

Supporting carers to manage pain medication in cancer patients at the end of life: A feasibility trial

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Abstract

Background: Carers of people with advanced cancer play a significant role in managing pain medication, yet they report insufficient information and support to do so confidently and competently. There is limited research evidence on the best ways for clinicians to help carers with medication management.

Aims: To develop a pain medicines management intervention (Cancer Carers Medicines Management) for cancer patients' carers near the end of life and evaluate feasibility and acceptability to nurses and carers. To test the feasibility of trial research procedures and to inform decisions concerning a full-scale randomised controlled trial.

Design: Phase I-II clinical trial. A systematic, evidence-informed participatory method was used to develop CCMM: a nurse-delivered structured conversational process. A two-arm, cluster randomised controlled feasibility trial of Cancer Carers Medicines Management was conducted, with an embedded qualitative study to evaluate participants' experiences of Cancer Carers Medicines Management and trial procedures.

Setting: Community settings in two study sites.

Participants: Phase I comprises 57 carers, patients and healthcare professionals and Phase II comprises 12 nurses and 15 carers.

Results: A novel intervention was developed. Nurses were recruited and randomised. Carer recruitment to the trial was problematic with fewer than predicted eligible participants, and nurses judged a high proportion unsuitable to recruit into the study. Attrition rates following recruitment were typical for the study population. Cancer Carers Medicines Management was acceptable to carers and nurses who took part, and some benefits were identified.

Conclusion: Cancer Carers Medicines Management is a robustly developed medicines management intervention which merits further research to test its effectiveness to improve carers' management of pain medicines with patients at the end of life. The study highlighted aspects of trial design that need to be considered in future research.

Keywords

Family caregivers, carers, medicines management, medication therapy management, analgesia, terminal care, cancer, pain, clinical trial, nurses

What is already known about the topic?

- Carers play an important role in managing patients' pain medicines at the end of life.
- Evidence suggests carers have concerns about pain medicines and lack information and support.
- Interventions for carers have not been adequately developed or tested for effectiveness.

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What this paper adds?

- A description of a complex intervention to support carers in managing medications at the end of life;
- Preliminary evidence of the intervention is acceptable, feasible and beneficial for patient–carer dyads;
- Identification of features trial design that could be successfully replicated on a larger scale as well as those that require modification.

Implications for practice, theory or policy

- The feasibility trial has helped illuminate important design issues to be considered in future research.
- The intervention should be evaluated further to examine its effect on outcomes in carers and patients.

Introduction

Many people with advanced cancer experience persistent pain¹ and are typically prescribed analgesics, including opioids. Carers – defined as ‘anyone who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support’ (<https://carers.org>) – often help patients to manage medicines, especially near the end of life (EoL), and their contribution can be crucial to enabling patients to remain at home.^{2,3} Medication management requires knowledge and practical skill and involves carers in monitoring and interpreting symptoms, as well as selecting, administering and evaluating the effectiveness of medicines.^{4,5} Internationally, research has repeatedly shown that carers experience difficulties as a consequence of their beliefs about pain and analgesics, particularly opioids,^{6–8} knowledge deficits⁹ and lack of access to information and support.^{10,11} Most studies conclude that health-care professionals need to provide carers with more information, training and continuing support.^{4,8,10–12}

While reports and small-scale evaluations of carer participation in medicines management can be found in the literature,^{13,14} these focus on practice development initiatives, and there is a lack of reliable research on effective methods of supporting carers with medicines management.¹⁵ No study has attempted to integrate interventions with routine palliative care, the majority of interventions lack theoretical underpinning and none were designed with input from carers and clinicians. Evaluating complex interventions in palliative care settings inevitably raises ethical and methodological challenges,¹⁶ but studies reviewed included limited discussion of these and none used qualitative methods to explore participants’ views on the feasibility and acceptability of interventions or study procedures.

Aims and objectives

The study reported here (author submission checklist available online) drew on authors’ previous experience of developing nurse-delivered interventions^{17,18} and followed Medical Research Council guidance on complex

interventions.¹⁹ Phase I aimed to develop a novel, theoretically based, intervention for carers of patients with advanced cancer designed to improve pain medicines management (Cancer Carers Medicines Management (CCMM)) to be delivered by nurses providing home-based palliative care. The aim of Phase II was to conduct a feasibility study, comprising a randomised controlled trial (RCT) and qualitative process evaluation, to test trial procedures and assess acceptability and feasibility of CCMM to carers and nurses to inform decisions concerning a full-scale RCT. Objectives were to determine rates of recruitment and retention, to test acceptability and feasibility of trial procedures, to investigate variability in outcome scores, to establish acceptability and feasibility of CCMM and to identify factors that promote or inhibit its utilisation.

Methods*Phase I: intervention development*

CCMM was developed using a multi-method, iterative process, with expert input from a purposive sample of patients ($n=3$), carers ($n=12$) and health professionals ($n=42$: 35 community and specialist palliative care nurses, 3 doctors and 4 pharmacists) from the study sites, who provided information on carers’ needs for support with managing medicines (see Online Appendix 1). The study also included carers from a wider geographical area, who took part in user involvement group consultations ($n=23$). Interview guides were developed from critical insights from the initial literature review and were focused on key medicines management issues and possible intervention components. Data from all sources were synthesised and with reference to a theoretical framework (Lazarus’ theory of adaptation,²⁰ underpinned by Ward’s representational approach to patient education²¹ and self-efficacy theory²²), a prototype intervention was developed. This was refined further using participatory methods (nominal group technique and ethnodrama) with two groups of nurses ($n=16$)

Table 1. Components of Cancer Carers Medicines Management (CCMM).

CCMM conversational process		CCMM toolkit: <i>Taking charge of cancer pain</i>
<i>Nurse initially works through the steps below in one face-to-face session with carer. At subsequent contacts nurse addresses any questions and revisits aspects of the conversational process.</i>		<i>Nurse introduces resources and tools as appropriate to meet individual needs for information and support identified through conversational process. At subsequent contacts, nurse reviews use of toolkit resources.</i>
Consent	Explain purpose, your role. Consent from patient to discuss pain management with carer.	Frequently asked questions about pain medicines: information about using morphine in Q&A format
Assess	Explore beliefs and previous experiences of cancer pain and pain medicines, assess support and other resources available and prioritise knowledge and skills needs.	Medicines chart: to be completed jointly by nurse and carer Record of medicines taken: for carer to chart regular and additional pain medication
Review	Prescribed and non-prescribed medicines. Review medicines chart if available or draw one up.	Pain diary: explanation and suggested simple format diary What works best for pain? Chart for collating information to help assess effectiveness pain management
Education	Provide coaching for the educational and information needs prioritised for this visit.	Anticipating tool: planning how to respond to situations that may arise
Review	Make plans for review and provide resources, if needed.	Stop, look, ask, listen and respond: tool to help carer decide what to do when they feel uncertain or overwhelmed about managing pain medicines
Support	Invite naming of what has been learnt, reinforce support available, including who to phone if any problems before planned review time.	Important local contact telephone numbers Details of organisations providing further information and support

working in community palliative care. A panel of nurses ($n=16$) and carers ($n=6$) then reviewed the refined CCMM materials to confirm relevance to clinical context.

CCMM addresses carers' beliefs, knowledge and skills and promotes self-evaluation of competence. It centres on a structured conversational process between nurse and carer, which has six components forming the acronym CARERS (Table 1).

Phase II: CCMM feasibility study

Trial design. A two-arm, parallel group, randomised controlled feasibility trial of CCMM was conducted at two sites, in south Wales (SW) and southern England (SE). Nurses were randomly allocated to intervention or control (usual care) arms of the study at each site. Clusters were of patient-carer dyads on the caseload of each nurse. This cluster design was used to minimise risk of contamination. The nature of the intervention precluded concealment of treatment allocation. Further details can be found in the study protocol.²³

Setting. In SW, health board-employed district nurses had generic caseloads that included patients with palliative care needs and in SE, two independent hospice palliative care providers employed nurse specialists to work in the community. These contrasting models are typical of nurse-delivered EoL care in the United Kingdom and were chosen to assess feasibility issues associated with each. Nurse volunteers for the study were sought at each site: invitations were given directly to nurses who had recently participated in EoL care training (SW) and issued via nurse managers (SE).

Prior to randomisation, nurses completed the Knowledge and Attitudes Survey Regarding Pain²⁴ to compare pain management knowledge across the two groups of nurses. Each nurse was given a sealed envelope containing group allocation, determined independently (by P.S.) using simple randomisation and concealed until nurses opened the envelopes.

Participants. The study used a consecutive convenience sample of patients on the study nurses' caseloads. Nurses screened patients for eligibility (see Table 2) and were asked to consider all dyads meeting eligibility criteria as potential participants, in combination with clinical judgment about appropriateness of inviting participation.

Intervention delivery. Intervention group nurses received one day's training on CCMM, designed and facilitated by specialist palliative care educators (S.A., S.D.). Training included preparation for and rehearsal of the CCMM intervention, as well as an overview of the study design and processes. To support intervention, delivery nurses were provided with a conversational process script, access to an online video demonstration and a prompt card. Nurses were asked to document use of CCMM components by completing a structured reflective record soon after each CCMM consultation.

Trial procedures. Study recruitment and data collection procedures are summarised in Table 3. Following carer completion of baseline questionnaires, nurses in the intervention group delivered CCMM to carers at the next appropriate home visit. At subsequent routine contacts,

Table 2. Carer eligibility criteria.

Inclusion criteria	Exclusion criteria
Aged 18 years or over	Non-English speaking
Supporting a patient with advanced cancer (no longer receiving potentially curative treatment) at home	Carers or patients were assessed by their nurse to lack capacity to consent ^a
Supporting a patient who had been prescribed analgesia for cancer-related pain	
Self-reported full or partial responsibility for managing the patient's medicines	
Agreement from the patient to take part	

^aCapacity to consent was judged to be present when the patient and carer could understand the information relevant to participating in the study, retain that information, use or weigh that information as part of the process of making the decision and communicate his/her decision.

nurses could address participants' questions and reinforce the intervention (Table 1).

Outcomes

Feasibility and acceptability. Data were collected on numbers of dyads screened, assessed as eligible, recruited and retained. Nurses' and carers' experiences of research procedures and CCMM (intervention group) or pain medication management practices (control group) were explored in face-to-face semi-structured qualitative interviews. Interview guides were informed by normalisation process theory (NPT), a framework for assessing compatibility of trial procedures with clinical practice and identifying factors that influence perception and utilisation of complex interventions.³⁰ Intervention group nurses' reflective records were used to capture intervention delivery and utilised in conjunction with interview data to assess fidelity of intervention delivery.

Carer and patient outcomes. Measures assessed for acceptability and responsiveness to CCMM exposure in carers were knowledge, beliefs and skills in cancer pain medicines management (Family Pain Questionnaire²⁶); self-efficacy in pain management (Zeiss Caregiver Problem-Solving Self-Efficacy²⁷) and strain (Caregiver Strain Index²⁸). A secondary outcome was patients' perceived pain (Brief Pain Inventory–Short Form²⁵). Data collection points were selected to test sensitivity of measures and to test feasibility of completing a measure at 4 weeks post-intervention in people approaching EoL. Carers also self-completed an assessment of mood (Profile of Mood State–Short Form²⁹) at baseline only. Carers in both intervention and control groups were asked to complete measures at baseline, 1 and 4 weeks and to take part in 1- and 4-week interviews.

Sample size. A target sample size of 30 patient–carer dyads per arm was selected to enable estimation of sample size for a possible follow-on RCT³¹ based on the outcome measure showing greatest change in response to CCMM. Previous research with a similar group of carers suggested we should assume a 50% non-participation and attrition rate;³² therefore, the plan was to approach up to 120 patient–carer dyads.

Analysis. Rates of eligibility, recruitment and attrition were calculated as percentages. Interviews were audio-recorded, transcribed verbatim and anonymised. Analysis, using the framework approach,³³ was led by one researcher (E.L. – carer interviews and J.A.H. – nurse interviews) with research team members (S.L., J.B.H., A.R. and C.M.) reading a sample of transcripts. For the nurse interviews, thematic frameworks, generated inductively and informed by NPT, were used to organise data. Due to the small sample size of carers, case reports were constructed; themes were synthesised from these into a composite, interpretive 'case study'.³⁴

Ethics approval. The study was approved by NRES Committee South Central Hampshire B (ref. 12/SC/0365, 4 September 2012). Research governance approval and permission for researcher access were granted by NHS organisations, independent healthcare providers and other gatekeeper bodies. All patients, carers and healthcare professionals participating in Phase II provided written informed consent.

Results

Phase II

Feasibility and acceptability of trial procedures

Recruitment and retention of nurses. The target number of 12 nurses took part in the study. Two nurses at each site (2 from control group and 2 from intervention group) withdrew for reasons unrelated to the research. A total of 10 nurses took part in post-study interviews.

Nurse pain knowledge and attitudes. Nurses at the two study sites had similar baseline pain knowledge and attitudes scores: nurse specialists (SE): mean=29/40, range=18–35; district nurses (SW): mean=27/40, range=24–31. Post-study re-testing showed little change (SE: 30/40, 25–34 and SW: 29/40, 26–32).

Randomisation. No difficulties were encountered in randomising nurses. At interview, some nurses said they had entered the study with a preference for the intervention

Table 3. Study recruitment and data collection procedures.

Timeline	Procedures		Data collected (intervention and control groups)
	Nurse	Researcher (for intervention and control groups)	
Routine nurse home visit at which participation invited	(Intervention and control group) – introduces study, invites participation, obtains verbal consent, completes eligibility questionnaire, gives carer baseline questionnaires to complete later, forwards patient contact details to researcher. Patient pain assessment at baseline.		Patient BPI-SF
Within several days phone call and collection of carer baseline data		Provides verbal information on study, arranges home visit to deliver study information sheets, collects self-completed carer baseline questionnaires, obtains written consent (patient and carer).	Carer FPQ, self-efficacy, CSI, POMS-SF, written consent
After baseline data received, next nurse routine home visit	Control group: usual care, patient pain assessment Intervention group: usual care + CCMM, nurse completes reflective record, patient pain assessment		Nurse reflective record (intervention group only)
After 1 week of nurse visit/intervention	Routine contacts: usual care, patient pain assessment Intervention group: usual care + CCMM, patient pain assessment	Face-to-face meeting with carer at home, collects completed carer questionnaires and demographic profile, interviews carer Reviews patient medical record	Carer FPQ, self-efficacy, CSI, carer demographics, carer interview, patient BPI-SF
After 4 weeks of nurse visit/intervention		Face-to-face meeting with carer at home, interviews carer and collects completed carer questionnaires Interviews nurse in work setting	Patient demographic and clinical details Carer FPQ, self-efficacy, CSI, carer interview, patient BPI-SF
After end of study data collection period	(Intervention and control group) – nurses invited to take part in interview		Nurse interview

BPI-SF: Brief Pain Inventory-Short Form;²⁵ FPQ: Family Pain Questionnaire;²⁶ Self-efficacy: problem-solving caregiver self-efficacy;²⁷ CSI: Carer Strain Index;²⁸ POMS-SF Profile of Mood States-Short Form;²⁹ CCMM: Cancer Carers Medicines Management.

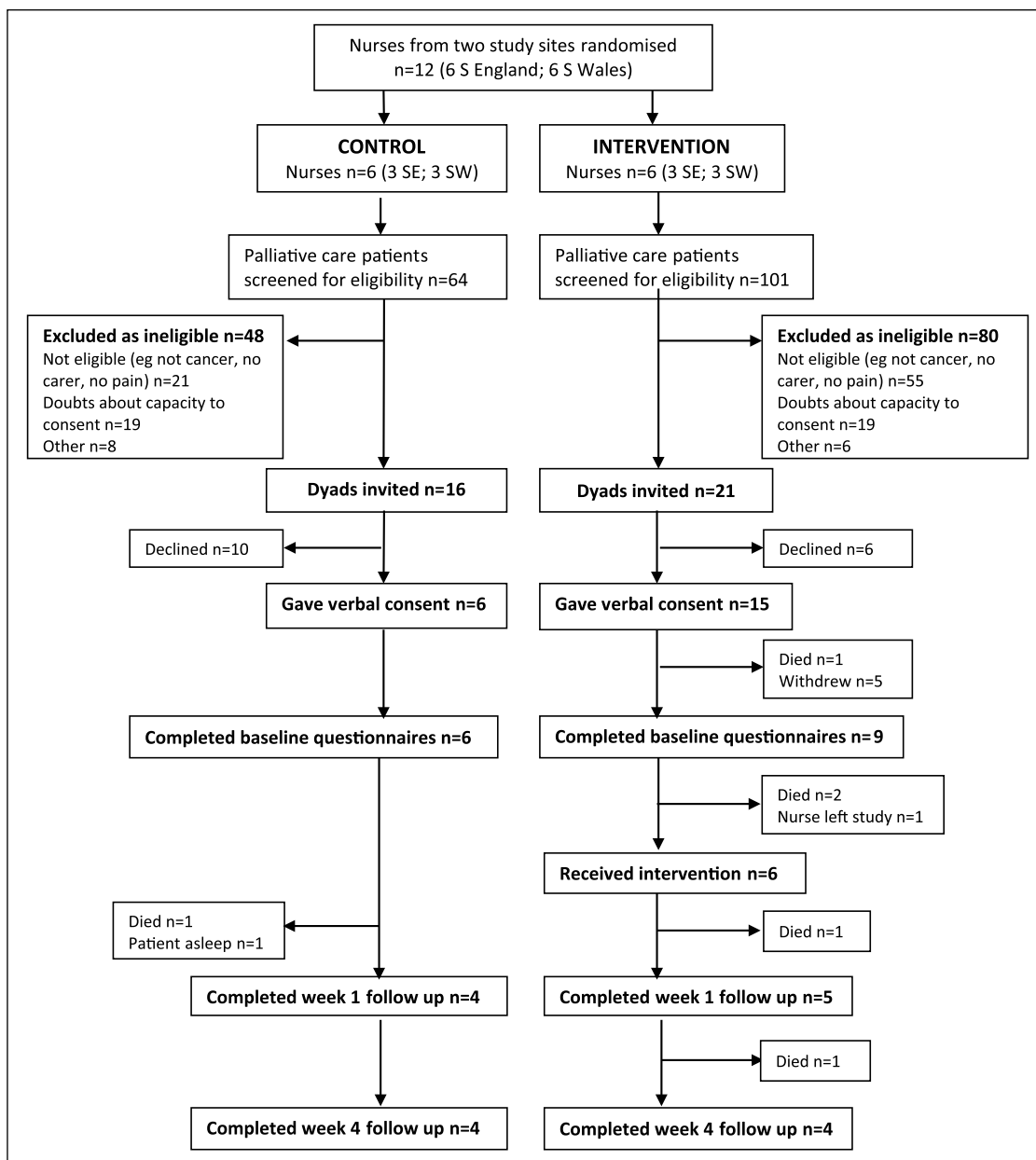


Figure 1. CONSORT flow diagram for the CCMM study.

group, but all accepted their group allocation. Analysis of interviews indicated control group nurses had not become aware of intervention details or altered their pain management practice. Interviews with carers did not reveal any concerns about their nurse’s group allocation.

Eligibility, recruitment and retention of carer participants. Data collection took place between March and September 2014. The flow of participants through the trial is shown in Figure 1. Full demographic and clinical data were collected on patients and carers (n=9) who completed the trial (see Table 4).

Nurses received fewer than predicted referrals during the study period and assessed a high proportion of them as

ineligible (78%) (reasons included non-cancer, no pain, no carer and other perceived physical or psychological demands on them). Initial estimates of referrals may have been inaccurate, but during the trial, contextual factors (i.e. reorganisation of nursing teams, staff turnover and sickness absence) and changes in clinical practice (e.g. patients being referred very close to EoL to district nurses) impacted unpredictably on the number of eligible patients. On average, nurses approached three dyads each during the 6-month data collection period (median=3 and range=0–8), obtained verbal consent from 1.75 dyads (median=1.5 and range=0–6) and recruited 1.25 dyads (median=1 and range=0–3).

Analysis of nurse interviews distinguished various obstacles to recruitment (Table 5). These included reports

Table 4. Carer and patient demographic and clinical data.

	Intervention group	Control group
Female (carer)	5 (100%)	3 (75%)
Female (patient)	2 (40%)	1 (25%)
Age (mean)		
Carer	54.6 years	57.5 years
Patient	72 years	69.5 years
Carer ethnicity		
White British	5 (100%)	4 (100%)
Carer educational qualifications		
No qualifications	3 (60%)	1 (25%)
Qualifications below University level	–	–
Qualifications at University level	2 (40%)	3 (75%)
Carer relationship to patient		
Spouse	1 (20%)	4 (100%)
Daughter	3 (60%)	–
Sister	1 (20%)	–
Cancer site		
Metastatic bone	4 (80%)	
Oesophagus	1 (20%)	
Spinal cord		1 (25%)
Lung and liver		1 (25%)
Bowel		1 (25%)
Missing		1 (25%)

of ‘protecting’ patients and carers from perceived additional burden and distress that might be raised by demands of the research and nurses’ not approaching some patients/carers to avoid their own disappointment caused by dyads declining participation.

The demographic and clinical profiles of participating dyads suggest that nurses were selective: carers were relatively young (mean age=56 and range=37–68) and the majority had university level education. Average scores for mood disturbance (POMS-SF; median=25 and interquartile range (IQR)=13–36) and carer strain (Carer Strain Index (CSI); median=4 (out of 12)) were low. Most dyads had medicines management routines in place, and carers reported experience of medicines management in their personal or occupational background.

Data collection. Feasibility of self-completed questionnaires for measuring carer outcomes was confirmed: 100% of POMS questionnaires were returned at baseline and approximately 90% of all other questionnaires were returned at each time point, with relatively few missed items or obviously incorrect responses.

Nurses completed 85% of patient pain assessments with the patient using Brief Pain Inventory–Short Form (BPI-SF). At interview, some highlighted difficulties, particularly for patients who were very ill or reluctant to talk about their illness. Several nurses described the assessment

as ‘cumbersome’ and ‘quite onerous’ and reported adapting the questionnaire. These findings raise questions about the feasibility of nurse-administered pain assessment using BPI-SF.

Three nurses completed reflective records for four of the six visits at which CCMM was initially delivered. The contemporaneous documents supplemented accounts of intervention delivery given in interviews. However, self-report provided insufficient data to reliably assess intervention fidelity; it would have been preferable to observe or audio-record a sample of nurse visits at which CCMM was used.

Acceptability and utilisation of CCMM

Nurses’ use of CCMM. Findings from intervention group nurse interviews ($n=6$) were mapped against NPT categories of implementation work (sense-making, participation, action and monitoring) to assess CCMM’s implementation potential and identify how it might be optimized.²³ Full details are provided in Online Appendix 2 and summarised below.

CCMM made clinical sense to nurses, who recognised the challenges faced by carers managing analgesia at the EoL and saw potential benefits in improving education and support. However, nurses did not find CCMM sufficiently new or distinctive, and said they were already using some components of the intervention, although this claim was not supported by control group nurses’ descriptions of routine practice. Nurses tended to equate CCMM with providing written information and resources, rather than seeing it as a conversational and educational process.

Positive experiences of CCMM training helped nurse engagement. However, due to low recruitment, each nurse used CCMM with only one or two dyads and not all nurses became confident delivering it. Nurses gave examples of CCMM benefiting carers, although some nurses were concerned that focusing specifically on pain could potentially increase patient/carers anxiety about this issue. At the end of the trial, CCMM was compared favourably with current practice because it offered a more systematic and comprehensive approach to supporting carer management of pain medicines. Nurses particularly valued the toolkit resources, that is, information about opioids and simple charts for documenting pain and medication, because they were of immediate practical value to carers.

Nurses found CCMM generally compatible with existing work practices: it was easy and quick to deliver and adaptable to family circumstances, concerns raised by carers and the time available during a visit. However, CCMM resources were not always used selectively as had been intended: nurses tended to give the complete toolkit to carers. Nurses found CCMM’s specific focus on pain medicines difficult to reconcile with their holistic approach to managing a range of EoL symptoms and associated medicines. They also suggested that expanding the intervention

Table 5. Factors influencing recruitment of study participants.

Obstacles	Illustrative quotes from nurse interviews (n = 10) ^a
Contextual factors: organisational change, team staffing levels, nurse workloads and variable flow of palliative care referrals (district nurses) A low proportion of palliative care referrals meeting study eligibility criteria.	'I then had a full caseload so I wasn't taking on any new patients for quite a long time. [...] We've had the consultants doing first visits and I would follow on afterwards because we've been so short staffed'. (N02cSE) 'when we had a new palliative patient I was keen to get there and then they weren't suitable. [...] some of the palliative patients don't have pain [...] If they had a care agency or they didn't have a regular carer [...] quite often they'd manage [their medication] themselves, if they had the capacity to consent'. (N14iSW)
Nurses' unfamiliarity with research recruitment, coupled with infrequent opportunities to use study procedures: nurses emphasised the need for practice to achieve a fluent approach they felt confident about. Incompatibility of recruitment procedures with nursing practice at a first visit: recruitment could be impeded by patient fatigue, time constraints on the nurse and difficulty assessing capacity to consent.	'I found [practising the recruitment procedure] quite helpful because it is difficult when you're adding something. [...] it was nice to be able to practice how you might approach it. And I think I felt much more comfortable doing that'. (N01iSE) 'to start with I found [introducing the study] difficult because there were so many other things that you had to talk about [at the first visit] and I tended to leave it to the end because I could then concentrate solely on that. But [pause] by that stage they'd kind of switched off. They'd had enough. [...] It was all too much to take on board'. (N11iSW)
Nurses 'protecting' patients and carers from additional burden or distress: some nurses did not approach eligible dyads they judged unable to cope with research demands.	'I felt quite uncomfortable [introducing the study] sometimes, because I knew it was going to add to the burden of everything else that they were doing'. (N01iSE) 'There was just so much anxiety and so many other problems [...] It was almost like [introducing the study] would have been too much and the thing that broke everything and it just fell apart'. (N04cSE)
Nurses' avoidance of difficulty and disappointment: some nurses described pre-judging patients' and carers' willingness to participate, to avoid invitations being declined, which they found discouraging.	'I always went with the idea this is a new palliative patient that could be a candidate for the study. [...] [in one case] you could see it was all a bit too much for them so it didn't seem appropriate. And another person was extremely deaf and his daughter didn't really engage [...] So I went in with an open mind but on certain cases [...] if I felt it would be a very difficult recruit I thought, well don't even initiate it, you know'. (N13iSW)
Recruiting fewer dyads than anticipated affected nurses' engagement and the priority they gave to the study	'when we were doing the training it's just right there. And then it slips to tenth place. And if you haven't recruited, it's twentieth place because you're doing this, this and this'. (N06iSE)
Facilitators	
Nurses' initial enthusiasm for participating in research and agreement with the purpose of the study	'I think anything that's going to improve patient symptoms and also the care, the support they get from the carers. I think often carers can be a forgotten group and they take a lot of responsibility. If there were tools that were going to be helpful that's a win-win situation'. (N03iSE)
Preparation and continuing support provided by the research team	'I think that was good the way we had instant access to you [researchers]. [...] you were OK with us phoning at any time. [...] particularly when we weren't that familiar with it. [...] and you followed us up regularly and you were accessible when we needed you. You were there which was nice'. (N01iSE)

[...]: text of transcript has been edited for clarity and brevity.

^aQuotes are tagged with a composite code that provides unique nurse study ID (first letter followed by two digits), group allocation (i or c, intervention or control) and study site (south England (SE) or south Wales (SW)).

to include life-limiting conditions other than cancer would increase its applicability and enhance its compatibility with palliative care nursing practice. Nurses also favoured introducing CCMM earlier in the course of a patient's illness, which was felt more appropriate and of greater benefit to carers.

Carer experience of CCMM. Nine family carers were interviewed (five intervention and four control; 17 inter-

views). Although carers had some difficulty in isolating CCMM from their overall experience of caring for a patient at the EoL, most commented on the value of CCMM resources in the toolkit, particularly for information, reassurance and supporting problem-solving. Within the data, we identified some positive changes in medicines management, such as increased acceptance of the need for opiates, knowledge being reinforced or enhanced and behavioural change, for example, responding more readily

to patients' requests for pain relief and improved systems in place for giving and recording medicines. There were no reports from carers of CCMM increasing the burden of caring or otherwise causing harm or distress (Online Appendix 3).

Discussion

Phase I enabled the development of a novel, theory-based intervention to support carer management of pain medicines, grounded in current EoL care context, as well as research and expert evidence. Although caution in interpretation is required due to the small sample, data indicate that the intervention was acceptable to nurses and carers, was feasible to deliver in practice, and showed some benefits.

Qualitative data from carers were suggestive of potential benefits for their knowledge, beliefs and behaviours related to management of pain medicines. However, some nurses reported that CCMM could potentially raise patient and carer anxiety through its focus on pain. Due to problems with recruiting our target sample size, we were unable to conduct a reliable analysis of variability in outcome scores and therefore select a primary outcome or determine sample size for future research. All carer outcome measures proved feasible to complete, with little missing data, suggesting suitability for future research, but nurses' reported difficulties measuring patient pain using the Brief Pain Inventory (BPI) and alternative methods may be required.

The need for CCMM made sense to nurses and was largely compatible with their clinical practice and helped to systematise it. However, nurses highlighted challenges caused by focusing solely on pain, and in future research, consideration should be given to expanding CCMM to include medicines used to manage other symptoms at EoL, making it more compatible with nurses' holistic focus. Nurses had some difficulty distinguishing CCMM from routine practice and tended to distribute the written resources indiscriminately to carers rather than engaging them in a conversational process. Nurses needed more opportunity to reflect on current practice and practise CCMM before the trial proper to be confident about and competent in using CCMM.

Some aspects of study design proved feasible and could be replicated in a larger scale trial: both specialist palliative care nurses and community nurses were recruited, and randomisation was acceptable; in keeping with findings from other studies,³⁵ using a cluster design with nurses randomised within-site did not prove problematic with respect to control group contamination. The study also reinforced the usefulness of qualitative methods of evaluation in studying experiences of acceptability and feasibility.

The main obstacle to feasibility was carer recruitment, partly attributable to fewer than expected eligible participants. Rather than simply accepting managers' estimates

of palliative care referrals, we could have carried out a rapid audit to check viability. Recruitment problems were also attributable to low proportions of eligible carers invited by nurses. Our findings are suggestive of a high degree of gate-keeping by nurses, similar to recruitment problems described in other recent trials.^{36,37}

Organisational issues and fundamental conflicts between clinical and research roles appeared to exist. Schildmann and Higginson¹⁶ recommend screening for eligibility is done by research staff, while Stone et al.³⁸ argue for careful monitoring of the recruitment process, so that reasons for low recruitment by clinical staff can be identified and managed. Research staff access to patients and carers may also be facilitated by recruiting at hospital discharge or through out-patient clinics.

Gatekeeping may also result in selection bias and thus a risk of inequity in patient and carer access to an intervention. The small sample of dyads recruited to this study did not appear to be typical – they were younger and functioning well – a theme in other studies.³⁹ In a pragmatic study, it is perhaps impossible to completely eliminate risks of selection bias, but checks can be introduced, so that biases can be identified. We did not collect data on all eligible participants, so could not systematically compare the characteristics of those nurses invited and those they did not. This should be part of the protocol of future studies in which healthcare professionals recruit participants, if ethics committees are prepared to allow this.⁴⁰

Finally, it may be important to reconsider the recruitment of dyads and focus on carer outcomes alone, as CCMM is a complex psychoeducational intervention for carers. Parallel consent of both patient and carer made the recruitment process complex with exclusion of some carers because the patient did not have capacity to consent. Others have also concluded that recruiting both patients and carers extends the recruitment phase.⁴¹

Conclusion

CCMM is a robustly developed, novel medicines management intervention which merits further evaluation to test effectiveness at improving carers' management of pain medicines with patients at EoL. This feasibility trial has helped illuminate important design issues that would need to be incorporated into a definitive trial.

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Declaration of conflicting interests

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