practice end-of-life care. Namaste Care is based around sensory experience: music, massage, colour, taste and scents and promotes person-centred care with adaptations made to the programme to reflect the resident's 'life story'. Namaste Care intervention is delivered in a dedicated space up to twice a day with each session lasting 2 hours.

The control arm will continue to deliver the normal care provided to the resident living in the care home.

The duration of the Namaste Care intervention will be 6 months and the follow-up for all arms will also be 6 months.

Intervention Type
Other

Primary outcome measure
This feasibility trial will consider two contender primary outcomes for a full trial:
1. Quality of dying (dementia), measured using CAD-EOLD at baseline, 2 weeks, 4 weeks, every 4 weeks thereafter for 6 months, 6 months or following death
2. Quality of life of the person with dementia, measured using QUALID at baseline, 2 weeks, 4 weeks, every 4 weeks thereafter for 6 months, 6 months or following death

Secondary outcome measures
1. Behaviours measured using Neuropsychiatric Inventory (NPI-Q) at baseline, 2 and 4 weeks
2. Pain measured using PAIN-AD at baseline, 2 and 4 weeks
3. Health economics measured using EQ-5D-5L at baseline, 2 and 4 weeks
4. Quality of end of life measured using ICECAP-SCM at baseline, 2 and 4 weeks
5. Capability of older people measured using ICECAP-O at baseline, 2 and 4 weeks
6. Economic evaluation in an end of life setting, measured using ICECAP-CPM at baseline, 2 and 4 weeks
7. Agitation measured using Cohen-Mansfield Agitation Inventory at baseline, 2 and 4 weeks
8. Sleep and activity measured using an actigraph for 4 weeks
9. Resource use (primary and secondary care services) measured at baseline, 2 weeks, 4 weeks, every 4 weeks thereafter for 6 months, 6 months or following death
10. Satisfaction of care from the perspective of a family member, measured using SWC-EOLD at baseline, 4 weeks, at least 8 weeks after death of the resident
11. Resource use from the perspective of a family member, measured at least 8 weeks after death of the resident
12. Person-centeredness in the nursing home, measured using Person Centred Assessment Tool pre-baseline and 6 months thereafter
13. Nursing home readiness for change, assessed using Alberta Context Tool pre-baseline
14. Nursing homes' readiness for Namaste Care (intervention and control arm), assessed using interview with nursing home manager pre-baseline
15. Staff turnover and sickness levels data obtained from nursing home manager pre-baseline and monthly thereafter for 6 months
16. Staff time, equipment and consumables used, identified from an interview with nursing home staff and looking at daily logs completed by nursing home staff

Overall study start date
01/01/2017

Completion date
30/11/2018

Eligibility

Key inclusion criteria
Inclusion criteria for residents:
1. Resident is a permanent resident within the nursing home (i.e. not present for receipt of respite or day care)
2. Resident has a formal assessment of advanced dementia, (based on the Functional Assessment of Staging of Alzheimer’s Disease (FAST) score of 6-7) made by the nursing home

manager or another experienced member of staff
3. Resident lacks capacity (capacity assessed and documented with an appropriate tool)
4. Resident has a key worker member of staff willing to provide proxy outcome data

Inclusion criteria for informal carers:
An informal carer meeting all of the following criteria will be eligible to join the feasibility trial if they:
1. Are above the age of 18 who self-define as a family member or friend who acts as an informal carer for a participant with advanced dementia
2. Have the ability to communicate in English

Inclusion criteria for nursing home staff:
Health and social care staff paid to provide care to individuals with advanced dementia within participating nursing homes will be eligible to participate in the study. This may include nursing home managers, Registered Nursing staff, care assistants and activity coordinators.

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
64 residents, up to 200 nursing home staff (final number will depend on size of nursing homes recruited), up to 64 informal carers

Key exclusion criteria
Resident exclusion criteria:
A resident meeting any of the following criteria will not be eligible to participate in the feasibility trial if the resident:
1. Is permanently bedbound and unable to leave their room
2. Is currently or recently involved in another research study or trial that conflicts with Namaste Care or with data collection during the course of the Namaste Care trial
3. Has the capacity to consent

Informal carer exclusion criteria:
If the informal carer cannot communicate in English, they will not be eligible to join the trial

Nursing home staff exclusion criteria:
If the nursing home staff member has delivered Namaste Care to a resident in a nursing home setting which is not involved in this trial

Date of first enrolment
01/12/2017

Date of final enrolment
30/05/2018

Locations

Countries of recruitment
United Kingdom

Study participating centre
To be confirmed
United Kingdom
-

Sponsor information

Organisation
Lancaster University

Sponsor details
Research Support Office B58
Bowland Main
Lancaster
England
United Kingdom
LA1 4YT

Sponsor type
University/education

ROR
https://ror.org/04f2nsd36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol for the overall study is available at https://njl-admin.nihr.ac.uk/document/download/2009487. This protocol briefly covers the trial phase of the study. It is anticipated the protocol for the trial phase of the study will also be published in a peer reviewed journal.

The findings from this study will be disseminated in a peer reviewed scientific journal and presented at conferences. This is estimated to be done after approximately one to two years after the trial is completed.

Intention to publish date
30/11/2019

Individual participant data (IPD) sharing plan
As a feasibility study the trialists do not anticipate future research uses for the data at this point in time. Anonymised quantitative outcome data will be available to others on request on completion of the study from Prof. Katherine Froggatt.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/11/2018	28/10/2019	Yes	No
Results article	results	01/01/2020	24/01/2020	Yes	No
Other publications	serious adverse event reporting procedures	20/01/2021	22/01/2021	Yes	No