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Improved quality of death and dying in care homes: a palliative care stepped wedge randomised control trial in Australia

Short title: improving quality of dying in care homes

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Abstract

BACKGROUND/OBJECTIVE: Mortality in care homes is high, but care of dying residents is often suboptimal and many services do not have easy access to specialist palliative care. This study examined the impact of providing specialist palliative care on residents' quality of death and dying.

DESIGN: A stepped wedge randomised control trial. Care homes were randomly assigned to cross-over from control to intervention using a random number generator. Analysis used a Generalised Linear and Latent Mixed Model. The trial was registered with ANZCTR: ACTRN12617000080325.

SETTING: 12 Australian care homes in Canberra, Australia.

PARTICIPANTS: 1700 non-respite residents were reviewed from the 12 participating care homes. Of these residents 537 died, and 471 had complete data for analysis. The trial ran between February 2017 and June 2018.

INTERVENTION: 'Palliative Care Needs Rounds' (hereafter 'Needs Rounds') are monthly hour-long staff-only triage meetings to discuss residents at risk of dying without a plan in place. They are chaired by a specialist palliative care clinician, and attended by care home staff. A checklist is followed to guide discussions and outcomes, focused on anticipatory planning.

MEASUREMENTS: This paper reports secondary outcomes of staff perceptions of residents' quality of death and dying, care home staff confidence and completion of advance care planning documentation. We assessed (i) quality of death and dying and (ii) staff capability of adopting a palliative approach, completion of advance care plans and medical power of attorney.

RESULTS: Needs Rounds are associated with staff perceptions that residents had better quality of death and dying ($p < 0.01$, 95% CI: 1.83-12.21), particularly in the 10 facilities that complied with the intervention protocol ($p < 0.01$, 95% CI: 6.37-13.32). Staff self-reported perceptions of capability increased ($p < 0.01$, 95% CI: 2.73, 6.72).

CONCLUSIONS: The data offer evidence for monthly triage meetings to transform the lives, deaths and care of older people residing in care homes.

KEY WORDS

palliative care, death, nursing home, advance care planning, older persons.

INTRODUCTION

The quality of death and dying is often not optimal in residential care for older people (hereafter ‘care homes’)^{1,2} despite high levels of mortality.³ Well managed death and dying is contingent on high quality interdisciplinary care,⁴ anticipatory care^{5,6} and resident-centred planning.⁷ Many residents will require specialist palliative care to manage complex symptoms in the last months of life.⁸ Relatives report that palliative care improves residents’ quality care and quality of dying.⁹ Specialist palliative care also improves the quality of life and death of residents,¹⁰ decreases deaths in hospitals,¹¹ and increases the amount of advance care planning,¹² Advance care directives that are tailored to individuals’ expressed wishes are also independently associated with better quality of death, for example reducing futile and burdensome medical interventions,¹³ and increasing staff skills in discussing end of life.¹⁴

Care home education interventions have improved outcomes for staff and residents requiring a palliative approach.¹⁵ Education in advance care planning, as part of palliative care provision has, for instance, led to increasing rates of completed plans and advance directives, improving consistency of clinical decision with resident preferences.^{5,16} Advance care planning interventions led by nurses are also shown to mitigate distress and improve communication with relatives.¹⁷ However, interventions are often inadequate to result in changing clinical behaviour, approaches are inconsistent, and the necessary steps for sustainable change are lacking.^{15,18}

Despite the benefits of specialist palliative care, there is limited robust evidence for its delivery in care homes,¹⁹ resulting in an urgent need to develop and rigorously test methods of improving the care of people in their last months of life. Approaches to care should be proactive,³ include discussions with residents and relatives about goals of care,²⁰ and focus on those with greatest symptom burden.²¹

The current study sought to establish, through a large robust prospective trial, whether an intervention called ‘palliative care needs rounds’ (hereafter ‘Needs Rounds’) which contained the best practice components of care home staff education, advance care planning, and proactive discussions about goals of care and formulating plans for residents with the greatest need, could improve staff perceptions of residents’ quality of death/dying, staff self-reported capability to care for people in the last months of life, and completion of anticipatory care documents.

METHODS

We applied a prospective stepped wedge cluster randomised control trial. The protocol for this study is in the supplementary materials. Stepped wedge was adopted as the most acceptable trial design as it avoided the moral concerns of a two arm trial given the efficacy of the intervention during pilot testing, and those of a wait-list control design due to the limited expected survival of residents.²² The design also allowed for management of clinicians’ workload through sequential roll-out. Residents were followed across both control and intervention phases. Masking of sites was not possible because it was not feasible to blind staff administering the intervention.

Facilities were eligible for inclusion if they were a care home for older people in the Australian Capital Territory. Twenty-six such facilities were in operation at commencement of the trial. Four facilities were excluded because they had been used in the pilot study, and were therefore considered contaminated. A further facility was excluded, as it was used by trial clinicians as a training site for using the intervention. The remaining 21 facilities were invited to participate; 12 opted into the trial, all of which were included. All residents in each facility were included in the

sample, and included in analyses, with the exception of respite residents, as they are a transient population where robust follow-up could not be guaranteed.

Randomisation and masking

Care homes were randomised to one of five clusters. Randomisation was performed by a researcher independent of the trial's assessment and delivery. Randomisation at the level of care home was to avoid contamination of staff exposure to the intervention if randomisation had occurred at the individual level. Simple randomisation was used, with sites allocated a unique code at the outset of the project. Sequence generation was managed through an internet-based programme which randomly selected sites for each step. Once randomisation was conducted, sites were informed of the timing of their facility's migration from control to intervention condition by the study's chief investigator.

Intervention description

The intervention consisted of Needs Rounds which have been described in detail elsewhere, including a checklist to guide practice.²³ Needs Rounds are monthly 60 minute triage meetings, where up to ten residents who are at greatest risk of dying without a plan in place and who have a high symptom burden are discussed. Risk stratification and case-finding was the theoretical model underpinning the intervention^{24,25} to promote equitable and efficient distribution of specialist palliative care services. Needs Rounds were run by specialist palliative care staff (two nurse practitioners and a clinical nurse consultant, who had access to advice from palliative medicine specialists). All trial clinicians were based in the specialist palliative care unit and provided the intervention face-to-face. Care home staff attending Needs Rounds included registered nurses, enrolled nurses, nursing aides, activities coordinators and managers.

Case-based education is integrated into the Needs Rounds, with each resident's bio-psycho-social and power of attorney status discussed to promote symptom management and identify opportunities to reinforce and extend staff knowledge. Needs Rounds discussion of residents frequently lead to additional steps which involved the resident directly, including multidisciplinary case conferences, completion of advance care planning and review/management of current/anticipatory medicines. Prior to commencement of the Needs Rounds, staff at each site were provided with a briefing regarding the aims of the intervention and practicalities of how it would function, including a recommendation to develop a system for identifying deteriorating residents to discuss. Site briefing notes are available from the corresponding author.

The control condition involved usual care, which consisted of the specialist palliative care clinicians providing ad-hoc clinical consultations when requested by facility staff or general practitioners.

The research team monitored all sites for fidelity to the intervention, grading them with a 3-tier rating system, namely low, moderate, and high fidelity. Fidelity was assessed by three methods. First, data were collected on the number of Needs Rounds offered and proportion taken-up. Second, a random sample of 20% of all audio-recorded Needs Rounds were assessed for adherence to the Needs Rounds Checklist.²³ Third, feedback from the specialist palliative care clinicians was assessed regarding site engagement with the intervention, for example engagement in organising case conferences, and take up of actions following Needs Rounds.

Procedure

The intervention commenced with two sites on 11th April 2017. Other sites crossed over from control bi-monthly in clusters of two or three. The last two sites crossed-over on 7th December 2017, with follow-up on all sites occurring monthly until cessation of data collection on 30th June 2018. Different cluster sizes reflected pragmatic constraints of clinicians' workloads throughout the course of the study. The trial ceased as planned six months after the final site received the intervention. New admissions to facilities were included in prospective data collection.

Ethics committee approvals were obtained from Calvary Public Hospital in Canberra (ref: 44-2016), National Capital Private Hospital Canberra (ref: 20/2/2017) and the Australian Catholic University (ref: 020685). Consent to run the trial was gained at site, rather than individual resident, level given the impracticalities of gaining informed consent from a large population (1700 people) many of whom were likely to have substantial cognitive impairment (with few appointed medical power of attorneys at commencement), with low risk to participants, and sufficient protection of participant privacy. This follows national guidelines for Australia.²⁶ The trial was registered with ANZCTR: ACTRN12617000080325. No methodological changes were made after study commencement.

Outcomes

The primary outcome was length of stay in hospital for care home residents and has been reported elsewhere.²⁷ Secondary outcomes looked at meaningful impacts for residents, rather than health-service budgets, and consequently focused on quality of death and dying, staff capability and anticipatory planning documentation. These outcomes were assessed via:

1. The *quality of death and dying inventory shortform (QODD)*.²⁸ This 17 item questionnaire examines four correlated but distinct domains: symptom control, preparation, connectedness and transcendence. The decedent's experience was rated by staff on a 0 to

10 scale, where higher scores indicate a better experience. The Cronbach's alpha for the QODD total score was 0.89,²⁹ though the scale was validated for relatives to complete, not staff. Following correspondence with the scale's originator confirming psychometric robustness of excluding items, one item on access to euthanasia was removed, as this was not legal where the intervention was delivered.

2. The *Capacity to Adopt a Palliative Approach (CAPA)* tool was used to assess staff self-reported capability and confidence in looking after people at end of life. The nine-item questionnaire has a uni-dimensional scale. CAPA total score was calculated based on the sum of scores from the questionnaire where higher scores indicate greater capacity. Internal consistency reliability is very high with a Cronbach's alpha of 0.95, and split-half reliability coefficient of 0.93.³⁰ The scale was completed at the start of each Needs Rounds by all care home staff in attendance.
3. Completion of advance care plans (ACP) and appointment of medical power of attorney (PoA).

Data collection

The QODD was completed by staff on all residents who died during the trial. Registered nurses and experienced team leaders in each facility were provided with training on completing the tool from the research or clinical team. Staff were chosen to complete the measure rather than relatives (per the tool's original design) as no suitable validated tool designed for staff completion exists and not all residents had families who visited. Having the same staff complete the QODD was a strategy to reduce variability (and increase reliability) in use of the measure. Approximately four

staff per facility were trained, to account for absences due to annual leave, sick leave and staff turnover. Training on the tool involved discussion of the items and then completing the QODD for three case-studies of recent deaths devised by the specialist palliative care team, to provide reassurance on reliability of completion. Further training was provided to staff where necessary.

Data on ACPs/PoA were collected monthly from participating facilities' records by the research team.

Analysis

The sample size for the primary outcome was derived initially from a two-arm randomised control design with 1:1 allocation ratio, with a power of study of 80% at a 2-tail significance level of 5% with an intervention effect size of 0.5. The initial calculation provided an estimated sample size of about 50 per arm and a total of 100. The calculation was then adjusted for the stepped wedge design,³¹ with the design effect calculated as 4.55, and a minimum total of residents required of 455, recognising that a larger sample would offer greater analytic power.

Descriptive statistics on outcomes were obtained as means, standard deviations, or frequencies and percentages. Simple comparisons of continuous variables by groups were conducted using Student t-tests. For categorical variables, Pearson Chi-squared tests were employed to examine the association between groups.

In addition to planned analysis of the entire QODD scale, the measure was grouped into two sections for further analysis: QODD-1 (10 items that applied to all deaths e.g. how often did the resident appear to have pain under control) and QODD-2 (6 items that applied in specific circumstances, e.g. whether kidney dialysis was used to prolong resident's life.) This separation

allowed analysis of areas that facility staff had the ability to impact, from those directed by other agencies. Further analysis compared outcomes between high/moderate fidelity sites and low fidelity sites, to allow examination of implementation potential.

For staff capability analysis, the “duration of exposure” was defined as the number of months the staff member’s facility had received the intervention. Staff scores were compared from baseline (zero intervention) to six months later (since 6 months exposure was the length of exposure for the last two sites to cross over into the intervention condition). Due to staff shift patterns and turnover, paired data analysis was not possible as many different staff attended Needs Rounds, with some attending monthly and others rarely.

Analyses were performed using Stata version 14.2.³² Generalised Linear and Latent Mixed Model (GLLMM, with random effects on cluster and fixed effects on time) was employed to compare treatment conditions for primary and secondary outcomes. The intervention effects were estimated from the GLLMM with adjustment for covariates identified from the bivariate analyses. A subgroup analysis was also conducted to examine the sensitivity of the estimated effect with the removal of two sites with very poor implementation fidelity. Students t-tests were used for the CAPA scores.

RESULTS

We recruited 12 sites that included 1700 residents, of whom 567 (33%) were discussed in Needs Rounds. Needs Rounds led to 422 case conferences, 231 new advance care plans and 190 referrals to specialist palliative care clinicians. Sites spent a total of 74 months in control and 124 months in intervention, as shown in Figure 1. One site withdrew at month 12. Of the 12 sites, five had

high fidelity, five moderate and two poor fidelity to the intervention procedures. Fidelity ratings are shown in Table S1.

537 residents died during the trial, of whom 471 (87.7%) had complete information for analysis. Resident demographics and characteristics were compared between those who died in the control and intervention phases, indicating a higher percentage of residents with ACPs and health directions among those who died during the intervention phase (Table 1), but otherwise comparable characteristics between groups.

Table 2 depicts the results on the means and standard deviations of both scores by treatment status. For QODD scores, the unadjusted average scores (and standard deviation) for the intervention and the control groups are 69.1 (s.d.=13.6) and 72.4 (s.d.=13.0) respectively. After adjusting for age, sex, PoA, health direct, ACP, Primary diagnosis, age-adjusted Charlson Comorbidity index (CCI) and the level of compliance using the Generalised Linear and Latent Mixed Model, the difference between the two groups was 8.07 and it was statistically significant ($p<0.01$, 95% CI: 3.77-12.37). Similarly, a significant difference was found in both QODD-1 and QODD-2 scores between phases, where the treatment effect was 8.97 and 6.16, respectively (QODD-1: $p=0.01$, 95% CI: 3.15, 14.80; QODD-2: $p<0.01$, 95% CI: 2.64, 9.69).

Sub-group analyses on intervention fidelity were conducted. Results obtained on the comparisons of the mean QODD, QODD-1 and QODD-2 scores between groups for high/moderate and low fidelity sites are presented in Panels B and C of Table 2. After adjusting for demographics and other residents' characteristics, the differences between intervention and controls phases for QODD, QODD-1 and QODD-2 were significantly higher in high or moderate fidelity sites compared to low fidelity sites, with estimated treatment effect of 10.40, 12.22 and 7.32,

respectively. For low fidelity sites, QODD scores fell after the intervention. This may be because first, low fidelity sites had, on average, a slightly higher (but not statistically significant) baseline QODD, and second staff may have deflated the score as they became disengaged from the intervention.

Figure 2 shows the adjusted change to QODD scores after the intervention for all sites and high/moderate fidelity sites.

Regarding staff capability, we compared CAPA total scores prior to the intervention with scores 6 months after the intervention commenced. Analysis demonstrated an average increase of 4.73 which was statistically significant ($p < 0.01$, 95% CI: 2.73, 6.72) (Table 3). This result suggests an improvement in staff capability in looking after people at end of life.

No harms, adverse events or unintended consequences were reported.

DISCUSSION

This is a high quality, fully powered, cluster randomised control trial demonstrating improvements in quality of death and dying from a specialist palliative care outreach approach to supporting care home residents, and is thus a substantial contribution to a sparse, but developing, evidence base.^{19,33,34} The data indicate that moderate or high fidelity to the intervention results in important improvements in staff appraisals of residents' deaths. Needs Rounds act as a substantial tool to meet this recognised international marker of quality end of life experience.

Our intervention is effective in improving staff awareness and capability in supporting residents in their final months of life. Late awareness of impending death impoverishes staff opportunities to ameliorate pain and other symptoms.³⁸ Our intervention focuses on residents with greatest symptom burden, providing specialist clinical care, education and anticipatory planning. Needs Rounds are therefore different to those which focus on care coordination,³⁹ primary palliative care,⁴⁰ or geriatric specialist services.⁴¹ Needs Rounds provide a much-needed structure and outcome for staff and residents.

Rates of advance care planning and appointment of medical power of attorney increased following implementation of Needs Rounds. This growth points to key activities which occur after the Needs Rounds, with care home staff actively engaging with families around discussing anticipatory care and anticipatory medicines. Proactive and anticipatory care discussions are established pathways to improving end of life care,^{13,16} reducing hospitalisations,⁴² and enhancing confidence to discuss death and dying,¹⁴ since care home residents' wishes are often unknown.⁴³ Improvements in care following ACP are well recognised.^{5,15,44} Our study is unique in assessing both advance care planning and quality of death,⁴⁵ despite the recognised link between planning, quality of care and quality of death. Needs Rounds support delivery of core pre-conditions for advance care planning in care homes.⁴⁶

Staff capability and confidence increased through use of Needs Rounds, a facet which is congruent with studies that have identified the powerful role of education for care home staff,^{47,48} enabling them to normalise and expect death of residents.⁴⁹ Good deaths in care homes are largely contingent on nursing staff.⁵⁰ Yet, it is recognised internationally that care home staff have suboptimal knowledge of palliative care.³³ Thus Needs Rounds offer an evidence based mechanism for improving staff capability and consequently improving resident deaths.

Limitations

The quality of ACPs and medical PoA documentation were not assessed, and consequently a rise in number of completions is not necessarily reflective of quality. The QODD was developed for completion by relatives, but for this study was completed by staff. Staff may have unconsciously inflated scores after crossing into the intervention condition, or become blunted in their distress over the course of the intervention. Staff who both attended Needs Rounds and completed QODD may have been particularly susceptible to bias in completing these measures.

It is not possible to determine the duration of exposure to the intervention at which improvements in staff capability plateau. Further study should be conducted on when staff maximise their capability and how best to maximise learning for staff not attending Needs Rounds regularly. Facilities varied in their engagement with the intervention, with consequent impact on outcomes. The implementation challenges reflect real-world working dynamics where facility cultures may ease or hinder the adoption of new interventions, and low/moderate fidelity sites found it hard to accommodate monthly meetings or did not recognise palliative care provision as a substantial deficit in their current practice.

We did not collect data on staff burnout or turnover, which future studies might fruitfully examine. Further work would benefit also from collecting follow-up data on staff who left the facilities and evaluate their capability to care for people in the last months of life. Collecting paired-data to track individual staff over time would also complement the unpaired data reported here.

The study was conducted only in Australian care homes. However, the commonalities regarding care home resident demographics, illness profile and staffing challenges, mean that the findings can be generalized to other countries and settings. Needs Rounds are easy to implement, and the approach and positive outcomes can be used internationally to enable care home residents to live well until they die.

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Conflict of interest

We declare no competing interests.

Author contributors

LF designed the methodology, and was the Chief Investigator for the study. LF, JK were responsible for study administration and management, and all authors were involved in ongoing implementation. WL and LL analysed the data. LL, WL, LF and JK interpreted the data. LF wrote the first draft of the manuscript. LF, WL, JK, NJ, JS and MC revised it critically for important intellectual content. All authors read and approved the final manuscript.

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Data sharing

Individual-level data collected for this study is subject to ethical and privacy restrictions. The conditions of ethical approval do not allow us to distribute or make available these data directly to other parties. Applications for data access should be made by contacting the Chief Investigator,

from researchers who have their study protocol approved by an appropriate research ethics review board.

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LEGENDS

Table 1: Characteristics of residents who died during the study by phases

Table 2: Quality of Death and Dying. QODD is the whole scale; QODD-1 are items questions that applied to all deaths, e.g. how often did the resident appear to have pain under control, and QODDI-2 questions that applied in specific circumstances, e.g. visits from a religious or spiritual advisor of the use of mechanical ventilator or kidney dialysis to prolong resident's life. QODD, QODD-1 and QODD-2 have values ranged from 0 to 100

Table 3: CAPA total scores

Figure 1: Participant flow

Figure 2: Change to Quality of Death scores. Possible values range from 0-100.

Supplementary materials legends

Supplementary Material S1: Palliative Care Needs Round Checklist

Table S1. Rating on the extent of fidelity with the intervention

Table S2: Stepped wedge cluster randomised trial (SW-CRT) reporting guidelines checklist

Table S3: TIDIER reporting guidelines

Supplementary file S2: Protocol