Study protocol for a feasibility trial of Cancer Carer Medicines Management (CCMM): an educational intervention for carer management of pain medication in cancer patients at end of life

Latter S, Hopkinson J, Lowson E, Duke S, Anstey S, Bennett M, Smith P, May C, Richardson A

Abstract

Background: Many people with cancer experience pain at the end of life. Family carers play a significant role in managing pain medication: a practical and nursing skill that is both central and critical to patient and carer. There is significant evidence this is problematic for carers and patients. Family carers often lack information and confidence, with some believing pain cannot be controlled and are concerned about medication becoming addictive. Carers' roles in cancer pain management have been neglected, and a carer-focused, tailored intervention has the potential to improve care in this area.

Methods/design: A feasibility study is being conducted (2013-2015) to test the feasibility, acceptability and efficacy of a newly developed intervention (Cancer Carers Medicines Management: CCMM) to improve carers' knowledge, beliefs, skills and self-efficacy for pain medicines management, and to decrease carer strain. The feasibility trial involves recruiting nurses and carers in two sites, to inform a follow-on randomised control trial focusing on effectiveness. This paper presents the feasibility study protocol.

Discussion: The feasibility trial aims to evaluate the feasibility and acceptability of the study methods and intervention, and to provide preliminary data concerning the intervention's impact. This will include the intervention's impact on carer outcomes using validated questionnaires measuring carer pain medication knowledge, beliefs and skills; self-efficacy and carer strain. Secondary outcomes from validated questionnaires and interviews will include perceptions of patient pain, burden of the intervention, and factors inhibiting or facilitating intervention use

Author details

Sue Latter, Professor of Nursing, Faculty of Health Sciences, University of Southampton, UK

Jane Hopkinson, Professor of Nursing, School of Healthcare Sciences, Cardiff University, UK
Elizabeth Lowson, Senior Research Fellow, Faculty of Health Sciences, University of Southampton, UK

Sue Duke, Senior Lecturer, Faculty of Health Sciences, University of Southampton

Sally Anstey, Lecturer, School of Health Sciences, Cardiff University, UK

Mike Bennett, St Gemma's Professor of Palliative Medicine, Faculty of Medicine and Health, University of Leeds, UK
Peter WF Smith, Professor of Social Statistics, Southampton Statistical Sciences Research Institute, University of Southampton, UK

Carl May, Professor of Healthcare Innovation, Faculty of Health Sciences, University of Southampton, UK

Alison Richardson, Clinical Professor of Cancer Nursing, Faculty of Health Sciences, University of Southampton and University Hospital Southampton NHS Foundation Trust

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Background

Pain is experienced by 71% of people with cancer approaching end of life (EOL) (Teunissen et al 2007). Unpaid carers providing EOL care (EOLC) at home to people with cancer play a significant practical and nursing role in managing medicines. This involves carers selecting, administering and evaluating the effectiveness of medicines used for control of pain (Kazanowski 2005; van Ryn et al 2011). Internationally, studies repeatedly identify that carers experience problems, including: beliefs that pain cannot be controlled and concerns about addiction (Ferrell et al 1995; Letizia et al 2004), hesitancy to administer analgesics (Lin 2000), knowledge deficits (Oldham and Kristjansen 2004) and insufficient information provision by nurses (Schumacher et al 2002; Bee et al 2008). Studies have also revealed the distress engendered through carers seeing a loved one in pain (Ferrell et al 1991;

Meeker et al 2011). These problems have been linked to a negative influence on patient pain management behaviours (Schumacher et al 2002) and adequacy of analgesic use and management of cancer pain (Lin 2000). Inadequate pain management has been linked with unnecessary hospital admissions (Trask et al 2006).

A systematic review (Bee et al 2008) of carers' practical needs as the EOL approaches at home, concluded that carer interventions should include as a minimum, education and training related to medication management and symptom control. However, most interventions to improve cancer pain have focused on the patient (Bennett et al 2009; 2011).

A recent systematic search (Meeker et al 2011) found five studies reporting interventions for carer cancer pain management. Four of these studies were directed at patient-family carer pairs (Ferrell et al 1995; Wells et al 2003; Keefe et al 2005; Lin et al 2006). One, a US study, focused solely on the family carer alone and was concerned primarily with coping (McMillan et al 2006). Studies' results indicated that carer education in pain management can improve knowledge and self-efficacy for pain management, reduce attitudinal barriers and carer strain, and benefit carer quality of life. Systematic reviews of interventions to address a range of cancer and palliative care carer needs (Harding and Higginson 2003; Stadjuhar et al 2010; Northouse et al 2010) identify the need to test the effectiveness of theory-based interventions for carers.

Candy et al (2011) conclude that successful interventions that promote effective medicines use are more likely to include components identified as important to consumers than ineffective interventions. Whilst strong international evidence on carer needs exists, and a small number of trials have been conducted, there is a lack of research into carer needs and interventions in the UK. In addition, research to date has not tested the potential impact of 'evidence-based' higher dose interventions involving a comprehensive educational program, follow up and higher resources allocation (Cummings et al 2011) and none have used a potentially widely generalizable model of training nurses to deliver an intervention during routine care.

This feasibility trial draws on previously developed and tested self-efficacy based interventions (Latter et al 2010) to underpin an educational intervention for carer pain medicines management in the home setting. Knowledge and skills are pre-requisites for self-efficacy (Bandura 1997). There is some limited evidence suggesting that patient and carer self-efficacy for managing cancer pain can influence patient and carer outcomes (Porter et al 2008). Theory on medicines adherence, focusing on carer beliefs about medicines' necessity and medicines concerns (Horne and Weinman 1999; NICE 2009), also underpin the intervention's development.

This feasibility study follows the Medical Research Council's recommendations for the development and evaluation of complex interventions (Campbell et al 2007; MRC 2008). The study aims to test the feasibility, acceptability and efficacy of a new intervention to improve carers' knowledge, beliefs, skills and self-efficacy for pain medicines management and decrease carer strain.

Methods

Research participation is via two research sites in south Wales and southern England: at one site, six community nurses are involved; and at the other, six nurse specialists working for independent specialist palliative care providers are involved.

Participation in this study by patients, carers and health professionals has approval from the Health Research Authority's National Research Ethics Service Hampshire B Committee (12/SC/0365). Each NHS body, independent health provider and other gatekeeper organisation granted research governance approval, permission and clearance for researcher access as appropriate prior to participation.

Design

This is a two arm, parallel group, cluster randomised control feasibility trial of an educational intervention for carer management of pain medication in cancer patients at end of life: Cancer Carers' Medicines Management (CCMM). Nurses are randomised to intervention or control (usual care groups) and the clusters comprise patient-carer dyads under the care of each nurse. Comparisons are made in carer and patient questionnaire outcomes at baseline, 1 and 4 weeks post intervention. A qualitative sub-study of the acceptability of CCMM and trial methods is included, with interviews conducted 1 and 4 weeks post intervention with carers, and with each nurse on study completion.

This study aims to inform a follow-on full-scale multi-centre trial (determining the effect of CCMM on carer psychological and emotional status outcomes and cancer patient pain) by testing the randomisation process; determining recruitment, attrition and adherence rates; investigating variability of carer outcomes and patient pain in carers exposed to CCMM; calculating an effect size to inform the power calculation; identifying, describing, and understanding key factors that promote or inhibit routine utilization of CCMM by nurses and carers; and identifying obstacles to the trial process, including acceptability and feasibility of including nurses and carers in a control arm.

Methods

Setting, recruitment and sample: nurses

Six community nurses in South Wales and six specialist community nurses working for independent specialist palliative care providers in southern England provide

Table 1: Timetable

Time	Activity or milestone
December 2013-January 2014	Ethics, research governance and site permissions and planning intervention testing
February-March 2014	Recruitment and randomisation of nurses, and training of intervention group nurses
March-August 2014	Study open for recruitment and participation of patients and carers; data analysis

written informed consent to participate. Invitations to participate are given via managers. The contrasting locations, settings and professional experience of nurses working in the community have been selected to test CCMM in varying contexts. Nurses are randomised in blocks by professional group to intervention or control (usual care) groups. Intervention group nurses participate in 1 day training facilitated by experienced nurse lecturers to offer CCMM through face-to-face consultation and introduction of carers to supporting resources, with follow up to reinforce the intervention and address carer questions in subsequent face to face and telephone contacts that take place as part of normal service delivery. Education methods include actor demonstration and participant rehearsal, peer feedback and discussion. At the end of the trial, control arm nurses will also be offered this training (assuming it is observed to have beneficial outcomes for carers and patients).

Setting, recruitment and sample: patients and carers

Unpaid carers are eligible for participation if they are: supporting a patient with advanced cancer (no longer receiving potentially curative treatment) at home who has been prescribed analgesia for cancer-related pain; willing and able to participate; have agreement from the patient to take part; age 18 or older; and self-report full or partial responsibility for the patient's medicines management.

Patients are excluded from the study if they lack the capacity to consent, as determined in accordance with the Mental Capacity Act 2005. Patients' capacity to consent is assessed on each occasion data are collected by the nurse or researcher. Carers are excluded from the study if they do not speak English, or if they have a clinical condition that precludes giving written informed consent.

All nurses are briefed by the research team on introducing patients and carers to the opportunity to participate in the study, and completing the Brief Pain Inventory (Cleeland and Ryan 1994) with patients, with coaching offered to assist with this.

Nurses introduce the opportunity to participate to eligible patients and carers, and those who are interested are asked to complete a form giving permission for contact details to be passed to the researcher. Nurses are asked to continue recruiting carers for a period of six months with the aim of each nurse recruiting five dyads who complete the study. Figure 1 outlines the patient and carer dyad pathway through the study.

Researchers are responsible for obtaining written informed consent from each participant. Verbal consent is sought for all subsequent data collection and participants are reminded that they are free to withdraw at any time without giving a reason.

Our maximum sample size of 60 carers completing the study is pragmatic. It is large enough to enable the estimation of sample size, number of nurses who would need to be approached and the recruitment and retention rate of carers for our follow-on RCT. Our earlier non-randomised studies involving palliative care unpaid carers (Hopkinson et al 2010) suggest that a 50% rate of non-participation and attrition should be assumed. Up to 120 patients and carers may need to be recruited to reach 60 patient-carer pairs completing the study. We are therefore investigating whether each of the nurses can recruit 5 carers who complete the study over a 6 month period.

Lancaster et al. (2004) recommend examining change in a group of 30 to estimate a sample size for an RCT, consistent with our selected carer sample for exposure to CCMM. Observed change in our measures will be used to decide our primary outcome measure in our follow-on RCT, estimate an effect of CCMM on this outcome and do a sample size calculation. Our sample size is also sufficient to generate qualitative data that can be usefully analysed (typically qualitative studies argue that data is saturated once 20-30 participants have been interviewed).

Intervention

The intervention aims to address carers' beliefs, knowledge and skills and their self-evaluation of their needs and pain medicines management. The intervention centres on a conversational process introduced by the nurse and conducted between the nurse and carer (the patient may also be included). This structured conversational process is used in combination with medicines-related resources in a toolkit, which are given to the carer for their use. The intervention is designed to be delivered initially face-to-face in one session, with the conversational process and resources re-visited at subsequent face-to-face visits and telephone contacts as appropriate.

Measures and interviews

To enable baseline comparisons of nurses' pain knowledge and analysis of changes over time, all nurses complete Knowledge and Attitudes Survey Regarding Pain (Ferrell and McCaffery 2008) at the beginning of the study before randomisation and at their interview at the end of the study.

Intervention group nurses document and reflect on the CCMM components practised after each completion of the CCMM consultation. These reflective records are designed to help the nurse and the research team to understand how CCMM is being used in clinical practice, its feasibility, acceptability and usefulness to nurses, carers and patients.

Outcome measures completed by patients, carers and nurses are detailed in Table 2 below. Apart from nurses completing the Brief Pain Inventory-Short Form (Cleeland and Ryan 1994) with patients at baseline and 1 and 4 weeks after initial delivery of CCMM, all other questionnaires are self-completed and collected by the researcher. Baseline questionnaires are given to the carer by the nurse in a sealed envelope at the visit when verbal agreement is given to participate.

Researchers make three research visits to each patient/carer: one to collect the completed baseline questionnaires; 1 week after initial delivery of CCMM, an interview and questionnaire completion; and 4 weeks after initial delivery of CCMM, an interview and questionnaire completion. At the research visit 1 week after initial delivery of CCMM, carers self-complete demographic information about age, ethnicity, educational attainment and occupation. This is to facilitate understanding of the intervention's feasibility and acceptability with different social groups.

Interviews focus on the work that participants need to do to effectively

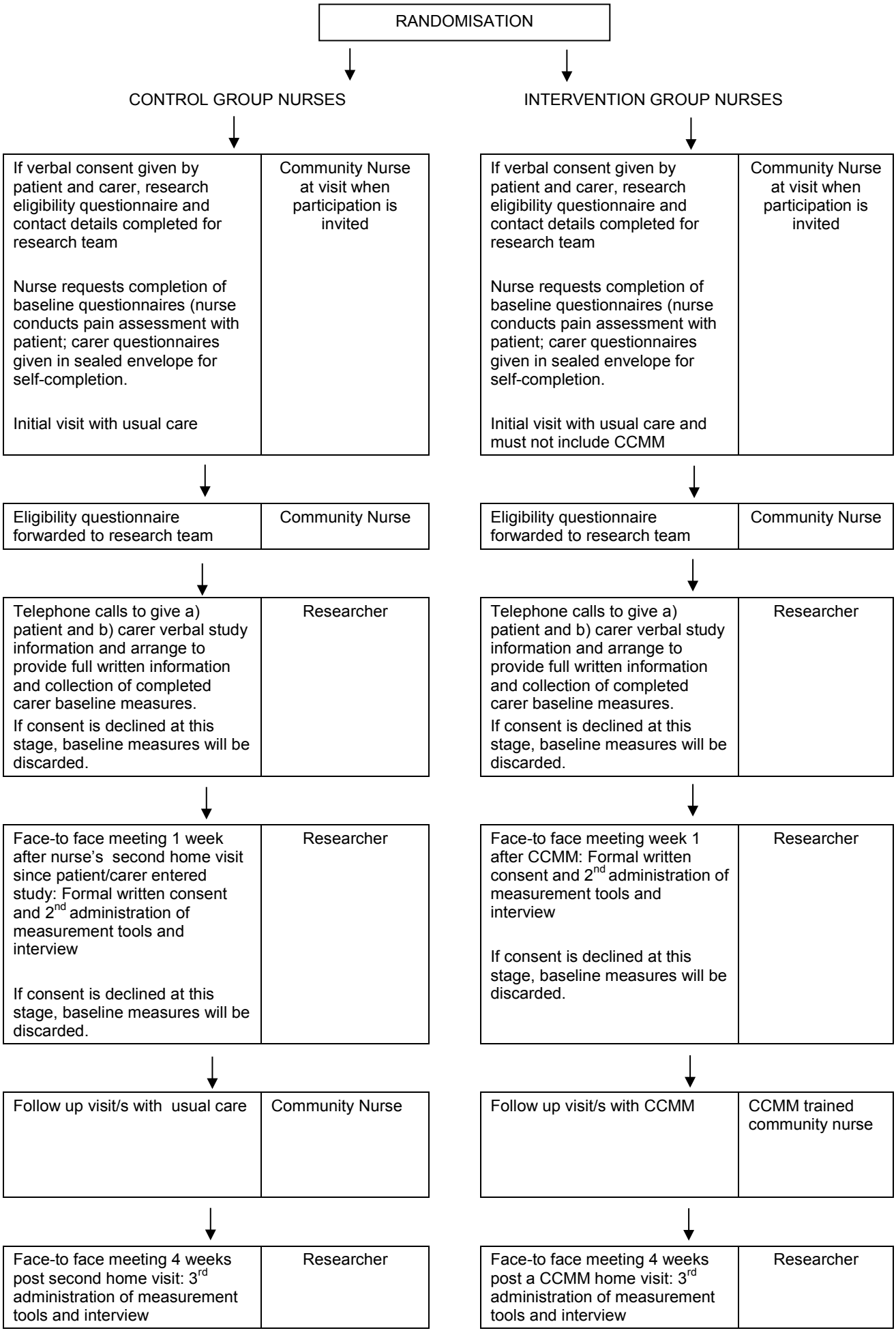

Figure 1: Patient and carer pathway through study

Table 2: Characteristics of outcome measures

	Measure	Outcome	Details	Time for completion
Carer outcomes:	Family Pain Questionnaire (FPQ) (Ferrell 2000)	Carer knowledge, beliefs and skills in cancer pain medicines management	Questionnaire: Likert scale 16 items	Baseline, 1 week and 4 weeks
	Caregiver Problem Solving Self-Efficacy (Zeiss et al 1999)	Carer self-efficacy in pain management	Questionnaire: Likert scale 4 items	Baseline, 1 week and 4 weeks
	Caregiver Strain Index (CSI) (Robinson 1983)	Carer overall strain	Questionnaire: Binary response 13 items	Baseline, 1 week and 4 weeks
	Profile of mood state -SF (POMS-SF) (Curran et al 1995)	Carer mood state	Questionnaire: 30 items	Baseline
Secondary outcome:	Process evaluation: Carer and nurse opinion of CCMM	Identify factors that promote or inhibit incorporation of CCMM into everyday use	Semi-structured conversational style interview	Carers : 1 week and 4 weeks Nurses : end of trial data collection
	Process evaluation: Carer and nurse opinion of process of research, including measures	Perception of burden / benefit	Semi-structured conversational style interview	Carers : 1 week and 4 weeks Nurses : end of trial data collection
Secondary outcome:	Brief Pain Inventory Short Form (BPI-SF) (Cleeland and Ryan 1994)	Patient perceived pain	Questionnaire: 9 items	Baseline at eligibility screening, and at week 1 and week 4 nurse until study exit

utilize CCMM and how this 'fits' with the work of keeping fidelity with trial procedures. The interview is primarily for the carer's participation but patients can also choose to participate with the carer. This qualitative sub-study and its interview questions are informed by Normalization Process Theory (NPT) (May et al 2009; Murray et al 2010), and use the NPT Toolkit (May et al 2011). NPT provides a conceptual framework for consideration of initiation, implementation, and sense-making about the CCMM intervention and its integration into existing caring practices.

Analysis

Descriptive statistics and graphical representations of the data will be used to examine i) recruitment and attrition, and ii) variability in our measures at both the level of individual carers and the level of summary measures grouping carers by nurse. We will also estimate a sample size for an RCT, which will include estimation of an intraclass correlation coefficient for nurses but we recognise this will be imprecise given the small sample size for this feasibility study. Qualitative interview data are recorded, transcribed, identifying details removed and analysed following the Framework method (Ritchie and Spencer 1994). Coding includes core concepts of Normalization Process Theory and inductively generated themes about factors inhibiting or promoting carer management of pain medication and CCMM specifically. All interview transcripts are independently coded by two researchers and the resulting analysis and codes discussed until agreement is reached.

Discussion

The intervention has the potential to enhance nurses' practice in the community to meet carers' needs in relation to pain medication management.

Testing the intervention and the research study design will provide understanding about the feasibility and acceptability of recruiting nurses for randomisation to intervention or control (usual care) groups, attrition and rates of invitation and recruitment of patients and carers to the study. It will also provide data about the feasibility and acceptability of, and

attrition rates in relation to patients' and carers' in the context of end of life care in the community in the UK.

We aim to use the study to determine the sensitivity of our outcome measures and to finalize decisions about the primary outcome measure for the follow-on Randomised Control Trial. The primary outcome measure will focus on carer psychological status and is likely to be the Family Pain Questionnaire (Ferrell 2000), due to its likely sensitivity to CCMM.

The end product of the qualitative sub-study will be a robust conceptual model of factors that influence participants' utilization of CCMM and fidelity to the trial procedures.

Data from this trial will be used to refine the intervention and contribute to the optimal design of an effectiveness trial. The study will also provide important information about the feasibility and acceptability of this intervention for carers of people living in the community with cancer pain at the end of life, and from the perspective of nurses introducing the intervention to carers.

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