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Palliative assessment and advance care planning in severe dementia: An exploratory randomized controlled trial of a complex intervention

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Abstract

Patients with advanced dementia often receive poor end-of-life care. We aimed to design and pilot a palliative care and advance care plan (ACP) intervention. Patients had undergone emergency hospital admission and had severe dementia. The intervention consisted of a palliative care patient assessment which informed an ACP discussion with the carer, who was offered the opportunity to write an ACP for the person with dementia. Carer–patient dyads were randomized to 'usual care' or the intervention. Carer-related outcome measures included the Kessler Distress Scale, Decision Satisfaction Inventory, Client Satisfaction Questionnaire and the Euroqol-5D, measured at baseline, six weeks, six months and three months after bereavement. The Satisfaction with End of Life Care in Dementia Scale was completed if the patient died. The 32 patient participants were physically frail and in the advanced stages of dementia: 62% had pressure damage to the skin, all needed feeding assistance and 95% were in pain. Nearly 50% died during the six-month follow-up period. Carers were difficult to recruit during acute admission; 33 patients and carers entered the study (22 intervention arm; 11 control arm). Only seven carers made ACPs. The care planning discussion was well received, but few carers wrote an ACP, despite intensive support from an experienced nurse specialist. Advance care planning is, in theory, a necessary intervention for people with severe dementia; the reluctance of carers to write plans needs to be explored further.

Keywords

Advance care planning, carers, complex intervention, dementia, palliative care, randomized controlled trial

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Introduction

The UK government's End of Life Care Strategy aims to improve care for those with all life-limiting conditions, not just cancer.[1] With the ageing population, dementia is increasing, occurring in 20% of those aged 80 or over. One in three people over the age of 65 years will die with dementia,[2] many of them on acute general hospital wards where they receive poor end-of-life care.[3]

A systematic review of the literature on palliative care interventions for people with advanced dementia found a lack of adequately powered clinical trials and that 'palliative care' was defined as a withdrawal of treatment or single interventions rather than a holistic approach.[4] An unplanned acute hospital admission is a critical event for a person with dementia in that 24% of those with severe dementia will die and at six months post admission mortality is as high as 50%.[5,6] Whilst various interventions have been developed to enhance advance care planning in nursing homes, for example the 'Let me Decide' programme in Australia[7] and the UK Gold Standards Framework,[8] no studies have focussed on the acute hospital. This may be an appropriate time to intervene and plan end-of-life care. The need for this is supported by qualitative research on the views and wishes of carers and health and social care professionals working with people with severe dementia.[9]

In this pilot study we aimed to assess the feasibility of implementing a two-component intervention to improve end-of-life care for people with advanced dementia. We report recruitment and randomization, attrition, explore a range of outcome measures and assess whether advance care planning is feasible for these patients and their carers.

Methods

A full description of the protocol has been published.[10] The study was approved by the local Research Ethics Committee.

Pre-trial preparatory work to develop the intervention

Phase I. The intervention was designed using the Medical Research Council (MRC) Complex Interventions Framework.[11] In phase one qualitative work the principal carers of 20 patients with severe dementia, (Functional Assessment Staging (FAST) stage 6d and above[12]) admitted to an acute medical ward were interviewed. Concurrently, 21 health care professionals from a range of disciplines, experience and care settings (acute hospital, nursing home and primary care) were also interviewed. We used framework analysis to identify, extract and analyse core themes.[13] Five main themes emerged: illness awareness, communication, pain awareness, attitudes towards end-of-life treatments/quality of life and hospitalization. Awareness of the terminal nature of advanced dementia was poor amongst both carers and health care professionals.[9]

Phase II. The qualitative data were used to design a two-component intervention: (i) assessment of the palliative care needs of patients; and (ii) a framework for the discussion of advance care planning with carers. To obtain the most pragmatic version of the intervention, we used an iterative process, interviewing successive groups of patients, carers and members of the clinical multi-disciplinary team. Protocol refinements were referred to the ethics committee for approval. This cycle was repeated twice. The intervention was delivered by a senior nurse experienced in dementia who also received palliative care training.

Final format of the intervention

Component 1: palliative care needs assessment of patient. The patient assessment took 30 minutes using a structured clinical approach that built on usual care. It covered a range of domains, including dementia severity (measured on the FAST scale[12]), the presence of delirium (Confusion Assessment Method[14]), communication, pressure sore risk (Waterlow scale[15]) and severity (Stirling scale[16]), food and fluid intake, swallowing and feeding. As there are no dementia pain scales validated for use in an acute hospital setting,[17] we used observational pain scales developed for use in other settings: the Abbey Pain Scale,[18] the PACSLAC[19] and the Doloplus.[20] The latter two scales have been identified in a recent systematic review as the most appropriate and clinically useful tools for detecting pain in people with dementia.[17] This assessment generated a list of active problems that were discussed with the clinical team. A management plan was formulated and documented in the clinical notes. Findings were used to inform subsequent discussions with the carer.

Component 2: discussions with carers. Up to four consultations (at least five days apart) were offered to carers. At first we attempted these discussions during the hospital admission (see Figure 1, CONSORT diagram 'Original Design'). However, it was difficult to engage carers at this time and patients were often discharged rapidly. We therefore amended the protocol (see Figure 1, CONSORT diagram 'New Design') to allow the carer discussion to occur in the community at a later date.

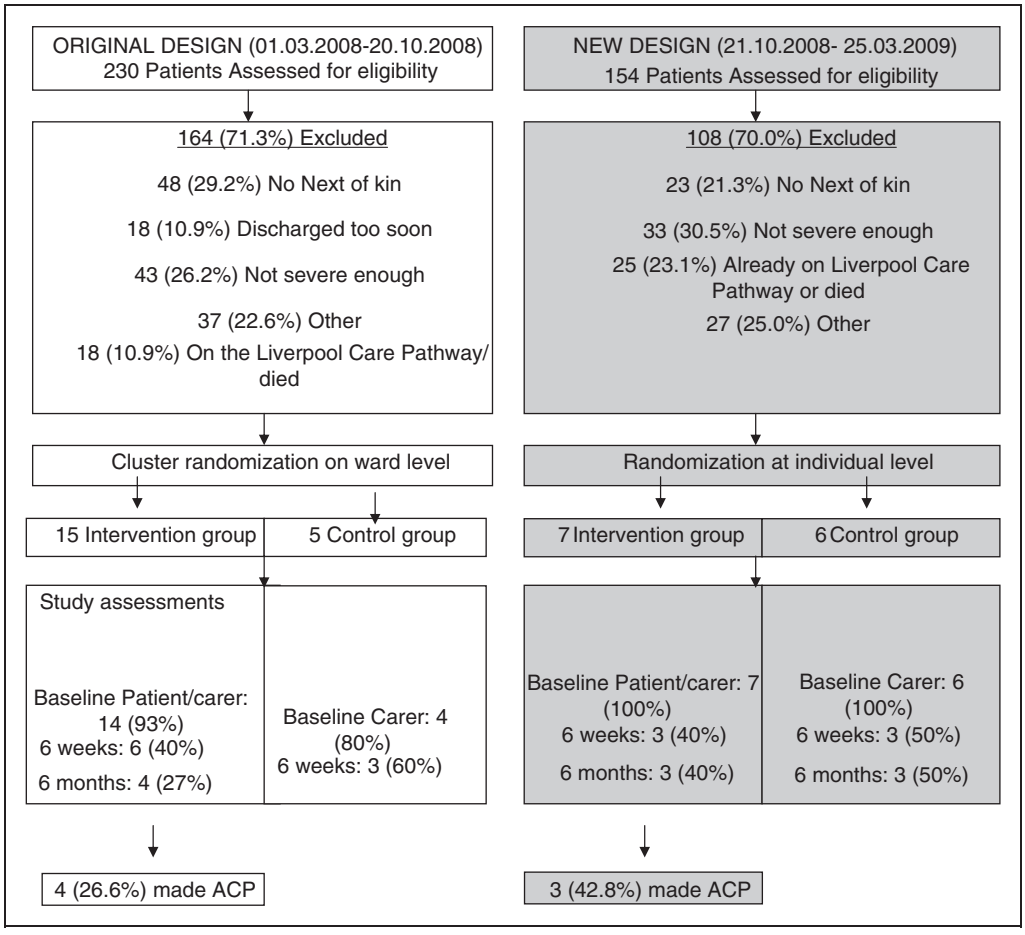

Figure 1. Consort diagram of recruitment.

First consultation: we used structured discussions with carers to assess: (i) level of knowledge about the patient's dementia; (ii) the severity of dementia and prognosis for the patient; (iii) the patient's physical needs; (iv) the social situation and current levels of social support; and (v) any records of previous preferences for care. We attempted to understand cultural, spiritual, health, social and financial needs experienced by the carer and the psychological support available to them. We inquired whether the person with dementia had made any previous advance directives or statements or had expressed any preferences for care. The discussion was summarized, and documented in a standardized format. Any issues of serious concern were discussed with the clinical team.

Subsequent consultations: we provided basic education on dementia as a neuro-degenerative disease, the prognosis of advanced dementia, the role of palliative care (focusing on palliative care as appropriate active care, NOT withdrawal of treatment) and advance care planning. Some carers wanted only basic information whilst others wished to receive as much information as possible. Specific issues discovered during the patient needs assessment were documented on a sheet that was used to guide this structured discussion. For example, if we identified that the person with dementia was showing non-verbal pain behaviours, we explained and interpreted these with the carer so that they could recognize these in the future.

Advance care planning. Advance care planning is a process of discussion between the patient and a health care professional including important values or goals for care, understanding about illness and prognosis and preferences for types of care or treatment that may be beneficial in the future.[21] People with advanced dementia may not have the have capacity to make complex decisions, thus carers were given the opportunity to formulate an advance care plan (ACP), including statements of preferences and wishes for the person with dementia using an adapted version of a tool developed by the UK National Health Service (NHS) (Preferred Priorities for Care).[8] The carers were asked to consider any views that the person with dementia may have expressed, whilst they still had the capacity to do so. Copies were placed in the medical notes, sent

to the general practitioner (GP) (and if relevant the nursing home) and kept by the carer.

Feasibility randomized controlled trial of the intervention with patient–carer dyads

We piloted this intervention in a two-arm feasibility cluster randomized controlled trial. We recruited from two acute medical wards served by separate medical teams, for patients aged 70 years or over, in an inner London teaching hospital serving a socioeconomically and ethnically diverse population. All new admissions on the intervention ward and control ward were screened for eligibility. We recruited patients with advanced primary degenerative dementia (FAST stage 6d or worse: urinary incontinence and needing assistance with all activities of daily living) with an unplanned admission for a treatable acute medical illness. Patients were included if they had an informal carer (family member or friend in regular contact, who did not act in any professional capacity, and who was next of kin or a 'key decision maker') who was able to give informed consent and assent for patients. Those consenting in the control arm were fully informed about the trial and received usual care. We aimed to recruit 40 patient–carer dyads to each study arm. As this was a pilot trial no power calculation was required and these numbers were chosen on pragmatic grounds.

Measures. Our main outcome was the number of carers making an ACP. We also tested a number of other outcome measures. Data on these was collected by an independent researcher.

(1) Carer-related measures

Kessler Distress Scale (KD10): a 10-item scale giving a total 'distress score' (range 10–50, higher scores indicating a higher level of distress) and a categorical score indicating whether participants are 'likely to be well', 'likely to have a mild mental disorder', 'likely to have moderate mental disorder' or 'likely to have a severe mental disorder'.

Euroqol-5D (EQ-5D): a measure of health status and quality of life, this comprises a five-item scale and a visual analogue scale indicating overall health state (scored 0–100 with lower scores indicating poorer health).[22]

Decision Conflicts Scale (DCS): measures uncertainty and difficulties in the decision making process.[23] Scores range from 0 (no decisional conflict) to 100 (extremely high decisional conflict).

Decision Satisfaction Inventory (DSI): gives an overall score of decision satisfaction (range 10–50, higher scores indicating less satisfaction).[24]

State Anger Scale (SAS): a subscale from the State-Trait Anger Expression Inventory (STAXI), which measures intensity of angry feelings at a particular time.[25] Scores range from 10 to 40, with higher scores indicating greater levels of anger.

Life Satisfaction Scale (LSQ): obtained from the Lancashire Quality of Life Profile, this is a seven-point 'ladder scale' anchored at 0, representing the 'very worst outcome that you could expect to have in life' and increasing to 7, with the top representing 'the very best outcome you could have expected'.[26]

Satisfaction with End of Life Care in Advanced Dementia Scale (SWC-EOLCD): measures satisfaction with end-of-life care (range 10–40) with higher scores indicating greater satisfaction. This was only completed after the patient had died, if the carer felt able, without undue distress.

We also included a general assessment of how care planning was experienced and noted whether the carer decided to formulate an ACP.

(2) Patient related measures

Pain and distress: carers were asked to indicate on visual analogue scales how much pain and distress they thought the person with dementia was experiencing. Scores ranged from 1 (no pain/no distress) to 5 (severe pain/severe distress).

Follow up

Guided by current evidence on survival time and prognosis for this patient group, follow-up assessments occurred at six weeks and six months.[5,6] Relatives of patients who died during the study were seen three months after the death to complete the DSI, Caregiver Strain Questionnaire (CSQ), EQ5-D, KD10, LSQ, SAS and SWC-EOLCD scales. We also investigated whether information could be collected about the care received at death. A qualitative analysis of how the structured assessment of patient needs may have influenced subsequent patient and carer experiences will be reported in a further case-study paper.

Results

Protocol amendments

The acute hospital admission was often not a suitable time for carers to take part in research as their main concern was the patient's care. We amended the study protocol to allow recruitment, consent and randomization at an individual level. Carer discussions were then offered after the person with dementia had left hospital. Computer-generated random allocation was performed

by an independent statistician. This removed the need for clustering at ward level and maximized recruitment (see Figure 1). Carers in both control and intervention groups were offered an information pack compiled from publicly available internet information and leaflets. This included an information sheet from the UK Alzheimer's Society on advanced dementia, a leaflet on advance care planning and one giving a simple definition of palliative care.

Recruitment rates

Recruitment and attrition are shown in Figure 1. We approached 384 patients with severe dementia. Seventy one (19%) had no available next of kin, 18 (5%) were discharged before they could be assessed for eligibility or before consent from carers could be obtained (original design), 76 (20%) did not have severe dementia, 43 (11%) died and 64 (17%) were not eligible for other reasons, such as no clear diagnosis and adult protection issues. One hundred and twelve were eligible. Of these, 39 (35%) carers of patients were not contactable, five patients (4%) died (original design), 35 (31%) declined and 34 (30%) consented. Thirty-three entered the study, 22 in the intervention arm and 11 in the control arm. Of these 33, 31 (94%) completed the baseline assessment, 15 (45%) the first follow-up assessment and 11 (33%) the second follow-up assessment. Twenty patients were assessed, and 17 carers took part in the carer discussions. Three patients died prior to finishing the discussions and two carers dropped out after the first meeting. Seven carers made an ACP.

Characteristics of study participants

The mean age of the patients was 87 years and the cohort was predominantly female (81%). Half had either urinary tract infections or pneumonia, and 41% had one or more re-admissions to hospital during the six-month study period. Sixty-nine per cent were admitted from residential or nursing homes. Carers (mean age 59 years), were mainly daughters and not involved in an active caring role (Table 1). There were no major

Table 1. Baseline characteristics of study participants by follow-up status

		Total ($n=32$) *n* (%)	Completed ($n=9$) *n* (%)	Withdrawn ($n=20$) *n* (%)	Died ($n=3$) *n* (%)
Carer characteristics					
Age (mean (SD) [range])		59 (13) [37–90]	60 (15) [37–80]	59 (13) [45–90]	54 (3.5) [52–57]
Gender (male)		17 (53%)	4 (44%)	11 (55%)	2 (67%)
Education ($n=25$)	Stopped before age 16	6 (24%)	2 (22%)	4 (27%)	0
	Educated post age 16	19 (76%)	7 (78%)	11 (73%)	1 (100%)
Employment ($n=28$)	Working	17 (61%)	4 (44%)	11 (69%)	2 (67%)
	Retired	7 (25%)	3 (33%)	4 (25%)	0
	Unemployed	4 (14%)	2 (22%)	1 (6%)	1 (33%)
Ethnicity	Caucasian	28 (88%)	9 (100%)	16 (80%)	3 (100%)
	Other	4 (12%)	0	4 (20%)	0
Religion	Christian	13 (41%)	5 (56%)	7 (35%)	1 (33%)
	Muslim	2 (6%)	0	2 (10%)	0
	Hindu	1 (3%)	0	1 (5%)	0
	Jewish	11 (34%)	3 (33%)	6 (30%)	2 (67%)
	None	5 (16%)	1 (11%)	4 (20%)	0
Carers' role	Full-time	5 (16%)	2 (22%)	3 (15%)	0
	No active caring	24 (75%)	5 (56%)	16 (80%)	3 (100%)
	Part-time	3 (9%)	2 (22%)	1 (5%)	0
Relationship	Husband	4 (13%)	2 (22%)	2 (10%)	0
	Daughter	13 (41%)	4 (44%)	8 (40%)	1 (33%)
	Son	11 (34%)	1 (11%)	8 (40%)	2 (67%)
	Niece	1 (3%)	1 (11%)	0	0
	Other	3 (9%)	1 (11%)	2 (10%)	0

(continued)

Table 1. Continued

		Total ($n = 32$) *n* (%)	Completed ($n = 9$) *n* (%)	Withdrawn ($n = 20$) *n* (%)	Died ($n = 3$) *n* (%)
Patient characteristics					
Age (mean (SD) [range])		87 (6.2) [71–96]	88 (6.6) [76–96]	86 (6.1) [71–95]	92 (5.3) [86–95]
Gender (male)		6 (19%)	0	5 (25%)	1 (33%)
Education ($n = 24$)	Stopped before age 16	12 (50%)	3 (50%)	6 (40%)	3 (100%)
	Educated post age 16	12 (50%)	3 (50%)	9 (60%)	0
Ethnicity	Caucasian	27 (87%)	9 (100%)	15 (79%)	3 (100%)
	Other	4 (13%)	0	4 (21%)	0
Mode of admission	Emergency service	29 (94%)	9 (100%)	17 (89%)	3 (100%)
	Other	2 (6%)	0	2 (11%)	0
Admitting diagnosis	Chest infection	9 (28%)	2 (22%)	6 (30%)	1 (33%)
	UTI	7 (22%)	4 (44%)	3 (15%)	0
	Dehydration	2 (6%)	1 (11%)	1 (5%)	0
	Pressure spore/sepsis	2 (6%)	0	1 (5%)	1 (33%)
	Other	12 (38%)	2 (22%)	9 (45%)	1 (33%)
Admission length	Mean (SD) [range]	24 (19) [3–91]	28 (26) [7–91]	21 (15) [3–62]	28 (21) [12–51]
Place of residence	Own home	9 (28%)	3 (33%)	6 (30%)	0
	Residential	6 (19%)	0	5 (25%)	1 (33%)
	Nursing	16 (50%)	6 (67%)	8 (40%)	2 (67%)
	Hospice	1 (3%)	0	1 (5%)	0
FAST scale	6d	1 (3%)	0	1 (5%)	0
	6e	12 (38%)	2 (22%)	10 (50%)	0
	7a	3 (9%)	2 (22%)	1 (5%)	0
	7c	7 (22%)	3 (33%)	1 (5%)	3 (100%)
	7d	4 (13%)	2 (22%)	2 (10%)	0
	7f	5 (16%)	0	5 (25%)	0
Readmissions	0	19 (59%)	5 (56%)	12 (60%)	2 (67%)
	1	9 (28%)	4 (44%)	4 (20%)	1 (33%)
	2	4 (13%)	0	4 (20%)	0
Advance care plan completed		7 (32%)	3 (60%)	3 (21%)	1 (33%)

UTI: urinary tract infection.

demographic differences between those patient–carer dyads that completed the study, withdrew or died before finishing the discussions (Table 1). Table 2 gives the study participant characteristics by randomization group.

Findings from patient assessments in the intervention group

The 22 patients in the intervention group were mainly bed-bound, although 10 (45%) spent some time in a chair. On the Stirling Scale, 38% had intact skin, 23% had discolouration of intact skin, 28% had partial thickness skin loss or damage to the epidermis or dermis and 2% had full thickness skin loss. The mean Waterlow score was 21.6 (SD 4.5, range 14–33), and 57% scored more than 20, indicating a high risk of developing pressure sores. All needed feeding assistance, 14 (63%) had poor oral intake and two were artificially fed. Thirteen patients (59%) had some degree of dysphagia and were on 'risk management' feeding. All were doubly incontinent.

Communication. All 22 patients had diminished levels of language. Seven (32%) were able to state simple preferences for food, indicate the presence of pain or understand simple instructions such as 'open your mouth'. The remainder used non-verbal communication, such as facial expressions. Six (27%) of the most severely affected patients (FAST scale 7d or 7f) displayed distressed behaviour during care tasks.

Pain. On the Abbey pain scale, one patient (5%) had no pain, nine patients (45%) had mild pain and

Table 2. Baseline characteristics of study participants by study arm

		Intervention $n = 22$ *n* (%)	Control $n = 10$ *n* (%)
Carer characteristics			
Age (mean (SD) [range])		60 (13) [44–90]	57 (12) [37–80]
Gender (male)		14 (64%)	3 (30%)
Education	Stopped before age 16	4 (25%)	2 (22%)
	Educated post 16 years	12 (75%)	7 (78%)
Employment	Working	9 (50%)	8 (80%)
	Retired	6 (33%)	1 (10%)
	Unemployed	3 (17%)	1 (10%)
Ethnicity	Caucasian	20 (91%)	8 (80%)
	Asian	2 (9%)	1 (10%)
	Other	0	1 (10%)
Religion	Christian	9 (41%)	4 (40%)
	Muslim	1 (5%)	1 (10%)
	Hindu	0	1 (10%)
	Jewish	7 (32%)	4 (40%)
	None	5 (23%)	0
Carers' role	Full-time	3 (14%)	2 (20%)
	No active caring	18 (82%)	6 (60%)
	Part-time	1 (5%)	2 (20%)
Relationship	Husband	3 (14%)	1 (10%)
	Daughter	8 (36%)	5 (50%)
	Son	10 (45%)	1 (10%)
	Niece	0	1 (10%)
	Other	1 (5%)	2 (20%)
Patient characteristics			
Age	Mean (SD) [range]	88 (6.1) [71–96]	85 (6.6) [76–95]
Gender	Male	5 (23%)	1 (10%)
Education	Stopped before age 16	9 (53%)	3 (43%)
	Educated post age 16	8 (47%)	4 (57%)
Ethnicity	Caucasian	20 (91%)	7 (78%)
	Other	2 (9%)	2 (22%)
Mode of admission	Emergency service	22 (100%)	7 (78%)
	Other	0	2 (22%)
Admitting diagnosis	Chest infection	6 (27%)	3 (30%)
	UTI	6 (27%)	1 (10%)
	Dehydration	1 (5%)	1 (10%)
	Pressure sore/sepsis	1 (5%)	1 (10%)
	Other	8 (36%)	4 (40%)
Admission length	Mean (SD) [range]	24 (16.3) [3–62]	23 (25) [7–91]
Place of residence	Own home	4 (18%)	5 (50%)
	Residential	4 (18%)	2 (20%)
	Nursing	13 (59%)	3 (30%)
	Hospice	1 (5%)	0
FAST scale	6d	0	1 (10%)
	6e	6 (27%)	6 (60%)

(continued)

Table 2. Continued

		Intervention $n = 22$ n (%)	Control $n = 10$ n (%)
	7a	1 (5%)	2 (20%)
	7c	7 (32%)	0
	7d	3 (14%)	1 (10%)
	7f	5 (23%)	0
Readmissions	0	14 (64%)	5 (50%)
	1	5 (23%)	4 (40%)
	2	3 (14%)	1 (10%)
Advance care plan completed		7 (32%)	~

UTI: urinary tract infection.

10 (50%) had moderate pain. None was assessed to have severe pain. Pain was chronic in five patients (25%), acute in four (20%) and acute or chronic in 11 patients (55%). On the Doloplus-2 scale, the mean score was 8 (SD 6.5, range 3–22), and 67% scored above the cut-off point (5 or above) indicating the presence of pain. Mean scores on the PACSLAC scale were 8 (SD 5.4, range 3–22). This scale does not currently have a scoring interpretation available.

Spiritual and religious needs. The religious affiliation of all patients was noted from carer interviews. Those who agreed to a care planning discussion said they wished their relative's religious needs to be respected at the time of death. Two patients were atheists and their carers emphasized that they should not be visited by a hospital chaplain. No unmet spiritual needs were identified.

Findings from carer discussions. It was difficult to conduct discussions in the hospital as no private room was available. Research interviews were not seen as part of clinical care and some carers preferred to remain at the patient's bed side. Using the amended protocol, discussions were held in the community where it was easier to discuss sensitive issues.

Some carers were very knowledgeable about the patient's status and prognosis, while others needed more time to explore the patient's situation. The seven carers who chose to make a written ACP were closely involved in the patient's care, saw them on most days of the week, viewed themselves as being key in co-ordinating and managing their relative's care and had witnessed their progressive deterioration. Two of the patients with an ACP died during the study period, both remaining in their home at the time of death as requested by the carer.

Of the seven carers who completed an ACP, two had clear wishes about the place of death and level of intervention preferred. The remaining five chose more open statements, such as, 'the family is aware of the complications related to swallowing difficulties but wish to make decisions about artificial feeding if and when needed'. None of the patients had expressed clear preferences to their carers about end-of-life care when they still had capacity.

Study outcomes

Attrition precluded statistical comparison of control and intervention groups, but some trends are suggested by the data (Table 3). Mean KD10 distress scores were higher in the cohort at baseline (mean 21.3) and decreased by the time of the final assessment (mean 14.7), increasing again around bereavement (mean 19.7). The proportion of carers who were rated in the 'well' category of the KD10 and the LSQ also showed a similar trend, with improvement in the months following the patient's index admission. Decisional conflict was higher at the time of hospital admission and increased in the carers receiving the intervention at each time point. Carer perceived health, as measured on the EQ-5D, improved after the initial admission. There were no observable trends in the carer ratings of patients' pain or distress.

We needed to access GP records of deceased patient to assess the end-of-life care received. We obtained ethical committee permission for this, but some GPs did not allow access. One GP sought legal advice and stated that unless we were able to show that the carer was a legal representative of the patient, that is, that they were executor of the patient's will, they were unable to let us view records. Obtaining such documentation was outside of the remit of this research.

Table 3. Study outcomes

Measure	Baseline			6 weeks			6 months			Post bereavement		
	Cohort ($n=31$)	Control ($n=10$)	Intervention ($n=21$)	Cohort ($n=15$)	Control ($n=6$)	Intervention ($n=9$)	Cohort ($n=11$)	Control ($n=4$)	Intervention ($n=7$)	Cohort ($n=4$)	Control ($n=1$)	Intervention ($n=4$)
Carer												
KD10												
Score, mean (SD)	21.3 (8.0)	22.7 (10.3)	20.7 (6.8)	16.5 (5.0)	13.8 (4.1)	18.9 (4.8)	14.7 (3.6)	15.0 (4.4)	14.6 (3.4)	19.7 (9.1)	10	23.0 (7.8)
KD10 category, *N* (%)												
Well	14 (46.7)	5 (50.0)	9 (45.0)	10 (76.9)	5 (83.3)	5 (71.4)	7 (77.8)	3 (75.0)	4 (80.0)	3 (75.0)	1 (100)	2 (66.7)
Mild distress	6 (20.0)	1 (10.0)	5 (25.0)	2 (15.4)	1 (16.7)	1 (14.3)	2 (22.2)	1 (25.0)	1 (20.0)	0	0	0
Moderate distress	6 (20.0)	2 (20.0)	4 (20.0)	1 (7.7)	0	1 (14.3)	0	0	0	0	0	0
Severe distress	4 (13.3)	2 (20.0)	2 (10.0)	0	0	0	0	0	0	1 (25.0)	0	1 (33.3)
Life satisfaction	4.5 (1.1)	4.6 (1.2)	4.5 (1.1)	5.1 (1.1)	5.5 (0.6)	4.9 (1.3)	5.4 (0.7)	5.5 (0.6)	5.4 (0.9)	3.8 (2.2)	6.0	3.0 (2.0)
DSI, mean (SD)	26.2 (4.7)	26.5 (6.7)	26 (3.2)	21.8 (7.0)	22.0 (8.1)	21.8 (6.6)	20.0 (7.0)	16.3 (4.8)	22.2 (7.9)	29.0 (6.2)	32	28.0 (7.2)
DCS	38.5 (19.3)	34.2 (23.5)	41.6 (15.8)	26.7 (17.5)	26	27.1 (14.9)	26.4 (17.0)	18.8 (8.7)	30.9 (20.0)	37.5*	†	37.5*
EQ-5D												
Score	0.7 (0.3)	0.6 (0.4)	0.7 (0.2)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.8 (0.1)	0.7 (0.3)	0.9	0.6 (0.3)
VAS, mean (SD)	67.5 (28.1)	62.7 (37.5)	69.8 (23.6)	76.5 (11.6)	79.8 (12.2)	73.6 (11.1)	80.3 (9.2)	80.8 (13.2)	80.0 (6.1)	75.0 (23.1)	92.0	69.3 (24.7)
STAXI												
Total score	12.5 (4.0)	12.9 (5.9)	12.3 (2.8)	12.1 (2.9)	11.3 (2.1)	13.0 (3.7)	10.6 (1.2)	11.0 (1.7)	10.4 (0.9)	18.3 (14.5)	10	21.0 (16.5)
SWC-EOLCD, mean (SD)	–	–	–	–	–	–	–	–	–	26.5 (7.3)	23.0	27.6 (8.5)
Patient												
Pain (VAS), mean (SD)	2.1 (1.0)	2.5 (0.5)	1.9 (1.1)	2.5 (1.4)	1.7 (0.6)	3.3 (1.5)	2.5 (1.3)	2.5 (2.1)	2.5 (1.3)	n/a	n/a	n/a
Distress (VAS), mean (SD)	2.7 (1.1)	2.7 (0.8)	2.8 (1.2)	2.3 (1.2)	1.7 (1.1)	3.0 (1.0)	2.3 (1.2)	2.5 (2.1)	2.3 (0.9)	n/a	n/a	n/a

*DCS was completed by one participant or † not completed.

KD10: Kessler Distress Scale, EQ-5D: Euroqol-5D, DCS: Decision Conflicts Scale, DSI: Decision Satisfaction Inventory, STAXI: State Anger Scale, LSQ: Life Satisfaction Scale, SWC-EOLCD: Satisfaction with End of Life Care in Advanced Dementia Scale, VAS: visual analogue scale.

Discussion

Development of the intervention

We were able to develop a clinically pragmatic intervention building on phase I work and informed by guidance from the MRC framework for developing complex interventions.[11,27] Our intervention comprised a specialist assessment of the patient's palliative care needs that informed an advance care planning discussion with the carer. The discussion aimed to aid future decision making and therefore improve the quality of and satisfaction with end-of-life care. Participation of the clinical multi-disciplinary team in reaching the final format of the intervention facilitated its integration with the clinical service.

Recruitment and attrition

We had hoped to recruit 40 patient–carer dyads to *each* study arm. However, we achieved 32 patient–carer dyads of whom 22 received our intervention. We found the acute medical ward a challenging environment in which to conduct this study. A third of patients admitted with advanced dementia did not have an informal carer/next of kin who could discuss and consider ACPs, rapid treatment and discharge of patients meant that 10% left the hospital before contact with carers could be made and carers were focussed on the immediate care of patients. As this was a pilot study, we modified our methodology to try and improve recruitment. We continued to conduct patient assessments during the admission but found the discussion with carers was best carried out after the person with dementia had been discharged from hospital. Despite this amendment, recruitment rates remained low, suggesting that the time of acute hospital admission was not optimal for engaging carers in advance care planning. Follow-up rates were low due to patient mortality and carer withdrawal.

Study population – patients

Our study population was in the advanced stages of dementia and physically frail: two thirds showed signs of pressure damage to the skin, all needed feeding assistance and 95% were experiencing mild or moderate pain. Of the 32 participants, nearly half died during the six-month follow-up period. This concords with other work[5] suggesting that our recruitment strategy correctly identified patients who were nearing the end of life.

Patient needs assessment

This was mainly observational and much of the required information could be obtained during routine care tasks. Establishing whether the patient fulfilled study criteria was problematic; information about function prior to admission was not always available and those with milder dementia may appear more advanced when physically ill. Nursing homes and GP surgeries were not willing to provide this information for a research project. The structured assessment was well received by clinical staff, particularly the information it provided regarding communication ability and pain. The assessment did not appear to cause distress to the patient and in a number of patients we found previously undetected pain; this was the principle information that was fed back to clinical teams.

Study outcome measures

We explored a range of outcome measures. The KD10 appeared sensitive in detecting carer distress around the time of hospital admission and after bereavement. The LSQ showed a similar pattern of response. The SAS did not show any trends during the study but, as would be expected, levels of anger did increase in carers during bereavement. Because of this we would anticipate just using the KD10 in future work. Decisional conflict appeared to increase in the intervention group as the study progressed. This may be due to chance or because carers who received the intervention were presented with more options and possibilities to consider, increasing the decisional conflict that they experienced. Carers reported that the SWC-EOLCD was easy to complete and the range of scores in our cohort reflected that found in the North American population used to validate the scale.[28] This scale shows high convergent validity with the DSI[28] and in further studies we would consider just using the SWC-EOLCD to reduce the burden of study measures.

Advance care plans

Advance care planning is a cornerstone of the government's end-of-life care strategy,[1] but we found it difficult to engage carers in formulating these. Only seven ACPs were made during this study, despite that fact that 22 patient–carer dyads received the intervention. Reasons for choosing not to make an ACP were complex and included conflicting family dynamics and a general unwillingness to address end-of-life care issues. Most difficulty occurred in accepting what was going to happen in the future, with an unwillingness to make decisions about hypothetical future scenarios.

The number choosing to make a written ACP does not necessarily measure the full effect of the intervention and may not be the most appropriate outcome. All carers were keen to receive more information about end-of-life issues in dementia and to have an

opportunity to express their concerns. They found the discussions very helpful, even if they did not go on to make an ACP. Perhaps these should be seen as part of a process of preparing carers for terminal stage of dementia. We found that the simple pack of information about dementia was well received by carers.

Methodological challenges

This pilot study highlights a number of methodological challenges. The acute hospital was not an easy environment in which to recruit study participants. Patients with advanced dementia do not have capacity to consent and many do not have carers to give assent for them. A randomized controlled trial of advance care planning for people over the age of 80 years, after acute hospital admission, has shown positive results but all of these study participants had capacity to participate.[29] Alternatively, independent advocates employed within the remit of the Mental Capacity Act may need to ensure that these patients receive better end-of-life care. Despite the fact that the study had ethics approval and carers gave consent for their participation and assent for the patient, we had great difficulty in accessing GP records to enable us to document care received at the end of life. We were unable to establish the reasons why so many carers withdrew; however, carers of people with dementia are often stressed and burdened.[30] Most of the carers in our study were daughters who lived away from the person with dementia and had full-time employment. The drop-out rates may be explained by the fact that this was not perceived to be an active 'treatment trial' that could directly improve patient care.

Clinical implications

Our intervention was delivered by a highly experienced nurse with a background in acute medical and dementia care. Over 100 patients were assessed for eligibility but only seven ACPs were made. Although most carers said they found the discussions helpful, many were reluctant to formulate an ACP. It has been suggested that discussion and provision of information are the most useful part of advance care planning with proxies,[31] but it is difficult to measure the 'benefit' of these.[32] Ideally, the person with dementia should consider making an ACP whilst in the earlier stages of the disease, when they have the ability to discuss such issues and can be more actively involved in making choices for their future care. There is evidence that older people who view a video depiction of a patient with advanced dementia are more likely to opt for comfort as their goal of care compared with those who just listen to a verbal description;[33] such tools could be adapted for people in the early stages of dementia.

We feel it is important to publish this 'negative' finding. Research governance and difficulties in accessing GP and community notes may mean that alternative methodologies to the randomized controlled trial need to be explored. Caplan et al.[7] demonstrated reduced hospital admissions after an advance care planning intervention for nursing home residents, but this occurred in the context of a whole system. The UK Gold Standards Framework[8] includes advance care planning for frail older people with dementia and audit data from this suggests an impact on end-of-life care. Demonstration of benefit may require a 'systemic' approach rather than our individual approach.[34]

Conclusion

Given the pressures of the acute medical environment, this intervention could not simply be added to routine clinical care. It may be that a specific staff role is developed to perform this work, which will have cost implications for acute trusts. This needs to be balanced against potential savings achieved by avoiding inappropriate acute hospital admissions at the end of life.[35] Advance care planning is a key aspect of the government's End of Life Care Strategy but this may not be feasible where proxies are involved for those lacking capacity. More evidence is needed on the benefits of ACPs developed by people with dementia before they lose capacity. Increasing evidence in other long-term conditions suggests that substantial proportions of people do not wish to make such plans.[36] This may be due to underlying attitudes related to denial of death, a belief in taking 'one day at a time' or the 'impossibility' of planning for the future.[36] Our pilot study has highlighted challenges in this type of work.

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Competing interests

The authors declare that they have no competing interests.

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