Original Article

PALLIATIVE MEDICINE

Palliative Medicine
1–13

DOI: 10.1177/0269216320905064
journals.sagepub.com/home/pmj
SAGE

Understanding usual care in randomised controlled trials of complex interventions: A multi-method approach

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Abstract

Background: Evaluations of complex interventions compared to usual care provided in palliative care are increasing. Not describing usual care may affect the interpretation of an intervention's effectiveness, yet how it can be described remains unclear.

Aim: To demonstrate the feasibility of using multi-methods to describe usual care provided in randomised controlled trials (RCTs) of complex interventions, shown within a feasibility cluster RCT.

Design: Multi-method approach comprising usual care questionnaires, baseline case note review and focus groups with ward staff completed at study end. Thematic analysis of qualitative data, descriptive statistics of quantitative data, followed by methodological triangulation to appraise approach in relation to study aim.

Setting/participants: Four general medical wards chosen from UK hospitals. Purposive sampling of healthcare professionals for usual care questionnaires, and focus groups. Review of 20 patients' notes from each ward who died during admission or within 100 days of discharge.

Results: Twenty-three usual care questionnaires at baseline, two focus groups comprising 20 healthcare professionals and 80 case note reviews. Triangulation of findings resulted in understanding the usual care provided to the targeted population in terms of context, structures, processes and outcomes for patients, families and healthcare professionals. Usual care was described, highlighting (1) similarities and embedded practices, (2) heterogeneity and (3) subtle changes in care during the trial within and across sites.

Conclusions: We provide a feasible approach to defining usual care that can be practically adopted in different settings. Understanding usual care enhances the reliability of tested complex interventions, and informs research and policy priorities.

Keywords

Randomised control trials, usual care, comparison, control, treatment, as usual, multi-method, mixed-method, complex interventions

What is already known about the topic?

- Usual care provided to patients is rarely described in detail in randomised controlled trials (RCTs) of a complex intervention in palliative care.
- To interpret the effectiveness of interventions tested within RCTs, the care provided in the comparison arm must be described.
- Approaches including the use of open-ended questions and observations have been used in trials to understand care provided but lack convergent validity.

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What this paper adds?

- Usual care provided in an RCT was characterised using a multi-method approach at different time points and from different professional perspectives.
- Similarities and variations in the care provided to patients within and across study sites and over time were identified refuting the assumption that all control participants received the same usual care.
- This paper provides a method for the classification of the usual care that should be embedded within RCTs of complex interventions.

Implications for practice, theory or policy

- Assumptions made about the usual care delivered to patients during intervention development may not always remain valid at the testing stage.
- Characterising usual care ensures that interpretation of findings of the effectiveness of the tested intervention is more valid.
- To avoid incorrect interpretations of complex interventions in palliative care, usual care is best characterised using a multi-method approach embedded within the design of RCTs.

Introduction

Towards the end of life, patients and their families have complex needs. In recent years, palliative care interventions have been developed to improve care.[1,2] While essential in all aspects of care, person-centred care, promoting autonomy and choice, is vital in palliative care provision.[3] However, palliative care practices and end-of-life care policies vary across care settings, and different patient populations.[4,5] Complex interventions have been evaluated using randomised controlled trials (RCTs) where the tested intervention was compared to 'standard' or 'usual' care.[6,7] Care may also vary at different time points during a trial. Usual care is the care the targeted patient population would be expected to receive as part of the normal practice and, within RCTs, refers to the care the participants who are not receiving the tested intervention receive.[8] Usual care should reflect locally adapted practices. While researchers have paid attention to clearly defining the interventions within trials,[9] scant attention has been paid to describing the characteristics of care provided to controls, and in some instances patients in the test arm in the absence of the intervention. This concern is amplified by international reporting guidelines for RCTs emphasising the importance of providing a detailed explanation of the comparison.[8,10]

Not detailing the care in comparison presumes all control participants receive a similar standard of care, within and across sites, and that usual care practices remain unchanged during the trial.[11] Taking part in a research study may influence the care provided within the control arm of an RCT.[12] If the usual care is incorporating the latest evidence, it may also resemble the tested complex intervention.[13] Without this information, interpreting the effectiveness of the intervention is challenging.[14] Providing clear descriptions of the intervention and usual care is critical for understanding the fidelity of implementation and delivery of an intervention tested across settings.[11] Defining usual care may also provide valuable information for further development of the complex intervention and inform its scalability to other settings, by benchmarking and identifying areas that could be improved to achieve a better quality of care.[15]

Attempts have been made to describe usual care, including open-ended questionnaires to gauge health professionals' understandings of care provided to patients.[9,14,16] Open-ended questions offer a practical approach to understand 'treatment-as-usual', yet the use of a single self-report method limits understanding to practitioners' views. Incorporating multiple data sources and triangulation across them enable exploration of different constructs of usual care.[17,18] Multi-method approaches such as direct clinical observations can be time- and resource-intensive.[19] Indirect methods, including using routine data, may be appropriate, particularly when used in multi-centre, large-scale trials.

We aimed to demonstrate how a multi-methods approach can be adopted to describe the usual care provided in RCTs of complex interventions. The usual care provided prior to the implementation of the complex intervention for the chosen intervention sites and the care provided in the control arms throughout the trial are described within the feasibility cluster RCT of the AMBER care bundle.[20] This is a complex intervention aimed at providing better care to patients whose situations are 'clinically uncertain', with an irreversible, deteriorating condition, and at risk of dying during their hospital admission.[20–23]

Methods

Design

Our study is a prospective, longitudinal, multi-method study within a parallel, feasibility cluster RCT of a complex

Table 1. Study sites.

Study arm	Cluster	Specialty	No. of beds	End-of-life care plan	Care Quality Commission rating[b]
Control site 1	1 general medical ward	• Rheumatology • Endocrinology	27	• Last days of Life Care Agreement	Requires improvement
Control site 2	1 general medical ward	• General medicine • Haematology • Diabetic medicine • Geriatric medicine	32	• Last days of Life Care Agreement • The Recognising Dying Assessment and the Individual Care Plan	Good
Intervention site 1	11 general medical ward[a]	• Care of the elderly	36	• End-of-life care plan	Requires improvement
Intervention site 2	1 general medical ward	• Respiratory • Endocrinology	30	• Individualised care plan for dying patients	Good

[a]Two separate wards were recently conjoined to become one ward shortly before the data collection.
[b]These ratings were captured at the time of the trial.

intervention (ISRCTN36040085).[5,20,24,25] Data were collected between June 2017 and August 2018.

Setting

Four district general hospitals[26] in England were randomised to the intervention and control arms of the trial (Table 1). Within each of these four hospitals, one general medical ward was purposefully chosen as the study ward based on the number of deaths. The selection process of study wards at each study site is detailed elsewhere.[20] As the usual care questionnaires and case notes reviews were conducted at baseline, prior to the implementation of the intervention, the baseline data from the two intervention study wards were also included for the description of usual care.

Data collection

The AMBER care bundle focuses on managing clinical uncertainty and improving communication within the multidisciplinary teams and with patients and families.[21] Exploration of usual care needed to enable comparison with this complex intervention by understanding the constructs of managing clinical uncertainty in current practice. Literature on existing methods of assessing usual care,[9,11] process evaluations[15,27,28] and integrative models of relations between the quality of care and health outcomes[29] was reviewed. As a result, we identified important aspects that were required to provide a clear understanding of the usual care provided across study sites. This included the context, healthcare professionals delivering the care, structures and processes in the wards and hospitals, and relevant anticipated outcomes of care for the patients, and their families. We chose methods which can be woven into the design of the cluster RCT, and the clinical context within the constraints of limited resources. We used the following data collection methods: usual care questionnaires, focus groups and case note reviews.

Usual care questionnaires

We used a self-report questionnaire to explore usual care with healthcare professionals. The questionnaire was administered in the control wards and the intervention wards at baseline only. We developed a study-specific questionnaire to document usual care across the whole trial (see Supplementary File 1). This enabled exploration of usual care aligned to key constructs of our intervention[9] and drawing on studies to inform the content and format. The questionnaire included 23 questions, mainly open-ended questions. The questions explored the structures, processes and outcomes of care,[15] including initial care planning, communication with families, recognising dying and clinical uncertainty, referrals and discharge procedures. We piloted the questionnaire at two wards of a London teaching hospital. The pilot explored the questionnaire content and format with questions subsequently re-worded for clarity. Pilot data were not included in the main data.

We purposefully sampled healthcare professionals based on their profession and seniority to aim to recruit five participants from each site with representation from across the multidisciplinary team (e.g. Medical consultant, Ward sister/manager, Junior doctor, Staff nurse, Healthcare assistant). Potential participants were identified and approached by the local research nurses working at the study sites.

Focus groups

Focus groups were undertaken in each site with clinicians after completion of data collection for the main trial outcome. The focus groups intended to explore the experiences of healthcare professionals in caring for, and communicating with, patients whose situations were clinically uncertain, and their families. We explored communicating with patients and their families about clinically

uncertain situations, teamwork and practices for enhancing communication of the healthcare professionals who worked on the control sites. The topic guide was informed by studies examining the intervention acceptability and use.[22,23] Eligible participants were identified and approached by the research nurses at each study sites, and a poster advertising the focus group for staff displayed on each ward. To enable participation, the focus groups were held at lunchtimes in meeting rooms on the study wards. Focus groups were led by either one of the researchers: J.K. (male) and C.J.E. (female) – both senior researchers experienced in complex interventions, palliative care and qualitative research. Field notes were taken (E.Y. and H.J.). Focus groups were audio-recorded and transcribed verbatim.

Case note reviews

The case note reviews[21] were conducted by a palliative care clinical nurse specialist at baseline in all four sites. The nurse specialist was the facilitator for the AMBER care bundle intervention. Case note reviews enabled exploration of more objective data on usual care to complement the self-report questionnaire data which may be subject to social desirability bias.[30,31] The note reviews comprised 10 patients who died during admission and 10 who died within 100 days of discharge. Each case note was randomly selected from the deaths during or after the admission. This intended to include case notes for individuals with a clinically uncertain prognosis during the admission. Case notes of the deceased patients were only accessed by hospital staff with clinical responsibility for the care in the ward. De-identified anonymous information was used as research data and shared with the research team. This method of case note review was part of the AMBER care bundle 'benchmarking' process to understand usual care at baseline and monitor changes over time.

Analysis

Qualitative data from the usual care questionnaires and focus groups were analysed separately. For the analysis of the focus group data, thematic analysis informed by the framework approach was conducted, to inductively code, organise and identify emerging themes.[32] The first steps of the coding and analysis were performed by E.Y. (female), who is a research assistant with experience in mixed-methods. To enhance analytical rigour, the researchers (E.Y., J.K., H.J.) reviewed coding and completeness of the framework. Where coding differed, issues were reconsidered by H.J., J.K., and E.Y. until a consensus was achieved.[33] Unusual or non-confirmatory views were examined and unwarranted claims about patterns were avoided. Excerpts were used to illustrate themes.

Usual care questionnaire data were analysed by E.Y. adopting a directed content analysis approach prior to triangulation.[34,35] Coding was deductive in terms of predetermined categories of structures, processes, and outcomes, similarities, variations, and changes over time. This methodology allows flexibility for survey designs which include quantitative, open-ended and closed-ended questions.[35]

Identifiable information was removed preserving confidentiality for both the focus groups and the usual care questionnaires. Qualitative data from the focus groups were managed in NVivo 11[36] and data from the usual care questionnaires were managed in SPSS.[37]

We used descriptive statistics for the numerical data in the usual care questionnaire and case note review data analysed using SPSS.[37]

The findings from three data sources were triangulated at the interpretation stage looking for correspondence (complementary information on the same issue), convergence (findings from different data sources agreeing), divergence (findings from different data sources contradicting each other), and silences (a theme or a finding arising from one data source and not from the others) after all data from different sources had been analysed separately.[38–40] The integration of findings from more than one data sources with a different methodology to address the same phenomenon is known as 'data triangulation'.[38,40] We believed that inter-method discrepancies may lead to a better understanding of usual care and in doing so highlight the areas for potential improvement. We also considered silences to be a possibility since, while using a multi-method approach, different methods will have varying strengths about contributing to the description of the usual care.

Research governance and ethical approval

Ethical approval was obtained from the National Research Ethics Committee–Camden and King's Cross (20 December 2016, REC Reference: 16/LO/2010) and Health Research Authority (25 January 2017). Research governance approvals were obtained from participating hospitals.

Results

Usual care questionnaires

Twenty-three healthcare professionals completed the usual care questionnaire at baseline (Table 2). We were able to purposively sample healthcare professionals across a range of professional groups and seniority. We initially aimed to recruit and obtain five questionnaires from each ward; however, one of the study wards was significantly larger than the others, as it has just been recently conjoined to an adjacent ward. Hence, we collected data from

Table 2. Professions who completed the usual care questionnaire.

Study arm	Control		Intervention	
Study site	Control site 1	Control site 2	Intervention site 1	Intervention site 2
Profession (*N*)	5	5	8[a]	5
Consultant	1	1	2	1
Ward sister/manager	1	1	2	1
Junior doctor	1	1	2	1
Staff nurse	1	1	0	1
Healthcare assistant	1	1	1	1
Physician associate	0	0	1	0

[a]Two separate wards were recently conjoined to become one ward shortly before the data collection.

eight instead of five healthcare professionals to have better coverage of the care provided in this ward. Although, initially, the usual care questionnaires were planned to be repeated at consecutive time points, this was not feasible within the short data collection period. Collecting data at baseline from a range of healthcare professionals was feasible. Completeness of the usual care questionnaires was high with a median of 97.6% (range: 58.3%–100%) of the questionnaire completed per participant. The questions within the usual care questionnaire were deemed as completed if the participant provided an answer, or stated that they did not know the answer. The usual care questionnaire took approximately 15 min to complete.

Focus groups

Two focus groups were conducted with healthcare professionals at two control site wards, attended by 20 healthcare staff ($n = 9$ and $n = 11$, respectively) (Table 3). Participants represented the multidisciplinary team, but there was no representation from nursing in control site 2 with staff shortages precluding attendance.

Case note reviews

Eighty case note reviews were completed (Table 4). Most of the decedents were aged above 71 years (55%) and had a primary diagnosis of cancer or respiratory disease.

Describing usual care across the study sites

By triangulating data from the focus groups, usual care questionnaires and case note reviews on the construct of usual care, we were able to define and classify usual care for patients whose situations were clinically uncertain. The classification comprised of (1) similarities and embedded practices, (2) heterogeneity within and across study sites and (3) subtle changes in the control arm during the study (Table 5). Within this trial's study sites, we observed similarities across the domains of admission and current care planning, communication with the patient and family, escalation decisions, recognition of the clinical uncertainty, and the emotional support provided to the staff members, whereas heterogeneity within and across the study sites was observed for documentation of deterioration and specialist involvement, advance care planning, decision-making processes and communication between ward staff, and competence and confidence of the ward staff in communication. Finally, subtle changes in the usual care were observed at the control sites, specifically relating to the changing attitudes towards referral practices to the palliative care team.

Discussion

We demonstrated how a multi-method approach can successfully be adopted within the financial and time constraints of a trial to describe comprehensively the usual care provided to the patient population targeted by the complex intervention. While widely used statements such as CONSORT[10] and TIDieR[8] call for a description of the care provided in the control group, no guidance is provided for how this information should be obtained, specifically for RCTs of complex, common in palliative and end-of-life care.[9] Building on from the literature and using a multi-method approach, we identified embedded practices and variability in care provided to patients across four sites within a multi-centre RCT, highlighting the importance of reliably collecting information on the quality of care, rather than assuming a similar standard of care. We also identified subtle changes in clinical practices of staff in the control arm from baseline onwards. While in the exemplified trial, changes in the control arm were small, in larger trials, understanding and monitoring for potential changes in the usual care practices hold an imperative value for the complex intervention's development and implementation.

Within the context of this trial,[20] where the complex intervention was designed to serve patients with a terminal diagnosis, and their families, quality of care and treatments can be highly variable.[4] Complex interventions tend to be subtlety modified during local adaptation, adding on to the heterogeneity of the usual care in clinical practice.[27] To

Table 3. Focus group participant characteristics.

Study site	Specialties in involved	Professionals involved (gender)	Duration
Control site 1 (*n* = 9)	Haematology Diabetes	Junior doctor (M) Occupational therapist (F) Ward sister (F) Research nurse (F) Research practitioner (F) Matron of research (F) Staff nurse (F) Palliative care consultant (M) Junior doctor (F)	60 min
Control site 2 (*n* = 11)	Rheumatology Endocrinology General practitioner	Consultant rheumatologist (M) Consultant endocrinologist (F) Physiotherapy technician (F) Research coordinator (F) Rheumatologist trainee (F) General practitioner trainee (F) Junior doctor (M) Registrar rheumatologist (M) F1 (F)	65 min

M: male; F: female.

Table 4. Baseline case notes review per study site and trial arm (*N* = 80).

Study arm	Control		Intervention		Total
Study site	1	2	1	2	(*N* = 80)
Descriptive variable, *n* (%)	(*n* = 20)	(*n* = 20)	(*n* = 20)	(*n* = 20)	
Age median (range)	83.5 (58–95)	78.5 (58–91)	88 (78–97)	71.5 (49–90)	81 (49–97)
40–60	2 (10)	2 (10)	0 (0)	3 (15)	7 (8.75)
61–70	2 (10)	3 (15)	0 (0)	6 (30)	11 (13.75)
71–80	4 (20)	8 (40)	2 (10)	6 (30)	20 (25)
81–90	8 (40)	6 (30)	11 (55)	5 (25)	30 (37.5)
91–100+	4 (20)	1 (5)	7 (35)	0 (0)	12 (15)
Primary diagnosis					
Cardiology	0 (0)	0 (0)	4 (20)	0 (0)	4 (5)
Cancer	12 (60)	9 (45)	2 (10)	6 (30)	29 (36.25)
Acute respiratory	5 (25)	7 (35)	5 (25)	2 (10)	19 (23.75)
Chronic respiratory	0 (0)	0 (0)	0 (0)	10 (50)	10 (12.5)
Stroke	0 (0)	0 (0)	0 (0)	1 (5)	1 (1.25)
Dementia	0 (0)	0 (0)	2 (10)	0 (0)	2 (2.5)
Sepsis	2 (10)	0 (0)	1 (5)	0 (0)	3 (3.75)
Frailty	0 (0)	0 (0)	1 (5)	0 (0)	1 (1.25)
Other	0 (0)	4 (20)	5 (25)	1 (5)	10 (12.5)
Clinical uncertainty documented					
Yes	18 (90)	15 (75)	18 (90)	12 (60)	63 (78.75)
No	2 (10)	5 (25)	2 (10)	8 (40)	17 (21.25)
Advance care plan in place					
Yes	4[a] (20)	8[d] (40)	7[b] (35)	2[c] (10)	21 (26.25)
No	16 (80)	12 (60)	13 (65)	18 (90)	59 (73.75)
Escalation plan documented					
Yes	15 (75)	12 (60)	18 (90)	13 (65)	58 (72.5)
No	5 (25)	8 (40)	2 (10)	7 (35)	22 (27.5)
CPR status recorded					
Patient for CPR	1 (5)	0 (0)	0 (0)	2 (10)	3 (3.75)
Patient not for CPR	16 (80)	15 (75)	20 (100)	15 (75)	66 (82.5)

(Continued)

Table 4. (Continued)

Study arm	Control		Intervention		Total
Study site	1	2	1	2	(*N* = 80)
Descriptive variable, *n* (%)	(*n* = 20)	(*n* = 20)	(*n* = 20)	(*n* = 20)	
No status recoded	3 (15)	5 (25)	0 (0)	3 (15)	11 (13.75)
Medical plan discussed & agreed with nursing staff					
Yes	9 (45)	15 (75)	19 (95)	16 (80)	59 (73.75)
No	11 (55)	5 (25)	1 (5)	4 (20)	21 (26.25)
Patient ± family discussion					
Yes	19 (95)	14 (70)	19 (95)	13 (65)	65 (81.25)
No	1 (5)	6 (30)	1 (5)	7 (35)	15 (18.75)
Daily follow-up with patient and family					
Yes	19 (95)	12 (60)	19 (95)	12 (60)	62 (77.5)
No – should have received	1 (5)	7 (35)	1 (5)	8 (40)	17 (21.25)
No – not indicated	0 (0)	1 (5)	0 (0)	0 (0)	1 (1.25)
Assessment of capacity					
Yes	11 (55)	20 (100)	10 (50)	7 (35)	48 (60)
No – it was not needed	7 (35)	0 (0)	9 (45)	12 (60)	28 (35)
No – it was needed	2 (10)		1 (5)	1 (5)	4 (5)
Preferred place of care					
Person's own home	3 (15)	7 (35)	2 (10)	10 (50)	22 (27.5)
Hospital	2 (10)	6 (30)	2 (10)	3 (15)	13 (16.25)
Care home	0 (0)	3 (15)	6 (30)	3 (15)	12 (15)
Hospice	3 (15)	1 (5)	1 (5)	1 (5)	6 (7.5)
Preference not recorded	11 (55)	1 (5)	6 (30)	3 (15)	21 (26.25)
Other (including undecided patients)	1 (5)	2 (10)	3 (15)	0 (0)	6 (7.5)
Preferred place of death					
Person's own home	4 (20)	3 (15)	1 (5)	3 (15)	11 (13.75)
Hospital	2 (10)	0 (0)	2 (10)	0 (0)	4 (5)
Care home	0 (0)	4 (20)	1 (5)	3 (15)	8 (10)
Hospice	3 (15)	1 (5)	2 (10)	0 (0)	6 (7.5)
Preference not recorded	11 (55)	9 (45)	3 (15)	12 (60)	35 (43.75)
Other (including undecided patients)	0 (0)	3 (15)	11 (55)	2 (10)	16 (20)
Patient and family wishes					
Wishes recorded	5 (25)	12 (60)	16 (80)	10 (50)	43 (53.75)
DNAR decision only	4 (20)	0 (0)	0 (0)	5 (25)	9 (11.25)
No wishes recorded	9 (45)	0 (0)	4 (20)	4 (20)	17 (21.25)
Patient declined discussion	1 (5)	8 (40)	0 (0)	1 (5)	10 (12.5)

CPR: cardiac pulmonary resuscitation; DNAR: do not attempt resuscitation.
Advance care plan in place by condition: site 1: [a]3 cancer; 1 acute respiratory; site 2: [b]1 cancer, 1 acute respiratory, and 5 other; site 3: [c]1 acute respiratory, 1 chronic respiratory; and site 4: [d]4 cancer, 3 acute respiratory, 1 chronic kidney disease.

optimise patient and family outcomes, care is expected to be personalised, where the patients and family members are seen as equal partners in decision-making regarding care.[41] Aspects of person-centred care, for example, coordinating and integrating care, ensuring continuity of care and multidisciplinary working,[41] rely on having embedded clinical structures and processes. This requires staff across different professional groups to actively engage with them as part of their usual practice. Understanding contextual aspects of the usual care across sites, variability among healthcare professionals, and triangulation with data from patients' notes enables researchers and intervention developers to map aspects of care expected to be uniform, and those expected to be heterogeneous. This knowledge assists in identifying the linkages between the mechanisms of a complex intervention and the intended outcomes, compared to the usual care within an RCT. As RCTs are accepted as providing the highest level of evidence,[42] defining the usual care by incorporating a multi-method approach within RCTs should represent a sensible methodological addition to this study design. This maximises the utility of findings on the processes as to how the intervention works to deliver the intended outcomes, and the requirements for use, compared to usual care.

Table 5. The classification of the usual care.

Similarities and embedded practices	
Admission and current care planning Initial medical history, assessment processes and care planning consistent across study sites. 87% ($n = 20$) of clinical staff reported completion on patient admission in usual care questionnaires; 73.9% ($n = 17$) stated specific time frame (within 6 and 12 h for control sites 1 and 2, respectively; and ⩽24 h for intervention sites at baseline). Presence of electronic scoring systems (e.g. *Patient at Risk Score*) mentioned in focus groups and usual care questionnaires at all sites to highlight patients for prioritisation during night/weekend shifts. All usual care questionnaire respondents stated medical plans reviewed daily; five stated this occurred rarely at weekends.	
Communication with patient and family Case note reviews identified patient and family discussions documented in clinical notes for most patients (range 65% ($n = 13$) at intervention site 2 to 95% ($n = 19$) at intervention site 1 (Table 4)). In case note reviews, daily follow-up discussions were present in 60% ($n = 12$) (intervention site 2 and control site 2) to 95% ($n = 19$) (control site 1 and intervention site 1). 82.6% ($n = 19$) of usual care questionnaire respondents stated contact would be made with family immediately if patient deteriorated, whereas three respondents stated informing another team member.	
Escalation decisions Case note reviews showed escalation plans, and decisions regarding 'do not attempt resuscitation orders' to range between 60% (control site 2) and 90% (intervention site 1), and 75% (control site 2) and 100% (intervention site 1) of patients' notes, respectively. 56.5% ($n = 13$) of usual care questionnaire respondents stated investigations stopped once patient recognised as dying and rarely a small percentage of patients would have further investigations. Three respondents highlighted escalation decisions relied on recognition of deterioration influenced by clinical uncertainty resulting in delays halting further investigations. Consequences of not recognising deterioration mentioned during focus group.	Illustrative quotes *You're told that by the doctor to take some blood when you get to the patient's arm and he has no access and he's been unconscious. So, you're trying to get access, but the situation is distressing for you, and distressing for the family.* (1018, Ward sister)
Recognising clinical uncertainty At baseline, usual care questionnaire respondents were familiar with factors relating to situations of clinical uncertainty. Across all sites, common responses referred to *poor treatment response* (30%, $n = 7$), followed by *poor scores* (17.4%, $n = 4$), multi-morbidities (13%, $n = 3$) and *frailty* (8.7%, $n = 2$). Documentation of clinical uncertainty across sites ranged (60% ($n = 12$, intervention site 2) to 90% ($n = 18$, control site 1)) of case note reviews. *Frailty* for recognising clinical uncertainty was mentioned during focus group.	*People who are getting frail and deteriorating slowly, it's a week or two after they get there.* (2020, Consultant)
Emotional support to staff All study sites possessed infrastructure for staff emotional support (e.g. electronic resources and counselling). However, usual care questionnaire and focus group respondents noted they rarely made use of services, turning to each other support.	*We've got a well-being system that can be accessed by any member of staff for support.* (1021, Research nurse) *I don't think any of us know about it. I tend to find that as nurses we provide support for one another about how difficult that conversation with that family and that kind of thing and we just look after one another, but there's no formal system that I'm aware of.* (1022, Staff nurse)

(Continued)

Table 5. (Continued)

Heterogeneity within and across study sites	
Documentation of deterioration and specialist involvement Management of clinical uncertainty differed between disciplines/sites. Usual care questionnaire identified divergence among respondents about whether clinical notes of patient would reflect 'death was likely to occur (during their hospital stay (or shortly after)', and patient/family's insight *(The dying person and their family were aware of situation)* into their clinical situation. All questionnaire respondents at control site 2 stated patients' notes include information about likely death, patient/family insight. At other study sites, opposing views indicated heterogeneity among healthcare professionals' practices within same ward about documentation practices and information provided to patients/families. Nearly all (92%, *n* = 21) respondents across sites stated feeling at ease with making palliative care referral, albeit with delays. At control site focus groups, a continuation of delays in recognising deterioration throughout trial present.	*Not recognising the patient is near 'end of life'*. (Intervention-Site-2004, Staff nurse) *Not having a senior clinical decision*. (Control Site-1005, Healthcare assistant) Doctors continuing to treat even though the patient is dying. (Intervention-Site-2002, Ward sister) *Uncertainty of doctors*. (Intervention-Site-1002, Ward sister) *Uncertainty in diagnosis*. (Intervention-Site-1006, Physician associate) *You think if these discussions had taken place maybe last week, then we wouldn't be at the point we're at now. You do ask yourself that quite a lot*. (1018, Ward sister)
Advance care planning Advance care planning documentation practices and supporting patients' preferences at end of life varied. Case note reviews at baseline identified documentation of advance care plans (range 10% (*n* = 2) (intervention site 2) to 40% (*n* = 8) (control site 2)). 21 of 80 patients had advance care plans documented. Patients' 'preferred place of care' recorded for 45% (*n* = 9, control site 1), 70% (*n* = 14, intervention site 1), 85% (*n* = 17, intervention site 2)–95% (*n* = 19, control site 2). 78.2% (*n* = 18) of usual care questionnaire respondents state 'the whole MDT, patient and family' involved in devising advance care plan. Staff acknowledged on-going process of advance care planning outside hospital with GPs. Int1005 referred to advance care planning as 'something which needs to be improved on the ward'. Other healthcare professionals from same site highlighted holistic approach involving other professionals. Responses about frequency of revising advance care plans with patients/family varied from not often enough (control site-2004 – Senior Doctor) to daily (control site 1005, control site 1004 – Junior Doctors). Triggers included *end of life, deterioration, poor prognosis, terminal illness, futility of treatments,* and *frequent admissions* given for advance care plan initiation. Of 23 responses to 'What are the triggers for devising or starting the necessary procedures for devising an advanced care plan for a patient on this ward?', only three respondents mentioned patient/family wishes to raise questions about patients' and families' roles in devising plan.	
Decision-making and communication between ward staff Medical teams' roles in devising medical plan highlighted by nursing and assistant/associate staff across sites in usual care questionnaires. Case note review identified agreement with patients' final medical plan with nursing staff (range 45% (*n* = 9, control site 1) to 95% (*n* = 19, intervention site 1)). Usual care questionnaire respondents (*n* = 20) reported involvement of multidisciplinary team in making decisions about patients' situations. However, views from focus groups did not concord with. Instead, possibility of team members to communicate concerns about patients highlighted by control site staff.	*I think it's hard for the front line staff to deal with because we're the ones who are taking the blood from them and we're putting cannula after cannula after cannula and not getting any joy and you know, many problems will come from just simply needing to treat but we get the front line. We have to stand and try to take the blood in front of the family and all that. It's different for a doctor to say 'Yes, carry on treating them'. But they're not actually the ones in the room delivering the care. I don't know. I think that's always quite hard on the nursing staff*. (1018, Ward sister) As a junior, you don't have much say really on dramatically changing management plans. Uhmm but anytime I do have I think that when I see a patient, I'm a bit uhmm there's a discrepancy between what I think, how they should be managed then what is currently being done, then discuss it with my seniors. (2011, Junior Doctor)
Competence and confidence in communication Although some senior healthcare professionals confident discussing situations of clinical uncertainty with patients/families, others stated in usual care questionnaires and focus groups lack of proficiency with this aspect of care. Hence, communication between healthcare professionals and patients whose situations were clinical uncertainty and families varied and depended on individuals' skills. Impact of individual attributes/contextual factors including limited time for communication highlighted during focus groups.	*I find it quite awkward. If you need to break bad news to them then you're going to, it's going to be emotional for yourself, isn't it? It's quite hard to break bad news and that's why people always look to somebody who's used to doing it a lot*. (1018, Ward sister) I find it very time-pressured, very limited time to deal with quite complex issues. (2020, Senior doctor/clinical lead)
Subtle changes in usual care at control sites Aspects of usual care provided to patients whose situations were clinically uncertain remained unchanged at control sites. However, changes in referral practices to palliative care team and improved confidence communicating with patients/families observed at control site 2. A senior doctor (baseline usual care questionnaire not comfortable making palliative care referrals for non-cancer patients) stated, during focus group, at end of trial her conduct improved, a view shared by colleagues. Although no changes during trial recorded at control site 1, plans for hospital-wide implementation of similar intervention mentioned during focus groups.	*It helps us I think reflect a bit more on non-cancer patients. . . To make the team more aware that this may be a group that we previously missed in terms of getting them identified and also support for end of life*. (2021, Senior doctor/clinical lead) Generally, escalation plan. Like, where they. . . if anything was to happen at that admission, how far would that patient and family want? What are their wishes? Would they want to be on ITU, tubed and that sort of stuff. . .? They sound quite similar; I'm thinking relating to AMBER. (1018, Ward Sister)

MDT: multidisciplinary team; GP: general practitioner; ITU: intensive therapy unit.

Historically, ensuring high-quality care to individuals involved standardising the usual care, and having interventions in place to deliver treatments and care, with little flexibility. However, there is a danger that these interventions can easily turn into 'tick-box' exercises and, in some instances, when not combined with adequate evaluation, may lead to harm instead of benefit to patients.[43,44] Increasing evidence points in the direction of a healthcare model which involves interpretation of research evidence for the delivery of person-centred care in clinical practice.[45,46] Describing the usual care within RCTs intends to illuminate understanding on the context by exploring differences between settings and levels of care in clinical contexts (e.g. micro, macro and chronosystems).[47] Understanding context is essential for embedding evidence-based change in clinical care to enhance clinical effectiveness for patients.

Our findings highlight important variability in the manner 'usual' care was provided within, and across study sites, having implications for both the way findings from similar RCTs of complex interventions are interpreted in terms of the comparator, and the requirement for successful implementation.[11] While findings converged on prioritising and informing patients and families about their clinical situation, we identified variance in healthcare professionals' perceptions of their competence in communicating with patients and families when prognosis was uncertain, involvement of each ward staff member in clinical decision-making, and effective communication between ward staff regarding patient's and family's knowledge. These findings highlight the lack of similar usual care in the control arm. Some control participants may have been receiving usual care that was different compared to the intervention; others may have received care similar to patients in the intervention arm. Heterogeneity of care received in the control arm, if not successfully contrived with randomisation, may reduce the chance of detecting potential effects of the tested intervention. Not having a clear understanding of the usual care and how it compares to the complex intervention could lead to overinterpretation of its benefits or deprive patients, whose needs remain unmet, of a potentially beneficial intervention.

Strengths and limitations

The use of a multi-method approach enabled detailed exploration of the healthcare professionals' perceptions on care provision, enhanced through case note reviews to provide a deeper exploration of specific clinical activities. Data triangulation enabled convergence and divergence across the data sets.

When considered in isolation, the findings from the usual care questionnaires and focus groups may be interpreted with caution due to subjectivity. Triangulation with the case note reviews overcomes this concern.

The data collection methods for characterising usual care were easy to implement within the context of a feasibility multi-centre, cluster RCT, with relatively limited resources. Capturing the important aspects of the care within the specified context is valuable, yet there were no available questionnaires which could be adapted for this study.[9] Hence, we developed the usual care questionnaire specifically for this study. While being piloted and proven to be successful in aiding in describing the usual care, this tool was not validated.

We were not able to obtain information on healthcare professionals who approached and those who refused to take part in the focus groups, or the usual care questionnaire; hence, opinions of those who participated in the study might differ from those who did not.

We are mindful of the absence of nursing representation in one of the focus groups. This limits our findings' transferability to other care settings. We wanted to purposefully include the nurses in the focus groups, proportionate to their integral role in patients' care. Although several nurses expressed interest and confirmed their availability beforehand, on the day of the focus group, no nurses were able to attend, due to urgent clinical commitments. This highlights the issues faced while conducting research in a real-life context. In future, studies should aim to improve nursing and allied-health professional representation by considering additional flexibility and resources in the study design to accommodate the unpredictable nature of clinical work.

We were not able to conduct direct observations of care due to logistical constraints. Direct observation of clinical practice might not always be feasible or ethically acceptable for vulnerable populations. However, studies should consider incorporating non-participant observation of care delivery to gain a better understanding of usual care, by cross-validating the quality of structure and process of care in RCTs of complex interventions.[15]

Case note reviews were completed by only one clinical nurse specialist. Having a single person responsible for data extraction might introduce rater bias. Where possible, a review of patients' notes should be carried out by two independent researchers, and report corresponding inter-rater reliability.

Conclusions

We have shown it is feasible and advantageous to use a multi-method approach to explore usual care in RCTs of complex interventions for patients nearing the end of life. We have highlighted embedded practices and knowledge, and variability in the usual care depending on healthcare professionals' skills, patient disease groups and contextual factors. This study makes a methodological contribution to the research field by providing a practical and feasible approach for describing usual care. While there has been a growth in the number of studies that have

evaluated complex interventions, to date, there has been a lack of agreement on how usual care can be defined. We successfully addressed this concern. To optimise the design of RCTs and improve evidence-based practice, future studies should adopt and develop the proposed multi-method approach in different settings. Within the context of limited funding opportunities for experimental studies, researchers conducting RCTs of complex interventions should aim to fully understand, and provide a definition of, the usual care. This would provide greater confidence in the study findings. Understanding usual care can strengthen the reliability of complex interventions tested in RCTs and accordingly set research funding and policy priorities.

Acknowledgements

We wish to acknowledge funding for this study from the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme, as well as support from the research managers at the NIHR Evaluation Trials and Studies Coordinating Centre. We are very grateful to the AMBER Care Bundle design (Dr. Irene Carey, Dr. Adrian Hopper, Susanna Shouls & Charlene Davis) team who worked with us for adapting the case notes review data extraction tool. We wish to thank Linda Launchbury, the palliative care clinical nurse specialist, who completed the case notes review at all study sites and acted as the clinical facilitator for the study intervention. We wish like thank the clinical staff at each of the four hospital sites for agreeing to be involved in this study and for participating in the focus groups and completing the usual care questionnaires. We would especially like to thank the principal investigators and the clinical teams at each the four hospital sites: Henry Penn – Northwick Park Hospital, London North West University Healthcare NHS Trust; David Brooks – Chesterfield Royal Hospital, Chesterfield Royal Hospital NHS Foundation Trust; Natalie Broomhead – East Surrey Hospital, Surrey and Sussex Healthcare NHS Trust; and Carole Robinson – Tunbridge Wells Hospital, Maidstone and Tunbridge Wells NHS Trust for agreeing to be involved in this trial. We express particular thanks to the research nurses working across each of the four trial sites, who were instrumental in the recruitment and making arrangements for the palliative care clinical nurse specialist to come in and conduct the case note reviews. We also wish to thank the non-clinical staff at each of the four trial sites for their input into the administration for facilitating communication between the research team and research nurses. We wish to thank our study steering committee members Liz Sampson, Morag Farquhar, Joanne Droney and Toby Prevost for their valuable input. We are grateful to Sylvia Bailey and Colleen Ewart who provided expert patient public engagement input throughout the project.

Author contributions

J.K., C.J.E., F.E.M.M., D.Y., W.G., A.P., S.B. and E.Y. made substantial contributions to the conception and design of the study. J.K., E.Y. and C.J.E. contributed to the organisation of the conduct of the study. E.Y., C.J.E., J.K. and H.J. carried out the study (including acquisition of study data). J.K., E.Y. and H.J. contributed to analysis and interpretation of study data. J.K., E.Y., H.J. and C.J.E. drafted the paper. All authors critiqued the output for important intellectual content and read and approved the final manuscript.

Data management and sharing

Data from this study are currently not available online. Further information about the research materials could be accessed from the lead author upon request.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: This paper presents independent research funded by the National Institute for Health Research (NIHR) under the Health Technology Assessment Programme (15 October 2017). C.E.J. is funded by a HEE (Health Education England)/NIHR Senior Clinical Lectureship. The views and opinions expressed are those of the authors and do not necessarily reflect those of the NHS (National Health Service), the NIHR, MRC (Medical Research Council), NETSCC (NIHR Evaluation, Trials and Studies Coordinating Centre), the NIHR or the Department of Health. The funders had no role in study design, data collection and analysis of the study.

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Supplemental material

Supplemental material for this article is available online.

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