A group intervention to improve quality of life for people with advanced dementia living in care homes: the Namaste feasibility cluster RCT

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Scientific summary

The Namaste feasibility cluster RCT

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Scientific summary

Background

Many people living with advanced dementia live and die in nursing homes. The quality of life, care and dying experienced by these people is variable, and the provision of high-quality care is challenging. There is a need to identify appropriate, cost-effective interventions that facilitate high-quality care towards the end of life, in nursing homes, that is appropriate for this vulnerable population. One intervention that has attracted interest from practitioners is the Namaste Care programme. Currently, little evidence is available of its efficacy or how to implement it successfully.

Objectives

The primary objective of this study was to ascertain the feasibility of conducting a full trial of the Namaste Care intervention. The feasibility aims were:

i. to understand how best to sample and recruit nursing homes into a cluster randomised controlled trial of Namaste Care
ii. to establish recruitment, retention and attrition rates at the level of the nursing home and of the individual resident, informal carer and nursing home staff
iii. to determine the most appropriate selection, timing and administration of primary and secondary outcome measures for a full cluster randomised controlled trial of Namaste Care against criteria of bias minimisation, burden and acceptability
iv. to assess the acceptability (to staff and family), fidelity and sustainability of the Namaste Care intervention
v. to establish the willingness of a large number of nursing homes, representing the range of nursing homes with respect to provider type, size and resident care needs, to participate in a full trial.

Prespecified criteria for progressing to a full trial included those regarding recruitment, attrition, primary outcome data collection levels, fidelity of intervention delivery, the acceptability and suitability of the intervention in a UK context, and the feasibility of sampling.

Methods

We conducted a three-phase study: (1) a realist evidence review, (2) intervention and implementation process refinement and (3) a cluster randomised controlled trial (with a process evaluation and economic analysis).

Realist evidence review

In a stakeholder-led realist literature review, we sought to determine which Namaste Care intervention elements work best for people living and dying with advanced dementia in the nursing home context. In phase 1 of the review, the scope was defined to enable concept-mining and theory development; 25 papers were identified in a scoping exercise. We undertook 11 interviews with stakeholders (user/patient representatives, dementia care providers, care home staff and researchers) and held a workshop with seven stakeholders and six research team members.

In phase 2 of the review, a systematic search of the literature identified 86 papers relating to Namaste Care. Following consultation with stakeholders, in a workshop ($n = 7$), interviews ($n = 4$) and with 40 end-of-life specialists, three context–mechanism–outcome configurations were developed. These configurations sit under the overarching theme of the importance of activities that enabled development of moments of connection for people with advanced dementia. The following elements need to be in place for Namaste Care to work for people living with advanced dementia:

1. structured access to social and physical stimulation
2. care home staff who are equipped to cope effectively with complex behaviours and variable responses
3. a framework for person-centred care.

This explanatory framework informed element prioritisation in the intervention refinement process.

Intervention refinement

A four-stage approach was adopted: (1) collating existing intervention materials using the explanatory framework; (2) exploring readability, comprehensibility and utility with staff inexperienced in Namaste Care; (3) using modified nominal group techniques with individuals with Namaste Care experience to refine and prioritise the intervention implementation materials; and (4) final refinement with a patient and public involvement panel.

Results

Eighteen nursing care home staff, one informal carer, one volunteer and five members of the public involvement panel were involved across the study stages. A 16-page A4 booklet was designed, with flow charts, graphics and colour-coded information used to ease navigation through the document. This was supplemented by infographics and a training package. The guide described the intervention dimensions and the process of implementation.

Intervention

Namaste Care is a complex dementia intervention delivering proactive, structured care focused on enhancements to the physical environment, comfort assessment and management, and ongoing sensory engagement that incorporates personalised activities to reflect an individual's life story and preferences, delivered in a group context.

Feasibility study in the context of a cluster controlled trial

A feasibility study was undertaken in eight nursing homes in England. The primary population was people with advanced dementia (assessed as having a Functional Assessment Staging Test score of 6 or 7) with an estimated life expectancy of < 3 months. We also recruited participants' main family or informal carer, and nursing home staff who were health-care staff paid to provide care to residents in nursing homes.

Trial inclusion/exclusion criteria

Clusters were defined as individual nursing homes, which were included if they were:

- nursing homes with at least 30 beds
- already providing palliative care using an established palliative care intervention
- able to identify six potentially eligible participants.

Residents were included if they:

- were permanently resident in the nursing home
- had received an assessment of advanced dementia (assessed as having a Functional Assessment Staging Test score of 6 or 7) (indicating a need for personal care assistance, urinary and faecal incontinence, reduced mobility and reduced ability to speak)
- had a lack of mental capacity
- had a key worker willing to act as a proxy for outcome data.

Consent was obtained through either a personal or a nominated consultee process.

The informal carer inclusion criteria stated that the person was to be an informal carer for a person with advanced dementia eligible for the trial.

Staff were included if they were health and social care staff who were paid to provide care in the nursing home; this included managers, registered nurses, care assistants and activity co-ordinators.

'Usual care' was defined as palliative care that was available and provided using established palliative care interventions in care homes.

Proposed primary/secondary outcomes and tools

One of the aims of the study was to establish the appropriateness, acceptability, timing and administration of instruments for a full trial. Two contender primary outcomes were considered for the full trial: quality of dying (dementia) (measured with the Comfort Assessment in Dying – End of Life Care in Dementia) and quality of life (measured with Quality of Life in Late Stage Dementia).

The following secondary outcomes were considered for the person with dementia, their informal carer and staff:

- person with dementia – sleep/activity (measured with actigraphy), neuropsychiatric symptoms (measured with the Neuropsychiatric Inventory – Questionnaire), agitation (measured with the Cohen-Mansfield Agitation Inventory) and pain (measured with the Pain Assessment in Advanced Dementia)
- informal carer – satisfaction with care at the end of life (measured with the Satisfaction With Care – End Of Life in Dementia)
- staff – satisfaction with care at the end of life (measured with the Satisfaction With Care – End Of Life in Dementia), person-centred care (measured with the Person-Centred Care Assessment Tool) and readiness for organisational change (measured with the Alberta Context Tool)
- health economics outcomes were measured with the EuroQol-5 Dimensions, five-level version, the ICEpop CAPability (ICECAP) measure for Older people and the ICECAP Supportive Care Measure
- other data – medication/service use (taken from medical records) and intervention activity (taken from a daily log).

A process evaluation was undertaken to provide explanatory data for the feasibility findings with respect to the acceptability, fidelity and sustainability of intervention delivery. Interviews were conducted with managers at baseline, and with staff and informal carers at the end of the study. Intervention delivery and usual care were observed.

Analysis

As a primary end point was not determined, no formal statistical tests of intervention effect were undertaken. Study data, alongside published data, were used to estimate a future sample size for a definitive study. Process evaluation data were analysed quantitatively (using descriptive statistics) and qualitatively (using framework analysis). Unit cost information was applied to the collected resource use data to provide initial estimates of cost-effectiveness, identifying the main drivers of efficiency. A health economics analysis focused on the feasibility and acceptability of using data collection tools to measure resource use at the level of the nursing home, the person with dementia, and family and society. Think-aloud analysis explored the ease with which staff acting as proxy for residents completed the ICECAP capability measures.

Results

Eight nursing homes consented to participate and to staff being recruited to the study. Two homes withdrew before the trial commenced, leaving four intervention and two control homes in the full data set. Residents were assessed for eligibility ($n = 243$), and 32 residents were enrolled. For enrolled residents, 20 informal carers consented to participate (and 12 of these carers provided demographic and proxy data). Ninety-seven staff were recruited over a 6-month period from eight facilities.

The number of beds overall ranged from 37 to 60, with the number of nursing home beds varying from 24 to 60. Two nursing homes were dual registered as they also provided residential care. The mean numbers of nursing beds were 48.5 (control homes) and 42.7 (intervention homes). Provider status was that six homes were private independent (four intervention and two control) and two were not-for-profit (intervention). Four intervention homes and one control home worked with a designated general practitioner. All of the nursing homes had engaged with a palliative care programme (Six Steps to Success, the Gold Standards Framework for Care Homes programme or a bespoke hospice programme).

Residents (individuals with advanced dementia) ($n = 32$) comprised 17 men (53%) and 15 women (47%). The median age of residents was 82 years (range 49–98 years). The type of dementia diagnosed varied (e.g. Alzheimer's disease, dementia with Lewy bodies, vascular dementia, other unspecified dementia). Informal carers ($n = 12$) comprised six men, five women and one person whose sex was not known. Six of the carers were spouses of residents, five were children of residents and one was a friend. Most of the nursing home staff ($n = 67$ from six participating nursing homes) were female ($n = 54$, 80%). The sample comprised care assistants ($n = 33$, 49%), registered nurses ($n = 13$, 19%), managers ($n = 8$, 12%) and other staff including activity co-ordinators ($n = 13$, 19%).

Primary outcome data were collected using Quality of Life in Late Stage Dementia for quality of life and Comfort Assessment in Dying – End of Life Care in Dementia for quality of dying, but the small number of deaths made the data from the latter less useful. Completion rates for primary outcomes were high at baseline and at 4 weeks (100% and 96.8%, respectively).

Of the secondary outcome data, the most relevant were from the Cohen-Mansfield Agitation Inventory. ActiGraph (Activinsights Ltd, Kimbolton, UK) devices were worn by the study participants and these largely remained in situ for the 28 days of data collection. The findings show a heterogeneous inactive population with variable sleep patterns.

In terms of fidelity, no nursing home was able to deliver the intervention twice per day, 7 days per week. Two facilities delivered the intervention on approximately two-thirds of the days in the study and two facilities offered the intervention on one-third of the days. There were gaps in provision owing to staff holidays. The mean session length across all sites was 1.33 hours (range 0.08–2.25 hours). The site offering the most sessions, twice per day for 92 days, offered generally shorter sessions lasting 1 hour. The observation of Namaste Care delivery showed that staff at times under-reported their activity, and issues with the length of sessions were identified in some instances. Greater reporting accuracy was noted when fewer staff members were delivering the intervention.

The recruitment of nursing homes, residents, informal carers and care home staff is feasible, although resources and time to support this are required. With respect to economics data, collecting resource use data was found to be feasible, although the quality of the data was variable in some areas. Nursing homes differed in the extent to which they incurred additional costs, with two incurring no additional costs and two incurring costs equivalent to an average of £222 per resident over a 4-week period. Staff proxy completion of the ICECAP measures was found to be challenging in parts, driven by an inability to communicate between the staff member and the resident under consideration. Nonetheless, all of the economics outcome measures (the EuroQol-5 Dimensions, five-level version, the ICECAP measure for Older people and the ICECAP Supportive Care Measure) could feasibly be collected by proxy, and high levels of completion were recorded for all measures.

The data on organisational readiness for change were collectable, but no conclusions can be drawn from the differences between facilities because of the small numbers of respondents.

In terms of availability of a sample for full trial, an analysis of the English Care Quality Commission data set as of 3 January 2019 identified 3719 nursing homes with at least 30 beds that were registered to care for people with dementia, and were rated 'good' or 'outstanding' by the Care Quality Commission, across the nine Care Quality Commission regions. This number increases to 4439 if sites are included that were rated as 'needs improvement'. A definitive trial would require 36 nursing homes with eight participants per nursing home cluster.

No adverse events were reported arising from the intervention. One adverse event arose from the use of the ActiGraph device; bruising was observed on one individual, with no lasting effect.

The criteria for proceeding to a full trial were partially met. The recruitment target was unachievable owing to the environment within which the intervention was delivered, as in some facilities lack of space precluded the recruitment of further residents until the death of a participant. There were no instances of attrition owing to practical or preference issues. The only withdrawal occurred because a participant moved to another facility for health reasons. The completion rate of the two contender primary outcome measures was high. The criterion for delivery of the number of Namaste sessions (at least one session held 7 days per week with an average length of 1.5 hours) was set without knowledge of the nursing home environments and working patterns within the sites. Namaste Care was acceptable to informal carers and staff, could be adapted to be delivered in different care environments, and reflected the components identified in the phase 1 realist review. A pool of potential nursing homes can be identified across England, reflecting different provider types. Changes for a future trial include using a pragmatic trial design; randomising by nursing home blocks; using outcome measures for agitation and social engagement; and revising the intervention specification.

Limitations

The outcome measure that focused on dying was less useful than anticipated. The selective recruitment by staff of informal carers may have shaped those carers' responses about their perceptions of intervention acceptability. The lack of blinding influenced the proxy completion of tools. Palliative care training as the usual care comparator is less relevant for this intervention than dementia care skills.

Conclusions

It is feasible to recruit and collect data using proxy-completed questionnaires, actigraphy, observation and interviews in the care home context. The intervention was delivered in each setting, but the fidelity to the originator's 'dose' was mediated by the nursing home environment, resources and staffing levels. Namaste Care is a palliative care, not an end-of-life (last month of life) care, intervention. Its core purpose is to provide activities that enable the development of moments of connection for people with advanced dementia.

Priorities

1. Delivering a complex, person-centred intervention for a heterogeneous population (albeit all with advanced dementia) in a group context, in different nursing home environments, requires the intervention and implementation process to be 'nursing home centred'.
2. A full trial design must have the flexibility to encompass the person-centred intervention delivery and nursing home-centred implementation processes.

3. Maximising learning from other Namaste Care-focused studies nearing completion can inform a future trial.
4. Consideration needs to be given to the measurement of agitation being a primary outcome of a future trial.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN14948133.

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This report

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