Funding Body	**Health Technology Assessment Programme**
Funding Opportunity	12/188/05 Self-management of pain relief, nausea and constipation for patients approaching the end of life
Chief Investigator	Michael Bennett St Gemma's Professor of Palliative Medicine
Host Organisation	Leeds Institute of Health Sciences University of Leeds
Full project title	Self-Management of Analgesia and Related Treatments at the End of life
Short title	SMARTE
Total Costs Required	£393,490
Proposed start date	1 September 2014
Duration (months)	24 months

Abbreviations used in this document

BMQ	Beliefs about Medicines Questionnaire
BPI	Brief Pain Inventory
CCMM	Cancer Carer Medicines Management
CNS	Clinical Nurse Specialist
CTRU	Clinical Trials Research Uni
EBCD	Experienced based co-design
ESAS	Edmonton Symptoms Assessment System
EQ5D	European Quality of Life – 5 Dimensions
FPQ	Family Pain Questionnaire
HCPs	Healthcare professionals
IMPACCT	Improving the Management of Pain from Advanced Cancer in the Community
NIHR	National Institute for Health Research
NPT	Normalisation Process Theory
NRS	Numerical Rating Scale
PAM	Patient Activation Measure
PPI	Patient and Public Involvement
SIMS	Satisfaction with Information about Medicines Scale
S-LANSS	Self-report Leeds Assessment of Neuropathic Symptoms and Signs
SMARTE	Self-Management of Analgesia and Related symptoms at The End of life
SMST	Self-management Support Tool

Contents

1. Summary of research

Despite there being a good understanding of patient and carer concerns regarding opioid analgesia and related side effects, much less is known about the optimal means of addressing these concerns which is why they have been highlighted by NICE guidance (1). We aim to develop a support tool to improve the management of medications for pain relief, nausea and constipation in patients with significant pain approaching the end of life within a theoretically informed behaviour change framework. The expected benefits of the SMST for patients will be improvements in symptom relief and increased confidence in managing medicines and related side effects by themselves, or jointly with their informal carer.

The SMARTE study will result in an SMST based on evidence synthesised within a behaviour change framework (2) and a manualisation strategy informed by self-efficacy theory (3). Using these theoretical frameworks we will develop an SMST that will characterise self-management knowledge and skills and encourage patients approaching the end of life to be actively involved in the management of their medications and symptoms. We will link this to behaviour change strategies designed to help patients and their carers feel empowered with increased knowledge and skills to recognise worsening symptoms, be able to self-initiate therapeutic adjustments and know how and when to access help from the medical system. We will use the explanatory models of Normalisation Process Theory (NPT) (4) to evaluate factors which will support implementation.

2. Background and rationale

Around 64% of UK individuals would choose to die at home (5). However, the actual place of death of patients with advanced disease does not currently correspond with their preferences (6), with one influencing factor being poor symptom management. We know that misunderstandings by patients regarding opioids inhibit good pain control. We also know from our own research that addressing these concerns leads to improvements in pain and symptom control (7). Helping patients and their informal carers to improve self-management of medicines to control pain and other symptoms at home is likely lead to increased quality of life and preferred place of death (8).

We are interested in adults (aged over 18 years) approaching the end of life, suffering from significant pain and being cared for in their own home. We want to develop a self-management support tool that enables these patients and their carers to more confidently manage medications for pain, nausea, constipation and drowsiness at home. We have designed this project with a patient centred approach at the heart of our development plan.

3. Evidence explaining why this research is needed now

The research recommendation 4.1 from recent NICE guidance on the use of opioids in palliative care calls for “clinically effective and cost-effective methods of addressing patient and carer concerns about strong opioids, including anticipating and managing adverse effects.” (1). Moreover, the NICE guidance indicates that as well as constipation and nausea, drowsiness is one of the most common side effects of pain medication and one that bothers patients most. All three side effects need to be addressed for optimal pain management and we therefore wish to extend the scope of the brief to incorporate drowsiness in the self-management support tool (SMST). Our research proposal is directly aligned to this call and represents an area of healthcare resource development which is highly relevant and has been identified as one with sustained interest to the NHS in the future.

4. Aims and objectives

We aim to develop a support tool to improve the management of medications for pain relief, nausea, constipation and drowsiness in patients with significant pain approaching the end of life. Our self-management support tool (SMST) will be developed using a patient centred approach and will be delivered in partnership with health care professionals (HCPs) in two UK regions. Ultimately we aim to establish the acceptability and up-take of our prototype SMST and determine the feasibility of evaluating this intervention within a larger trial. We have interpreted the brief so that we will focus on patients who are treated with, or due to start treatment with, opioids for pain and that experience (or anticipate) adverse effects of these medications.

Our objectives are divided into three distinct phases which is in-line with the MRC framework on developing and evaluating complex interventions and NPT(9).
[1] Development objectives (Phase I)

- Establish a PPI panel
- Establish the content of a prototype SMST and a manualisation strategy that includes a protocol to standardise (i) the training of HCP and (ii) the delivery of the intervention by HPCs to patients and carers
- Understand self-management needs and capabilities of patients and carers.
- Define usual care

[2] Modelling objectives (Phase II)

- Refine and co-design the prototype SMST and manualisation

[3] Feasibility assessment objectives (Phase III)

- Assess acceptability and up-take of the SMST in a mixed-methods observational study involving patients, informal carers and HCPs from 4 palliative care services
- Assess the feasibility of obtaining outcome data for a larger trial

5. Research plan

Phase I – Development
Design: Evidence synthesis
Aim: To generate theoretically informed prototype SMST

Literature Reviews: To accelerate development of the SMST we will undertake a rapid synthesis of the findings from the IMPACCT NIHR programme grant and the Cancer Carer Medicines Management (CCMM) study (see 'research grants held'). These projects will detail the optimal content, format, timing and delivery of an educational intervention and help us understand the best way for carers to support the use of pain medicines for patients with pain from advanced cancer. We will undertake a rapid review of the literature on supported self-management for medications in long term conditions as well as end of life care. We will define what is currently delivered as 'usual care' (i.e. the support usually provided to patients and informal carers in the use of medications for pain relief, nausea, constipation and drowsiness) by conducting a review of clinical guidelines and policy documents.

Qualitative interview: The findings of the Phase I rapid reviews will be used as the basis for exploring patients' and carers' views to enable co-design of the optimal content, format, timing and delivery of medicines self-management information.

Method: An in-depth, semi-structured interview protocol will be used with six pairs of consenting patients and carers; two patients due to start opioid treatment, two taking weak opioids and two taking strong opioids to obtain a spread of experiences. We will also interview four HCPs; two clinical nurse specialists in palliative care and two community matrons experienced in general palliative care of long term conditions. Recruitment procedures are detailed in section 13; all Phase I interviews will take place in West Yorkshire community palliative care services. Interviews will be completed at a place most convenient to the patients, for example, at their home, the palliative care service (hospice) or other convenient setting. The arrangement for interview will be confirmed in writing. Although it is possible that undertaking patient and carer interviews separately would allow for the discussion of personal and sensitive issues, our experience of conducting couples interviews suggest that participants often value an opportunity to discuss issues together, particularly where practical issues of joint concern are of interest. Patients, carers and HCPs will be invited to complete written consent forms, which will be reviewed and signed at the end of the interview to check that each participant would still like to be included in the study. Patients and carers will be reminded of their right to withdraw at any time and/or choose not to answer a question. Interviews will be guided by a set of prompts (topic guide) and will be audiotaped, transcribed verbatim and thematically analysed. Patients, carers and HCPs will be reimbursed for any travel costs incurred.

Topic guide: Patient and carer interviews will explore their understanding of the concept of self-management, their willingness and perceptions of their ability to self-manage, and their requirements for education or additional support in order to successfully self-manage symptoms related to of end of life care. HCP interviews will explore current practice related to support for patients and carers on medicines self-management in the community. HCP interviews will also explore the description of usual care and compare and contrast it to their standard care practices.

Design of prototype SMST: Based on the evidence synthesis and thematic analysis of the interviews we will develop the content of a prototype SMST and manualisation strategy. We will form a dedicated PPI panel by disseminating the SMARTE study via JG, our PPI co-applicant, to local and national PPI groups. We will use the PPI panel to gain feedback on the content of the prototype SMST and co-design Phase II focus groups. We will undertake study set-up work for Phases II and III.

Expected output of Phase I: development of a prototype SMST and manualisation strategy; detailed description of usual care; establish dedicated PPI panel; study set-up work for Phases II and III.

Phase II – Modelling
Design: Experience based co-design focus groups.
Aim: To generate stakeholder input into the progressive co-design of the prototype SMST.

Method: Two stakeholder focus groups per region (West Yorkshire and Hampshire) will be conducted with patients with pain approaching the end of life and their informal carers, HCPs and commissioners (see section 10 for inclusion criteria). Our researchers, including our PPI co-applicant will facilitate and contribute to focus groups. Data from these will be taken to our PPI panel for review and discussion. Conclusions from this exercise will be used as a basis for two additional focus groups per region with the same group members. In total 8 focus groups will be conducted in Phase II. The focus group data will be thematically analysed by the research team and iteratively reviewed by our PPI panel.

Focus groups procedure: Inclusion and recruitment procedures are detailed in sections 10 and 13 respectively. Focus groups participants will be split between West Yorkshire and Hampshire and will take place at one of the two sites within each region. If an individual would like to participate but is unable, or unwilling, to participate in a focus group, a one-to-one interview will be arranged instead. One-to-one interviews will be completed at a place most convenient to the participant, for example, at their home or over the telephone. The arrangement for attending a focus group or one-to-one interview will be confirmed in writing for participants. The focus groups/interview will be audio-recorded. The focus groups/interviews will be led by the Research Fellows and facilitated in West Yorkshire by our PPI co-applicant (JG) and in Hampshire by a PPI panel member who will be identified in Phase I. Prior to commencing focus group discussions, the discussion leader will explain the study verbally, including the need to audio record the session. Participants will then be invited to complete written consent forms, which will be reviewed and signed at the end of the discussion/interview to check that the each participant would still like to be included in the study. If the participant is interviewed by telephone the consent form will be read out and consent recorded as part of the audio-recording of the interview. A copy of the consent form will be mailed to the participants. All participants will be reminded of their right to withdraw at any time and/or choose not to answer a question. Within the focus groups, group rules will also be agreed which include respecting the confidentiality of other members and any issues discussed within the group. Each focus group will involve a discussion leader and a facilitator to take additional notes, and a topic guide will be used to move participants through issues requiring their input.

Topic guide: Consenting participants will be asked to comment on the appropriateness of the prototype SMST and to identify barriers and facilitators to its introduction into a range of practice settings. Each aspect of the prototype SMST and manualisation strategy will be considered in detail by each focus group.

Sample size: We will invite approximately 35 people (10 patients, 10 carers, 10 HCPs and 5 service providers/commissioners) to take part in focus groups.

Expected outcome of Phase II: This iterative process of refining the prototype SMST and manualisation strategy will integrate the experiences and perspectives of patients, informal carers, HCPs, commissioners and the research team. The refined SMST will be a carefully co-designed intervention ready to be subjected to feasibility testing in Phase III of the study. Completion of study set-up work for Phase III.

Phase III – Assessing feasibility
Design: Pre-post observational study to assess uptake and acceptability of the refined SMST.
Aim: Determine uptake and acceptability of the refined SMST.

Procedure: Consenting patients and their carers will be recruited as described in section 13. The LCRN research nurse will invite eligible patients and carers to complete written consent forms prior to any study procedures taking place. A copy of the consent form will be mailed to them. All patients and carers will be reminded of their right to withdraw at any time and/or chose not to answer a question. Following consent, an initial face-to-face discussion with the CNS will be arranged and confirmed in writing. The purpose of this initial meeting will be to discuss the study and using the SMST. Those patients and carers who are still interested will arranged a further visit with the CNS and will be contacted by one of the Research Fellows via telephone to collect the baseline questionnaire measures.

Anticipated delivery of intervention: Patients and carers will meet with their CNS (after providing baseline data) to identify problems and concerns they may have regarding self-management of medication for pain relief, nausea, constipation and/or drowsiness. They will also establish their self-management capabilities with the CNS. Depending on the concerns and capabilities discussed, the CNS will provide relevant self-management information from the SMST. This will lead directly to developing the self-management action plan which will outline the self-managements roles and tasks. It is expected that the action plan will be reviewed by the CNS on a weekly basis for the 6 week duration of the study, but this timetable will be driven by the needs of the patient and carer.

Follow-up: Patients will be followed up by the one of the Research Fellows on Days 14, 28 and 42 via telephone and/or face to face to collect questionnaire data. Date of death will be recorded for all patients. Patients and carers will be interviewed between weeks 2-6 to obtain a spread of user experiences from initial use to longer-term use. Conducting patient and carer interviews within the follow-up period will also ensure that very frail patients can still contribute their experiences. CNSs will be interviewed after follow-up has closed for all patients.

Qualitative interviews: Consenting patients and their carers will be interviewed separately (maximum 60 interviews). In the early design stages of this work patient/carer pairs will be interviewed together, but at this stage it is important to explore issues separately, as there may be reluctance to disclose issues such as carer burden and needs without confidentiality. The interviews will be guided by a set of prompts (topic guide) and will be audiotaped and transcribed verbatim. Anonymised transcripts will be thematically analysed enabling the range and nature of the issues described to be explored and organised.

Topic guide: The interviews will explore issues related to the uptake, use and acceptability of the refined SMST (including barriers and facilitators to use), as well as adherence and changes in medication use. Interviews will also explore experiences of completing the questionnaires and the length of follow-up to inform the feasibility of collecting tailored patient-reported outcomes for a larger trial. In addition, HCP interview will explore the fidelity of delivery and contamination by interviewing CNSs who delivered the intervention and 4-8 CNSs who did not, once all patient follow-up has completed. Participants will be reimbursed for any travel costs incurred.

Sample size: 30 patients and their carers will be recruited as per Browne (10). Within the recruitment period approximately 450 new patients in total will be referred to the four services. Assuming 67% of patients have pain of which 50% are eligible, then approximately 150 eligible patients will be screened and informed of the SMST and asked to comment on its acceptability in principle. This will provide an estimate of patients acceptability of the SMST regardless of whether the patient thus entered the study or not, with a maximum precision estimate for a 95% confidence interval of 0.028 (i.e. 0.5 +/- 0.028). Furthermore, a sample size of 30 patients will allow the 95% confidence interval around the proportion of patients with at least a 30% reduction in average pain intensity on the BPI to be calculated within 0.164 degrees of precision assuming a 30% response rate (0.3 +/- 0.164).

Recruitment rate: Approximately 2-3 patients/month/palliative care service for four months = 30 patients overall via LCRN nurses. Four months recruitment allows for staggered start dates between services.

Expected outcome of Phase III: assessment of the uptake and acceptability of the refined SMST; feasibility of gathering outcome data (including assessment of missing data); assessment of fidelity of the delivery strategy and assessment of contamination.

6. Health technologies being assessed

A patient decision aid or SMST should help patients make informed choices about managing their healthcare by taking into account their values and preferences and those of their informal carer(s) (11). We have defined an SMST as a set of materials and coaching procedures which delivers knowledge, facilitates the generation of specific action plans and enhances the user's capacity to monitor and reflect on their actions. Ideally patients and their carers using our SMST should feel empowered with increased knowledge and skills to recognise worsening symptoms, be able to self-initiate therapeutic adjustments and know how and when to access help from their local healthcare system. We envisage that our SMST will include the following four components.

Initial assessment

At the initial meeting the Clinical Nurse Specialist (CNS) will discuss with the patient and their informal carer what strategies they already use to manage their medications for pain relief, nausea, constipation and drowsiness. The CNS will discuss what roles and tasks are required by each person to engage patients and their informal carer in self-management and encourage behaviour change. This initial assessment may also include a discussion about: (i) concerns and fears about using opioids; (ii) barriers and fears about self-management; (iii) prioritising symptoms to self-manage; (iv) providing the necessary information to support self-management; (v) trade-offs between symptom management and side-effects and how they will deal with the outcomes.

Information provision

The CNS will provide relevant information about managing medications for pain relief, nausea, constipation and/or drowsiness. This information will present benefits and burdens of medications in verbal, written, or audio-visual formats and will encourage a conversation about the trade-offs between symptom management and side-effects and how the consequences of these compromises might be dealt with.

Competencies based action plan (assessing capabilities)

Following provision of information, the CNS will undertake a competency based assessment of the patient's ability to self-manage, with support from a carer where appropriate. The purpose of this assessment is to identify the issues and situations that patients and carers feel they would like to self-manage. The CNS work with the patient and their carer to identify and record the self-management tasks that are required. This will form the basis of the self-management action plan. The CNS will help patients to develop their self-management action plan by balancing their values and preferences with the tasks and requirement of medication management alongside the possible side-effects.

Coaching, monitoring and modification

Strategies to encourage self-management require patients and their informal carers to change their behaviour and adopt new roles. Patients and carers must shift from a position of passively receiving medical information to actively engaging with supported decision making about their healthcare. For patients to successfully fulfil this new role they must feel that they can legitimately occupy it, understand what is required of them to fulfil this role and receive role support from a professional. This process of legitimisation begins with the initial assessment and provision of information and it continues through the collaborative development the self-management action plan. Finally, to maintain and encourage this behaviour change a timetable of regular monitoring of self-management progress must be established between the CNS, patient and carer.

7. Design and theoretical/conceptual framework

The overarching conceptual framework we have drawn on to develop this application is experience based co-design (EBCD) (12). We have embedded this approach into the development, modelling and feasibility testing phases of the SMARTE study to develop a carefully co-designed SMST. EBCD was originally proposed by Bate and Robert in 2006 as a method of redesigning healthcare processes from the patient's perspective (12). More recently EBCD has been used in the development of complex computer based patient response systems. However, to the best of our knowledge this is the first description of using ECBD to develop a complex SMST intervention.

The process of EBCD begins by interviewing patients and staff separately to understand their experiences as service users and service providers. This first step involves listening to their concerns

and suggestions for improvements or adaptations. It is important for the researcher to spend time to understand the treatment pathway and observe usual care. In the second step, findings from the interviews are fed back to patients and staff in a focus group setting to encourage, discussion of the findings, identify priorities for development, and collaboratively co-design the outcome (12). We have drawn directly from the EBCD model of designing complex interventions to structure the development, modelling and feasibility testing phases of the SMARTE study.

Within the EBCD conceptual framework we will draw upon the following commonly used behavioural change theories to inform the content and implementation of our SMST.
(i) The behaviour change wheel (BCW) is a novel method for characterising and designing behaviour change interventions (2). The BCW describes a method for improving the design and implementation of evidence based practice by characterising the content of intervention and linking it to an analysis of targeted behaviour. In essence this means understanding an individual's capability and motivation for undertaking a change in behaviour and providing the necessary opportunity to support this change.
(ii) Self-efficacy theory (SET) refers to an individual's beliefs about their capabilities for learning and performing actions at designated levels of performance (4). In the case of self-management of medicines, SET proposes that barriers to behaviour change must be identified and addressed. First, patients must believe that they are legitimately allowed to occupy the role of "self-manager". Second, patients must understand what is required of them to undertake this role; e.g. the self-management tasks must be identified and recorded. Finally, regular external role-support should be provided to maintain and encourage self-management.
(iii) Normalisation process theory (NPT) is a framework used to understand, develop and evaluate complex interventions (13). NPT is designed to help researchers identify factors that promote or inhibit the routine incorporation of complex interventions into everyday practice. It also explains how these interventions work, looking not only at early implementation, but beyond this to the point where an intervention becomes so embedded into routine practice that it 'disappears' from view (i.e., it is normalised). The NPT focuses on the work that individuals and groups do to enable an intervention to become normalised. There are four main components to NPT: coherence (or sense-making); cognitive participation (or engagement); collective action (work done to enable the intervention to happen); and reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention). We have embedded these principles into the development, modelling and feasibility testing phases of the SMARTE study to ensure we carefully co-designed our SMST intervention.. In the SMARTE study NPT will be used to help the research team evaluate the mechanisms and processes through which our support tool (and the manualisation strategy) enhance patients' self-management efficacy of medicines and associated therapies/side-effects. Practically, this means we will use NPT to map-out the components of the SMARTE intervention and understand the how these components dynamically facilitate behaviour change in patients and healthcare professionals.

8. Target population

Patients living at home who are suffering significant pain and are approaching the end of life, their informal carers, HCPs, and local service providers and commissioners of specialist palliative care services in West Yorkshire and Hampshire.

9. Inclusion and Exclusion criteria

Patients will be included if they are:
[1] approaching the end of life - defined as patients with an incurable advanced disease, considered to be within the last year of life,
[2] experiencing significant pain: assessed using Brief Pain Inventory (BPI) and defined as a score of =>4/10 pain severity sub-scale and =>4/10 pain impact sub-scale (14)
[3] treated with, or starting, opioid analgesia
[4] experiencing, or anticipating, adverse effects of nausea, constipation and drowsiness
[5] living at home and being cared for by specialist palliative care services in West Yorkshire and Hampshire.
Patients will be excluded if they lack of capacity to consent to inclusion.

Staff will be included if they are:
[1] Clinical Nurse Specialists (CNSs) part of a community palliative care team or;
[2] Service providers or managers of specialist palliative care services or;
[3] local commissioners of palliative care services;

[4] and working within palliative care services in West Yorkshire and Hampshire

10. Setting and context

The research will take place in four specialist palliative care services within two geographically separate English counties. Two services are based in West Yorkshire (St Gemma's Hospice and SueRyder Wheatfields Hospice) and two in Hampshire (Countess Mountbatten Hospice and Oakhaven Hospice). These four sites each provide consultant led palliative care services supported by full multidisciplinary teams within an inpatient unit, a community nursing team and a day hospice. Patients treated by these services include all those with advanced progressive disease including cancer, end stage respiratory, cardiac and renal failure, and neurological disorders. All four sites have engaged in NIHR research projects before with the co-applicants.

11. Search Strategy

Phase I evidence synthesis:

We will synthesise the outcomes from IMPACCT and CCMM projects by holding a one day research summit between CCMM and IMPACCT teams to summarise the main findings and identify links with SMARTE. Using rapid review methodology proposed by Ganann et al. (15) , we will undertake electronic database searches and summarise the evidence on supported self-management for medications in long term conditions as well as end of life care. We will define what is currently delivered as 'usual care' (i.e. the support usually provided to patients and informal carers in the use of medications for pain relief, nausea, constipation and drowsiness) by conducting a rapid review of clinical guidelines and policy documents.

12. Sampling

All patients and their carers will be identified via LCRN nurses working within the four recruitment sites; two in West Yorkshire and two in Hampshire. See Letter of Support in Uploads section for supporting documentation from the four palliative care services involved.

12.1 Sampling strategy and follow up duration

For all three phases of the proposed project, we plan to recruit from community and day-care palliative care services within the four sites described above. This offers the most efficient access to patients with pain who are approaching the end of life and that are living at home. In the UK, between a quarter and a third of patients die within two weeks of referral to palliative care services, and 65% die within 3 months. In addition to developing an SMST, the SMARTE study will determine whether we can achieve a balance between sampling efficiency and trial retention which will inform the design of future studies. We have chosen to limit our follow up to 6 weeks because the risk of short survival means that demonstrating early and sustained improvements in self-management within a few weeks of referral is critical if the intervention is to be of value.

12.2 Recruitment process

Patients and carers: The two research fellows will discuss study recruitment with healthcare professionals at each of the four sites and provide recruitment flyers and information leaflets that can be given to interested patients and carers by the HCPs. All patients and their carers will be identified via LCRN nurses working within community and day-care palliative care services at the four recruitment sites; two in West Yorkshire and two in Hampshire. LCRN nurses will assess all newly referred and existing patients against the above eligibility criteria. All eligible patients, and their informal carer, will be given a recruitment flyers and information leaflets which summarise the SMARTE study. Patients and carers who are interested in participating will be seen by LCRN research nurses working at each site who will check eligibility (against the above criteria), provide patient information sheets. LCRN research nurses will obtain consent at least 24 hours after providing patients' and their carers' with an information sheet to ensure that they have had time to consider their participation. Before consent is obtained patients' and their carers' will be offered the opportunity to ask questions about the study and their participation. Depending on the phase of the project, patients and informal carers will then be invited by the LCRN research nurse to interview or focus group with the research fellow (Phase I and II), or be invited to take part in the educational intervention which will start by meeting with the trained CNS for an initial meeting regarding the SMST within the observational study (Phase III).

Staff: We will ask healthcare professionals, service providers and local commissioners from participating sites to take part in the project. Within Phase I, the research fellow in Leeds will invite clinical staff working at the West Yorkshire sites to take part in interviews via project flyer and emails. Within Phase II, we will recruit HCPs and service providers/managers at each site in a similar way. To recruit commissioners for this phase of the project we will firstly invite lead commissioners for palliative care at the four sites to participate in focus groups with HCPs. However we recognise that this time commitment may be challenging for commissioners so we will offer a more flexible approach which is to interview them at their office. Within Phase III, we will invite eight CNSs (two per site) that are interested in our project to receive training in the delivery and monitoring of the SMST and for each CNS to then support four patients using the SMST. These CNSs will be interviewed by the research fellow at the end of the study to explore their experience and to gauge fidelity of delivery. Similarly, up to eight CNSs that did not deliver the intervention within the four sites will also be invited for interview to explore their knowledge of the content of the SMST and whether they altered their usual care practices in any way to incorporate any of the components of the intervention.

13. Data collection

Phase I

In phase I we plan to undertake three rapid reviews on:
(i) the outcomes from IMPACCT and CCMM studies;
(ii) the evidence on supported self-management for medications in long term conditions as well as end of life care;
(iii) clinical guidelines and policy documents to define what is currently delivered as 'usual care'
We will collect audio-taped interview transcripts from the development interviews with patients and carers, as well as HCPs. In collaboration with our PPI panel we will generate a prototype SMST and manualisation strategy based on the rapid evidence synthesis and the stakeholder interviews.

Phase II

In phase II we will collect audio-taped transcripts of the eight focus groups. These transcripts will be anonymised and thematically analysed. Summary findings will then be interpreted with our PPI panel to generate a refined version of our SMST and manualisation strategy.

Phase III

Screening questionnaire
We will collect the following data from the screening questionnaire:

- Age and gender
- Nature of life limiting disease
- Level of support
- Living arrangements
- Acceptability of SMST in principle

Qualitative interviews
Audio-taped transcripts of patient, carer and CNS interviews.

Questionnaire based measures
Pain
The short form Brief Pain Inventory (BPI) is a brief and simple to use tool to assess the severity of pain and its impact on daily function in clinical and research settings (14). The BPI uses simple numeric rating scales (NRS) from 0 to10 that are easy to understand and easy to translate into other languages. On the BPI, mild pain is defined as a worst pain score of 1 - 4, moderate pain is defined as a worst pain score of 5 - 6, and severe pain is defined as a worst pain score of 7 - 10. The BPI has been used extensively around the world to measure the severity and interference of pain in patients with cancer and other causes of pain (14).

The S-LANSS is a self-report version of the Leeds Assessment of Neuropathic Symptoms and Signs which identifies pain of a predominately neuropathic origin, as distinct from nociceptive pain without the need for clinical examination (16). The S-LANSS is simple to use a nine item tool. The first two items ask patients to shade the area of most pain on a body manikin and rate the intensity of their pain in the last week on a 0-10 NRA (0=no pain, 10=pain as severe as it could be). The following

seven ask about symptoms and signs related to neuropathic features of pain, each item is scored yes or no. Scores for the seven symptom and sign items are summed and weighted to give a score between 0-24. Scores ≥12 indicate likely neuropathic pain.

Self-efficacy and confidence
The Patient Activation Measure (PAM) is a tool to gauge the knowledge, skills and confidence necessary to manage one's own healthcare (17). PAM is a 13 item uni-dimensional measure to assess patient activation and engagement in healthcare decisions. Each item is scored on a four point Likert scale anchored strongly disagree to strongly agree. Item responses are summed to give a scale score between 0-100. Higher scores typically indicate individuals who are more pro-active in managing their health and have skills and confidence to do so. Alternatively the scale items can be grouped to categorise patients into one of four activation levels along an empirically derived continuum (17).

Cognitive representation of medications
The Beliefs about Medicines Questionnaire (BMQ) is a method for assessing cognitive representations of medications and consists of two sub-scales which can be used separately (18). We have selected the BMQ-Specific sub-scale which assesses representations of medication prescribed for personal use. This sub-scale comprises two 5 item factors assessing beliefs about the necessity of prescribed medication (Specific-Necessity) and concerns about prescribed medication (Specific-Concern). Concerns are based on beliefs about the danger of dependence and long-term toxicity and the disruptive effects of medication.

Intensity of common symptoms
The Edmonton Symptom Assessment System (EASA) is a ten item tool designed to assess common symptoms in palliative care patients (19). It was originally developed in cancer patients but has been extensively used in all end of life care conditions. We have modified the last item on the scale *'other problems'* to represent drowsiness. Each item is scored 0-10 representing the severity of the symptoms at the time of assessment. Higher score indicate more severe symptoms.

Carer experience
The Family Pain Questionnaire (FPQ) is a 16 item scale that assess the knowledge and experience of a family caregiver in managing chronic pain (20). This tool has been validated for use in clinical practice as well as for research and is completed by the primary caregiver. The FPQ includes two sub-scales: 9 items that measure knowledge about pain and 7 items that measure the caregivers experience with pain. All of the items scored 0-10 NRS (0 = the most positive outcome and 10 = the most negative outcome). Items for each sub-scale are summed separately to give a score for knowledge and a score for experiences. Higher scores indicate poorer outcomes.

Health related quality of life
The European Quality of life – 5 Dimensions (EQ-5D) questionnaire is a simple six item generic measure of health status for clinical and economic appraisal (21). It measures the responders self-perception of mobility, self-care, usual activities, pain/discomfort and anxiety/depression as well as overall health status (rated 0-100, 0 = worst imaginable health state, 100 = best imaginable health state). It is applicable to a wide range of health conditions and treatments and provides a simple descriptive profile and a single index value for health status that can be used in simple economic evaluation of health.

Satisfaction with information
The Satisfaction with Information about Medicines Scale (SIMS) is a 17-item tool designed to assess the extent to which patients feel they have received enough information about prescribed medicines (22).

Patient records
We will ask patients to give their consent for us to check their patient and pharmacy records. From these records we will collect data on health care resource use, date and place of death.

14. Data analysis

14.1 Phase I
NVivo version 10 will facilitate textual data management. Anonymised transcripts from patient/carer interviews and the HCP interviews will be analysed using a simple thematic analysis. This will enable the range and nature of issues described by participants to be explored and organised. Methodological rigour will be ensured through standard procedures of reflexivity, reliability and validity (23). During analysis, regular meetings will be held by the interviewer/researcher (the Research Fellows in Leeds and Southampton) who will undertake the initial analysis, and a second researcher to agree emerging themes from the data. Inter-rater reliability will be maximised by ensuring that the second researcher codes 20% of all transcripts. Any discrepancies in coding will be resolved by the two researchers and if this is not possible, by the wider research team. Codes will then be organised into a broader thematic framework. We will examine the range of responses on particular issues with a clear emphasis on the design of the prototype self-management manual. Findings will be linked to the wider context of existing literature and policy, as identified by the rapid review.

14.2 Phase II
NVivo version 10 will facilitate textual data management. The transcripts from the focus groups will be anonymised and subject to a simple thematic analysis to identify key issues and barriers regarding the improvement of the SMST. As for Phase I, these will be checked by a co-researcher to ensure rigour. Issues of importance to the different stakeholders will be compared and contrasted. The results will be summarised and presented to the PPI panel, with whom we will discuss the implication of the focus groups findings and make recommendations for any necessary changes to the design of the prototype and/or strategies for its introduction into practice. A refined SMST will then be used for a reiteration of second round focus groups.

14.3 Phase III
[1] Screening questionnaire: Acceptability will be assessed via the collection of detailed screening data, in particular for eligible patients who do not consent to enter the study. Screening information will aim to collect patient characteristics which may act as confounders such as disease (cancer, non-cancer), living arrangements, support, sex and age.

[2] Qualitative interviews: NVivo version 10 will facilitate textual data management. Anonymised transcripts will be analysed using a simple thematic analysis which will enable the range and nature of issues described by participants to be explored and organised. Methodological rigour will be ensured through standard procedures of reflexivity, reliability and validity (23). During analysis, regular meetings will be held by the interviewer/researcher who will undertake the initial analysis, and a second researcher to agree emerging themes from the data. Inter-rater reliability will be maximised by ensuring that the second researcher codes 10% of all transcripts. Any discrepancies in coding will be resolved by the two researchers and if this is not possible, by the wider research team. Codes will then be organised into a broader thematic framework. The perspectives of patients and carers will be compared and contrasted, generating theory to support the selection of individualised SMST delivery and outcome measurements.

[3] Quantitative analysis: Analysis will focus on descriptive statistics and confidence interval estimation, rather than formal hypothesis testing. Eligibility and recruitment rates will be reported to assess the feasibility of recruitment to a larger study. Follow up rates, dropout rates and the levels of missing data (by reason, including death) will be reported to describe the population and determine the optimum follow up schedule. Outcome measures will be summarised overall, and by time-point, disease state, age, gender, level of support (present/absent) and recruitment site to provide estimates of influence of confounders on primary study outcomes, as well as estimates of variability to inform the sample size for a larger study. The primary outcome for estimating sample size will be a measure of response rate according to a ≥2 point reduction in average pain intensity on the BPI (14).

15. Dissemination and projected outputs
15.1 Dissemination plans
Overall approach to dissemination
We understand that dissemination is a continuous process and we have embedded opportunities for dissemination throughout this project, in line with our Institute Knowledge Transfer strategy. We will use an iterative approach to include key local and national stakeholders and members of a dedicated PPI panel in the development of our SMST. This will ensure that the outputs meet the needs of our target patient audience as well as demonstrating integration into existing healthcare systems.

Dissemination to patients
A six-monthly newsletter will be circulated among our research participants (patients and informal carers), their families, representatives from local hospice networks, palliative care patient and family groups and palliative care charities to inform them of our progress and generate awareness. We will also publicise a local research summit meeting for local stakeholders to be held at the end of the project to thank everyone involved, summarise the findings from the project and encourage further involvement in palliative care research projects.

Dissemination to local palliative care clinicians, commissioners and service providers
In addition to the above research summit, we will hold a dissemination and feedback event for staff at local clinical commissioning groups and the four palliative care services involved in the project. The aim of this meeting is to summarise the findings of the project and evaluate the successes and difficulties of conducting the SMARTE study. We hope that by providing specific dissemination and feedback at a local level we will facilitate and maintain strong local research networks for the future.

Dissemination at national policy level
At a national level we will engage with the NICE implementation team to feedback our progress. This is in line with the research recommendations from recent NICE guidance on opioids in palliative care and includes dissemination through local and national NHS organisations. We will also engage with national charities, such as Macmillan Cancer Support (via their magazine for professionals, Mac Voice) and Independent Cancer Patient Voices to generate awareness of the SMARTE study at a national level.

Dissemination at international academic level
We will disseminate to the academic community through engagement in local, national and international scientific meetings and publications in academic journals.

15.2 Expected Output of the research/impact
To develop and refine a SMST to improve the self-management of medications for pain relief, nausea, constipation and drowsiness in patients with significant pain approaching the end of life, delivered in partnership with health care professionals. We will use a patient centred, experience based co-design approach to model the intervention within a theoretical framework ensuring it reflects the needs and experiences of our target population within the UK.

To develop and refine a manualisation strategy that enables the SMST to be delivered by CNSs. We will develop this strategy with HCPs, service providers and clinical commissioners ensuring that it can be readily integrated into NHS services.

Description of standard care pathway will be developed during Phase I literature review and interviews. In addition to informing the current proposal this description of usual care will also act as a benchmark for service providers of how ‘best’ care derived from research and policy in the literature fits against usual care derived from our findings in Phase I. This will ensure a clear understanding of existing systems in the practice setting.

Our Phase III feasibility study will determine whether it is feasible to undertake a larger trial.

16. Plan of investigation and timetable

16.1 Research timetable

The project plan of investigation is summarised below detailing the schedule of key stages and their duration. See section 17.2

Study preparation (M1-6)

- Pre-study set-up: Ethics and R&D approvals (two months prior to commencing study)
- M1 Staff recruitment
- M1-2 Establish PPI Panel

Phase I (M1-6)

- M1-2 Evidence synthesis and literature reviewing
- M2-3 Observe clinical practice
- M3-5 Patient interviews
- M4-6 Develop content of SMST with PPI panel
- M2-6 Phase II and III study set-up

Phase II (M7-13)

- M7-8 Set up focus groups
- M8-9 1st round focus groups
- M10 1st refinement of SMST with PPI panel
- M11-12 2nd round focus groups
- M13 2nd refinement of SMST with PPI panel

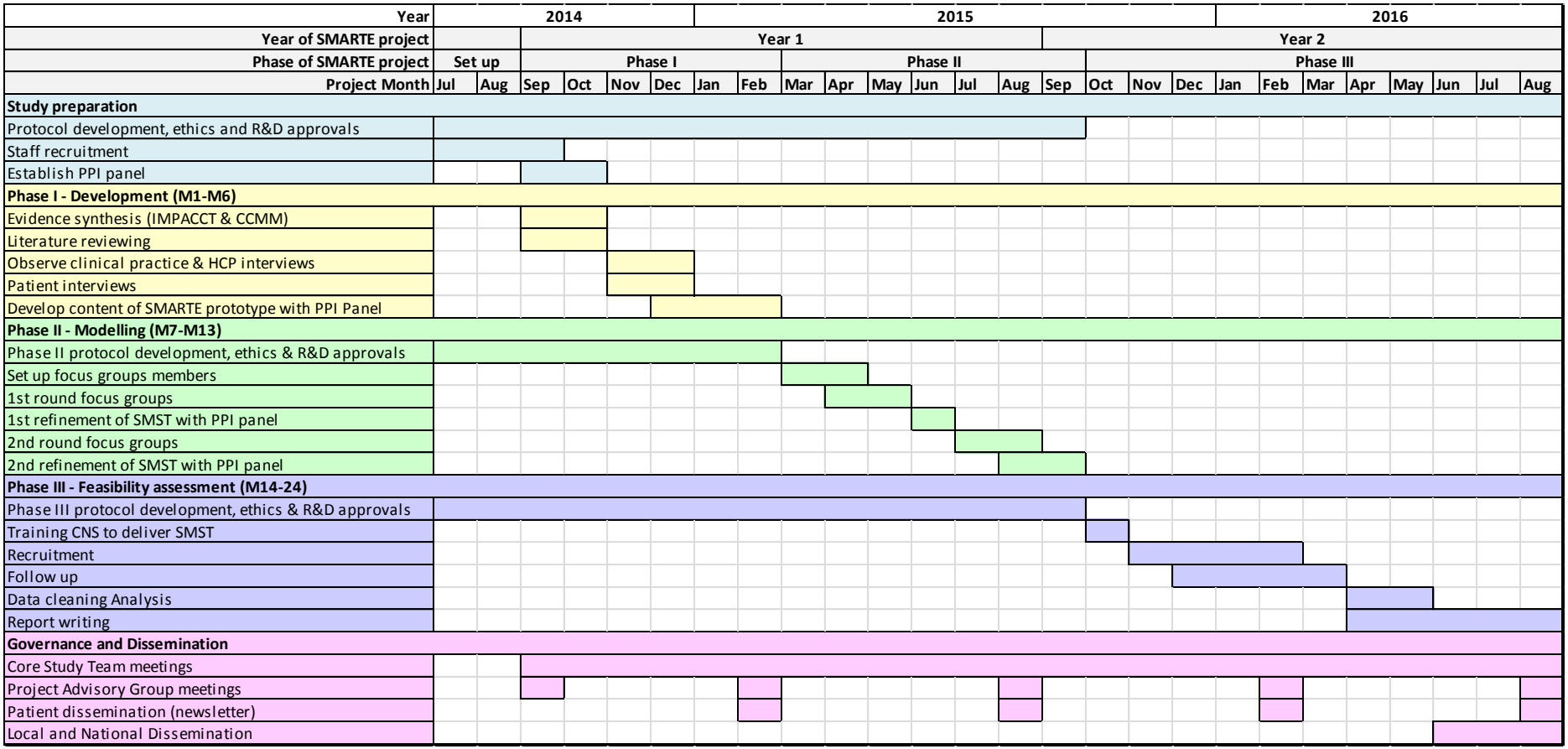
Phase III (M14-24)

- M14 Training of CNS to deliver SMST
- M15-18 Recruitment
- M16-19 Follow-up
- M20-21 Analysis
- M20-24 Report writing and dissemination

Governance and Dissemination

- M1-24 Weekly Core Study Team Meetings
- M1/6/12/18/24 6 monthly Project Advisory Group meetings
- M6/12/18/24 6 monthly patient new letter
- M22-23 Local research summit, staff feedback event, national dissemination

17.2 SMARTE Gantt chart of project plan and timetable



17. Project management

The project will be overseen by Professor Michael Bennett (MB). The Research Fellow in Leeds (RF-L) will be responsible for the day-to-day project management, including ethics/governance approvals, daily project tasks and managing recruitment site in West Yorkshire. RF-L will be supervised by MB and report directly to the Core Study Team on a monthly basis. The day-to-day management of project tasks and recruitment sites in Hampshire will be undertaken by the Research Fellow in Southampton (RF-S). The RF-S will be supervised by Professors Sue Latter (SL) and Alison Richardson (AR), and will report directly to the Core Study Team on a monthly basis.

A Core Study Team (CST) will be formed, consisting of MB, RF-L, RF-S, SL, AR, JG**.** RF-L and RF-S will liaise with each other and their supervisors on a weekly basis, or more frequently if needed. Meetings will be mainly via teleconferencing and web-based conferencing (GoToMeeting Software). The CST will monitor the day-to-day progress of the project, coordinate tasks and deal with problems. Co-applicants outside the CST (including PPI panel members) will be invited to attend the CST meetings at strategic points based on their expertise and the stage of the project. Where appropriate the project administrator will facilitate meeting arrangements and take minutes

A Project Advisory Group (PAG) will be formed consisting of the CST and all other co-applicants and will meet twice a year face-to-face. We will invite 2 members of the PPI panel to contribute to the PAG meetings. The PAG will monitor overall progress, coordinate phases of research, discuss problems and oversee the budget and financial issues and review results. The PAG will oversee the strategic progress of the project by reviewing the success of each key stage of the project against the monitoring framework, which will include the research timetable and Success/Progression criteria. The PAG will advise the CST at key decision-points. The project administrator will arrange the PAG meetings and produce minutes and reports.

18. Approval by ethics committees

The main ethical issue of this study relate to consent, anonymity, potential loss of money through travel and information provided to patients. To address these, where appropriate, out of pocket expenses will be reimbursed. With regards to consent, we will only recruit patients who have the mental capacity to understand the research process, and who also have the capacity to undertake elements of self-management for the six weeks study duration. All patients, carers and HCPs will be invited to take part in any of the three phases of the SMARTE study and will be free to decline and this will be made clear before and during their participation. It will be made clear that there may be no direct benefit to taking part in the interviews and focus groups in Phase I and II but that we will use this findings to inform the content of the SMST which will be testing in the Phase III observation study.

All patients, their carers and HCPs will be given an information sheet detailing the study procedures to allow them to make an informed decision about their participation and will only be recruited if they agree to take part. In addition, a verbal explanation of the study will be offered ahead of the beginning of each interview/focus group/observation study, and consent will be checked again at the end. All participants involved in any stage of the SMARTE study will be reminded of their right to withdraw at any point without giving an explanation. Confidentiality will be maintained by agreeing with focus group members that all discussion are to be treated as confidential to the group, and that the identity and/or views of other members are not to be reported outside.

To ensure anonymity, participants will be given a unique ID number which will be noted on interview transcripts and questionnaires, thus preventing participants from being identified. In addition, any identifiable details, such as names of people, places or institutions will be removed from interview/focus group transcripts ensuring that participating individuals will not be identifiable to the wider research team or PPI panel members. Digital recordings will be held on a dedicated secure University server and will only be accessible to those directly involved in the interviews and analysis. All quotations in reports, publication and presentations will be presented in an anonymous format. The contact details of participants will be held securely on a dedicated University server for the duration of the study, and after this time will be deleted. We plan to submit the relevant documents for ethical approval in February and March 2014 prior to the start date in April 2014.

19. Patient and Public Involvement

We have had sustained patient and public involvement with all stages of the application. JG is our PPI co-applicant and brings with her broad experiences as a cancer service user, an end of life carer and a community nurse. JG is a member of wide range of PPI consumer groups and partnership groups, as well as a member of local and national cancer and non-cancer PPI strategy groups, including Yorkshire Cancer Research Network (YCRN), Cancer Research UK (CRUK) and Health Technology Assessment Programme (HTA).

JG has formed an integral part of our development team from inception of the research project through to drafting and submission of the application. Through JG's broad connections to a range of relevant research networks, we will seek to establish a dedicated PPI panel throughout the research process, from the development of the intervention to reporting and dissemination of findings.

Within the first months of the project we will establish a dedicated PPI panel via JG, our PPI co-applicant, and local and national PPI groups. We will ask our PPI panel to be involved in all aspects of SMARTE project including:
[1] co-designing the prototype SMST in Phase I;
[2] developing participants information resources for Phases I, II and III;
[3] informing the design of the Phase II focus groups;
[4] interpret the data from the patient and carer interviews/focus groups in Phases I, II, and III;
[5] dissemination events throughout Phases I, II and III.
We have budgeted for dedicate funds to support this PPI work. We will offer training for PPI members via the Macmillan Cancer Support 'Making a difference' training workshop. On-going support will be provided by the study team, based on the needs of the individual PPI members.

JG will continue to be involved as a member of the Project Advisory Group. Another 2 members of PPI panel will be invited to join the Project Advisory Group. JG and the PPI panel will play an active role in key decisions. In particular we will ask them to contribute to the development of patient information resources and to contribute to the development of the ethics application, to ensure the research is carried out in an ethical and respectful way. All PPI panel members will be invited to take part in dissemination activities, helping to ensure findings are accessible to a wide audience. As with the development of the grant proposal, PPI in this trial will be an iterative process. The experiences of our PPI panel members will be fed back to the research team as needed, to ensure that PPI is being carried out in a meaningful way.

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Appendix 1

Appendix 1. Response to board feedback points
Here we provide detailed responses to each feedback point from the board. This section is an expansion of the section 'Changes from first stage application' in the full application form.

1.1 "The pilot RCT was deemed unnecessary and should be removed with a resulting substantial reduction in costs."
The pilot RCT has been removed and replaced with an observational study focusing on qualitative assessment of the up-take and acceptability of our manualised self-management support tool (SMST). This change has had three major implications: (i) a reduction in length of the study from 30 months to 24 months; (ii) a substantial reduction in costs of approximately £110,000; (iii) a significant increase in the qualitative content of the study (see point 1.9 below). The removal of the pilot RCT has substantially reduced the input from Leeds CTRU as they will no longer coordinate this aspect of the SMARTE study. However, their expertise will be maintained in an advisory capacity to provide support and guidance on study coordination and statistical analysis. This has resulted in reduction of CTRU costs from £165120 to £23241. The overall budget for SMARTE has been reduced by approximately £110,000, after taking into account study management costs which were previously held within the CTRU budget.

1.2 "The board would like clarification on what the applicants are developing in their on-going Programme Grant study and explain how it might overlap with this proposed research."
We appreciate the opportunity to clarify the potential synergy with, and divergence between, the IMPACCT NIHR programme grant and the SMARTE study. In the full application these are detailed in the section 'Research CV, Research grants held'.

The IMPACCT NIHR programme grant is designed to develop and deliver an educational intervention for all patients with cancer which reduces barriers to good pain control through provision of information alone. We envisage that the SMST developed within SMARTE will include an initial assessment with a Clinical Nurse Specialist (CNS) to discuss problems and concerns and engage patients and carers in self-management. This will be followed by the provision of information to facilitate shared decision making about symptom management. These first two components of the SMARTE SMST will potentially overlap with IMPACCT (though SMARTE will not be focused exclusively on cancer pain). However, the crucial difference will be the addition of supported self-management coaching and monitoring delivered by CNSs within SMARTE. After initial assessment, the CNSs will then discuss with the patient and their carer the self-management tasks and explain the collaborative and supportive nature to self-management. The CNS will then undertake a competency based assessment to develop a self-management action plan. This will be followed up with regular coaching, monitoring and modification of the action plan by the CNS to support the patient and carer and facilitate the behaviour change. Our vision is that all patients with pain at the end of life might benefit from the adapted IMPACCT intervention, and that patients assessed as capable and willing to self-manage would additionally receive the 'SMARTE package' to enhance their skills (see table below).

Table describing the synergy and differences between IMPACCT and SMARTE

	IMPACCT	SMARTE
Patient population	Cancer pain	Pain from any advanced disease
Type of intervention	Educational intervention only	Supported self-management
Main components	(i) initial assessment of problems (ii) provision of educational material	(i) initial assessment of problems (ii) provision of educational material (iii) competencies based action plan (iv) regular coaching and monitoring
Content of educational material	Causes of pain Lifestyle adaptations Allaying fears about opioids Importance of communication with professionals	Causes of pain Lifestyle adaptations Allaying fears about opioids Importance of communication with professionals
Content of competencies based action plan	None	Identification of medication management situations Identification of medication management tasks Strategies for behaviour change
Formalised programme of monitoring progress and supported self-management	None	Regular programme of monitoring and adaptation of action plan to support self-management and encourage behaviour change
Intended outcome	Improved pain control through reduction in recognised barriers	Improved pain control through reduction in recognised barriers Improved medication management for pain, nausea, constipation and drowsiness

1.3 "The applicants should provide more detailed information on the self-management component proposed."

We have provided a detailed explanation of the components of the proposed SMST in section 7 'Health technologies being assessed'. In brief, the self-management components which are proposed have been specifically designed within theoretical frameworks for encouraging behaviour change and enhancing self-efficacy. We expect the SMARTE SMST will include the following components:
(i) an initial assessment of needs;
(ii) the provision of relevant information;
(iii) a competencies based action plan to identify self-management tasks;
(iv) regular monitoring and adjustment of self-management tasks to facilitate behaviour change.

1.4 "The board felt that the dissemination and impact had not been adequately described."

We have received additional advice and guidance from the Yorkshire and Humber RDS manager on enhancing our dissemination and impact strategy. This has been described in detail in the 'Dissemination and Outputs' section of the full application. In brief, we have written a guiding statement of our approach to dissemination and how this will enhance the impact of our intervention. We have described our strategic plans for disseminating our findings to patients, public, local service providers and commissioners, at national forums including the NICE implementation team, and international peer review journals and conferences. We have stated that we understand that dissemination is an iterative and continuous process. We have embedded opportunities for dissemination throughout the SMARTE study, in line with our Institute Knowledge Transfer strategy.

1.5 "The applicants should describe how they intend to deal with contamination."
We have outlined our justification and plans for dealing with contamination in the 'Research Plan, Other Information, point [2]' section of the full application. We intend to deal with the issue of contamination in the Phase III observational study by interviewing 1-2 CNSs from each recruitment site who did not deliver the intervention. We will to discuss with them their awareness of the study details and the content of the intervention. If non-study CNSs were aware of the intervention and its content we will explore further whether they altered their usual care practices in any way to incorporate any of the components of the intervention. We aim to understand whether it is possible to train some CNSs in a team to deliver the SMST without influencing the practice of non-intervention CNSs in the same team. This will inform the decision whether a future RCT will need to be a cluster randomised design or not.

1.6 "The board felt that PPI involvement should be enhanced."
We have received additional advice and guidance from the Yorkshire and Humber RDS PPI advisor on enhancing our PPI content. This has been described in detail in the 'Patient and Public Involvement' section of the full application. We have described our plans to recruit a dedicated PPI panel to support the SMARTE study. In practice we will ask our PPI panel to be involved in (i) co-designing the prototype SMST, (ii) informing the design of the Phase II focus groups, (iii) interpreting the data from the patient and carer interviews, (iv) dissemination events. We have budgeted for dedicated funds to support this PPI work. We will offer training for PPI members via the Macmillan Cancer Support 'Making a difference' training workshop. On-going support will be provided by the study team, based on the needs of the individual PPI members. We have included funding within our budget plan for supporting PPI panel members.

1.7 "The applicants should specify which are the participating sites and confirm that they have agreed to participate."
Please find letters of support from 4 participating palliative care services in 'Uploads, Letters of Support'.

1.8 "The board would like more clarity on the outcome measures proposed and suggest the applicants consider confounders likely to affect outcomes, e.g. support, gender and age."
Further justification and details on the outcome measures proposed and how we plan to consider confounders has been provide in 'Data collection' of this detailed project description. To consider confounders likely to affect outcomes, in Phase III, we will collect patient characteristics such as disease (cancer, non-cancer), living arrangements, support, gender and age in both screening and study data collection. The impact of confounders will be investigated for both the acceptability of the SMST in screened patients, and during qualitative interviews with patients by drawing on their experiences relating to these factors.

1.9 "The board felt more qualitative work on developing the intervention was required"
We have fundamentally shifted the focus of this proposal to enhance the qualitative content of our bid and have provided a detailed explanation of the methodology we propose to use in 'Data collection' and 'Data analysis' sections of this document. We have emphasised our patient centred approach by using the principles of Experience Based Co-design (EBCD) to guide the development and modelling phases of our proposal which are theoretically informed by behaviour change and self-efficacy theories. Finally, we have grounded our feasibility assessment of up-take and acceptability of our SMST in a qualitative evaluation of user experiences, supported by quantitative assessment of key clinical, health economic and healthcare resource measures to estimate primary study end points.

1.10 Additional changes made since outline application

1.10.1 Research Fellow Post in Southampton

The contract length and for the Research Fellow (RF) post in Southampton has changed from 18 months at 50% FTE to 14 months at 100% FTE to reflect the increased need for qualitative work within the modelling stage and greater study management within the feasibility stages of the project. The RF in Southampton will be required to start in Month 6 to develop relationships and networks with local research partners to facilitate recruitment and data collection for Phases II and III.

1.10.2 Additional expertise in Psychology

In line with the feedback to demonstrate greater clarify on the self-management components of our intervention, we have included Professor Stephen Morley as a co-applicant. He is a Professor of Clinical Psychology and has researched and published in the field of pain for 25 years. He is currently section editor for the European Journal of Pain and formerly associate editor of Pain. He is internationally recognised for his expertise in the psychological treatment of chronic pain, specifically behavioural change, and the impact of pain on personal identity.