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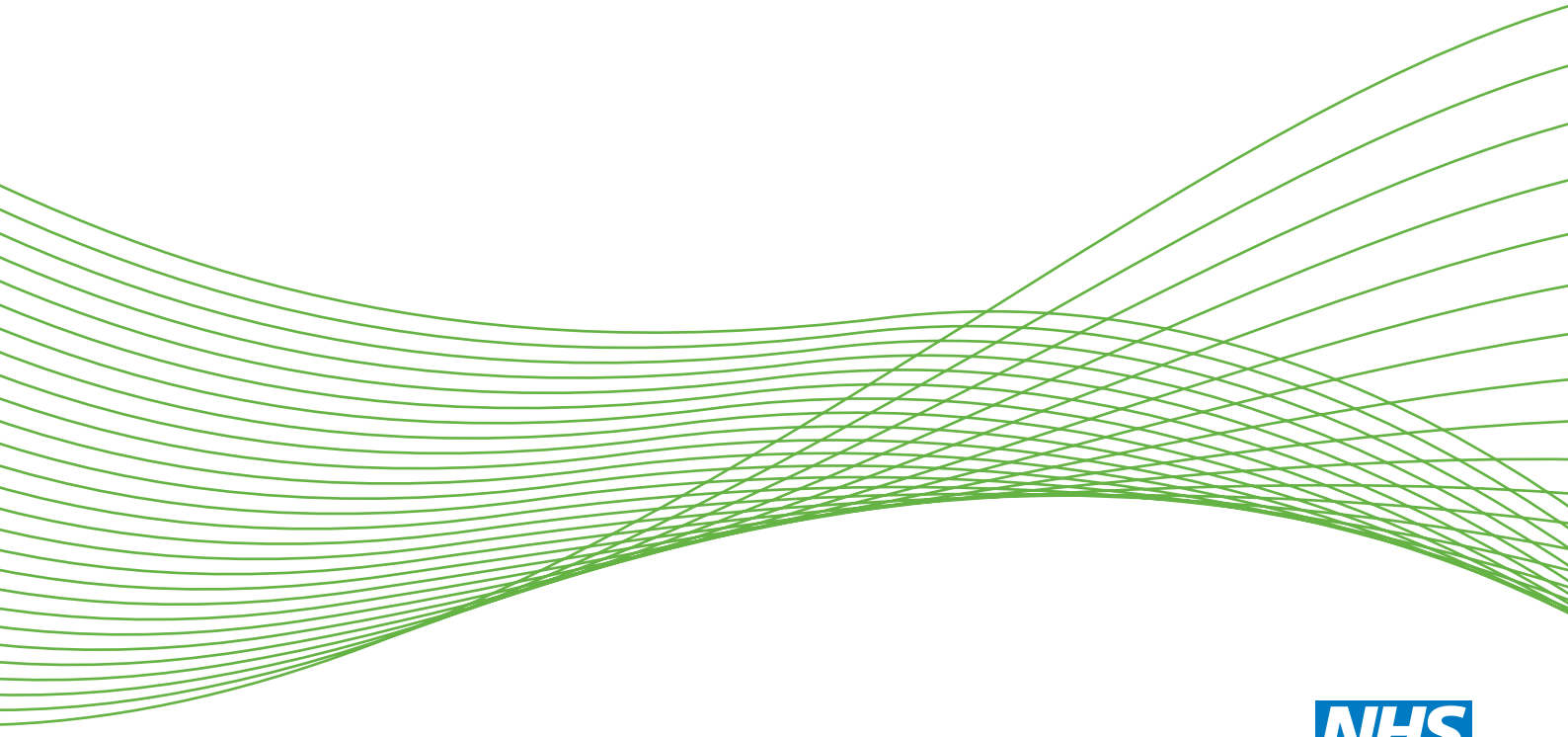

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Michael I Bennett,[1]* Matthew R Mulvey,[1] Natasha Campling,[2] Sue Latter,[2] Alison Richardson,[2] Hilary Bekker,[1] Alison Blenkinsopp,[3] Paul Carder,[4] Jose Closs,[5] Amanda Farrin,[6] Kate Flemming,[7] Jean Gallagher,[1] David Meads,[1] Stephen Morley,[1†] John O'Dwyer,[1] Alexandra Wright-Hughes[6] and Suzanne Hartley[6]

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Abstract

Self-management toolkit and delivery strategy for end-of-life pain: the mixed-methods feasibility study

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†In memoriam

Background: Pain affects most people approaching the end of life and can be severe for some. Opioid analgesia is effective, but evidence is needed about how best to support patients in managing these medicines.

Objectives: To develop a self-management support toolkit (SMST) and delivery strategy and to test the feasibility of evaluating this intervention in a future definitive trial.

Design: Phase I – evidence synthesis and qualitative interviews with patients and carers. Phase II – qualitative semistructured focus groups and interviews with patients, carers and specialist palliative care health professionals. Phase III – multicentre mixed-methods single-arm pre–post observational feasibility study.

Participants: Phase I – six patients and carers. Phase II – 15 patients, four carers and 19 professionals. Phase III – 19 patients recruited to intervention that experienced pain, living at home and were treated with strong opioid analgesia. Process evaluation interviews with 13 patients, seven carers and 11 study nurses.

Intervention: Self-Management of Analgesia and Related Treatments at the end of life (SMART) intervention comprising a SMST and a four-step educational delivery approach by clinical nurse specialists in palliative care over 6 weeks.

Main outcome measures: Recruitment rate, treatment fidelity, treatment acceptability, patient-reported outcomes (such as scores on the Brief Pain Inventory, Self-Efficacy for Managing Chronic Disease Scale, Edmonton Symptom Assessment Scale, EuroQol-5 Dimensions, Satisfaction with Information about Medicines Scale, and feasibility of collecting data on health-care resource use for economic evaluation).

Results: Phase I – key themes on supported self-management were identified from evidence synthesis and qualitative interviews. Phase II – the SMST was developed and refined. The delivery approach was nested within a nurse–patient consultation. Phase III – intervention was delivered to 17 (89%) patients, follow-up data at 6 weeks were available on 15 patients. Overall, the intervention was viewed as acceptable and valued. Descriptive analysis of patient-reported outcomes suggested that interference from pain and self-efficacy were likely to be candidates for primary outcomes in a future trial. No adverse events related to the intervention were reported. The health economic analysis suggested that SMART could be cost-effective. We identified key limitations and considerations for a future trial: improve recruitment through widening eligibility criteria, refine the SMST resources content, enhance fidelity of intervention delivery, secure research nurse support at recruiting sites, refine trial procedures (including withdrawal process and data collection frequency), and consider a cluster randomised design with nurse as cluster unit.

Limitations: (1) The recruitment rate was lower than anticipated. (2) The content of the intervention was focused on strong opioids only. (3) The fidelity of intervention delivery was limited by the need for ongoing training and support. (4) Recruitment sites where clinical research nurse support was not secured had lower recruitment rates. (5) The process for recording withdrawal was not sufficiently detailed. (6) The number of follow-up visits was considered burdensome for some participants. (7) The feasibility trial did not have a control arm or assess randomisation processes.

Conclusions: A future randomised controlled trial is feasible and acceptable.

Study and trial registration: This study is registered as PROSPERO CRD42014013572; Current Controlled Trials ISRCTN35327119; and National Institute for Health Research (NIHR) Portfolio registration 162114.

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List of abbreviations

BPI	Brief Pain Inventory
CCMM	Cancer Carer Medicines Management
CEAC	cost-effectiveness acceptability curve
CI	confidence interval
CNS	clinical nurse specialist
CRF	case report form
CRN	clinical research nurse
DAM	decision-analytic modelling
DVD	digital versatile disc
EORTC-QLQ C30	European Organisation for Research and Treatment of Cancer – Quality of Life Questionnaire C30
EQ-5D	EuroQol-5 Dimensions
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
ESAS	Edmonton Symptom Assessment Scale
GP	general practitioner
HCP	health-care professional
HTA	Health Technology Assessment
ICECAP-A	ICEpop CAPability measure for Adults
ICER	incremental cost-effectiveness ratio
ID	identification
IMPACCT	Improving the Management of Pain from Advanced Cancer in the Community
IQR	interquartile range
K–M	Kaplan–Meier
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NMB	net monetary benefit
PPI	patient and public involvement
PSS	Personal Social Services
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
RCT	randomised controlled trial
REC	Research Ethics Committee
SD	standard deviation
SES	Self-Efficacy for Managing Chronic Disease Scale
SIMS	Satisfaction with Information about Medicines Scale
SMART	Self-Management of Analgesia and Related Treatments at the end of life
SMST	self-management support toolkit
VOICES	National Survey of Bereaved People

Plain English summary

Pain affects most people approaching the end of life and can be severe for some. Opioid pain medicines (such as morphine) are effective, but evidence is needed about how best to support patients who are approaching the end of life in managing these medicines.

By reviewing published research and interviewing patients, carers and health-care professionals, we designed a self-management support toolkit (SMST). This consisted of factsheets, a pain diary, medication chart and a goal-setting sheet. We trained clinical nurse specialists in palliative care to deliver the tool using a four-step coaching process [the Self-Management of Analgesia and Related Treatments at the end of life (SMART) intervention]. We then asked the trained nurses to trial the SMART intervention with a group of patients over a 6-week period. The purpose of this trial was to see what patients, their carers and nurses thought of the SMST and to decide if it was possible to run a larger trial.

Many patients were unable to take part because they were not prescribed strong enough painkillers or were too unwell. We approached 37 patients, and 19 took part. The SMART intervention was acceptable and valued by patients and nurses. In general, the study nurses delivered the intervention as planned. We were able to collect information from patients on a regular basis and that this was not too much for them. We interviewed the nurses at the end of the trial and this showed that we need to make some refinements to the study: allowing patients on more types of painkiller to be included and providing more training support to nurses. Based on these findings we have concluded that a larger study in the NHS is feasible. This will determine whether or not SMART can provide cost-effective benefits to patients who are approaching the end of life.

Scientific summary

Background

Between 45% and 56% of patients with advanced cancer experience pain of moderate to severe intensity before they die, and pain is frequently reported in patients approaching the end of life. Patients at the end of life report that their preferred place of care and death is home. Poorly controlled pain at the end of life can have a negative impact the quality of life for both patients and carers. Patients and their carers face daily dilemmas on the best way to balance pain relief with adverse effects of analgesia and the consequent impact of both on daily activities. One important influence on the quality of pain management for patients at home concerns the information and understanding that they have regarding their pain and their analgesic medication. Addressing the concerns and knowledge of patients leads to improvements in pain control and this process relies on specific contexts that support behavioural change in patients, carers and health-care professionals (HCPs).

Aim and objectives

We aimed to develop an intervention that enables patients approaching the end of life and their carers to more confidently manage medications for pain (specifically strong opioids), nausea, constipation and drowsiness at home. We then aimed to test the feasibility of evaluating this intervention in a future clinical trial.

Phase I objectives

- Understand self-management needs and capabilities of patients and carers related to strong opioid medication.
- Define the content of a prototype self-management intervention and a delivery strategy.

Phase II objective

- Refine the prototype intervention and delivery strategy.

Phase III objectives

- Assess acceptability and uptake of the intervention in a mixed-methods observational study involving patients, informal carers and HCPs from four palliative care services.
- Assess the feasibility of obtaining outcome data for a larger definitive trial.

Methods

Phase I: development

Phase I described the intervention development process and consisted of exploratory mixed methods using literature scoping searches and semistructured qualitative interviews.

Initial qualitative work to develop a contextual framework of self-management within palliative care

Semistructured interviews were conducted with patients and carers to identify medicines and self-management needs at the end of life and explore perceived barriers to and facilitators of managing medicines at home.

Scoping the literature

Evidence synthesis exercises were conducted to:

- evaluate the content and form of previous self-management interventions
- identify key systematic reviews of support self-management in long-term conditions and factors that enable HCPs to support patient self-management
- identify existing public guidance on supporting pain and analgesia self-management in end-of-life context.

A theoretical underpinning of supported medicines self-management was developed through literature searches and informed by key learning points from previous studies conducted by the research team.

Initial contextual work and evidence synthesis activities defined the content and form of a prototype self-management intervention and delivery strategy.

Phase II: refining and optimisation

Refining the intervention

Qualitative semistructured focus groups and interviews with patients, carers and specialist palliative care health professionals (including service managers and commissioners) were conducted to refine the content of the intervention resources and delivery strategy by exploring concepts of supported self-management and defining patient, carer and health professional roles within the context of end-of-life care. This process ultimately generated a prototype version of the Self-Management of Analgesia and Related Treatments at the end of life (SMART) intervention.

Optimising the intervention

The prototype SMART intervention was further developed and refined through an iterative process of focus groups and interviews. Findings from the focus groups and interviews were mapped to the prototype intervention components, resulting in the self-management support toolkit (SMST) resources and an educational approach to delivering these resources within the context of community palliative care services. The SMST resources were reviewed by the patient and public involvement panel members, specialists palliative care HCPs and a specialist in health literacy.

Phase III: feasibility testing

We conducted a multicentre mixed-methods single-arm pre–post observational feasibility study. The feasibility study was conducted in four community palliative care services: two in Yorkshire and the Humber and two in Hampshire. Within each community palliative care service, between two and four community-based clinical nurse specialists (CNSs) were trained in the delivery of the SMART intervention, and there were 12 overall (referred to as study nurses). Study nurses attended a half-day training workshop facilitated by an expert nurse educator to enable them to deliver the intervention.

Patients were identified by screening study nurses' caseloads and were eligible if they were aged > 18 years, lived at home, were prescribed strong opioid analgesia, were cared for by specialist community palliative care services, were considered by the clinical team likely to survive beyond 6 weeks of follow-up and had the capacity to consent.

Eligible patients who provided written informed consent (hereafter referred to as participants) were seen by a study nurse who delivered the intervention to them. Study nurses delivered the SMART intervention each time they visited their participants (and a carer when appropriate) during the 6-week study period (each visit was referred to as a 'SMART visit'). Study nurses were asked to visit participants a minimum of three times during this 6-week period (i.e. at least once a fortnight). During each visit study nurses were required to use a conversational approach to go through the educational delivery approach and provide the resources from the SMST as required.

Data were collected from participants by researchers at baseline and at the 2-, 4- and 6-week follow-up time points. Data were collected using self-reported outcomes measures for pain [Brief Pain Inventory (BPI)]; self-efficacy [Self-Efficacy for Managing Chronic Disease Scale (SES)]; common end-of-life symptoms [Edmonton Symptom Assessment Scale (ESAS)]; quality of life [EuroQol-5 Dimensions (EQ-5D)]; and satisfaction with medication information [Satisfaction with Information about Medicines Scale (SIMS)]. Final data collection from participants' health records was carried out at the end of the study to capture patients' health-care resource use and analgesic prescription during the 6-week follow-up period.

Results

Phase I

This early development phase contextualised a framework of supported self-management within palliative care services. Qualitative interview identified five key themes, which were used to shape early thinking about the dimensions of the intervention. The literature scoping exercises resulted in a theoretical underpinning of supported self-management at the end of life and a description of the potential components of self-management intervention and a nurse-led educational approach to delivery within community palliative care services. The intervention components were further developed to generate a preliminary model of supported self-management and the content and form of the prototype intervention.

Phase II

A total of 38 patients, carers and palliative care HCPs were recruited from hospice- and hospital-based palliative care services in Hampshire and Yorkshire. The results highlighted the ever-changing process of self-management enacted on a continuum of behaviours that were dependent on the responsibility taken by the patient, carer and specialist nurse. The model of supported self-management was tested within the context of end-of-life care, and the roles of patients, carers and CNSs were defined.

Mapping the findings from the focus groups and interviews onto the prototype intervention component ultimately generated the SMART intervention that comprised both a SMST and a four-step educational delivery approach. The SMST included eight factsheets, a pain diary, a medication chart and goal-setting sheets. The four-step educational approach consisted of a needs assessment, information provision, goal-setting and regular review and coaching of self-management progress.

The intervention was designed to be delivered via a feasibility study to patients by community-based palliative care CNSs. The approach to delivery involved nesting the intervention in a clinical encounter (nurse–patient consultation) and was enacted through a conversational process.

Phase III

Study nurse training

Prior to starting recruitment, the 12 study nurses attended a training workshop to enable them to deliver the SMART intervention. Responses to the reflective style of the workshop were mixed, but the nurses generally felt that the four-step educational delivery approach mirrored normal practice and they valued the training materials supplied during and after the training workshop. Regular fortnightly contact was

maintained between study nurses and the research team to provide additional training materials and support throughout the study period.

Participant recruitment

Of the 417 patients assessed for eligibility in 4 months, 103 (25%) were screened eligible and 19 (5%) were recruited to participate. Seventeen participants (89%) received the intervention and 15 (79%) completed 6 weeks' follow-up. Four participants withdrew from the study (two died, one withdrew from researcher follow-ups and one was admitted to a nursing home). Baseline characteristics were similar across the four recruitment sites: the median (range) age was 66 (48–88) years, 58% were female and 18 out of the 19 participants had advanced cancer.

SMART intervention fidelity and acceptability

Ten participants (53%) received the intervention as planned (i.e. started within 7 days of baseline data collection, received at least a minimum of three SMART study nurse visits, received tailored staged information provision, goal-setting and regular review and coaching). A further four participants (21%) received all of the factsheets on their first SMART study nurse visit, although all other elements of the intervention were delivered as planned. Three participants (16%) received the SMST resources but did not receive the minimum three SMART study nurse visits and two participants (10%) did not start the intervention.

End-of-study interviews with participants and carers revealed that the SMST resources (the factsheets, pain diary, medication chart and goal-setting sheets) were universally seen as acceptable and were perceived as beneficial as they addressed relevant fears and concerns and stimulated participants to ask further questions and seek additional help. The goal-setting sheets were particularly valued and seen as beneficial by participants and carers. The study nurses universally perceived the goal-setting and regular review process as acceptable and deliverable. They identified the goal-setting as a core component of the intervention and perceived value in it because it formalised and evidenced their specialist practice.

The end-of-life context provided a complex set of circumstances within which study nurses had to deliver the intervention. Consequently, not all participants were able to fully engage with all elements of the intervention; however, overall, the four-step educational approach appears to have been acceptable and was adhered to by the study nurses.

Feasibility of collecting participant self-reported outcome data

The level of missing data from the self-reported outcome measures was extremely low. There was no change in average pain scores; however, there was a slight reduction in interference from pain [–1.6, 95% confidence interval (CI) –2.8 to –0.4] and a modest increase (0.7, 95% CI 0.3 to 1.2) in self-efficacy scores. There was no overall change in the intensity of common end-of-life symptoms (ESAS), health-related quality of life (EQ-5D) or satisfaction with information about medicines (SIMS). The number of participants with clinically meaningful reduction in average pain and pain interference were summarised. These data show that, at follow-up weeks 2 and 6, there were more responders based on pain interference than on average pain intensity. The results suggest that the SES and BPI pain interference scale are the most responsive to change and should be considered for the primary outcome for a definitive trial. Participants generally found the outcome measures to be acceptable.

Feasibility of conducting a cost-effectiveness evaluation of SMART

An economic evaluation was conducted to assess the feasibility of estimating cost-effectiveness of SMART compared with usual care in patients at the end of life who receive opioids. The costs of developing and implementing the SMART intervention were relatively modest. The SMART intervention led to cost savings and yielded incremental quality-adjusted life-years (QALYs) in a base case and many of the deterministic sensitivity analyses. These QALY gains are small, although this is to be expected as this population has a limited survival time in which to benefit. In general, the results are robust to one-way parameter changes and SMART appears to be cost-effective compared with standard care alone. The feasibility aspects of this

study suggest that conducting a cost-effectiveness evaluation in a definitive trial setting should be possible. Furthermore, the results indicate that a low-cost intervention, such as SMART, could be cost-effective in this population even if the impact on pain and side effect management were modest and suggest that further research is warranted.

Conclusion

We have shown that the evaluation of a supportive self-management intervention for patients requiring analgesia, and who are approaching the end of life, is feasible. We have demonstrated that our research process, study nurse training schedule and intervention delivery strategy are feasible and acceptable within a sample of community-based individuals approaching the end of life, their carers and palliative care CNSs. Our success criteria were largely met and, for those that were not, we have identified clear means to succeed within a future trial through a detailed process evaluation of our feasibility study. The key considerations in the design of future definitive trial have been identified, and we believe that this is now feasible to undertake.

Study and trial registration

This study is registered as ISRCTN35327119; PROSPERO CRD42014013572; and National Institute for Health Research (NIHR) Portfolio registration 162114.

Funding

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Chapter 1 Supporting self-management of analgesia and related treatments at the end of life

Summary of Health Technology Assessment brief

In October 2012, the Health Technology Assessment (HTA) published a commissioning brief entitled 'Self-management of pain relief, nausea and constipation for patients approaching the end of life'. Applicants were asked to address the research question of whether or not a patient support tool could improve the self-management of medication for pain, nausea and constipation in patients approaching the end of life. This call was based on the recognition that:

> *Enhanced patient-family health decision making can improve the overall quality of end of life care. As life-limiting illnesses progress, the number of disease related symptoms typically increases. Medication regimens can be complex and pain, nausea and constipation are among the common symptoms that often fluctuate and may be appropriate for self-management by patients and their family carers. Patient decision aids have been shown to be effective in facilitating informed decision making and it may be that a self-management aid could help patients and their families to manage their medication regimens to improve pain, nausea and constipation symptom control. A feasibility study is needed to develop a support aid and to assess its acceptability.*

This report contains the research conducted in response to this brief (see *Appendix 1* for full HTA brief).

Summary of current evidence and policy context

Approximately 160,000 people die from cancer each year in the UK, a number that is expected to rise to 193,000 by 2030.[1] Evidence suggests that 45–56% of patients with advanced cancer (72,000–89,600 each year in the UK), experience pain of moderate to severe intensity before they die.[2,3] Detailed information on pain in patients approaching the end of life with non-cancer diseases is less widely available.

Since 1986, the focus of pain treatment for patients approaching the end of life has been the use of strong opioids based on the World Health Organization's 'analgesic ladder'.[4] Initial studies suggested that this approach could control pain in around 73% of cancer patients.[5,6] Despite widespread availability of strong opioids in the UK, at least 32% of patients with cancer are undertreated for their pain.[3,7]

Patients at the end of life report that their preferred place of care and death is home.[8] The National Survey of Bereaved People (VOICES) has evaluated the perceptions of the care given to recently deceased persons (not just those with cancer) since 2011.[9] In 2015, only 18% reported that pain was controlled 'completely, all the time' at home, compared with 38% in hospital and 63% in hospice. Not surprisingly, uncontrolled pain is the most frequent reason for community-based cancer patients to contact out-of-hours primary care services.[10]

Although there is evidence that improved pain management for patients with advanced disease is associated with involvement of palliative care, the evidence base is not consistent in reflecting significant methodological heterogeneity.[11] Little is known about the service constituents that are responsible for improved pain management.

In 2008, the Department of Health published a strategy for end-of-life care as it recognised that many people did not have what could be described as a 'good death': being treated as an individual with dignity

and respect, being without pain and other symptoms, being in familiar surroundings and being in the company of close family and/or friends.[12] A National Institute for Health and Care Excellence (NICE) quality standard was subsequently issued in 2011 to define and support high-quality end-of-life care, specifically including pain management.[13]

In 2016, the British Medical Association interviewed 269 members of the public and 237 doctors regarding the provision of end-of-life care by the NHS.[14] For both the public and doctors, pain was the most feared aspect of dying, echoing the findings of the national VOICES survey and underlining the importance of good pain control at the end of life.

A succession of key reports have emphasised the urgent need to improve end-of-life care services in the NHS because of unacceptable variation in access to and experience of care.[15] The Leadership Alliance for the Care of Dying People's *One Chance to Get it Right – Improving People's Experience of Care in the Last Few Days and Hours of Life*[16] recognised that pain and symptom control should be among the five key priorities of care in the NHS. In 2015, NHS England led *Ambitions for Palliative and End of Life Care: A National Framework for Local Action 2015–2020*,[17] which described access to care and maximising comfort as two of its six ambitions for improving services. The Parliamentary Health Committee on End of Life Care reported in 2015 that round-the-clock access to community nurses and specialist outreach palliative care for pain relief are some of the actions that could facilitate a shift in quality of care.[18]

The Palliative and End of Life Care Priority Setting Partnership, led by the James Lind Alliance, undertook a survey of 700 patients and carers and a similar number of professionals involved in end-of-life care, regarding research priorities.[19] Of the 83 shortlisted areas, one-third of the top 10 research priorities related to symptom management, with pain specifically mentioned. In response to this, the National Institute for Health Research (NIHR) undertook a themed review of palliative care research that it funds, summarised in the NIHR report *Better Endings*.[20]

Overall, NIHR research has identified persistent inequalities and variations in care, with poorly co-ordinated services and limited access to specialist palliative care. In addition, place of death may not be the most important aspect of care for many; managing pain and other symptoms and the quality of care are key for patients and their family, whatever the setting. These reports,[12–15] all published in the last 2 years, serve to highlight that although good-quality end-of-life care can be defined, currently within the NHS patients experience poor pain control at home, the public remain understandably fearful of a painful death and there is unacceptable variation in access to good care in the NHS. Providing better support to enable patients to self-manage with more confidence is likely to be an important mechanism in improving outcomes for patients with pain from advanced disease.[21] Therefore, this research proposal was timely and important in supporting NHS priorities and informing ways to improve the experiences of dying patients and those that survive them.

Background rationale

One important influence on the quality of pain management for patients at home concerns the information and understanding that patients have regarding their pain and their analgesic medication. Misunderstandings by patients regarding opioids inhibit good pain control[22] and we have found that this is particularly true for older patients.[23] Our own research has also shown that patients and their carers face daily dilemmas on the best way to balance pain relief with the adverse effects of analgesia and the consequent impact of both on daily activities.[24,25] Attitudes and knowledge of health-care professionals (HCPs) towards opioids is likely to influence the quality of information provided to patients[26] and the increasing complexity of opioid choices in end-of-life care may further reduce the confidence of non-specialist practitioners.[27]

However, addressing the concerns of patients leads to improvements in pain control,[28] and this process relies on specific contexts that support behavioural change in patients, carers and professionals.[29–31]

Although education and self-management support are largely seen as nursing tasks rather than medical tasks,[30] our research suggests that pharmacists can make important contributions too.[32,33]

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,[34] which is why they have been highlighted by NICE guidance.[35] Simple information in the form of leaflets or video may help,[36] but may be insufficient to make a tangible impact on patients' perceptions of confidence to self-manage.

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.[35,37] 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 extended the scope of the HTA brief to incorporate drowsiness in the intervention.

Feasibility study aims and objectives

We aimed to develop an intervention that enables patients approaching the end of life and their carers to more confidently manage medications for pain (specifically strong opioids), nausea, constipation and drowsiness at home. We designed this project with a patient-centred approach at the heart of our development plan, nested within a theoretically informed behaviour change framework. The expected benefits of the intervention for patients were improvements in symptom relief, feeling empowered with increased knowledge and skills to recognise worsening symptoms or adverse effects, being able to self-initiate therapeutic adjustments and knowing how and when to access help from the health-care system.

We defined our intervention as a set of materials and coaching procedures that deliver knowledge, facilitate the generation of specific action plans and enhance the user's skills to monitor and reflect on their actions. We judged that our intervention would be optimally delivered by clinical nurse specialists (CNSs) who work within specialist palliative care teams. We thought that patients would be most likely to benefit from the intervention if they were adults (aged > 18 years), approaching the end of life, suffering from significant pain and being cared for in their own home, being treated with, or due to start treatment with, opioids for pain, and experiencing (or anticipating) adverse effects of these medications. We were particularly keen to embed the principles of experience-based co-design into the development, modelling and testing of our prototype intervention, and to evaluate this within a theoretical framework for characterising and designing behaviour change interventions.[38,39]

Our objectives were divided into three distinct phases, which is in line with the Medical Research Council framework on developing and evaluating complex interventions.[40] We also planned to use the explanatory models of normalisation process theory to evaluate factors that will support implementation.[41] This would offer a clear path for implementation into the wider NHS should the effectiveness of the intervention be established in a future definitive randomised controlled trial (RCT).

Phase I: development objectives

- Establish a patient and public involvement (PPI) panel.
- Establish the content of a prototype intervention and a manualisation strategy that includes a protocol to standardise (1) the training of HCPs and (2) the delivery of the intervention by HCPs to patients and carers.
- Understand self-management needs and capabilities of patients and carers related to strong opioid medication.
- Define usual care.

Phase II: modelling objectives

- Refine the prototype intervention and manualisation strategy.

Phase III: feasibility assessment objectives

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

Patient and public involvement

We have had sustained PPI throughout all stages of the Self-Management of Analgesia and Related Treatments at the end of life (SMART) study. PPI has been an integral part of all our study processes from inception and development of the research ideas, development of the funding application, through to delivering the research project and interpreting the study findings. We have engaged with PPI in a number of ways. First, through a PPI coapplicant (JG), we benefited from expert PPI input to help prioritise the research question and ensure that the delivery of the intervention is undertaken in a way that is meaningful and relevant to patients approaching the end of life and their carers. Second, in the first phase of the project we established a dedicated PPI panel that informed and helped refine the content and delivery strategy of the SMART intervention as well as review patient study materials (i.e. information sheet, consent form, patient questionnaire). Last, we recruited an independent PPI representative to be part of the Steering Committee, which has oversight and responsibility for the project, and gave the study team insight and direction throughout the design, delivery and completion of the project.

Success criteria

Ultimately, we aimed to establish the acceptability and uptake of our prototype self-management support toolkit (SMST) and determine the feasibility of evaluating this intervention within a larger trial. In order to judge whether or not we had achieved our aims, we agreed our success criteria beforehand to be as follows.

Phase I

- Establishment of a PPI panel and assessment of members' support and training requirements.
- Development of a usual-care protocol based on literature review and clinical practice observations.
- Development of prototype intervention materials, manualisation strategy and usual care protocol.

Phase II

- Establish members of focus groups.
- Development of refined intervention materials and manualisation strategy.

Phase III

- Sampling strategy: recruit three patients per month at each site within 4 months.
- Feasibility of data collection: key clinical and health economic measures, and health-care resource measures, have sufficient complete data to estimate primary study end points.
- Trial experience: patients and carers reporting acceptable and sustained use of intervention materials.

Chapter 2 Development of the SMART intervention

Phase I: overview of initial contextual work

This chapter describes the intervention development process. First, it summarises the literature scoped to inform the development of the intervention. Second, it recounts the exploratory activities undertaken with specialist palliative care health professionals, patients and carers, to derive a concept of self-management of analgesia (opioids) and related treatments (for nausea, constipation and drowsiness) at the end of life.

Through this development process it was possible to generate a preliminary model of self-management that was then tested further through interviews and focus groups with patients, carers and HCPs. This chapter will also describe how this model was then used to specify and inform the components, including content and form, of the SMART intervention. This process aligned with the theoretical modelling phase of the Medical Research Council framework for complex interventions.[42,43]

Initially, contextual work was performed to frame self-management within the field of palliative pain management. Much is written about self-management, but the focus is predominantly on long-term condition management.[44] However, a survey of 90 cancer patients living at home receiving community-based palliative care identified three key factors associated with successful pain management.[45] The first factor is maintaining a sense of control over managing medicines by modifying the schedule of taking medicines around daily routines and planned activities. The second factor is negotiating a balance (trade-off) between symptom control and the impact of medicines' side effects on cognitive and physical functioning. Furthermore, Hansen *et al.*[46] identified that 40% of end-of-life patients regularly do not use analgesia despite reporting moderate to severe pain and indicating an awareness that regular medication was the most effective self-management behaviour for controlling pain. These authors concluded that patients were making important trade-offs between pain relief and the side effects of medications and this helped maintain a sense of control. The third factor associated with successful pain management identified by Bennett *et al.*[45] is a broad base of support. Community palliative care nurses and community pharmacists were seen as key HCPs supplemented by support from a carer (family member or friend). The authors concluded that a community-based intervention that is flexible and responsive to patients' needs, involving carers and community-based HCPs, is most likely to be successful.

Information provision has been identified as a fundamental component of interventions in advanced disease.[37,47] Tailored information provision equips patients and carers with the necessary skills and confidence to drive behaviour change.[39,48] However, on its own it is insufficient to drive significant improvements in patient-reported outcomes, such as pain and quality of life. Contextual factors associated with successful pain management are the development of a trusting relationship with health-care providers, having dedicated time to focus on medicines management and confidence in exerting self-control over a daily analgesic routine.[47,49] Identifying patient and carer needs was recognised by NICE as the basis for delivering tailored support in its guidance on improving supportive and palliative care for adults with cancer.[37] Therefore, in addition to information provision, regular assessment and review of patient needs is a key component in supporting self-management of pain medication in this context.[37,47]

In order to understand the context more fully, six semistructured interviews were initially undertaken with patients and carers recruited from a palliative care outpatient service. Interviews focused on identifying the

need to self-manage medicines at the end of life and exploring perceived barriers to and facilitators of managing medicines at home. This led to the delineation of five themes:

1. communication and understanding
2. addressing fears and concerns
3. information requirements
4. carer-specific needs
5. making trade-offs.

These themes were used to shape early thinking about the dimensions of the intervention, which were further refined in later phases, as described below.

Evidence synthesis

Scoping of the literature

Scoping of the literature was undertaken following the preliminary work described above. The objective of this exercise was to examine:

1. the content and form of previous interventions effective in improving pain management by patients (see *Appendix 2*)
2. key systematic reviews of what can be done to support self-management across a range of long-term conditions of relevance to this particular application at the end of life
3. key literature and reviews that identify factors that enable HCPs to support patient self-management
4. existing public guidance based on NICE clinical guideline 140 – *Opioids in Palliative Care* (*Box 1*)
5. description and potential components of self-management at the end of life (*Box 2*).

Theoretical underpinning of the intervention

The literature-scoping work informed the selection of theory focused on self-efficacy and behaviour change to best suit the developing intervention. Self-efficacy is a key component of Bandura's social cognitive theory.[54,55] The theory of social cognition states that knowledge acquisition can be directly related to observing others within the context of interactions and experiences. According to this theory, self-efficacy is the belief in an individual's capabilities to organise and carry out courses of action to manage situations. Bandura states that behavioural techniques can be used to target the four sources of self-efficacy: mastery experience, role modelling, verbal persuasion and the regulation of physiological and affective states. Michie *et al.*[39] undertook a systematic search and consultation with behaviour change experts to identify frameworks of behaviour change interventions. These were then evaluated for comprehensiveness, coherence and a clear link to a model of behaviour. A new framework was subsequently developed to fully meet all these criteria: the behaviour change wheel. The wheel characterises behaviour change interventions around nine intervention functions aimed at addressing deficits in one or more of three essential conditions for behaviour change: Capability, Opportunity and Motivation (termed the COM-B system). The behaviour change wheel identifies three main target constructs (sources of behaviour), which are capability (physical and psychological), motivation (automatic and reflective) and opportunity (social and physical). Around these target constructs are nine intervention functions (education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring and restrictions), which represent ways to address deficits in one or more of the target conditions.

Key learning from studies conducted by the team

The intervention development was also informed by key learning from two studies undertaken by members of the research team. These were Cancer Carer Medicines Management (CCMM),[56] funded by Dimbleby Marie Curie Cancer Care, and Improving the Management of Pain from Advanced Cancer in the Community (IMPACCT), a programme grant funded by the NIHR (RP-PG-0610-10114).

BOX 1 Existing public guidance

Guidelines reviewed

- NICE (2012) information for managing pain with the strong opioids in people with advanced progressive disease – information for the public.[37]
- All Wales Medicines Strategy Group: *Opioids in Palliative Care – Patient Information Manual*.[50]

Information covered

Managing pain with strong opioids: some treatments may not be suitable depending on your circumstances, definition of palliative care and its purpose of alleviating pain and discomfort to improve quality of life.

Information about taking strong opioids: if you are offered strong opioids, HCPs should explain when and why strong opioids are used to treat pain; how effective they are likely to be at relieving your pain; about taking strong opioids for background pain and breakthrough pain, including how, when and how often to take them; how long pain relief should last, possible side effects and signs to watch out for that might mean there is too much of the medication in your system; and how to store strong opioids safely.

Discussing your concerns: if you are worried about addiction and side effects, your HCP should reassure you that addiction is very unlikely and that you will be monitored for side effects. Strong opioids can be offered at different stages and doing so does not necessarily mean that you are close to the end of your life.

Starting treatment with opioids: different forms, short acting vs. slow release, no standard dose.

If you have trouble swallowing: if pain is stable you should be offered a patch.

Reviewing pain control: need for regular reviews especially at the beginning.

Continuing treatment: sustained-release form.

Treating breakthrough pain: immediate-release form, advice from specialist if uncontrolled.

Managing side effects

Constipation: definition and statement that it affects nearly everyone who takes strong opioids. You should be offered laxatives and a description of how laxatives work; they can take time to work so take them as advised and your HCP may change the type of opioid if your constipation is severe.

Nausea: you may experience feeling sick when starting strong opioids or when the dose is increased, but this is likely to last only a short time. If it persists, you should be offered anti-sickness medication.

Drowsiness: you may experience mild drowsiness or problems with concentration when starting strong opioids or the dose is increased, but this is likely to last only a short time. Your HCP should warn you that having problems might affect your ability to carry out some tasks, such as driving. If you have severe or long-lasting problems and your pain is under control, your HCP may discuss the possibility of reducing the dose of opioid with you. If your pain is not controlled, then your HCP may consider changing the opioid and if the problems are not relieved by these changes then your HCP may seek specialist advice.

Questions to ask a HCP: tell me more about strong opioids for pain relief? Can you tell me about the side effects associated with taking strong opioids? Will I become addicted to strong opioids? How long will it take for this medication to work? What do I do if I am still in pain after taking strong opioids? What are my options for taking some other type of pain relief? Can you give me some written material about strong opioid treatment?

Sources of more information: CancerHelp UK, Macmillan Cancer Support, British Pain Society and NHS Choices.

BOX 2 Description and potential components of self-management at the end of life

Reference: Johnston *et al.*[51]

The above authors provided a definition (via concept analysis) of self-management support within the context of palliative care:

> *. . . Assessing, planning, and implementing appropriate care to support the patient to be given the means to master or deal with their illness or its effects.*

The authors proposed eight potential professional roles to support self-management. These roles were undefined but labelled as advocate, educator, facilitator, problem-solver, communicator, goal-setter, monitor and reporter.

References: Schumacher *et al.*[52,53]

These authors demonstrated that, for oncology patients (and their carers) in the USA, the practical experiences of day-to-day management of pain medications could be both challenging and onerous. Navigating the systems with complex webs of people and rules was a lengthy and tedious challenge causing frustration, effort and added anxiety. These issues revolved around getting prescriptions, obtaining medicines, understanding, organising, storing, scheduling, remembering and taking.

Understanding

Once patients and carers obtained medicines they were immediately faced with understanding the medicines they had brought home. Lack of understanding led to uncontrolled pain. Many areas of confusion were evident; keeping the purpose and names of medications straight was one. Medication names were 'not in English' (i.e. plain English); many referred to medicines by appearance, and the use of abbreviations was seen as confusing, as were drugs with similar names. Lack of understanding about maximum daily dose limits was common (including not knowing that opioids do not have a dose ceiling). Understanding the meaning of dosing intervals was an issue for some (e.g. every 3 days). Utilising the wide variety of information sources was challenging and information printed on packs and inserts was too small for some to read.

Organising

Organising presented a host of issues because of the sheer number and various forms of medicines prescribed for regular use, p.r.n. (as required) or both. Participants used a wide range of highly individual strategies: elaborate daily rituals involving, for example, zip lock bags; differentiation of medicines by colour; lining up of medicine bottles with magnifying glass; taking out pills and putting them into a glass. Lack of organisational systems presented safety risks such as medicines sitting out in glasses:

> *Participants used their home environments for pain medication management in highly individualized ways. Countertops, drawers, tables, windowsills, cabinets, boxes, bags, dishes, alarm clocks, whiteboards, computers, and mobile devices were all used. Individuals and pets living in the home were taken into account. Visitors were a consideration, especially visiting grandchildren.*
>
> *Schumacher* et al. *p. 787*[53]

Storing

This refers to putting medicines safely away. Hiding medicines from patients was a strategy used when carers feared that the patient would get confused and take too much. Storing medication generally involved hiding them and locking them up.

BOX 2 Description and potential components of self-management at the end of life (*continued*)

Scheduling

This refers to working out the best time to take medicines in relation to daily lifestyles. Some used pain as a cue to take next regular dose earlier than scheduled, rather than take rescue medicines; this fitted with the mindset of taking medicines only when pain is present.

Remembering

Remembering use of dosette boxes helped but this was not failsafe. All affected by fatigue, drowsiness and confusion.

Taking

This was straightforward for most, but some experienced challenges (e.g. erroneously cutting sustained-release pills).

The SMART intervention drew on carer needs for medicines management at the end of life identified from the CCMM study (see *Appendix 3*), including needs for information about pain medicines and side effects, changing beliefs about opioids and providing skills and opportunities for self-evaluation. The results of the CCMM study also showed that a conversation-driven intervention, delivered by nurses in routine practice and supported with a toolkit of resources, was acceptable to carers and to nurses and was compatible with their existing practice. CCMM showed some evidence of benefit in influencing carers' knowledge, beliefs and behaviours related to management of pain medicines. Principles of the CCMM conversational process (assessment, education and review), as well as elements of the toolkit (information leaflets, medication chart, pain diary and contact details for local and national services), informed the development of the SMART intervention.

Learning from the IMPACCT study was derived from a review of the optimal components of educational interventions for advanced cancer pain, which was carried out as part of the study (see *Appendix 4*). In this meta-review,[57] the authors used Michie *et al.*'s[39] behaviour change wheel as theoretical underpinning. Mapping findings from six reviews and two papers led to identification of five out of the nine behaviour change wheel intervention functions. These were considered essential for successful interventions:

1. education, for example providing written information about pain management, including analgesic and non-pharmacological approaches
2. training, for example providing instruction, demonstration and coaching of new skills (techniques for managing daily drug regimes, relaxation techniques)
3. enablement and persuasion, for example overcoming cognitive and emotional barriers to pain management through addressing concerns about tolerance or addiction
4. environmental restructuring and resources, for example incorporating the delivery of education for self-management into the usual care provided by specific health professionals, such as specialist nurses, primary care practice nurses and community pharmacists
5. modelling, for example patients talking to other patients about their successful use of various pain management strategies.

Phase II: refining and detailing the intervention

This section describes the work undertaken to refine and detail the intervention. In particular it describes a series of interviews and focus groups conducted with patients, carers and HCPs. These data sources, together with work described in the previous section, were used to derive the content and form of the intervention for SMART.

Aim

The aim of this phase of the study was to refine and detail an intervention for self-management of analgesia (opioids) and related treatments (for nausea, constipation and drowsiness) at the end of life.

Objectives

The literature scoping informed the objectives and these were to:

- explore views regarding the nature and components of supported self-management regarding analgesia and related treatments at the end of life, and test our preliminary model of self-management in this context
- introduce participants to, and ask for their views on, aspects of self-management in this context – in particular our selected definition of supported self-management in palliative care (Johnston *et al.*[51]) and practical difficulties regarding supply and medicines taking encountered by patients (Schumacher *et al.*[52,53]) (see *Table 2*).

For HCPs, the objectives were to:

- reveal the self-management promoting activities and behaviours already used by specialist palliative care HCPs and gain views on the professional supportive self-management roles proposed by Johnston *et al.*[51]
- rehearse previous examples of interventions to test possible delivery modes and how these could link to existing patterns of practice.

For patients and carers, the objectives were also to:

- understand what supported self-management at the end of life was for them
- explore patient and carer needs using the framework of Schumacher *et al.*'s[52,53] commonly encountered practical difficulties regarding supply and the taking of medicines
- gain views regarding potential options for the content, form and delivery of the intervention.

Approach to data collection

Focus groups and interviews were held in two geographical regions: Hampshire and Yorkshire. They were conducted with patients, their carers and specialist palliative care health professionals (including service managers and commissioners).

Inclusion criteria

Patients were included if they:

- were aged $\geq$ 25 years and considered to be in the last year of life
- were experiencing pain
- were being treated with, or starting, opioid analgesia
- were experiencing, or anticipating, adverse effects of nausea, constipation and drowsiness
- were living at home
- were being cared for by specialist community-based palliative care services in Hampshire or Yorkshire
- had capacity to consent.

Carers were included if:

- they were the primary carer of a patient meeting the above inclusion criteria and
- the patient gave consent to their involvement.

Health-care professionals were included if they were:

- CNSs and doctors who were part of specialist palliative care teams or
- service providers or managers of specialist palliative care services or
- local commissioners of palliative care services.

Sampling strategy and recruitment

To access a range of individuals (HCPs, patients and carers), we aimed to recruit 35 participants via various strategies across four hospices and two acute NHS trusts. The sampling and recruitment strategy is detailed in *Table 1*.

TABLE 1 Sampling strategy and recruitment to interviews and focus groups

Hampshire		
HCPs[a]		
Acute trust 1 + hospice 1: eight hospital-based CNSs, six consultants and one specialist registrar were invited to participate. Of these, two hospital-based CNSs attended the focus group. 18 community palliative care CNSs were invited to participate, five attended the focus group that occurred at this hospice	Hospice 2: staff across the hospice were invited to attend. Three attendees participated in the focus group at this hospice and a further three travelled to attend the focus group at the other hospice	Acute trust 2: one lead nurse/ commissioner was invited to take part in an interview and this took place
Patients and carers[b]		
Acute trust: 17 patients were referred via a hospital-based palliative care team, all except four were approached by the researcher (seven did not meet the eligibility criteria). Two patients were recruited and interviewed	Hospice 1: 39 patients and carers attending day hospice sessions were informed about the study. Five patients and two carers (who met the eligibility criteria) approached the researcher after these sessions and four patients and two carers were recruited ($n = 6$)	Hospice 2: six patients were referred by day hospice staff as meeting the study's eligibility criteria. All were spoken to by the researcher and five patients were recruited, with two carers ($n = 7$)
Yorkshire		
Focus groups[c]		
HCPs: an entire community palliative care CNS team based at a hospice were invited to take part in a focus group and all attended on the day ($n = 4$). One palliative care consultant was invited to take part in an interview and this took place	Patients and carers: 10 eligible individuals were approached via a hospice outpatient clinic. Of the 10, four attended the focus group, four had agreed to participate but failed to attend, and two declined	

a Two focus groups (at both hospices 1 and 2) were held in Hampshire for HCPs.
b At the point of recruitment, patients and carers were asked whether or not they would prefer to take part in a focus group or interview. All stated a preference for interviews; therefore, no patient and carer focus groups took place in Hampshire.
c Two focus groups, one for HCPs and another for patients and carers, were held in Yorkshire.

Focus group and interview guides

Topic/interview guides (as well as supporting slide/card packs) were developed to meet the study objectives (see *Appendices 5–8*). A number of tools were used to manage the interview and focus group discussions:

- a definition of supported self-management in the context of palliative care (Johnston *et al.*[51])
- eight proposed professional roles to support self-management in the context of palliative care (Johnston *et al.*[48])
- the practical difficulties around supply and medicine taking encountered by patients and carers in the work of Schumacher *et al.*[52,53]
- the content and form of previous interventions to improve pain management by patients.[58–61]

The interviews and focus groups were conducted by the study's researchers. The focus groups were conducted with a co-facilitator another researcher with expertise in the field, present to aid moderation.

Data analysis

The audio files from the interviews and focus groups were professionally transcribed. They were listened to by the researchers alongside the transcripts to check for complete accuracy. Both study researchers familiarised themselves with the data by reading and rereading the transcripts and identifying key issues, concepts and themes. Initial coding took the form of indexing on the transcripts, and each research fellow summarised the key themes from the data related to the sites in their regional area. The themes were discussed for comparative purposes. Natasha Campling then coded the entire data set for all issues, aspects and themes that were relevant to supported self-management in this field. Coding was performed in NVivo (version 11; QSR International, Warrington, UK) utilising framework analysis.[62]

The development process

The process of intervention development is illustrated in *Figure 1*. The contextual work and literature scoping informed a preliminary model of supported SMART. This model, a definition of self-management,[51] practical difficulties related to supply and medicine-taking[52,53] and the content and form of previous interventions[58–61] were used as tools within the focus groups and interviews to gain participants' views. The result was development of a concept of self-management, to inform the required components (including the content and form) of the intervention: a four-step educational approach and toolkit, plus a training package to enable nurses to deliver the intervention within a feasibility study.

Findings from the intervention development interviews and focus groups

The sample

The sample was composed of 38 participants recruited via the two geographical regions of Hampshire and Yorkshire (*Table 2*). The demographics for the HCPs and patients and carers are presented in *Tables 3* and *4*.

Concept of supported self-management in analgesia and related treatments at the end of life

The development process, informed by the varied sources of learning outlined in *Evidence synthesis*, enabled the generation of a preliminary model of supported self-management in analgesia and related treatments at the end of life. The model was tested, within this specific context, through the interviews and focus groups with patients, carers and HCPs. The model included the self-management definition, professional roles outlined by Johnston *et al.*[51] and the practical difficulties regarding medicines access, supply and taking outlined by Schumacher *et al.*[52,53]

This process revealed new components of supported self-management within the end-of-life context. It displayed an ever-changing process enacted on a continuum of behaviours dependent on the responsibility taken by the patient, carer and specialist nurse. This was a complex web of behaviours, varying day by day, if not hour by hour, within this context. With continual disease progression, there were frequent changes in symptoms and side effects from both medication and palliative treatments, with behaviours profoundly

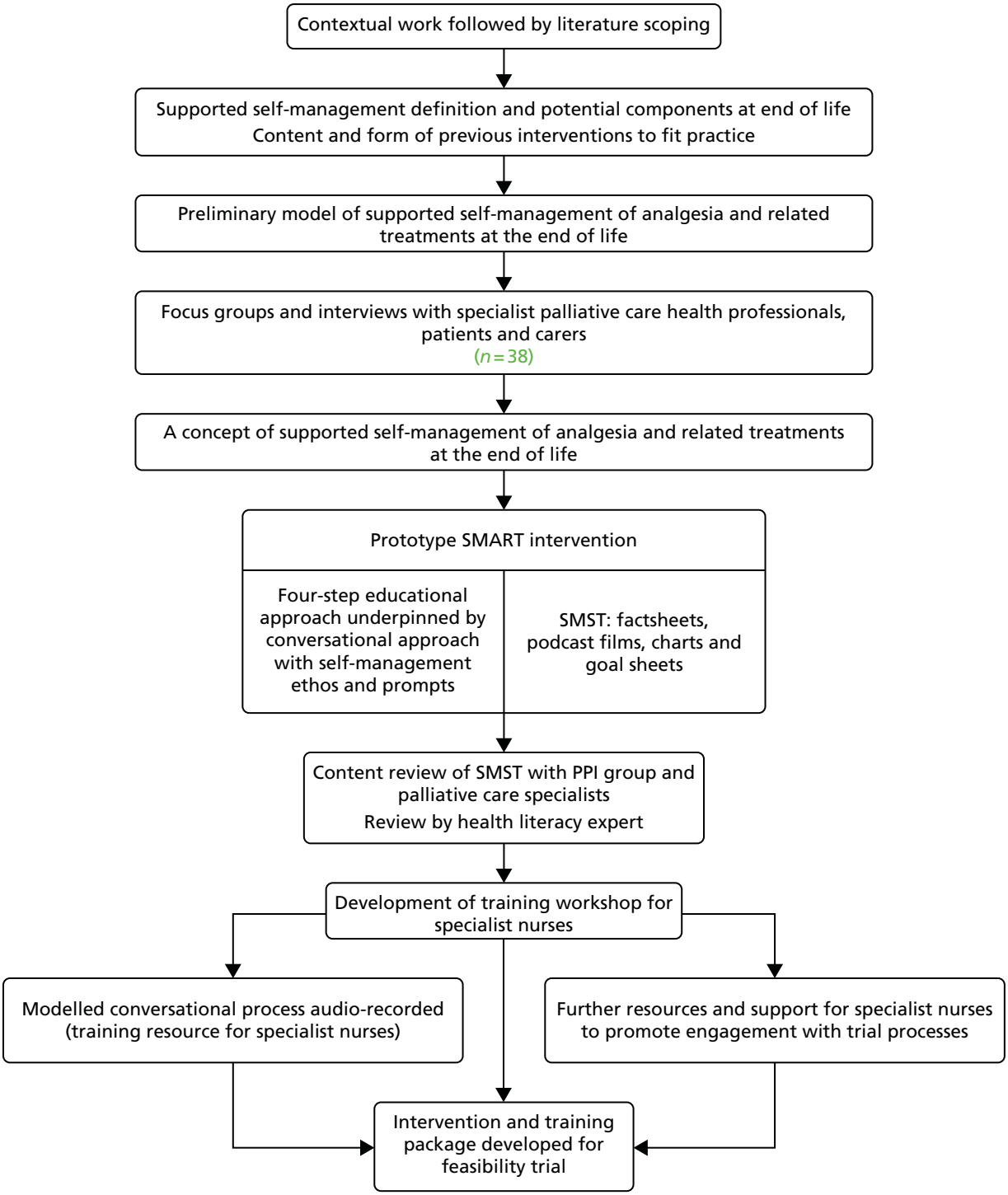

FIGURE 1 Intervention development process.

affected. This context was complicated by the surrounding 'swirl' of what individuals and their families were already striving to deal with, the wider context of psychological distress and high levels of carer strain. Individuals in this context could be struggling to cope with a palliative care diagnosis and there was anxiety and clinical depression of both patients and/or carers. Consequently, the capabilities of the patient and carer fluctuated greatly, influencing supportive self-management roles and the required behaviours of the specialist nurse.

TABLE 2 Intervention development interviews and focus groups sample

Patient and carer sample ($n = 19$)	HCP sample ($n = 19$)
Yorkshire	
1 focus group, $n = 4$ patients	1 focus group, $n = 4$ CNSs
	1 face-to-face interview, $n = 1$ consultant
Hampshire	
11 interviews, $n = 11$ patients, $n = 4$ carers	2 focus groups: $n = 10$, 9 CNSs + 1 specialist registrar; $n = 3$, 2 inpatient unit nurses, 1 lecturer/practitioner
	1 telephone interview, $n = 1$ lead nurse/commissioner
Overall total	
38 participants	

TABLE 3 Health-care professional demographics

Demographic characteristic	HCPs, n ($N = 19$)
Sex	
Female	18
Male	1
Professional background	
Nursing	17
Medicine	2
Main working environment	
Hospice inpatient	4
Hospice education	1
Community	10
Hospital	2
Community and day hospice	1
Hospital, hospice and community	1
Length of time in current post	
Years, mean (range)	7 (0.5–24)
Length of time in palliative care specialism	
Years, mean (range)	13 (1–27)

The concept is presented here as it is key to understanding the development and form of the intervention. The key components of the concept, the issues of responsibility and the supported self-management roles of the patient, carer and CNS are outlined. *Figure 2* is a diagrammatic representation of the concept.

Patient roles

Some study patients participated in managing their medicines almost entirely themselves; however, this was the experience of a small minority. Those who had nurse specialist input and/or a carer who played a role in supporting self-management enacted their own roles differently as a result, leading ultimately to a change in their resulting behaviours. This was the experience of the majority of the patient sample. The roles undertaken by patient participants are mapped to the roles to support self-management proposed by Johnston *et al.*[51] in *Table 5*.

TABLE 4 Patient and carer demographics

Demographic characteristic	Patients, *n* (*N* = 15)	Carers, *n* (*N* = 4)
Sex		
Female	7	4
Male	8	0
Age		
Years, mean (range)	66 (47–84)	69 (52–80)
Cancer site		
Bile duct	1	
Breast	1	
Colon	1	
Lung	4	
Lung (pleural mesothelioma)	1	
Oesophagus	1	
Pancreas	1	
Prostate	3	
Skin (melanoma)	1	
Uterus	1	
Educational level		
Degree level or above	4	2
Below degree level	6	2
No qualifications	5	

The patients often played an advocacy role on their own behalf, for example requesting alternative analgesics/opioids where they found the side effects unacceptable and they were unable to manage them. They also educated their carer, if they had one, regarding their medicines so that if their condition changed or they had a bad day then they could rely on them to safely administer their medications. This often took the form of listing their medications, creating a simple timetable of what they took and when and keeping this in a location within their home that could be easily referred to. This aided their communicator role whereby they transferred relevant information regarding their medicines, their effectiveness and their experience of side effects to HCPs [particularly general practitioners (GPs) and CNSs]. Those patients who were under the care of a community palliative care CNS often set joint plans/goals with their CNS, whereas others not under the care of a CNS made their own plans and goals and/or negotiated these with their GP (e.g. coming off a neuropathic agent because of unacceptable side effects).

In addition, the patients facilitated relationships with their HCPs and carers so as to aid access to their medicines. Patients worked at relationships with those who were key to managing their medicines and supporting their self-management: CNSs and GPs, as well as community pharmacists. They often found that knowing their pharmacist aided the supply and stocking of their medicines, resulting in them obtaining their medicines quickly and without delays in the system. At times, pharmacists put in repeat prescription requests for patients because of these relationships, meaning that the patient then just had to arrange to collect the medications from the pharmacy or could use pharmacy delivery services, when available.

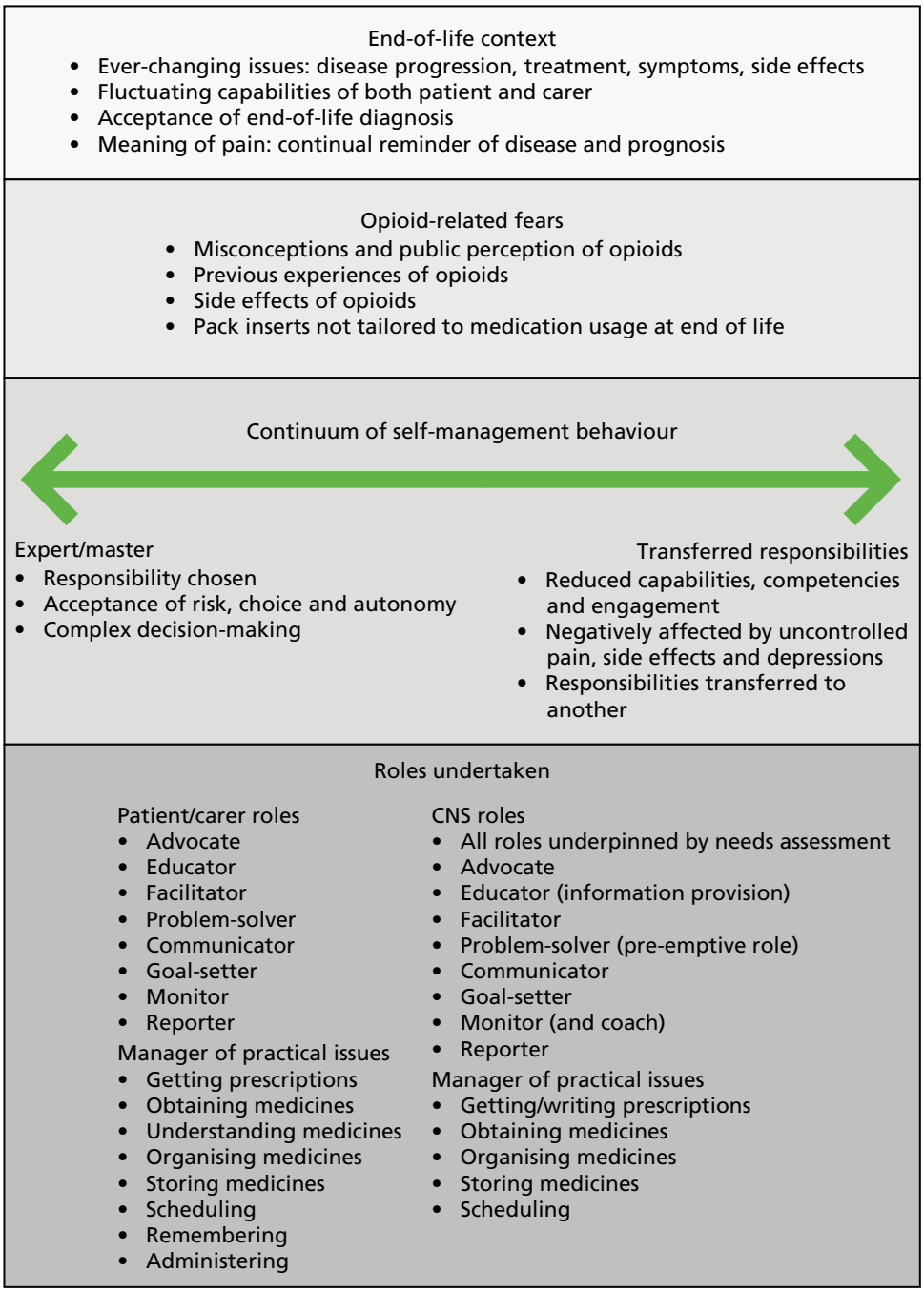

FIGURE 2 A concept of supported SMART.

The role of facilitating/managing the practical issues related to supply and medicine-taking was frequently an onerous one for patients. They had to get prescriptions, obtain the medicines, understand them once they had been dispensed, organise the medicines at home to keep track of them, store them, schedule them around their routine, remember to take them and, finally, actually administer them.

The patients played a problem-solving role navigating the difficulties in the medicines supply system. They also problem-solved the side effects of their opioids, making decisions to appropriately balance the benefits of pain control with a manageable level of side effects. This was an individual balance (e.g. titrating laxatives on a daily basis to offset the common side effect of constipation). Others for whom nausea was an issue titrated antiemetics on a daily basis. The side effect of drowsiness led some to delay doses or take smaller doses to minimise this. Furthermore, at times a small minority of expert self-managers made complex decisions regarding the dose of opioid to take when it was prescribed within a range.

TABLE 5 Roles undertaken by patient participants

Johnston *et al.*[51] roles to support self-management	Intervention development interview and focus group participants		
	Patients	Carers	CNSs
Advocate	For themselves (e.g. requesting alternative opioids/ forms if side effects are not acceptable)	Total advocacy role when needed	Right type and route of drug
Educator	Of carer if required, anticipation of future changes (i.e. planning for worsening condition)	Of patient and CNS when needed	Refining knowledge for individuals, providing instruction
Facilitator	Of relationships/access to medicines (e.g. GP, HCPs and carer, carer and community pharmacist)	Manager of the practical supply and medicine-taking issues when needed	Preparing for transitions, 'home feels like you have not got someone to speak to just around the corner'
Problem-solver	Access to medicines and navigating the supply system, side effects management and off-setting doses	Pre-emptive (e.g. regarding stock management or suggesting need for breakthrough analgesia)	Best drug and side effect profile for individual, sorting out when supplies get in a muddle, pre-emptive problem-solving ('always have a plan B')
Communicator	Of relevant information to all – family and HCPs	'Is it helping?' Encouraging discussion with patient	Picking style of communication for individual, knowing the family and patient (mediator as well as communicator)
Goal-setter	Self-planning, planning with a GP or joint planning with CNS	Often in relation to getting out and about (e.g. getting out of the house for a coffee, going to a favourite place)	Proposing options and allowing the individual to decide what they would prefer and putting a plan together
Monitor	Writing down of breakthrough doses and noting effectiveness	Diary recording	How much information has been understood? Monitoring involvement of patient in decisions and reviewing effectiveness of medicines
Reporter	Of relevant symptom experiences and side effects	Evaluation of the effectiveness of the medications	To wider palliative care team and GPs

The patients monitored their symptoms, side effects and the effectiveness of their medicines, often keeping their own records of this, particularly in relation to the administration of 'as required' doses for breakthrough pain. This was facilitated by the input of community palliative care CNSs or GPs, who prompted patients to consider how much were taking, when they were taking it and how they found it (H2HCPfocusgroup). As a result, the patients were often in a position to accurately report their relevant symptom and side effect experiences, and changes, to their HCPs.

Carer roles

The supportive self-management roles of the carer fluctuated in relation to changes in the competencies and engagement of the individual patient. However, a few patients had always handed over responsibility for medicines management to their carer: 'she just always did it . . . I tend to be . . . not worried enough about it you know. I basically need looking after that's the truth of the matter' (H1Pt004). The roles undertaken by carer participants are mapped to the roles to support self-management proposed by Johnston *et al.*[51] in *Table 5.*

Carers often took on an all-encompassing advocacy role for the patient, particularly when difficulties arose with challenging side effects or poorly controlled pain. Advocacy took the form of working or facilitating the supply system in relation to managing all the practical issues of getting prescriptions, obtaining the medicines, understanding the medicines, organising the medicines in the home environment to keep stock of them, storing them safely, scheduling them around the patient's routine, remembering (i.e. reminding the individual to take the medicines) and actually administering the medicines if required.

Facilitating and advocating on behalf of the patient in relation to obtaining the medicines was complex, onerous and a hugely time-consuming process for many carers. One patient outlined his difficulties (lengthy delays) in obtaining his fentanyl patches through a non-palliative care specialist pharmacy. This left his wife needing to make in-person visits to speak to the pharmacist on his behalf, only for her to be equally frustrated and leave the pharmacy without the patches, in tears, because she could not answer the question 'Who's prescribed these?':

> H2Pt004: *I'm not sure if it's the chemist . . . when I rang through and said 'Here look, what about these patches?' and the woman said 'What are they?' And then I said to her – and she said 'Yes, well we have got them down on the list, but I don't know where they are.' So in actual fact, on like that again . . .*
>
> Carer: *If you lived alone, somebody very elderly . . .*
>
> Researcher: *Yes, you need someone to work the system.*
>
> Carer: *Yes! Yes!*

As with the various roles of the patient and CNS, the carers' roles were complexly interwoven. The facilitator role for carers, as in the following example, was one of monitoring pain and the effectiveness of medicines via a pain diary. In turn, this facilitated the administration of analgesia by the carer to the patient, creating the end result of confidence and control over the situation:

> *. . . I would take an example actually it was quite difficult, as a facilitator it's not quite between health-care professionals and patient, it was actually between patient and carer. And it goes back to what we were saying earlier on about carers being reluctant to give it [morphine] or patients being reluctant to take it. And it's where a diary was very useful 'cos it actually empowered the carer to feel that she was doing something useful to help with her spouse's pain but also that she felt more in control that she wasn't giving it more often than she should do or she was writing that it had an effect or didn't have an effect and where they were going with it. And she was far happier to give it if she was documenting things than just on his say so that 'I'm in pain', and he was saying that 'I'm in pain and she won't give it to me' . . . She admitted she wasn't giving it because she was frightened she was going to be giving too much and how would she know when to stop and the diary actually facilitated being able to give [it], it was confidence . . .*
>
> *H1HCPfocusgroup*

Carers often played a monitoring role highlighting and watching for condition, symptom and side effect changes. Indeed, their monitoring was often astute because of the acuity of observation by someone who knew the patient best. As a result, carers could play an educator role of both the patient and CNS, highlighting these changes as required. This linked closely with their communicator and reporting role, as carers often aided the monitoring of the effectiveness of medicines by asking the patient simple questions such as 'Is it helping? Does that help?':

> *. . . And every so often, I say to you don't I? 'How are you on the laxatives?' And it seems ridiculous doesn't it, because . . . that's the best [thing] that's happened, is you've managed to get it [opioids vs. constipation] at a level which is not a problem for you haven't you . . . ?*
>
> *Carer-H2Pt004*

Consequently, the carers encouraged discussion with the patient and could report this information to HCPs, the CNS and GP as required.

The carers often took a lead in establishing small goals for the patient that they knew were of importance to the individual. With effective medicines and side effect management, goals frequently set were in relation to getting out of the house and continuing to visit favourite places for the individual.

The role of problem-solver was arguably the greatest of the roles played by the carer. In the words of one carer, 'I try and stop problems happening' (Carer-H2Pt004). As with the CNS problem-solving role, this was in the main pre-emptive carer role, resolving potential problems. This was particularly the case in terms of asking the individual about their pain, so as to be able to administer 'as required' analgesia. Carers also pre-emptively stock managed, requesting medicines before they ran out, and chased GP practices for prescriptions and pharmacies if medications had not been dispensed as requested (e.g. in a different form or were missing).

Clinical nurse specialist roles

In order to evaluate which roles were required, and at what point, the nurses assessed the competencies not only of the patient but also of the carer. The roles undertaken by the CNSs are mapped to the roles to support self-management proposed by Johnston *et al.*[51] in *Table 5*. It was recognised that nurses' provision of supportive self-management roles would fluctuate in relation to patient and carer needs and that at times the roles would be challenging:

> *. . . I think all of these [roles] will probably peak in difficulty, at times depending on the situation. As a professional, there could be a nightmare sometimes, in a person's home advocating for that patient, if . . . you have a family who have distinct feelings that are opposing the patient, that's really . . . difficult. The monitoring, there will be times when that, even on the inpatient unit, that's got to be a challenge at times, depending on the complexity of the patient, and the capacity of the staff, and staffing levels . . .*
>
> *H2HCPfocusgroup*

Within this challenging context, the nurses emphasised the importance of ensuring that the individual patient had the right drug via the right route. For them this was a clear role of advocacy:

> HCP1 (H2HCPfocusgroup): *I met a lady with head and neck cancer that was really compromising her mouth and she was just starting on opiates, thought patch that's going to be the best way to go . . . Spoke to the GP who said fine, then they changed their minds and went back to the tablets because someone in the practice had gone on a palliative care course and was told that MST [Morphine Sulfate Tablets modified release] it's cheap and cheerful start everyone on that. So then the relative rings up we've just gone to collect the patches and it's tablets so I'm like 'Oh god' ring up again, 'there is a reason why we said patches, I know they're expensive but she can't open her mouth'. So like ridiculous!*
>
> HCP2 (H2HCPfocusgroup): *It's about being that patient's advocate isn't it . . .*

The supportive communicator role was vital to the nurses and they emphasised the complexity of communicating well to 'the agenda of the patient' using language that would be understood, while highlighting 'what they need to know, because they might not be interested in all the things that you want to say' (H2HCPfocusgroup):

> *. . . I think you have to really pick your style of communication with each individual, this is what X was saying about knowing your family, knowing your patient, 'cos sometimes you are as much a mediator as communicator. We can sometimes have a relative that just simply doesn't believe in morphine . . . they will withhold it from them . . . And then others where they will perhaps give a little too much, then you have to sort of be kind in how you say these things, because they want to make it better . . . Yes, so communication is quite hard; you have to get that right, don't you . . . ?*
>
> *H2HCPfocusgroup*

All the supportive roles of the CNS interlinked and overlapped, particularly that of communicator and educator. This role of educator was viewed as one of providing 'instruction and information regarding medicines' (H2HCPfocusgroup). The ever-increasing role of the internet as a source of information for patients and their families was also recognised so that the supportive role of the nurses was often seen as one of helping to 'refine' this knowledge for individuals. The need to provide education for carers specifically was viewed as important, but it was argued that these supportive needs may not be met in practice:

> *. . . You get carers who the knowledge gap is so huge for them, they want to help they want to know what to do and we need to be filling that knowledge gap for them appropriately . . . I think for the carer what they want is the right information and we don't currently meet that need I don't think. We try . . .*
>
> *H1HCPfocusgroup*

In order to meet the informational needs of patients and their carers (within their educational role) the nurses recognised that a number of issues needed to be identified and then addressed. In summary, they were:

- the starting point, working out how the individual best learns and then tailoring the information to this; verbal information reinforced by written information (+ technological alternatives if possible) at the right pace, via stepwise provision
- identifying the types of pain and which medications are best suited to the types of pain for that individual
- outlining each medicine, what it is, what it's for and how to take it
- explaining the requirement to adjust medications on an ongoing basis and establishing this as baseline understanding; highlighting that there are always alternatives if pain is uncontrolled or side effects are viewed as intolerable
- informing on the side effects, the benefits versus the burdens and the likelihood of the individual experiencing them
- outlining the need for laxatives and working out the balance between opioid dosage and laxatives required for the individual
- discussing and revealing the individual's fears, challenging and correcting opioid-related preconceptions
- explaining the lack of dosing ceilings for opioids and being clear regarding the relative lack of required dosing intervals for 'as required' doses for breakthrough pain
- highlighting the importance of monitoring the effectiveness of the medications (especially in relation to the pain experience); the need to record breakthrough doses so that regular opioid doses can be increased/altered if required
- signposting the individual and carer to contacts for concerns/questions, outlining the most suitable contacts for specific situations that the individual may encounter.

Within their problem-solving role, the nurses sought to work out the best drugs and dosages with the most tolerable side effect profiles for the individual, recognising that this required fine tuning over time, often in conflict with the end-of-life context. The nurses also assisted the patients/carers with problem-solving in relation to the practical (supply and administration related) issues of getting prescriptions, obtaining the medicines, organising the medicines at home, storing the medicines safely and scheduling the medicines around their daily routines. For example:

> *. . . Getting prescriptions . . . we spend a lot of our time trying to sort that out, and you can understand how patients really struggle with [it]. I mean one chap . . . it has taken so many phone calls and so much of my time . . . a youngish intelligent chap and he has just really struggled with that. I think the other issue is sometimes they get 28 tablets and then you change them, then that knocks their whole sort of repeat prescription out of balance . . . When you're wanting dosette boxes as well they're really difficult, they've already started, then you're adding something in and changing them, to add bits in, that's really problematic . . .*
>
> *H1HCPfocusgroup*

This could be a time-consuming role for nurses as medication supplies got 'out of sync' for patients with any prescription alteration. For example, increases in dosage meant that supplies lasted for shorter periods and ran out in advance of supplies of other medications.

The problem-solving role was often implemented in a pre-emptive way. This was referred to as 'mind-reading' or being 'a problem-solver in advance', which necessitated always having 'a plan B' (such as knowing who to contact or consideration and education of the individual patient in relation to potential crisis episodes, e.g. chest inflections or bowel obstruction):

> *. . . You're anticipating, you're pre-empting what might happen to be able to talk it through with that patient and to that carer to be able to give them you know a toolkit of who to ring, when to ring and why they might ring. How to deal with the uncertainties of do I ring now, do I ring later, but the security of knowing that there is somebody to ring . . .*
>
> *H1HCPfocusgroup*

The professional participants stressed the imperativeness of this pre-emptive problem-solving role and the fact that it mirrored the wider requirements of end-of-life care in general:

> *. . . The notion of the discussion about symptom control and analgesia and medicine things, the pre-emptive nature of it links in with the much bigger picture, doesn't it, I think of palliative and end of life care now. The fact that all of it is about pre-empting and pre-planning, advance care planning, you know the Gold Standard Framework; getting people on a register and pre-empting their kind of deterioration, all of those things. It mirrors in a more distilled way the bigger picture of things . . .*
>
> *H2HCPfocusgroup*

Indeed, part of the pre-emptive problem-solving role within the context of end of life was the requirement to prepare individuals and their carers for transition not only in terms of deterioration of condition, but also in terms of transition between care settings, frequently between inpatient units/hospices and home. This could also be seen as integral to the role of facilitator, whereby the nurses prepared the patients and their carers for these transitions by enabling them to use inpatient stays 'like a pit-stop' where they could initiate, develop or refine their information and knowledge of medication management. For example:

> *. . . So part of it before they go home is about talking through what our rationale has been for their medicines and what type of pain we're looking at to take for certain things. What we'll have on the discharge sheet that goes with them, there's like a medication chart of what their drugs are and why they take them, when they take them but you can be a little bit more distinct can't we on the type of pains so they've got some slight signpost, as to what to take, where when and how . . .*
>
> *H1HCPfocusgroup*

Another professional role was that of goal-setting. This was often about proposing different options to the patient in relation to their medicines management, allowing the individual to decide between the proposed courses of action and then putting a joint plan together based on the individual's preferences. These plans were then relayed and discussed with the wider palliative care team and GPs as needed (to support medication changes) under the role of reporter. Furthermore, the CNS role of monitor intermeshed in practice with the role of goal-setter (involvement in decision-making and shared responsibility where possible). The nurses continually monitored 'how much the patient has understood':

> *. . . Whatever you do, if you are setting goals if you are solving a problem, or if you are educating, whatever you are doing you have to check that . . . the message has arrived . . .*
>
> *H2HCPfocusgroup*

. . . In terms of monitoring as well I think it's about involving the patient in those decisions isn't it so you know having given them some education actually when you're reviewing things you know saying to them so are you happy then that we're still on the same dose for now, you know they've got that involvement in that haven't they, it's like an agreed shared sort of responsibility . . .

H1HCPfocusgroup

The monitoring role was seen as an imperative professional responsibility, particularly when starting individuals on new medications. The nurses also emphasised the value of face-to-face monitoring in the context of end of life. In the words of one:

. . . You can see people's responses, you can work with them at their timing to answer questions. I mean one gentleman I went into, I talked to him about his medication, and reading his bottles, and actually I discovered he couldn't read. And it was something as basic as that, making sure that . . . I then put symbols on there that he felt represented like his water tablet, I put a droplet of water on a little label on his bottle. So I think it's a blended approach really, you know, just to phone them up, say 'How are you doing?' and if you sense that this is not going . . . The things you are listening to aren't representative of somebody managing, then you actually go back and reassess them face to face; there is nothing quite like eyeballing a patient . . . !

HCPW001

The continuum of self-management behaviours

The patient, carer and CNS roles outlined above were enacted on a far-reaching continuum. This continuum of behaviours ranged from, at one end, expertise and mastery, with the individual taking full responsibility for complex decision-making, accepting the associated risks, to, at the other end, transfer of responsibility to another (the carer and/or CNS) because of patients' and carers' reduced capabilities and engagement in self-management behaviours, sometimes negatively affected by uncontrolled pain, the side effects of opioids (particularly drowsiness), clinical depression and memory loss:

HCP1 (H2HCPfocusgroup): *I've seen both sorts . . . Obviously this is reflecting a distinct change in the type of patient we are seeing as well. I would say the younger ones coming along are becoming masters; they are gaining information from the internet, using every resource they have; they are thinking outside of pure medication as being an option for their pain control, and yes, I have seen . . . I can think now in my mind's eye of a 'master'. But prior to when I began in Hospice care, everybody needed to be told, and there remains a little group of people, usually in the older age groups that still need that and actually feel quite burdened by being expected to choose, and make decisions.*

HCP2 (H2HCPfocusgroup): *Very much so. There is a shift in people's tendency. Before it was 'You decide, you are the expert', now it is 'Wait a moment, I am the expert of my body and my health, so I . . . give me the knowledge, give me the information so that I can make an informed decision'.*

Researcher (H2HCPfocusgroup): *Is it something that you negotiate with patients, whether you expect them to self-manage and master all these things? Or is it something that is sort of tacitly understood?*

HCP1 (H2HCPfocusgroup): *. . . You can tell, straight away when you start talking to them about what they understand and what they want from us; that comes across very quickly, which group they are going to fall into . . .*

All study participants highlighted the individual-level variation in the range of self-management behaviours enacted:

> *. . . You'll get some who don't want anything to do with their medicines and you sort it out and then people that want to know everything will want to do their own as much as they can . . .*
>
> *H1HCPfocusgroup*

Those patients who, when discussing the role they played in managing their medicines, reported feeling in control, often referred to how relatively 'lucky' they were in terms of being able to 'think about it and work it out'. These individuals at one end of the continuum had accepted full responsibility for their role and were in their eyes 'doing it all' themselves, but with backup strategies in place and knowledge of whom to contact if anything changed.

The HCPs often spoke about those individuals at polar ends of the continuum but there was also wide variation in behaviours and choices made by those individuals who were not at either end of the continuum. Indeed, behaviours and choices were never static, but ever changing. In addition, there was wide variation within the group of individuals assessed by their HCPs as 'self-managing' of their analgesia and related treatments. For example, one professional discussed a patient who was managing his medications, but without the adjustments that she ideally would have recommended:

> *. . . A man that's really angry and frustrated, he's young but he was diagnosed late. He's had lots of frustrations with chemo, and things like that. So he's quite resistant to changes, and that's fine, so we've just left him [medication wise] as he is; he's not managed quite properly, not adequately in our eyes, but he is doing what he wants to do at the moment, so he's doing it . . .*
>
> *H4HCPfocusgroup*

Where does the responsibility lie?

The competencies and engagement of the individual, and their acceptance of responsibility, affected their enactment of self-management behaviours and, thus, the roles required of the carer and CNS. The CNSs recognised the importance of assessing the individual's ability to understand, their capabilities and their potential engagement (what the individual was currently doing and what they would like to do):

> HCP1 (H4HCPfocusgroup): *. . . Asking them to go to through their medicines, some people haven't got a clue, and other people don't even need to get the boxes or list out and they can tell you absolutely everything they've had, and they've got lists and the diary, and it all written down. And other people haven't got a clue.*

> HCP2 (H4HCPfocusgroup): *As well as trying to establish what level of understanding they've got, you are using that information about how much they have engaged with their medicines and things to try and determine the scope for them to self-manage . . .*

For the nurses, it was about recognising that individuals make their own analgesia-related choices within their home environments and that their autonomy to do so should be respected:

> *. . . I always say that it's their pain and it's up to them how they choose to manage it we can give them the medications or the tools but you know ultimately if they're happy to live with a certain level of pain, they don't want to use their medications, that's their choice we're there just to give them and advise them how to use things but ultimately it's up to them . . .*
>
> *H1HCPfocusgroup*

Indeed, some patients made deliberate decisions to withhold or reduce doses of opioids to offset the side effects that they were experiencing. These decisions were about balancing pain control against the things that they wished to achieve:

> *. . . So if I've got pain, sometimes I won't have that [oxycodone immediate-release formulation; OxyNorm, NAPP Pharmaceuticals], and I choose not to, because I don't want to get tired and sleepy as I want to drive, or I want to do something, so I'll manage it in a different way, not necessarily by taking drugs . . .*
>
> *H3Ptfocusgroup*

The context of end of life

The overarching context of end of life had a profound influence on the supportive self-management behaviours of the patient, carer and CNS. Within this context, there were ever-changing issues related to continual disease progression and subsequent changes in symptoms and side effects from both medication and palliative treatments. As a result, the behaviours were ever changing.

This context was further complicated at the end of life by the surrounding swirl of what individuals and their families were already striving to deal with (the wider context), and of psychological distress and anxiety as well as high levels of carer strain. Thus, individuals in this context may be struggling to cope with a palliative care diagnosis and there may be anxiety and potential clinical depression of both patients and/or carers. As a result, the capabilities of both the patient and carer fluctuated greatly, influencing the supportive self-management roles and the required behaviours of the CNS in particular.

Opioid-related fears

The data demonstrated that patients' and carers' behaviours in relation to opioid management were strongly affected by misconceptions and common public perceptions of these medicines. It was commonplace for patients and their carers to hold fears or assumptions regarding opioids:

- fear that the individual taking them will become addicted to these medicines, 'you hear of so many people get[ting] addicted to certain things' (H1Pt004)
- assumption that there is a ceiling dose for opioids as with other medicines
- fear of overdosing, even by taking just one extra dose
- fear that these medicines are 'killers' because of press accounts of abuse of opioids (H2HCPfocusgroup)
- assumption that the individual will develop a tolerance to the opioids and the pain will therefore not be controlled as a result
- fear that death of the individual is imminent if they are started on opioids [i.e. 'I'm dying' (H1HCPfocusgroup)]
- fear that if the individual takes these medicines now then there is 'nothing later' for them to take in the future 'so I'll avoid it if I can' (H1HCPfocusgroup).

These fears and assumptions affected the self-management behaviours of patients. This was clearly articulated by one focus group participant who required a hospice admission as a result:

> *. . . My self-management wasn't terribly good, that's why I ended up in here [the hospice] in the first place. But it wasn't to do with side effects, because I don't actually suffer particularly bad side effects. It's more to do with the psychological attitude that I was taking morphine, and that I didn't want to over-take and the doctors kept saying to me 'No we are giving you such small doses you can self-medicate, you can up this to 5 mls, etc.'. So it was getting my head around that, because I've spent a lifetime of being the sort of person that just carries on; never go to the doctors, that's why I ended up here! You know, I've never been one to take a lot of painkillers, and now I'm sitting here, I've got*

> *lower back pain, and I could do with some morphine! But I just thought 'Oooh, I'll just wait till after this study [focus group]', that's the sort of person I am. So it's been sort of, just 'cos I'm strong, a Yorkshire woman that doesn't like to admit failure or weakness, I think that's been the main issue with me . . . At the time I was taking . . . morphine, and it was for pain relief. And I had the slow release, and that was OK, every 12 hours. And then if I needed to have the little extra, you know, I was the same as the other ladies, 'Oh I don't think I'll be taking any of that!' you know. Until somebody did once say to me one day 'You know you are on a very low dose you know', and I thought 'Ooooh! How dare you!' I thought I was a hard drug taker!*
>
> *H3Ptfocusgroup*

The HCP also highlighted that carer-held fears could be projected onto the patient, negatively affecting self-management behaviours:

> *. . . sometimes the fears of the relatives project on to the patient. The patient might start out all right, and then the minute they say to their nearest and dearest, or the next door neighbour 'I'm on this now' and then they just get all these horror stories, and then you've got that to kind of circumvent as well. So you know, it's never black and white . . .*
>
> *H4HCPfocusgroup*

Arguably, the most common fears related to opioid usage were not the ones referred to above, but were related to the side effects of the medicines themselves:

> *. . . I think probably the greatest fears are not so much the addiction but sedation or constipation and again it's a reluctance, 'I won't take it unless I need to 'cos I don't want those effects' . . .*
>
> *H1HCPfocusgroup*

Patients referred to being reluctant to take opioids for fear of both constipation and drowsiness. The fear of constipation and the subsequent difficulties in balancing doses of laxatives with opioid intake was particularly troublesome for some. A number of the sample had accounts of faecal impaction requiring admissions; as a result, the fear of constipation was profound:

> *My main concern is that if I get some pain, I take extra morphine. I'm on a patch at the moment, so if I change the dose of the morphine, I have to change the dose that I take of the laxative. And of course, the first time 'oh yeah, OK, let's bang it up by another one of the sachets'. And of course I was then for the next 2 days on the loo! So 'oh let's cut it down', by which time 'Oh god I haven't been to the loo now for 2 days!'*
>
> *H2Pt004*

> *I've never before seen people so frightened of constipation, as he has been.*
>
> *Carer*

The SMART intervention

The development process and resulting conceptual work described above generated the SMART intervention that comprised both a four-step educational approach and a SMST. The intervention was designed to be delivered via a feasibility study to patients by community-based palliative care CNSs. The approach to delivery involved nesting the intervention in a clinical encounter (nurse–patient consultation) and was enacted through a conversational process.

The four-step educational approach

The four-step educational approach was maintained from the study protocol, with data confirming that such an approach was an appropriate way to proceed. Our contextual work had identified that needs assessment, information provision and regular review were important components of a supported self-management intervention that would potentially fit well into nurses' usual practice processes. Goal-setting (with associated action plans) was proposed following expert educational psychologist input (SM) as the mechanism by which information provision could lead to behaviour change. In addition, a meta-review of self-management interventions for long-term conditions identified that action plans for deteriorating conditions were a key component of successful interventions.[21] The approach was designed to sit alongside the everyday practice of specialist nurses, with four cyclical steps to occur at each nurse–patient visit.

Step 1: needs assessment

A detailed assessment of patients' needs is part of usual specialist practice and was intended to take place at all SMART study nurse visits between the CNS and patient. The CNSs were to identify specific concerns and needs related to self-managing opioid medicines at home, such as:

- fears and concerns related to taking opioids and their side effects
- self-management capabilities and issues preventing supported self-management of opioids at home (e.g. getting prescriptions and obtaining medicines or dealing with breakthrough pain)
- relevant contact information for further advice and information.

Step 2: information provision

Verbal information reinforced by the provision of SMST resources. Following needs assessment, the CNSs were to discuss any issues raised and use the SMST to provide tailored, staged and relevant educational materials via the study resources (outlined below).

Step 3: goal-setting

Development of a self-management focused action plan. The third step aimed to guide patients towards developing self-management focused goals at each visit. CNSs were to help patients identify goals that were achievable through a set of actions that could be reviewed and modified at each visit.

Step 4: review and coaching

Review of the action plan and provision of support. The intent was for the trial CNSs to review patients' self-management capabilities and progress at each visit and provide coaching and support to develop, maintain and improve self-management behaviour. This was planned to involve the reviewing of self-management goals and the evaluation of action plans. Nurses were also to focus on identifying barriers for individuals to meet self-management goals or steps in their action plans, suitable supported self-management strategies for the trial patient and/or carer and problem-solving techniques. Follow-up and reinforcement of information and self-management strategies were planned to reflect usual patterns of and forms of contact and review (i.e. face to face and via telephone).

The self-management support toolkit

The evidence from the data was mapped to components of the intervention (both the educational approach and proposed SMST resources), resulting in the framework outlined in *Table 6*. The framework also linked the intervention components to the target participant understanding and behaviour in relation to self-management, including the behaviour source,[39] the target supportive self-management roles of the specialist nurse,[51] the self-efficacy techniques to be used by the nurse[54,55] and the intervention function,[39] and served to ensure a theoretically modelled intervention.

TABLE 6 Data mapping to intervention components and scope of toolkit resources

Target participant understanding/behaviour	Target professional self-management role[a]	Self-efficacy technique[b]	Intervention component	Evidence from the data	Target construct (behaviour source)[c]	Intervention function[d]
Willingness to self-manage opioids and side effects	1, 2, 3	Verbal persuasion	Recruitment and consent process pre-intervention delivery; educational approach	Majority see it as part of their responsibility: *you've got to look after yourself quite a bit, and then know who to turn to if you can't find the answer*	Capability; motivation	Education; persuasion
Shared understanding of side effects	2, 5	Mastery experience	Educational approach; factsheet	Importance of acknowledgement. Need for 'normalisation' to reduce fear. For patients, opioid drowsiness not always perceived as diminishing. Prescription of laxatives but 'they never said you will need it'. Lack of focus on opioid nausea and drowsiness by HCPs	Motivation	Education
Self-titration to negate side effects (drowsiness and constipation)	2, 4, 5, 6	Verbal persuasion; mastery experience; role modelling	Educational approach; factsheet	Unmet need. Patients learn this through trial and error, accounts of 'crisis' situations with impaction, underdosing to control drowsiness	Capability	Training; incentivisation; enablement
Misconceptions and unnecessary fears regarding opioids	2, 5	Verbal persuasion; mastery experience; emotional regulation	Educational approach; factsheet	Issues: holding back on medications (e.g. stock piling for a rainy day); ceiling amount and as needed 4-hourly dose; 'I'm imminently dying'; addiction; tolerance	Motivation	Education; persuasion; enablement
Safe drug administration: control of what taking, why and when (+ safe storage and not removing medicines from boxes)	2, 3, 5, 7, 8	Verbal persuasion; mastery experience; role modelling	Information chart (what, when, rationale, appearance); dosette box if required; podcast – patient	Some unmet needs here: some 'muddled' patients not always aware of drug names or purpose; using pet names for drugs, etc.; confusion over millilitres vs. milligrams; literacy level; need for removal of 'old' drugs; information chart would be helpful for carers too	Capability	Education; training; modelling; enablement
Recognition of pain patterns	2, 4, 5, 7	Verbal persuasion; mastery experience	Educational approach; factsheet; pain diary	Importance in order to control pain	Capability; motivation	Education; persuasion; incentivisation; training

continued

TABLE 6 Data mapping to intervention components and scope of toolkit resources (*continued*)

Target participant understanding/behaviour	Target professional self-management role[a]	Self-efficacy technique[b]	Intervention component	Evidence from the data	Target construct (behaviour source)[c]	Intervention function[d]
Monitoring the effectiveness of the medicines	2, 3, 4, 5, 6, 7, 8	Verbal persuasion; mastery experience; role modelling	Educational approach; factsheet; pain and side effect diary; podcast – HCPs	Importance for HCPs to be able to goal-set and manage symptoms effectively, shared responsibility with patient	Capability; motivation	Education; persuasion; incentivisation; training; modelling; enablement
Control over practical issues: checking stock, ordering, collecting, etc.	1, 2, 3, 4, 5	Verbal persuasion; mastery experience; role modelling	Factsheet; podcast – patient	Practical issues can be onerous, sapping energy unnecessarily (physical journeys, lack of syncing of supplies, etc.)	Capability; motivation; opportunity – physical	Education; incentivisation; modelling; enablement
Checking of dispensed medicines	2, 7, 8	Verbal persuasion; mastery experience	Educational approach factsheet	Not always right: supplies may be missing or not in correct form. Use community pharmacist as resource	Capability; motivation	Education; persuasion; training
Back up plans: knowledge of who to contact, when, plus out of hours	1, 2, 3, 4	Verbal persuasion; mastery experience	Educational approach; factsheet	Key message in patient/carer data – unmet needs	Motivation	Education; enablement
Understanding of initial verbal information giving reinforced by additional resources	2, 3, 5	Verbal persuasion; mastery experience; role modelling	Factsheets; podcasts; list of good websites, signpost where to go	Patients and/or carers 'bombarded' with information. Recognition that where information is given in it is not always taken in and that it needs to be reinforced by other resources	Capability; motivation	Education; training; modelling; enablement

a 1, advocate; 2, educator; 3, facilitator; 4, problem-solver; 5, communicator; 6, goal-setter; 7, monitor; 8, reporter.[51]
b Self-efficacy technique: mastery experience, role modelling, verbal persuasion and the regulation of physiological and affective states.[54,55]
c Target construct (behaviour source): capability (physical and psychological), motivation (automatic and reflective), opportunity (social and physical).[39]
d Intervention functions: education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring, restrictions.[39]

As a result of this framework, the SMST resources were developed to address the evidence from the data. The resources comprised eight factsheets, two podcasts, a pain diary, medication charts and goal-setting sheets. The factsheets were drafted to encompass all the core themes and issues outlined by the patients, carers and palliative care HCPs. They went through iterative cycles in the development process. The study PPI group was asked to review the content of all the factsheets, as were specialist HCPs from two different palliative care teams who were not going to be involved in the feasibility study (in order to prevent potential issues of bias and/or contamination). The final stage of development was review of the factsheets by an expert in health literacy (HB). The presentation and structure of the facts were recast with reference to the evidence on how people make sense of illness and decisions about treatment.[63,64] Factsheet content did not change, but readability was improved (assessed using Simple Measure of Gobbledygook readability formula[65]) by shortening sentences and eliminating some longer words (except drug names). The text was subdivided in all the factsheets into small titled sections to facilitate review by patients, with spaces provided for patients and carers to write notes or questions. These changes improved the factsheets' health literacy and utility to support patients' reasoning about treatment in the context of their experience of illness and lifestyle.

The factsheets

1. Managing pain with opioid medicines.
2. Contacts for advice and further information.
3. Getting prescriptions and obtaining medicines.
4. Organising opioid medicines.
5. Fitting pain control into my daily routine.
6. Checking opioid medicines are managing pain.
7. Common concerns when taking opioid medicines.
8. Keeping on top of side effects.

The eight factsheets are reproduced in *Appendix 9*. Each factsheet was designed to be used as a standalone educational resource or in combination to provide a set of educational materials relevant to the trial patient. Only factsheet 2 (contacts for advice and further information) was a core factsheet resource that the CNSs were asked to deliver to the respective trial patient on their first SMART visit.

The podcast films

The data demonstrated that individuals value resources being available in various forms to meet individual need. Therefore, two audio-visual podcasts were developed as an alternative medium:

- 'The Practical Issues of Managing Medicines' – when a patient described the practical methods (self-management strategies) they used to monitor their medication stock levels, order new medicines and organise them at home.
- 'Monitoring the Effectiveness of Medicines' – two experienced palliative care specialists discussed why monitoring the effectiveness of medicines is valuable in relation to self-management and why specialists may ask individuals to do this.

Structured guides (see *Appendices 10* and *11*) were written from the data to guide filming and the films were edited to produce two short 5- to 6-minute podcasts. This length of the podcast files was guided by the data, which suggested that patients and carers would watch short films and could benefit from them. Furthermore, it is known from existing resources (such as www.healthtalk.org/) that there is value that patients place in hearing authentic voices recounting their experiences and strategies in dealing with health-related issues and problems. Even when strategies are not ones that individual patients are likely to use themselves, it can help them to consider alternative strategies that might work for them. The podcasts were designed to be delivered to patients on a digital versatile disc (DVD) or memory stick (for computer use).

The pain diary and medication chart

In order to develop versions of a pain diary and medication chart to suit this specific context, existing medication charts and pain diaries used at the sites were requested and reviewed. In addition, a selection were sampled from online sources (e.g. professional-focused medication administration records) and patient-focused booklets (e.g. those produced by Macmillan Cancer Support). Two resource charts resulted in:

1. a pain diary to record and track pain which could be used by the patient (and their CNS) to monitor the effects of opioid medication and any side effects (see *Appendix 12*)
2. a medication chart which could be used to help patients organise, remember and take their medicines (see *Appendix 13*).

The goal-setting sheets

The final SMST resources, self-management-focused goal-setting sheets, were developed in consultation with an expert educational psychologist (SM). They were entitled 'Things I would like to achieve over the next week' (see *Appendix 14*) and were the second of two core resources of the SMST (the first being the 'Contacts for advice and further information' factsheet). The sheets were designed so that a trial patient could set one or two key goals at each visit and then with the help of their CNS set an action plan with small, practical steps to meet the goals. At the bottom of each sheet was space for the patient to review with their CNS the progress, or otherwise, that had been made in meeting the goals so as to inform development of the action plan where needed.

Training development

A training package was developed prior to the feasibility study to enable the study nurses to deliver the intervention. The training package was developed from the following:

1. A philosophical standpoint and definition of self-management at the end of life derived from our developing conceptual analysis (*Evidence synthesis* and *Phase II: refining and detailing the intervention*) and drawn from the work of Johnston *et al.*[51]
2. To date, there has been a lack of specification in the literature about how self-management focused conversations regarding analgesia and related treatments at end of life should be enacted – it is not known what practitioners do and need to do to help support patients to self-manage. To illustrate the nature of a conversation in this context, a conversation was modelled using ethno-drama from a real-life case exemplar, by nurse educators for Masters students attending a module on cancer, palliative and end of life care.
3. Literature focused on the self-management of long-term conditions, such as systematic reviews and practice guidelines (e.g. Canadian practice guidelines on self-management in chronic care[66]), which emphasises the importance of action-planning was also used to inform the training development, as were the delivery strategies of similar educational interventions by specialist nurses as part of complex intervention studies.[67]
4. An awareness that those delivering the intervention would be both self-selecting and palliative care nurses specialists with pre-existing expertise and skills.

The research team built on the four-step educational approach of needs assessment, information giving, goal-setting and review and coaching to develop a training approach that modelled the four steps within a therapeutic conversational process between the specialist nurse and patient. The educational approach and conversational process were underpinned by recognition of the importance of:

- good communication skills, identifying concerns, clarifying and exploring
- not imposing solutions to professionally identified problems and being open to all patient-identified concerns
- agreeing realistic goals and action plans and reviewing these at each visit – noting detail on whether or not the action plan was followed and the patient's ability to carry out the plan.

A bespoke training package resulted, comprising a workshop session, combined with additional resources for the study research fellows to deploy with the nurses over the course of the trial to reinforce nurses' engagement in the study and support their delivery of the intervention. Further details regarding the training package are given in *Chapter 3, SMART intervention*.

Conclusion

The work presented in this chapter was undertaken to define the concept of supported self-management at the end of life and to develop the theoretical underpinning for the content of the intervention. This work provided a basis on which to develop and refine the content of the intervention through interviews and focus groups with patients, carers and HCPs. The findings from these activities resulted in the development of a theoretically informed behaviour change intervention to enable study nurses to deliver the intervention. We had planned to embed the principles of experience-based co-design within this phase of the work, and to a large extent this was achieved. However, the constraints on working with a population of very sick people meant that we used an iterative process and, where possible, sought views and involvement in a number of different ways. In summary, the development process resulted in the SMART intervention comprising a four-step educational approach and SMST, both of which are summarised in *Box 3*. The intervention was to be delivered to the individual patient by their community-based palliative care CNS using a conversational process, within the context of a clinical consultation. Mechanisms of impact through which the SMART intervention is hypothesised to lead to a medicines self-management behaviour change are summarised in a logic model (*Table 7*).

BOX 3 The SMART intervention

The four-step educational approach

(1) Needs assessment

Assess beliefs, behaviour and knowledge related to pain and pain medicines.

(2) Information provision

Provide specific information (discuss content of appropriate factsheets + podcasts).

Provide 'contacts for advice' factsheet at first visit.

(3) Goal-setting

Collaboratively set goals based on the patient's needs (complete 'things I would like to achieve . . .' at each visit).

Complete 'what I will do to help get me there' to enable the goals to be met (small practical steps).

(4) Review and coaching

Plan follow-up (face-to-face visits and telephone calls).

Identify barriers, strategies, problem-solving techniques and support.

BOX 3 The SMART intervention (*continued*)

The SMST

Factsheets

- Managing pain with opioid medicines.
- Common concerns when taking opioid medicines.
- Keeping on top of side effects.
- Checking opioid medicines are managing pain.
- Getting prescriptions and obtaining medicines.
- Organising opioid medicines.
- Fitting pain control into my daily routine.
- Contacts for advice and further information.[a]

Charts

- Pain diary.
- Medication chart.

Podcast films

- Monitoring the effectiveness of medicines.
- The practical issues of managing medicines.

Goal-setting

- Goal-setting sheets.[a]

a Core SMST resources that every patient received.

TABLE 7 The SMART logic model of process evaluation of the SMART intervention

Problem	Opportunity	Intervention description	Implementation	Mechanisms of impact	Outcomes of individual elements of the intervention	Outcomes of the overall intervention
Enhanced supported decision-making can improve overall quality of end-of-life care. People living with advanced disease often experience fluctuating symptoms that require complex medication regimens. Supporting self-management could help patients and their family to manage their medications to improve pain and related symptoms	Development of a SMST that will be delivered by nurses, designed to help patients improve their knowledge, skills and confidence to manage medicines for pain, constipation, nausea and drowsiness	Four-step supported self-management process *Step 1, needs assessment* – identify current medicines management behaviours, beliefs, knowledge of pain medicines *Step 2, information provision* – tailored information specific to identified concerns which will positively alter behaviour, address beliefs *Step 3, setting self-management goals* – realistic and achievable plan that responds to concerns and has potential to improve pain management *Step 4, regular review* – set a date to review the action plan and provide additional information and coaching	*Nurse delivery:* the four-step educational approach will be delivered by specialist palliative care nurses working with community-based patients over a minimum of three sessions. The first session should be within 1 week of baseline data collection. Study nurses will assess self-management needs, provide tailored information and plan pain management goals (steps 1–3). Over the 6-week follow-up study, nurses will provide at least two additional follow-up meetings to review self-management needs, provide additional educational resources and review success with goals (step 4) *Nurse training to deliver the intervention:* study nurses will attend a half-day training workshop that will cover concepts and key features of self-management; the components of the intervention and the conversational process; who will use the educational resources with patients; worked-examples and practice using resources with patients; ongoing support (peer-to-peer support and support from research fellows)	1. *Needs assessment:* prioritisation of needs that are most important to the patient and, therefore, most likely to motivate engagement with intervention, 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 assessment may also include a discussion on barriers and fears about self-management and prioritising symptoms to self-manage 2. *Educational materials:* this information will present benefits and burdens of medications in verbal, written and audio-visual (podcast) 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. Specific information on obtaining and managing medicines, allaying fears and concerns about opioids, how to get help	Clearly identified needs and improved patient and carer engagement in self-management via increased knowledge of obtaining and managing medicines and how to access support. Clearly identified action plans to support goal achievement. Patients 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 health-care system	Reduced pain intensity and reduced interference from pain in daily activities. Reduced need for out-of-hours support. Improved quality of life and self-efficacy

continued

TABLE 7 The SMART logic model of process evaluation of the SMART intervention (*continued*)

Problem	Opportunity	Intervention description	Implementation	Mechanisms of impact	Outcomes of individual elements of the intervention	Outcomes of the overall intervention
			Resources to support nurse training: nurses will also receive the following resources to support the training: a diagrammatic representation of the four-step SMART intervention; the definition of self-management in palliative care and related professional roles; self-management conversational prompts to use with patients; an audio-recording of a modelled self-management conversation; summary sheet for making action plans with patients *Ongoing support for duration of trial:* to support the study nurses throughout the trial, the research fellows will meet with them regularly (approximately once a week) to support them to provide the intervention to their patients	3. *Goal-setting:* actions agreed with patient that are realistic and achievable and linked to needs assessment. Identify and record the self-management tasks that are required with patient and carer. Support patients to develop their self-management action plan by balancing their values and preferences with the requirements of medication management alongside the possible side effects. 4. *Regular review:* sustaining behavioural change, adapting goals, monitoring progress; enhance the patient's capacity to monitor and reflect on their actions and understand what is required of them to fulfil this role and receive support from a professional		

Note
Patients living at home (with or without a carer) wishing to be more confident in self-management of medicines for pain, constipation, nausea and drowsiness. Patients and carers living with fears about opioids (side effects of these medications) and the symbolism of opioids meaning a rapid and painful decline towards death. Patients experience fluctuating symptom burden that can be unpredictable. Patients and carers dealing with multiple health-care systems – they do not experience a joined-up service where everyone knows about their situation and needs.

Chapter 3 A feasibility study assessing the SMART intervention and trial processes

Introduction

This chapter focuses on Phase III of the SMART study: the feasibility study. As outlined in *Chapter 2*, *The SMART intervention*, the SMART intervention is designed to support self-management of analgesia and related treatments for patients approaching the end of life. It was developed with HCPs, patients and carers to distil best practice, and reviewed by our dedicated PPI panel.

Aim and objectives

The aim of the feasibility study was to assess both the feasibility of undertaking a definitive RCT and the acceptability of the SMART intervention. This aim was achieved by collecting data on the following specific objectives:

- patient, carer and nurse eligibility, recruitment and follow-up rates
- fidelity of the SMART intervention delivery (see *Trial outcomes* for definition)
- patient, carer and nurse acceptability of the SMART intervention
- contamination of non-study nurses (i.e. the feasibility of blinding non-study nurses working within study recruitment sites)
- completion rates, variability and suitability of patient-reported outcomes
- the extent of carer involvement.

The data from this feasibility study will be used to inform the design, intervention delivery strategy, sample size, outcome measures and operational aspects of a definitive trial aimed at establishing the effectiveness of the SMART intervention.

Design and setting

We conducted a multicentre mixed-methods single-arm pre–post observational feasibility study of the SMART intervention in patients living at home with advanced pain recruited from four community palliative care services.

The SMART intervention is an evidence-based supported self-management educational intervention delivered by CNSs in partnership with patients (and carers when appropriate) living at home with pain from advanced disease. The aim of the SMART intervention is to improve pain management and quality of life by enabling patients and carers to better self-manage analgesia (specifically strong opioids) and related treatments. The feasibility study was conducted in four community palliative care services: two in Yorkshire and the Humber and two in Hampshire. Within each community palliative care service, between two and four community-based CNSs were trained in the delivery of the SMART intervention (referred to as study nurses hereafter), which was a total of 12 overall. In addition, two research fellows co-ordinated trial recruitment and follow-up. Data were collected at baseline and at the 2-, 4- and 6-week follow-up time points.

Patient and public involvement

Specific engagement for this feasibility study took place via regular study meetings and individual correspondence with PPI panel members. PPI panel members have been closely involved in the design and delivery of this feasibility study. PPI representatives were involved with:

- reviewing the content and format of the SMART intervention materials and the nurse delivery strategy
- reviewing and feeding back to the study team on the draft patient study materials, including the self-reported outcome measures included in the patient questionnaire, which led to the removal of one questionnaire [Beliefs about Medicine Questionnaire(3)] as panel members felt the wording to be inappropriate for the end-of-life context.

Ethics approval and research governance

Research ethics approval was sought in September 2015 from North West – Lancaster Research Ethics Committee (REC). Provisional ethics approval was given on 10 October 2015 with a request for further clarification on seven minor points (no changes to the protocol were requested). Favourable ethics opinion was confirmed on 27 October 2015 (REC reference number 15/NW/0797). Following favourable ethics opinion from the REC, management permission (research and development approval) was obtained from University Hospital Southampton NHS Foundation Trust's research and development department, as well as local site approvals.

Amendments to protocol

There was one substantial amendment, which outlined three changes to the protocol. This was approved on 23 November 2015 and the changes to protocol are summarised below.

1. Changes to patient-reported outcome measures: replacement of the Self-Management Ability Scale[68] with the Self-Efficacy for Managing Chronic Disease Scale (SES)[69] and removal of the Beliefs about Medicines Questionnaire,[70] because it was felt to be too burdensome for participants to complete.
2. Change to assessing fidelity of delivering the SMART intervention: study nurses would be asked to audio-record the nurse–patient consultations when the SMART intervention was used.
3. Change to wording of 'weekly' to 'regular' review of patients' progress with goal-setting review so that the protocol reflects study nurses' usual practice.

See *Appendix 15* for communication with the REC.

Participants

Participants were adults with advanced disease living at home (with or without a carer) and prescribed opioid medication and experiencing (or anticipating) side effects from these medications.

Eligibility criteria

Patients were eligible for participation if they:

- were aged $\geq$ 18 years
- had been prescribed strong opioid analgesia
- were living at home
- were being cared for by specialist community palliative care services
- were considered by the clinical team likely to survive beyond 6 weeks of follow-up
- had the capacity to provide informed consent.

Patients were ineligible for participation if they:

- had insufficient literacy or proficiency in English to contribute to the data collection that was required for the research.

Carers were eligible to take part in an end-of-study interview if:

- they were the primary carer of a patient meeting the above inclusion criteria
- the patient whom they cared for had consented to their involvement.

Recruitment procedures

Sites

Study nurses and patient participants (and carers, when appropriate) were identified from community palliative care services at four hospices: two in Hampshire (site codes HANTS1 and HANTS2) and two in Yorkshire and the Humber (site codes YKHB1 and YKHB2). Identifying patients from community palliative care services offered the most efficient access to patients approaching the end of life who were living at home. Hospital-based palliative care services were used as recruitment sites for the focus groups and interviews described in the previous chapter. However, patients recruited from hospital-based palliative care services were either inpatients or in transition between inpatient and community health-care services and, therefore, not living in their own homes. Therefore, it was decided not to recruit from hospital-based palliative care services for the feasibility study as the focus was to identify patients who were managing pain in their own homes.

Nurse recruitment: identification and consent

At each recruitment site, between two and four community-based palliative care CNSs were identified by contacting service team leaders; 12 CNSs (hereafter referred to as study nurses) were identified from the four recruitment sites. An invitation was sent to all CNSs in the four community teams to attend a brief presentation by the SMART study research team. Following this, CNSs interested in the study were invited to attend a half-day workshop at which they received further information and training on the trial procedures and delivery of the intervention.

All study nurses who were trained to use the SMART intervention were also invited to take part in a one-off face-to-face interview at the end of the trial. Study nurses were given a recruitment pack (see *Appendix 16*) by a researcher, who explained the purpose of the qualitative interview. Study nurses were asked to provide written informed consent to take part in an interview with the research no less than 24 hours after receiving a recruitment pack and having had sufficient opportunity to ask any questions about their participation.

Non-study nurses working with research active sites were identified by contacting community service-lead CNSs. An e-mail was sent to lead CNSs with a link to an online survey and a request to circulate among all palliative care CNSs within their teams.

Participant recruitment: eligibility, approach and informed consent

Potentially eligible patients were identified by screening all new referrals and existing patients on study nurses' caseloads against the eligibility criteria. Screening caseloads was done by a clinical research nurse (CRN) or researchers with the study nurses. This activity was recorded on a screening log (see *Appendix 17*), kept at each site. Before eligible patients were approached, their participation was discussed among the study nurse, researchers and wider clinical team to consider patients' capacity to participate.

Eligible patients were first approached face to face by their CNS, who gave a verbal explanation of the study and provided them with a recruitment pack, consisting of an invitation letter, a patient information

sheet and a consent form (see *Appendix 17*). At this point, patients not interested in participating were thanked for their time and asked if they would say briefly why they refused participation and, if willing, whether or not they thought the SMART intervention was acceptable in principle.

To identify carer participants, patients who were interested in the study were asked if they had a main informal carer (family member or friend) who may also be interested in participating in an interview with a researcher. If a main informal carer was identified, they were provided with a recruitment pack for carers (see *Appendix 17*).

Patients (and carers) interested in knowing more about participating in the SMART study were asked to provide their contact details and told that a researcher would contact them to discuss the study in more detail and answer any questions that they may have about participation. At this point, all subsequent recruitment and consent activities were completed by a researcher or CRN.

Patients were then contacted by telephone or face to face by a researcher to discuss the SMART study and answer any questions they had about participation. At this point, patients who refused participation were thanked for their time and asked if they would say briefly why they did not wish to participate.

Following provision of the recruitment pack, patients and their carers were given at least 24 hours to consider their participation and were encouraged to discuss the study with their family/friends and other HCPs.

Patients (and carers) willing to participate were asked to provide full written informed consent, following which they were recruited into the trial, and hereafter are referred to as participants.

This study nurse-led approach to identification and introduction and researcher/CRN-led approach to recruitment was the most efficient way to identifying eligible interested patients while keeping the burden of recruitment to a minimum for the study nurses and separate from their clinical practice.

Recruitment schedule

We estimated that within a 4-month recruitment period approximately 450 new patients would be referred to the four recruitment sites included in our study. We assumed that two-thirds of patients would have pain ($n = 300$), of which 50% would be eligible ($n = 150$). Based on these assumptions, we conservatively estimated that 20% of eligible patients would agree to participant ($n = 30$), which gave a predicted recruitment rate of eight consented participants per month across all sites for 4 months.

The SMART intervention

Training of the clinical nurse specialists

A bespoke training package was designed (outlined in *Chapter 2*, *Training development*), comprising a half-day workshop session. Following the training session, additional resource packs were developed for the study researchers to deploy with the nurses over the course of the trial to reinforce their engagement in the study and support their delivery of the intervention.

All 12 study nurses attended an initial SMART training workshop. The workshops were run in Hampshire and Yorkshire, with nurses from the two hospices in each region attending the same workshop. Sessions were facilitated by an expert Nursing and Midwifery Council-registered nurse educator who leads postgraduate palliative and end-of-life care education provision. In attendance, and acting as co-facilitators, were two study researchers. Sessions were experiential in approach, requiring reflection and demonstration of practice, and were run using the SMART training plan (*Table 8*) and supported with resources developed by the research fellows for the study nurses (see *Appendix 3*).

TABLE 8 The SMART training plan

Time	Activity	Facilitator prompts
13.00–13.10	Thanks Housekeeping Overview of plan, setting scene of intervention and approach to training (ask questions as go along, repeat things as needed, centred on participants) Introduction to each other and the things that they have been thinking about in terms of getting ready to provide the intervention	Facilitator to make a mental note of the things participants have been thinking about as these will be good examples later of the importance to assess beliefs, behaviours and knowledge
13.10–13.20	Warm-up exercise: the nature of self-management and conversations	Ask participants to select one or two cards from a range of possibilities – cards are pictorial, depicting wide variety of different scenes and patterns. Ask participants to choose the card(s) that bring to mind the features of self-management present in the clinical example they have been thinking about in preparation for the session: *We asked you to think of an example from your practice that brought to mind what self-management means in your practice. Keeping these features in your mind, choose a card or couple of cards that best depict these features* Once everyone, including facilitators, have a card(s), ask participants to talk in pairs about their cards and the features of self-management that they have in mind. Allow 5 minutes per person
13.20–13.30	Identify key features of self-management	Feedback to group: explain rules of feedback, each person asked to feedback. Feedback not commented on, time for discussion afterwards, once everyone has fed back. Ask each person to hold up their card(s) and explain the features of self-management that the card brings to mind. Once everyone has fed back, the facilitator summarises features that have been raised and integrates this with the features of self-management emphasised within the intervention. Facilitator emphasises that the intervention is designed to enhance pain management through enhanced self-management of pain medications

continued

TABLE 8 The SMART training plan (*continued*)

Time	Activity	Facilitator prompts
13.30–13.45	Introduce focus of conversational process: identify and build on what the participants intrinsically know about conversations	Ask the participants to go back into their pairs and think back to the conversation that they had about the cards, when they were explaining reasons for choosing the selected cards. Ask the participants to describe the process of the conversation that they had together: How did they start? How did the conversation develop? How did it become focused? How did it finish? Facilitator lays out a conversational process on the wall or floor or table using A4 sheets of paper in different colours for each phase of conversation (four phases as above). The phases of conversation are labelled on the coloured paper. Ask the participants to 'walk through' the conversation they had together – this is best done by physically walking through (walking along the process on the floor/along the wall). Facilitator draws out what happened at each phase and makes a note on a Post-it® note (3M, Cynthiana, KY, USA) of what happened and agrees with whole group where this Post-it note belongs. When all pairs have completed this process, facilitator summaries the process of conversation in terms of what the purpose is of each phase and frames this in relation to the intervention (e.g. so this phase of the conversation is about identifying a focus, a title for the rest of the conversation, this phase is about transmitting understanding the focus and clarifying meaning, this phase of the conversation draws the points together and shapes the next thing to happen – in this case what you will feed back to group, in clinical practice what actions you will take). Facilitator then links this conversational process with the SMART intervention – we are going to use a similar conversational process in this intervention, so one of the key points is that you already know the process we are going to follow, the key thing is that this conversation needs to carry the things that will make the intervention different from an everyday conversation
13.45–14.00	Outline conversational phases and components	Facilitator walks participants through intervention conversational process emphasising the four different components. Reinforce this process by providing a diagram of the process. Go through process illustrated within the diagram, giving examples of how the process would flow in clinical practice when discussing pain medicines with a patient
14.00–14.15	Introduce next part of the session	Next hour focused on the interventional process, going to put what we know about self-management and conversational process into practice in relation to supporting self-management of pain medicines. Facilitator models intervention process with colleague – brief example
14.15–14.30	Break	During break facilitator outlines an example on board which is going to be used for the rehearsals
14.30	Welcome everyone back	Facilitator summarises what has happened so far and plan for this part of the session – to work closely through the process as a group, using the case outlined on board, using forum theatre technique

Time	Activity	Facilitator prompts
14.30–15.00	Participant-worked example	Intervention-worked example – participants guiding facilitator in the interventional process
15.00–15.10	Introduce next section – resources Overview of resources available for use within the intervention and principle of these being a toolkit	Short presentation of resources available and how these are intended to be used
15.10–15.25	Practice introducing and using resources	Participants to work in pairs and practise how they would introduce a resource to a patient and how they would shape this part of the conversation to encourage self-management. Pairs to make a plan about what they need to do to get to know the resources – ask them to write an action plan that follows what is needed in a self-management plan – realistic, time orientated, outcome orientated, etc. Then ask them to add an action around the whole intervention – what they need to do to be able to provide intervention
15.25	Introduce last section of day – ongoing support	Group discussion – facilitator introduces purpose of this last section – how to support each other and how the researchers can support them to provide the intervention. The process for eliciting this information will follow the intervention thus allowing participants to model and reinforce the process and give them additional vicarious experience of the intervention. Facilitator asks participants to work in pairs, taking 10 minutes each to work through process of peer reflective support – each taking role of peer supporter and peer discussant. Use intervention process to shape reflective conversation: 1. 'Can you tell me what concerns you about providing the intervention?' 2. 'Which of these concerns is most pressing?' 3. 'What is it about this concern that bothers you?' 'What could you do to help with this concern?' 4. 'When would it be good to review how you are getting on?' Introduce review resources – capturing concerns, accessing information and reviewing goals and support needs
15.45	Bring things together Ask participants to summarise by explaining the intervention in their own words Finish round by asking researchers to summarise the intervention in their own words Close, thank participants, summarise plan for follow-up and resources available	

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During the workshop session, it became apparent that the nurses wanted further detail on the research process, such as eligibility criteria, screening, approach and consent, before they felt able to give their attention to intervention delivery itself. As a result, these processes had to be outlined by the co-facilitators. This took time during the workshops, leaving no time to model the conversational process for and with the nurses, or the goal-setting, in particular the process of effective action-planning once goals are set. To respond to this, additional resource packs were created for the study nurses following the workshops. It was the intention that these resources would be given to the nurses via weekly opportunities to reflect on delivery of the intervention through face-to-face visits with the study researchers.

Additional resource packs comprised (1) a 30-minute nurse–patient modelled self-management-focused conversation between two skilled nurse educators (one of whom was the workshop session facilitator), which was supplied as an mp3 file on a memory sticks with an expectation that nurses would listen to the 'model' conversation; (2) self-management conversation prompts (see *Appendix 18*), outlining potential questions mapped to the four steps of the educational approach; and (3) a 'making action plans' document (see *Appendix 19*), outlining specific actions needed to help a patient meet their self-management focused goal(s). The use of these resources enabled the researchers to provide ongoing coaching and support to the study nurses during the trial and additionally helped to promote ongoing engagement of the nurses.

In order to help formalise and aid standardisation of the approach to ongoing nurse engagement, an aide memoire for the researchers to use with the study nurses at site visits was developed, which prompted questions related to the nurses' experience of each step of the educational approach (see *Appendix 20*). A related framework to standardise the documentation of these discussions via researcher field notes was also developed (see *Appendix 21*).

Interventions details and schedule of delivery

Study nurses were asked to begin using the intervention with participants within 7 days of consent and baseline data collection. As described in *Chapter 2*, *The SMART intervention*, the SMART intervention comprised both a four-step educational approach and a SMST. In brief, the four-step educational approach was designed to reflect the everyday practice of specialist nurses and included an assessment of participants' needs, provision of information, goal-setting and review and coaching of self-management progress. The SMST comprised eight factsheets, two podcast films, a pain diary, a medication chart and goal-setting sheets.

It was intended that the intervention would be delivered by study nurses each time they visited their participants (and a carer when appropriate) over the 6-week study period (each visit was referred to as a 'SMART visit'). Study nurses were asked to visit participants a minimum of three times during this 6-week period (i.e. at least once a fortnight). During each visit, study nurses were required to use a conversational approach to go through the four steps of the educational approach and provide the resources from the SMST as required. As a minimum, study nurses were required to provide the factsheet 'Contacts and further information' and the goal-setting sheets as core resources at their first SMART intervention visit.

Assessment and data collection

Screening data collection

Screening data were collected by a researcher or CRNs on all the patients on the study nurse's caseload. Data were collected on sex, age, referral status (existing patient or new referral) and eligibility.

Baseline data collection

The researcher or CRN completed the baseline case report form (CRF), which captured data on participants' medical history (e.g. type of advanced disease, date of diagnosis), reason for referral to palliative care, palliative treatments received (within the past month) and current medications for pain, nausea and constipation. The baseline CRF also asked participants whether or not, in a future study, they would take

part if they were randomised to receive either the intervention or standard care as usual (yes/no response). This question was included to inform the acceptability of randomisation processes in a future definitive trial.

Participants were also asked to complete an outcome measure pack comprising five validated self-reported outcome measures on pain, self-efficacy, common symptoms, quality of life and satisfaction with medicines information. These outcome measures are described in *Participant self-reported outcome measures*.

Follow-up schedule

Participants were followed up for 6 weeks from the date of baseline assessment. Six-week follow-up was chosen because the risk of short survival in this population meant that demonstrating early and sustained improvements in self-management within a few weeks would be particularly important in this context. During the 6-week follow-up period, participants were contacted by a researcher at three time points post baseline:

1. week 2 (day 14)
2. week 4 (day 28)
3. week 6 (day 42).

The exact timing of follow-up visits was flexible to fit around participants' medical and other appointments, although efforts were made to keep follow-up visits within ± 2 days of the scheduled appointment date. Follow-up visits were usually conducted face to face between the participant, their carer and a researcher. Participants were offered a telephone follow-up if this was more convenient.

At each follow-up visit the researcher completed a follow-up CRF and asked the participant to complete the outcome measure pack (as described above). The follow-up CRF captured data on any of the following activities since the last follow-up (or baseline) visit:

1. which factsheets had been given to the participant
2. whether or not any self-management goals had been set (or reviewed)
3. whether or not the participant and/or carer had watched either of the video podcasts.

Participant and carer interview

As part of the final follow-up visit (week 6) participants (and carers, when appropriate) were asked to take part in an audio-recorded face-to-face semistructured interview together with a study researcher. Participants and carers were interviewed together. The topic guide for these interviews focused on two broad areas. First, participants and their carers were asked what they thought about taking part in the trial and how they were managing their medicines. These questions were intended to explore participants' and carers' acceptability of trial procedures, what they thought of the intervention itself and how it had been delivered to them by their CNS. These questions were designed to understand the extent to which participants and their carers were aware of the formalised educational process, the acceptability of the SMST resources (i.e. what they liked and did not like about it), their continued use of the intervention and whether or not their participation had any effect on their confidence with managing medicines. Interview guides are reproduced in *Appendix 22*.

Study nurse interview

In addition to participant and carer interviews, all study nurses were invited to take part in an audio-recorded semistructured interview after follow-up had closed for all participants at their site. These interviews covered a range of topics designed to capture their experiences of participating in the research process (including the training workshop), as well as their views on the acceptability of the intervention and whether or not they felt that they could integrate it into their clinical practice. The topic guides for the study nurse interviews are reproduced in *Appendix 22*.

Final data collection

At each site, when the last participant had completed 6 weeks of follow-up (or had withdrawn from the trial) a final data collection CRF was completed to capture the following data on all patients at that site:

- date of death or date last known to be alive
- place of death and preferred place of death (if known)
- health-care resource use over the 6-week follow-up period (these data are reported in *Chapter 4* as they relate to the health economic evaluation of the overall intervention)
- current medication prescribed for pain, nausea and constipation.

Adverse events

The intervention was evaluated within a patient population with advanced disease and who are approaching the end of life. Thus, it was expected that episodes of acute illness or infection, new medical problems and deterioration of existing medical problems would occur and could result in prolonged hospitalisation, hospital readmission, significant or permanent disability or incapacity, or death. In recognition of this, events fulfilling the definition of an adverse event or serious adverse event were not reported in this study unless the event resulted from administration of any research procedure.

Non-study nurse data collection: assessing contamination

To inform the design of a future definitive trial, it was considered appropriate to evaluate whether or not within individual sites the practice of non-study nurses was influenced as a consequence of working in a team where their colleagues were using the SMART intervention. To assess contamination, an online survey was sent to all non-study nurses working in the community palliative care teams at the four recruitment sites. The survey captured data on:

- demographics (age, sex, grade/band)
- duration of palliative care experience
- whether or not they were an independent prescriber
- whether or not they were aware of the SMART study and what it was about
- whether they had discussed the SMART study with colleagues who were using the intervention
- if they were aware of the study or had discussed it with a colleague, whether or not this had influenced their own practice supporting medicines management with their patients.

A copy of the online survey questions to non-study CNSs is reproduced in *Appendix 23*.

Participant self-reported outcome measures

Pain was measured using the short-form Brief Pain Inventory (BPI).[71] Using a 0–10 numerical rating scale (anchored 0, 'no pain', and 10, 'pain as bad as you can imagine'), the BPI allows respondents to rate their worst, least and average pain intensity during the past 24 hours, as well as present pain. The responses to the four pain intensity items are reported separately. Using a 0–10 numerical rating scale (anchored 0, 'does not interfere', and 10, 'completely interferes'), respondents are also asked to rate the extent to which pain interferes with general activity, mood, walking ability, normal work, relations with other people, sleep and enjoyment of life.

Self-efficacy was measured using the SES (adapted for palliative care).[69] This scale contains six items that assess an individual's confidence with managing symptoms of illness and was adapted for a palliative care context. Each item is measured on a 1–10 numerical rating scale, anchored 1, 'not confident at all', and 10, 'totally confident'.

Symptom burden was measured using the Edmonton Symptom Assessment Scale (ESAS).[72] The ESAS is a 10-item tool designed to assess common symptoms in palliative care patients. Each item is measured using a 0–10 numerical rating scale anchored 0, 'no (symptom)', and 10, 'worst (symptom)'. The ESAS was

originally developed in cancer patients but has been extensively used at end of life. The final item, 'other problems', was modified to represent drowsiness.

Health-related quality of life was measured using the EuroQol-5 Dimensions, five-level version (EQ-5D-5L),[73] which is a standardised, generic measure of health-related quality of life. It provides a single index value for describing and valuing health status calculated from a simple descriptive profile consisting of the following five dimensions: usual activities, self-care, mobility, pain/discomfort and anxiety/depression. The EQ-5D-5L index is reported not in this chapter, but in *Chapter 4*, as it relates to the health economic evaluation of the overall SMART intervention. The EQ-5D-5L also provides an overall measure of health-related quality of life by asking respondents to rate their present health state from 0, 'worst health you can imagine', to 100, 'best health you can imagine', which is reported in this chapter.

Satisfaction with medicines information was measured using the Satisfaction with Information about Medicines Scale (SIMS),[74] which consists of 17 items about the types of information required to facilitate safe self-management. For each item, respondents are asked to rate the amount of information they have received using the following response scale: too much, about right, too little, none received or none needed.

Trial outcomes

For consistency, reporting of the feasibility study outcomes is presented in line with the trial aims (see *Aim and objectives*): to assess the feasibility of conducting the trial procedures and the acceptability and fidelity of the SMART intervention to participants, carers and study nurses.

Feasibility of conducting trial procedures

Process outcomes providing measures of the feasibility of study procedures included eligibility rates, recruitment rates and follow-up rates at 2, 4 and 6 weeks; the fidelity of delivery (i.e. number of SMART intervention visits delivered per participant); completion and acceptability of participant self-reported outcome measures; completion of patient health-care records to collect outcomes; estimates of variability in patient-reported outcome measures; the extent of contamination of non-study nurses working in research-active teams; and level of carer involvement based on the number of carers willing to take part in a face-to-face interview.

The feasibility of conducting the study procedures was also assessed through semistructured face-to-face interviews with participants, carers and study nurses. Interview guides were developed (see *Appendix 22*) to explore the feasibility of the trial processes.

Choosing a primary outcome measure for a definitive trial

The primary aim of a definitive trial would be to observe a reduction in average pain intensity (measured using the BPI average pain intensity item) and is therefore a candidate primary outcome for a future definitive trial. However, the complexity of symptom control within an end-of-life population may mean that the average pain intensity scores do not improve over the course of the study period despite the participant having received some benefit from using the intervention with their study nurse. It is recognised that changes in pain interference (measured as a composite score of the seven interference items on the BPI) and self-efficacy (measured on the SES), may be more responsive outcomes. As outlined in the logic model presented in *Chapter 2* (see *Table 7*), the SMART intervention is aimed at improving medicines self-management behaviours; therefore, it is possible that participants may have experienced improvements in self-efficacy and interference from pain (mediated via information provision, goal-setting and regular review and couching) without any direct improvement on pain severity score. Indeed, stability in pain severity score over the study period may indicate improvements in overall medicine self-management in the context of declining health. Therefore, the BPI pain intensity, pain interference measure and the SES self-efficacy score were assessed as candidate primary outcomes for a definitive trial.

Fidelity of intervention delivery

Intervention delivery 'as planned' was defined as:

- initiation within 7 days of baseline
- a minimum of three SMART study nurse visits over the 6-week follow-up period
- assessment of participants' self-management needs/requirements (step 1)
- tailored information resource provision from the SMST (step 2)
- self-management goal-setting and action-planning (step 3)
- regular review and coaching of self-management goals (step 4).

To assess whether or not the SMART intervention was delivered as planned, nurses were asked to record the details of each SMART visit on a standardised CRF. This form captured information on:

- self-management needs identified and discussed
- intervention factsheets provided to participants
- self-management goals set or reviewed
- changes made to participants' analgesic medication and who made the change
- details of any additional contact with participants between SMART visits.

The number of CRFs completed per participant was used as a proxy indicator of the number of SMART study nurse visits each participant has received. When study nurse CRFs were missing, participants' clinical records were searched for evidence of a SMART visit having taken placed. To capture evidence of goal-setting, the goal-setting sheets were printed on carbon copy paper: the top copy was kept by the participants in their SMST folder, one copy was kept by the study nurses in the participant's notes and one copy was collected by the researchers (either from the study nurse or from the participant at each follow-up visit) as evidence of goal-setting having taken place. When goal-setting sheets were missing, participants' clinical records were searched for evidence of goal-setting.

Fidelity of the intervention delivery was also assessed by the researchers. At each follow-up visit the researchers completed a CRF capturing data on which SMST resources had been received by participants since the previous follow-up, whether or not the participants had set or reviewed their self-management goals, whether or not they had watched the video podcasts (if yes, which ones) and whether or not they were still using the SMART intervention.

In addition to the above quantitative assessment of intervention delivery, fidelity was also assessed during interviews with participants (and carers) after they completed 6 weeks of follow-up and with the study nurses at the end of the trial. Interviews included questions focusing on the extent to which the intervention had been delivered as intended as well as any barriers to or facilitators of delivering the intervention or using the intervention.

Finally, in order to develop an 'intervention delivery fidelity checklist' to be used in a future national multicentre definitive trial, study nurses were asked if they would be willing to audio-record their patient consultations when they used the SMART intervention. It was intended that these audio transcripts would be judged against a checklist of key elements required for intervention delivery.

Acceptability of the SMART intervention

Acceptability of the SMART intervention was assessed during recruitment by asking all patients who received an information pack whether or not they thought the intervention was acceptable in principle (yes/no response).

During the study period participants' and carers' acceptability of the intervention was assessed quantitatively by evaluating the number of participants agreeing to use the intervention compared with the number indicating that they were still using the intervention at each follow-up. Participant and carer

engagement with the SMST was assessed at each follow-up visit by the question 'Are you still using the SMART toolkit?'.

The end-of-study interviews with participants, carers and study nurses (described above) also assessed acceptability and usage of the SMART intervention. Interview guides (see *Appendix 22*) were developed to explore participants', carers' and study nurses' experience of using the intervention.

Sample size

A practical approach was taken to recruit an adequate sample size to evaluate the feasibility of conducting a definitive trial. Browne[75] suggests that when previous data sets are not available to estimate the sample size required to achieve a planned power to conduct the necessary quantitative evaluations, a pilot sample of 30 participants per arm is sufficient to estimate the population standard deviation (SD). A sample size of 30 patients would allow the 95% confidence interval (CI) 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 (participants with $\geq$ 30% reduction, 0.3 ± 0.164).

Analysis plan

The overarching approach to data analyses (for both qualitative and quantitative outcomes) was informed by the recommendations of Moore *et al.*[76] regarding process evaluation of complex interventions. The logic model presented in *Chapter 2*, *Conclusion*, establishes the causal assumptions underpinning the mechanisms of action of the SMART intervention. The qualitative and quantitative analyses described here focus on developing this understanding by evaluating the data in terms of its mechanisms of actions and the consequences that will trigger behaviour change.

Qualitative data: analysis of interview data

The audio files from the interviews were professionally transcribed. They were listened to alongside the transcripts by the researchers (NC and MM) to check for complete accuracy and ensure data familiarity. The data were coded utilising framework analysis[62] by indexing transcripts for all issues relevant to the feasibility of conducting the trial processes (i.e. deliverability), acceptability and usage of the intervention, perceived benefits and any potential disadvantages of both the research design and the intervention.

The interview data were analysed within a framework designed for the study based on the recommendations of Moore *et al.*[76] regarding process evaluation of complex interventions. The analysis framework, and the ultimate higher level of analysis, focuses on the mechanisms of action, the participant, carer or study nurse responses to the research design or intervention, the mediating factors and the consequences.

The analyses of qualitative findings are presented in full in *Appendix 24*. These analyses focus on the feasibility and deliverability of the trial processes, acceptability and usage of the intervention, perceived benefits and possible disadvantages of both the research design and the intervention itself, including the four-step educational approach and the SMST.

Quantitative data

Unless otherwise stated, all percentages were calculated using the total number of participants (or forms completed) within the relevant population, which was the denominator (i.e. excluding all participants with missing data for that variable). All percentages, means, medians, interquartile ranges (IQRs), ranges, SDs, standard errors and 95% CIs will be rounded to one decimal place (or two significant figures for numbers < 0.1). To account for the variation in the amount of intervention received by participants, all calculations and analyses were performed on an intention-to-treat basis (i.e. based on all consented participants). This pragmatic approach to include all consented participants was taken as it more closely reflects the real-life

situation in which the amount of palliative care support received by patients varies. All calculations and analyses were carried out using Stata® version 12 (StataCorp LP, College Station, TX, USA).

Assessing feasibility of conducting trial procedures

Recruitment and retention

The feasibility of the recruitment strategy was evaluated by summarising the screening, eligibility, approach and consent processes and included the numbers of participants involved at each stage and reasons for non-participation. A recruitment flow diagram depicts the course of participants throughout the screening and recruitment process. A recruitment graph presents monthly and cumulative recruitment figures. These data were summarised overall and by recruitment site.

Demographic characteristics for consented participants are presented overall and by research site. The number/proportion of participants with a carer and consenting carer was summarised, as were carer reasons for non-participation and the details of the consenting carer. Participant retention during follow-up, including the number of participants withdrawing or who were lost to follow-up (hereafter referred to as dropouts), together with the timing and reason for dropouts, is presented overall and by recruitment site.

Acceptability of randomisation

Participants' acceptance of being randomised to either standard care or SMART intervention was assessed by summarising the number/proportion of participants indicating that they would agree to be randomised.

Participant self-reported outcome data

Completion rates of all participant responses to the questionnaire packs as well as missing item-level data were summarised at each time point. In this section of the analysis, missing data were classed as a category in their own right, and all percentages were calculated using the total number of participants or forms expected in the relevant population as the denominator (i.e. including participants with missing data for that variable). As outlined in our initial grant application, we had hoped to explore the impact of potential confounders, such as disease state, age, sex, level of support and recruitment site, on the potential for participants to benefit from the intervention. However, owing to the small number of participants taking part, statistical analysis was not conducted to explore potential confounders.

Summary statistics and corresponding 95% CIs are reported for participant self-reported outcomes at each time point and mean differences were calculated between baseline and 6-week follow-up time point. The number and proportion of participants with a meaningful reduction in average pain intensity and pain interference were summarised as recommended by Dworkin *et al.*:[77] a decrease in BPI pain intensity of ≥ 2.0 points or $\geq 30\%$; and a decrease in BPI pain interference of ≥ 1 point at each follow-up time point compared with baseline.

To evaluate the performance of candidate primary outcomes (described in *Trial outcomes*) for a definitive trial, statistical and contextual factors were taken into consideration. These included the proportion of missing data, any evident floor or ceiling effects, precision (variability) of the outcome measures based on 95% CIs (around mean responses at each time point, mean difference score between baseline and 6-week follow-up and the SD of responses) and responsiveness to change based on the observed effect size and the distribution of change by 6 weeks.

Survival following study entry

To understand how close to the end of life participants were, the number of days between study entry and date of death were calculated for participants with a known date of death (i.e. who died during the follow-up period or after follow-up but before the final data collection). For participants known to be alive at the end of the study, the median (range) number of days between baseline and the date the patients were last known to be alive was summarised.

Derivation of participant self-reported outcomes

For the four pain intensity items on the short-form BPI[71] (pain at its 'worst,' 'least,' 'average,' in past 24 hours and pain 'now'), the mean item response was calculated with scores ranging from 0 to 10, with higher scores indicating greater pain intensity. A pain interference score was obtained by calculating the mean of the responses to the seven pain interference items (where four or more of the seven items were completed). Scores ranged from 0 to 10, with higher scores indicating greater interference from pain.

For the SES,[69] a summary scale score was obtained by calculating the mean of the six items (where four or more items were completed). Scores ranged from 0 to 10, with higher scores indicating higher self-efficacy.

For the ESAS,[72] a summary score was obtained by calculating the mean of the nine symptom items (pain, tiredness, nausea, depression, anxiety, drowsiness, appetite, well-being and shortness of breath), which were summed at each time point to give the mean scale score representing the extent of symptom burden. Scores ranged from 0 to 10, with higher scores indicating increased symptom burden.

A measure of health-related quality of life was derived by summing the present health state item on the EQ-5D-5L[73] at each time point. The item is scored from 0 to 100 and then divided by 100. Item scores are reported between 0 and 1, with higher scores indicating better health status.

Responses to the 17 items on the SIMS[74] were summed (responses too much, too little and none received are scored 0; responses about right and none needed are scored 1), to give a total satisfaction score at each time point. Scores range from 0 to 17, with higher scores indicating higher satisfaction with information received about medicines.

Fidelity and acceptability of the SMART intervention

Intervention delivery and fidelity

The uptake and retention rate of the intervention were evaluated by summarising the number of SMART visits each patient had from a study nurse during the 6-week study period. These data were summarised as the mean number of SMART visits received by all participants. The analysis was evaluated within the context of total screening and eligibility rates, as well as the number of participating CNSs, to provide an indication of overall capacity to deliver the intervention per protocol. The average length of time for each intervention SMART visit was also summarised, together with the number (and proportion) of participants receiving at least three SMART visits.

Adherence to the SMST delivery strategy for the education resources (the factsheets, the pain diary, the medication chart, podcast films and goal-setting sheets) was assessed by summarising which resources were present in participants' SMST folders at each follow-up visit. The number/proportion of patients indicating that they had watched the podcast films at each follow-up visit was also summarised.

Acceptability

Acceptability of the SMART intervention was assessed, primarily summarising data from the qualitative semistructured interviews with participants, carers and study nurses. Quantitative evaluation of participants' acceptability was achieved by first summarising responses to the 'acceptable in principle' question, and then by comparing the SMART intervention uptake rate with the number of participants reporting that they are still using the intervention at 6 weeks follow-up. For all participants, reported use of the factsheets and DVD podcasts, as reported at the follow-up visits with the study researcher, will be summarised.

Data accuracy

To evaluate the accuracy of data input, a random check of 20% of the data entered into the trial database was carried out prior to data cleaning and analysis. This process identified that data entry accuracy was very high: > 99% across all the questionnaire and study CRFs.

Missing data

Attempts were made to retrieve missing data via a thorough data cleaning process, including a 10% check of all data entered by hand. Every effort was made to obtain complete dates for all key data. Completion rates of all participants' responses to the outcome measures packs as well as missing item-level data were summarised at each time point. Within this section of the analysis, missing data were classed as a category in their own right and all percentages were calculated using the total number of participants or forms expected in the relevant population as the denominator (i.e. including participants with missing data for that variable).

Participant recruitment, retention and characteristics

Participant flow

Figure 3 presents the Consolidated Standards of Reporting Trials (CONSORT) flow diagram of participant recruitment from screening through consent and intervention delivery to follow-up completion. In total, 417 patients were screened against the eligibility criteria (*Figure 4*), of whom 103 (24%) were eligible. Of the eligible patients, 37 (36%) were approached, of whom 22 (59%) were interested and 19 (51%) consented and were recruited and are hereafter referred to as participants. Of the 19 consented participants, 15 (79%) completed 6 weeks of follow-up. A total of 17 participants (89%) received the intervention.

Over the 4 months of the trial, the recruitment rate was 4.75 consented participants per month. *Figure 5* presents the weekly recruitment figures for each site (bars) and the weekly cumulative accrual rate against target accrual rate (dotted line). The median (range) days between approach and consent was 7 (4–39) days.

Recruitment sites

HANTS1 and HANTS2 were the two community palliative care services in Hampshire; YKHB1 and YKHB2 were the two community palliative care services in Yorkshire and the Humber. Stacked columns in *Figure 5* show the weekly recruitment rate by site. The dots and lines show target cumulative accrual rate (black line) and the actual cumulative accrual rate (blue line).

Eligibility criteria

Table 9 summarises the screening activity undertaken across all sites and presents basic demographics for patients screened. Based on previous studies undertaken by the research team, we had assumed that 66% of screened patients would be ineligible for participation; however, 314 out of the 417 patients (75%) screened were ineligible. The primary reason was not having been prescribed strong opioid analgesia (*Table 10*). Our screening procedure did not stipulate rescreening of ineligible patients, which may have identified patients who had subsequently been prescribed opioid analgesia. The researcher field notes taken during the screening process identified that many patients were ineligible because they were not prescribed strong opioids but were prescribed weak opioids for pain.

The interviews with study nurses revealed that the eligibility criteria were initially seen as acceptable by being relatively broad. However, the study nurses were surprised by the lack of individuals who met the eligibility criteria. Moreover, those who did meet the eligibility criteria often had complex end-of-life needs and would have been 'on their reserves to do it [very fatigued and only just able to participate]' (H2CNS002). One study nurse responded that 'It's interesting that . . . there's quite a lot of patients that aren't even on opioids' (H1CNS002). Another study nurse indicated that 'I was surprised in a way that I didn't have any patients that would be applicable for the study . . . maybe, that shows how complex the patients are that come to us, and how quickly people who may possibly have been suitable deteriorated' (H1CNS004).

A mediating factor in the low eligibility rate was the number of study nurses involved in the study. Across the four sites there were 37 full-time equivalent CNSs, of whom 12 (33%) volunteered to take part in the

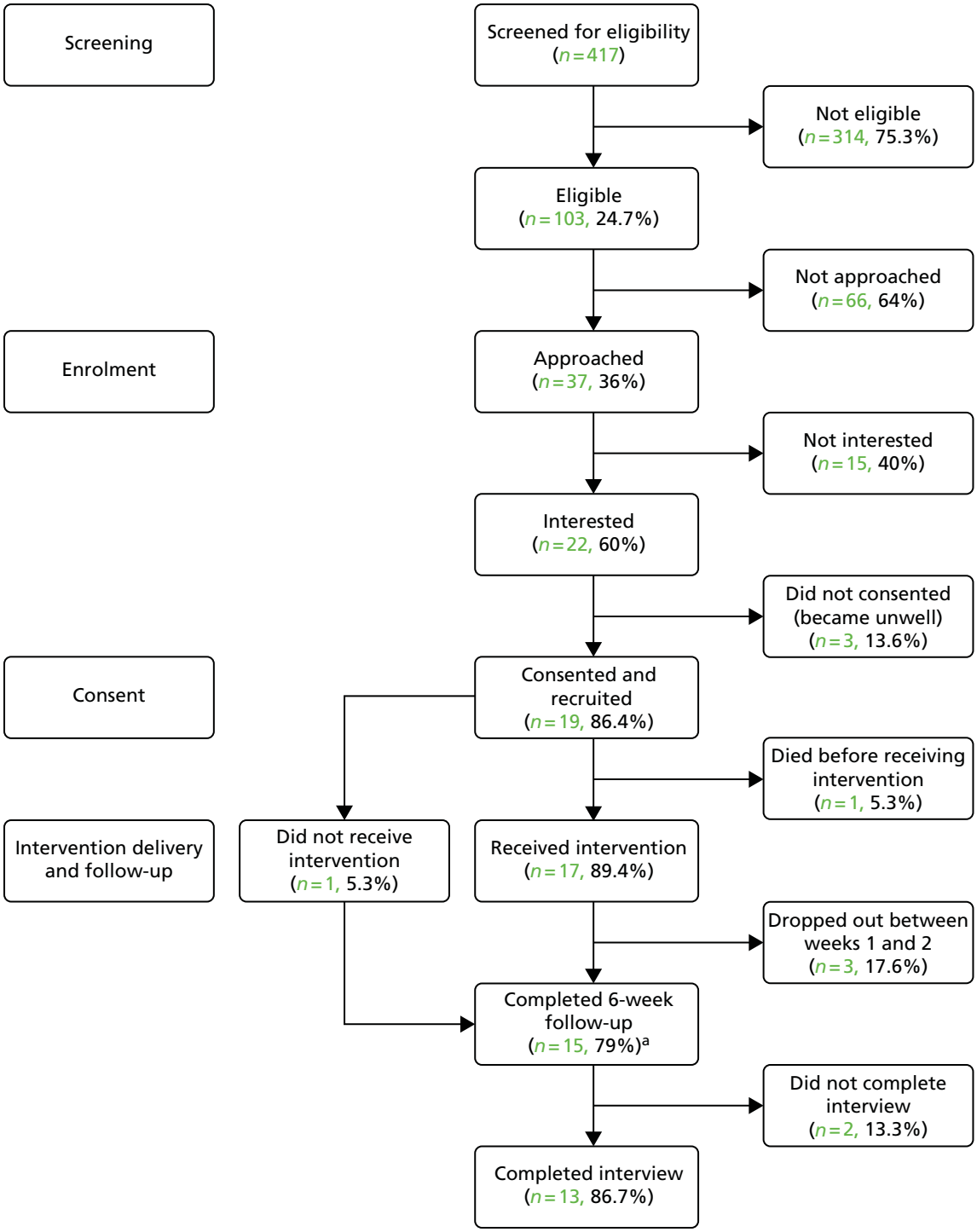

FIGURE 3 The CONSORT flow diagram of recruitment. a, Calculated as the proportion of consented participants.

SMART study. Consequently, the pool of patients available to screen was smaller than expected and those who were 'eligible' often had very complex needs that were not captured by the broad eligibility criteria.

Patient referral rate

We had assumed that approximately 450 new patients would be referred to the four community palliative care services during the recruitment period (a rate of 112 per month). As we recruited only 12 nurses to take part in the study, the actual number of new referrals from these 12 study nurses over 4 months of recruitment was 202 (a rate of 50 per month).

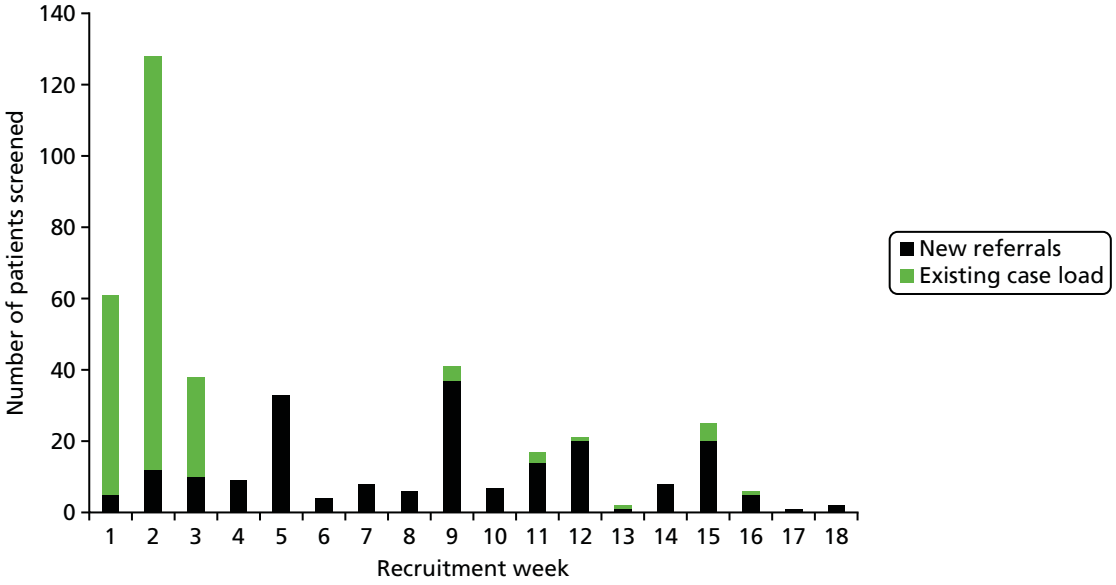

FIGURE 4 Weekly screening rates by referral status.

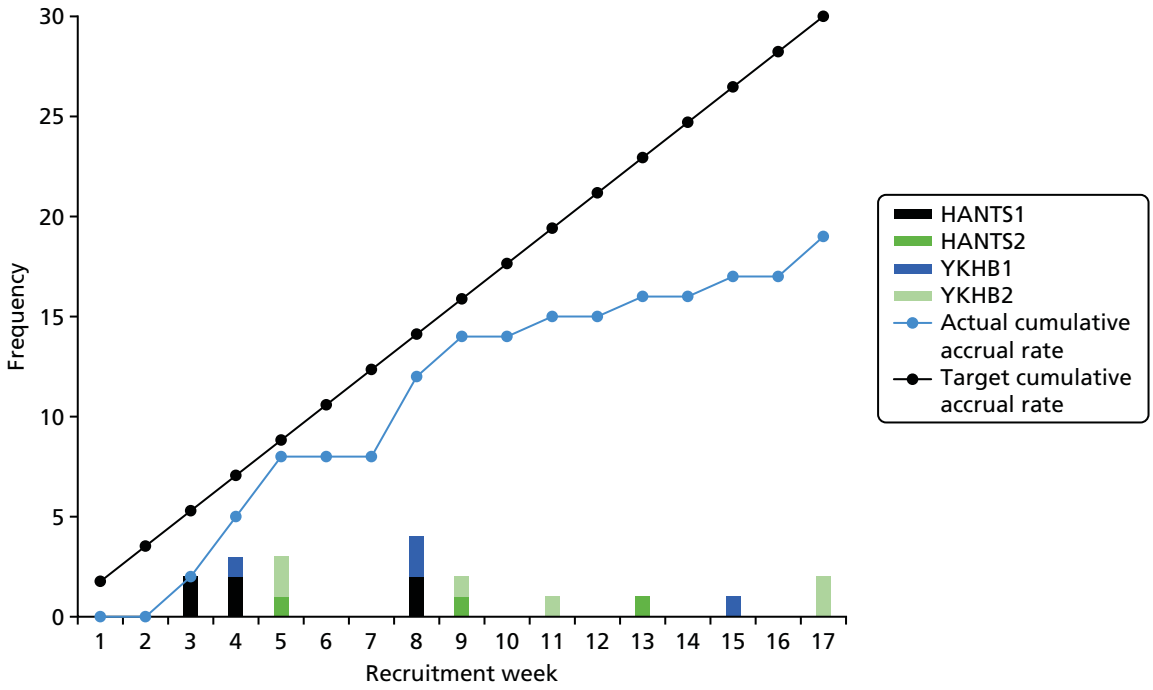

FIGURE 5 Weekly recruitment figures by site.

Screening and initial approach processes

The initial screen for eligible patients included screening all existing patients on the study nurses' caseloads. Subsequent caseload screening was of new referrals (see *Figure 4*). Consequently, 54% ($n = 227$) of all patients were screened within the first 3 weeks of recruitment, resulting in 70% ($n = 72$) of all eligible patients being identified within the same 3-week period. Given that study nurses' appointments with patients were usually weekly, fortnightly or 'as required', they had to prioritise which patients they approached first based on the next appointment date. This meant that many eligible patients identified in the first 3 weeks of the trial were not approached (reasons described below), or by the time the study nurses were able to see them had become ineligible because of declining health (i.e. they were not anticipated to survive more than 6 weeks).

TABLE 9 Demographic data of screened patients

	Recruitment site, *n* (%)				
Variable	**All**	**HANTS1**	**HANTS2**	**YKHB1**	**YKHB2**
Screened	417 (100)	148 (35.5)	57 (13.7)	148 (35.5)	64 (15.4)
Sex					
Male	118 (45.3)	60 (40.8)	28 (50)	71 (48)	29 (45.3)
Female	227 (54.7)	87 (59.2)	28 (50)	77 (52)	35 (54.7)
Age (years)	73 (22–97)	72 (37–97)	76 (35–95)	74 (39–96)	69 (22–92)
Referral status					
New	202 (48.4)	64 (43.2)	33 (57.9)	95 (64.2)	10 (15.6)
Existing	215 (51.6)	84 (56.8)	24 (42.1)	53 (35.8)	54 (84.4)
Eligible					
Yes	103 (25.4)	24 (16.9)	18 (35.1)	39 (26.4)	22 (33.4)
No	314 (74.6)	124 (83.1)	39 (64.9)	109 (73.6)	42 (65.6)
Approached[a]					
Yes	37 (36)	9 (36)	10 (55.6)	13 (33)	5 (22.7)
No	66 (64)	15 (64)	8 (44.4)	26 (67)	17 (77.3)
Interested[b]					
Yes	22 (60)	7	4	7	4
No	15 (40)	2	6	6	1
Consented[c]					
Yes	19 (86.4)	6	3	6	4
No	3 (13.6)	1	1	1	0

a Denominator is the number of eligible patients.
b Denominator is the number of patients who were approached.
c Denominator is the number of interested patients.
Note
All data are presented as *n* (%) except age which is median (range).

TABLE 10 Reasons for screening failures and why patients were not approached

Reason for screening failures	*n* (%)
Not prescribed strong opioid	168 (53.5)
< 6 weeks survival	61 (19.4)
Patient lacks capacity to consent	29 (9.2)
Patient not living at home	19 (6.1)
Discharge	18 (5.7)
Strong opioids for breathlessness	11 (3.5)
Other	8 (2.5)
All	314 (100)

Just over one-third of eligible patients were approached and invited to participate in SMART (see *Figure 3*). Reasons for the low approach rate were largely missing because of low CRF completion rates (71% missing; *Table 11*); however, end-of-study interviews and researcher field notes provided more explanatory evidence. Study nurses indicated during interviews that approaching eligible patients was not a problem in itself (i.e. patients were not intrinsically opposed to finding out about the research). However, the often complicated and rapidly fluctuating circumstances of the end-of-life context meant that it was often not appropriate to approach eligible participants about participating. In addition, some patients had already been approached about participating in other drug trials and study nurses felt that they 'couldn't burden them with something else at that time' (H1CNS002). Many eligible patients, as a result of their complex situation, were frequently admitted to alternative care settings (hospital, hospice or nursing home) for symptom control or respite care; therefore, study nurses found it challenging to find a relatively stable period during which to approach them about participating.

Another factor affecting the screening and approach processes was the contact time between study nurses and researchers or CRNs to undertake screening activity, which was not consistent across all sites due to pressure on study nurses' time and the size of their caseloads. The number of patients screened per CNS varied from 17 to 68 (median 36). Maintaining weekly appointments with each CNS to screen new referrals and review recruitment of eligible patients was challenging and, although the screening process was seen as deliverable and acceptable by the study nurses, they were very aware that they (and sometimes the CRNs) were not available when they had said they would be for screening appointments. One that responded: 'It was only tricky because of time' (H1CNS002). Existing pressures on study nurses and their often high caseloads meant that screening appointments frequently needed to be rearranged/reattempted, with the result that screening was missed on some weeks. One study nurse stated she found the screening onerous and two said they would have preferred to screen with just the researcher (rather than screening with two people, e.g. the CRN and research fellow). Consequently, screening was undertaken regularly, but not always on a weekly basis.

Participant recruitment

Despite the low approach rate, the proportion of patients interested in participating after reading the information sheet was higher than expected (60%; see *Figure 3*). The majority of those who refused to participate did so because they felt that they were too unwell at the time of being asked. Participant interviews revealed two primary motivations for taking part:

1. It was an opportunity to give something back and to help others.
2. It was a way for them (and their carer) to learn something new that might help them to manage their pain.

TABLE 11 Reasons eligible patients were not approached

Reason patients were not approached	*n* (%)
Died	7 (10.6)
Discharged	3 (4.5)
Inpatient	4 (6)
Too unwell	2 (3)
Other	3 (4.5)
Missing[a]	47 (71)
All	66 (100)

a Data not recorded on CRF. Reason for not approaching patients was explored during interviews with study nurses to identify bias that may have been introduced into the recruitment process.

Of the 37 patients who were given an information sheet, 19 (51.4%) consented to participate (hereafter referred to as participants), of whom nine (47%) also had a carer who consented.

Nurse recruitment

Across the four sites, 12 CNSs were trained to deliver the SMART intervention with their patients. The demographic details of the 12 study nurses are summarised in *Table 12*. Eleven of the 12 nurses completed an interview with a researcher at the end of the trial about their experiences of being part of the trial and delivering the intervention.

Three study nurses (25%, two in Hampshire and one in Yorkshire and Humber) recruited no participants. Three study nurses (25%) recruited one participant each, three (25%) recruited two participants each, two (17%) recruited three participants each and one (8%) recruited four participants.

Study nurses were asked whether or not they would be willing to audio-record their consultations with participants when using the SMART intervention to enable the research team to develop an intervention delivery checklist to assess fidelity. This was generally met with apprehension by the study nurses, although

TABLE 12 Demographics of study nurses and non-study nurses

	Nurses, *n* (%)	
Variable	Study (*N* = 12)	Non-study (*N* = 15)
Site		
HANST1	4 (36.4)	4 (26.7)
HANTS2	2 (18.2)	3 (20)
YKHB1	3 (18.2)	4 (26.7)
YKHB2	3 (27.3)	4 (26.7)
Age		
Median years (range)	53 (49–54)	51 (43–62)
Sex		
Female	12 (100)	15 (100)
Band		
6	2 (16.7)	4 (26.7)
7	10 (83.3)	9 (60)
8	0 (–)	2 (13)
Time working in palliative care		
Median years (IQR)	8.2 (1–16.7)	10.5 (3.75–15.5)
Independent prescriber		
Yes	6 (54.6)	4 (26.7)
No	5 (45.4)	11 (73.3)
Take part in an interview		
Yes	11 (92)	
No	1 (8)	

Note
Data are presented as *n* (%) except for 'age' and 'time working in palliative care' which are presented as median (range) and median (IQR).

the majority agreed to do it. To allow study nurses time to get used to using the intervention it was decided that they would start recording SMART intervention consultations with their second participant. However, the completion rate for this part of the study was poor, primarily because half of the study nurses recruited one participant or none. In the end, only two nurses (in Hampshire) audio-recorded their SMART intervention consultations; however, this provided insufficient data to test an intervention delivery checklist. For a future definitive trial, alternative methods should be considered.

Baseline participant characteristics

Participants' baseline demographic factors and clinical characteristics were broadly similar across the four sites (*Table 13*). Participants recruited from the two Hampshire sites had slightly lower (worse) Australia-modified Karnofsky Performance Scale score than the two northern hospices. There was a range of disease types, with the most common being breast cancer (26%), followed by liver or pancreatic cancer (16%). One patient had a non-cancer diagnosis (liver cirrhosis). Although the study was open to patients with any type of advanced disease, we found that most of those on strong opioids, and, therefore, eligible for the study, were patients with cancer.

TABLE 13 Participant baseline demographic factors and clinical characteristics

	Recruitment site, *n* (%)				
Variable	All	HANTS1	HANTS2	YKHB1	YKHB2
Participants recruited	19 (100)	6 (31.6)	3 (15.8)	6 (31.6)	4 (21)
Age (years)	66 (48–88)	68 (63–88)	68 (51–73)	60 (48–82)	59 (50–69)
Sex					
Male	8 (42.1)	2	1	2	3
Female	11 (57.9)	4	2	4	1
Karnofsky score					
Entry	60 (50–70)	55 (50–60)	50 (50–70)	60 (60–70)	70 (60–70)
Completion	60 (40–60)	60 (50–60)	50 (0–50)[a]	60 (40–70)	65 (30–70)
Primary disease					
Breast cancer	5 (26.3)	1	2	4	1
Lung cancer	4 (21)	3	1	1	1
Bowel cancer	1 (5.3)	1		1	1
Gynaecological cancer	1 (5.3)	1			1
Pancreas/liver cancer	3 (15.8)				
Liver cirrhosis	1 (5.3)				
Bone cancer	1 (5.3)				
Head/neck cancer	1 (5.3)				
Metastatic sarcoma	1 (5.3)				
Unknown primary	1 (5.3)				
Time to referral[b]					
Days	211 (17–414)	17 (9–570)	40 (12–292)	414 (211–505)	172 (19–330)
Weeks	30 (2–59)	2 (1–81)	6 (2–42)	59 (30–72)	25 (3–48)

TABLE 13 Participant baseline demographic factors and clinical characteristics (*continued*)

Variable	Recruitment site, *n* (%)				
	All	HANTS1	HANTS2	YKHB1	YKHB2
Reason for referral					
Pain only	8 (42.1)				
Psychological support only	1 (5.2)				
Pain + psychological support	6 (31.5)				
Other symptoms	4 (21)				
Pall treatments					
Yes	10 (52.6)	0	2	4	4
No	9 (47.4)	6	1	2	0
Treatment types					
None	9 (47.4)	6	1	2	1
Chemotherapy	6 (31.6)	0	2	3	2
Chemotherapy + radiotherapy	3 (15.8)			1	1
Ascites drainage	1 (5.3)				
Carer recruited[c]					
Yes	9 (47.5)	4	2	1	2
No	10 (52.6)	2	1	5	2
Completed 6-week follow-up					
Yes	15 (79)	5	2	5	3
No	4 (21)	1	1	1	1

a Completed Karnofsky score based on two participants due to one dropout.
b Time elapsed between advanced disease diagnosis and referral to community palliative care: data available on 15 of 19 participants.
c $n = 8$ spouse/partner, $n = 1$ friend.

Notes
Data for sex, primary disease, reason for referral, palliative treatments, carer recruited, completed 6-week follow-up are presented as *n* (%). Data for age is presented as median (range). Data for Karnofsky score and diagnosis to referral presented as median (IQR).

There were differences in the median time from diagnosis of advanced disease to referral to palliative care services between the Hampshire and Yorkshire recruitment sites: the median (IQR) time between diagnosis and referral in Hampshire was 4 (IQR 2–61) weeks compared with 38.5 (IQR 9–59) weeks in Yorkshire and the Humber. The end-of-study interview data with the study nurses from both Hampshire sites emphasised that late presentation at diagnosis (i.e. more advanced disease) meant that many patients referred to palliative care services were close to the end of life and subsequently had limited exposure to specialist palliative care services.

Across all four sites, the most common reasons for referral to palliative care services were for pain control and psychological support. Just over half of participants ($n = 10$) were undergoing palliative treatment at the time of enrolment. Six patients were receiving palliative chemotherapy and three were receiving palliative chemotherapy plus radiotherapy.

At baseline, all participants were prescribed at least one strong opioid for pain relief (*Table 14*). Two participants (10%) had one strong opioid prescription, 15 participants (79%) had two strong opioid prescriptions (for background and breakthrough pain), one participant (5%) had three strong opioid prescriptions [two background (tablets + patch) and one breakthrough] and one participant (5%) had five strong opioid prescriptions. Of the 15 participants who received two strong opioid prescriptions, three (16%) were also prescribed a weak opioid. Co prescribing rates of laxatives, antiemetics, neuropathic analgesics and non-opioid analgesics were 74% ($n = 14$), 79% ($n = 15$), 68% ($n = 13$) and 74% ($n = 14$), respectively.

Randomisation acceptability

During the baseline visit, participants' general willingness and acceptability of randomisation was assessed by asking the question, 'If the study had been designed so that those taking part would be randomly selected to receive either the intervention or standard care would you have taken part?'.

TABLE 14 Baseline medication summary

Variable	All, *n* (%) (*N* = 19)
Strong opioid	
None	0
1–3	18 (94.7)
≥ 4	1 (5.3)
Weak opioid	
None	16 (84.2)
1–3	3 (15.8)
≥ 4	0
Non-opioid analgesic	
None	5 (26.3)
1–3	14 (73.7)
≥ 4	0
Neuropathic analgesic	
None	6 (31.6)
1–3	13 (68.4)
≥ 4	0
Laxative	
None	5 (26.3)
1–3	14 (73.7)
≥ 4	0
Antiemetic	
None	4 (21)
1–3	14 (73.7)
≥ 4	1 (5.3)

Note
All participants reported that they were taking at least one strong opioid for pain relief.

A total of 17 out of 19 participants (89%) responded to this question by saying that they would. One participant did not understand the concept of randomisation and, therefore, preferred not to comment either way. One participant–carer dyad indicated anxiety about the relinquishing of control associated with randomisation and that maintaining control of 'critical decisions in palliative care' was important to them and this was the reason why they would not have agreed to randomisation.

Researcher follow-up

All follow-up visits were conducted by one of two researchers, face to face at participants' homes. Overall, participant retention was high: of the 19 participants who consented, 15 (79%) completed 6 weeks of follow-up (see *Figure 3*). One participant completed all follow-up visits with a researcher but did not receive the intervention because of complex pain management issues that prevented the study nurse from devoting time within the consultation to initiating the use of the SMART intervention. Therefore, of the 19 consented participants, 14 (74%) received the intervention and completed 6 weeks of follow-up. However, an intention-to-treat analysis approach was taken to account for the variation in the amount of SMART intervention received by participants; therefore, all consented participants were included in the analysis. As such, the denominator at baseline was 19 and at all follow-up time points was 15.

Withdrawals

The end-of-life context meant that many patients experienced uncontrolled symptoms (not just pain) and infections during the course of the 6-week study period. Despite this, relatively few participants were lost to follow-up. There were four dropouts, all associated with a rapid unexpected decline in health:

- One participant died 1 week after consenting, having received no SMART study nurse visits (only baseline data obtained).
- One participant died between baseline and the 2-week follow-up, having received two SMART study nurse visits (only baseline data obtained).
- One participant withdrew from researcher follow-up visits because of uncontrolled pain in week 2 (prior to week 2 follow-up), but continued to use the goal-setting element of the SMART intervention with the study nurse on four more occasions (baseline data obtained + evidence of four goal-setting sheets from the study nurse).
- One participant withdrew between baseline and the 2-week follow-up because of declining health and was subsequently moved to a nursing home where they were no longer managing their medicines; this participant received one SMART study nurse visit (only baseline data obtained).

In order to capture accurately why, when and from what participants withdraw, a future trial should explicitly record what parts of the trial participants are withdrawing from (i.e. the research elements or the intervention elements).

Acceptability of study length and frequency of follow-up visits

The 6-week study period was universally seen as 'about right' or 'just right' by the participants and their carers: 'I think it's just about right actually, you probably need that length of time to get any results' (H2Pt019) and 'It seems to have gone quick' (H1Pt001-C). The study nurses also appeared to agree on the acceptability and deliverability of a 6-week study period.

In terms of the deliverability of follow-up appointments with researchers, *Figure 6* shows that in the majority of cases it was feasible to conduct three follow-up visits within a tight time frame of 2 days either side of the scheduled fortnightly follow-ups. Nevertheless, it was not always possible to conduct follow-up visits within this tight time frame (see *Figure 6*). This is not surprising given the complex nature of participants' homes.

Interview data revealed that participants and carers all stated that the frequency of researcher visits (fortnightly) was acceptable, and some looked forward to these visits. Participants responded, 'It's been

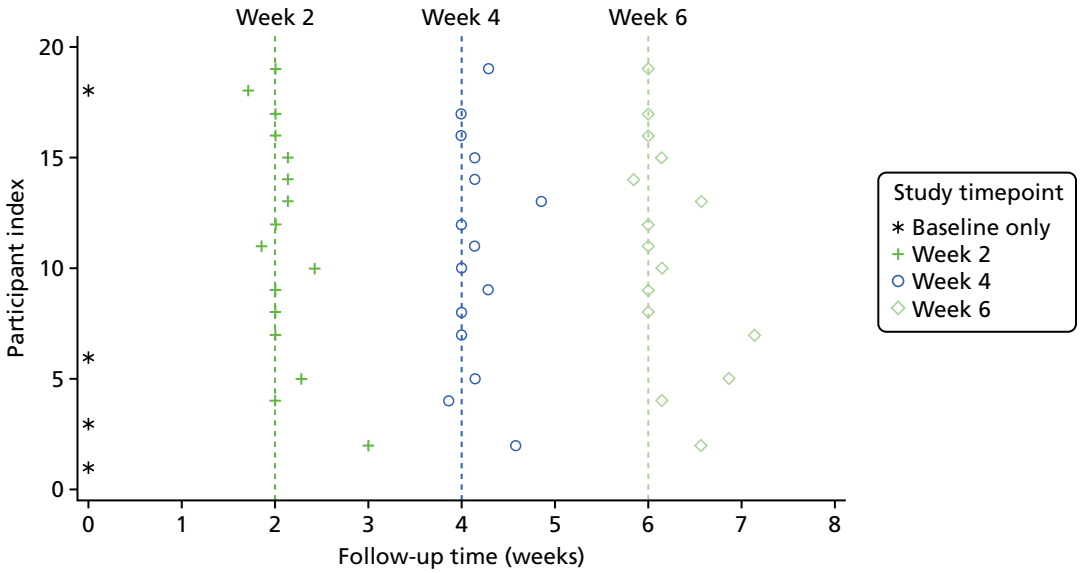

FIGURE 6 Time elapsed between baseline and researcher follow-up visits.

very nice you coming in' (H2Pt019) and 'It's been lovely. I enjoy you coming . . . you're so easy to talk to, you ask the right questions' (H1Pt009). These responses indicate that people approaching the end of life valued taking part in a research study and that they saw the researcher as external to their care team and were able to develop a positive relationship with them over the 6-week duration of the study.

Participant and carer interviews

Thirteen participants completed an interview with a researcher (*Table 15*). Although nine carers consented at baseline to participate in an interview, only seven were available to complete an interview with a researcher.

Survival following study entry

At the close of the study, three participants were known to have died. Two participants died during the follow-up period at 21 days and 14 days following baseline assessment, respectively. One patient died after the follow-up period, 71 days following baseline assessment. Two participants withdrew from the study follow-up data collection for reasons of declining health; the number of days between study entry and withdrawal was 14 days in one case and 27 days in the other. These data are summarised in *Figure 7*.

Fidelity and acceptability of the SMART intervention

Intervention delivery

To what extent was study nurse training provided as planned?

During the interviews, study nurses were asked to comment on the training workshop (described in *SMART intervention*). Responses to the experiential, reflective style of the training workshops were mixed; they varied widely from generally or overtly positive through to neutral and negative responses. The reflective nature of the session appealed to some, whereas others found it challenging and preferred alternative approaches (e.g. along the lines of advanced communications training, accompanied by a video of a modelled conversation and then subsequent group discussion). However, critical reflection on existing practice is necessary to stimulate change, which is fundamental to the intervention delivery.[78,79] Nevertheless, there was a general view that the sessions covered what the nurses needed to know in anticipation of their study involvement.

TABLE 15 Post-study participant interviews

Variable	*n* (%)
Number of participant interviews completed	13 (68.4)
Previous (or current) occupation[a]	
Manual worker	5 (38)
Health-care worker	2 (15)
Professional/managerial	4 (31)
Academia	2 (15)
Qualifications[a]	
None	4 (31)
Below university degree	6 (46)
University degree or higher	3 (23)
Number of carers present[a]	7 (54)
Carer occupation[b]	
Manual worker	2 (29)
Health-care worker	2 (29)
Professional/managerial	3 (42)
Carer qualification[b]	
None	1 (14)
Below university degree	5 (71)
University degree or higher	1 (14)

a The denominator is the number of participants who completed an interview ($n = 13$).
b The denominator is the number of carers who completed an interview ($n = 7$).

There was a mixed reception to the underpinning self-management ethos of the sessions. During the workshops, the Johnston *et al.*[51] definition of self-management support in palliative nursing was explored, as well as the related eight professional roles from advocate to reporter (see *Appendix 25*). Some of the study nurses appeared to readily understand the supported self-management ethos, whereas others were more challenged by it. The self-management ethos of the study and the training sessions challenged the professional behaviours and identity of some of the specialist palliative care nurses, whose therapeutic role is often measured by their effectiveness to ameliorate pain. The nurse interviews also revealed that it was harder for some nurses to adapt their practice from imposing their views (i.e. telling patients how to use opioids) to collaborative discussion. Such discussion focused on the individual patient using and developing their own self-management strategies as result of the information provided by the nurse.

There was feedback that the four-step educational approach was viewed as akin to usual specialist practice, but some nurses felt that the workshop sessions made the four steps seem more complicated than it actually was. The nurses generally felt that the four-step approach mirrored normal practice and, consequently, was not viewed as being distinctive or novel. The study nurses reported that they valued the training materials supplied during and after the training workshop (see *Appendices 18* and *19*, and *Figure 8*). In particular, the nurses liked the figure illustrating the self-management conversation prompts mapped to the four steps of the educational approach (see *Figure 8*). Despite this, there was variation in the extent to which nursers referred to the training resources over the course of the study, with the majority of use being at the start of the trial.

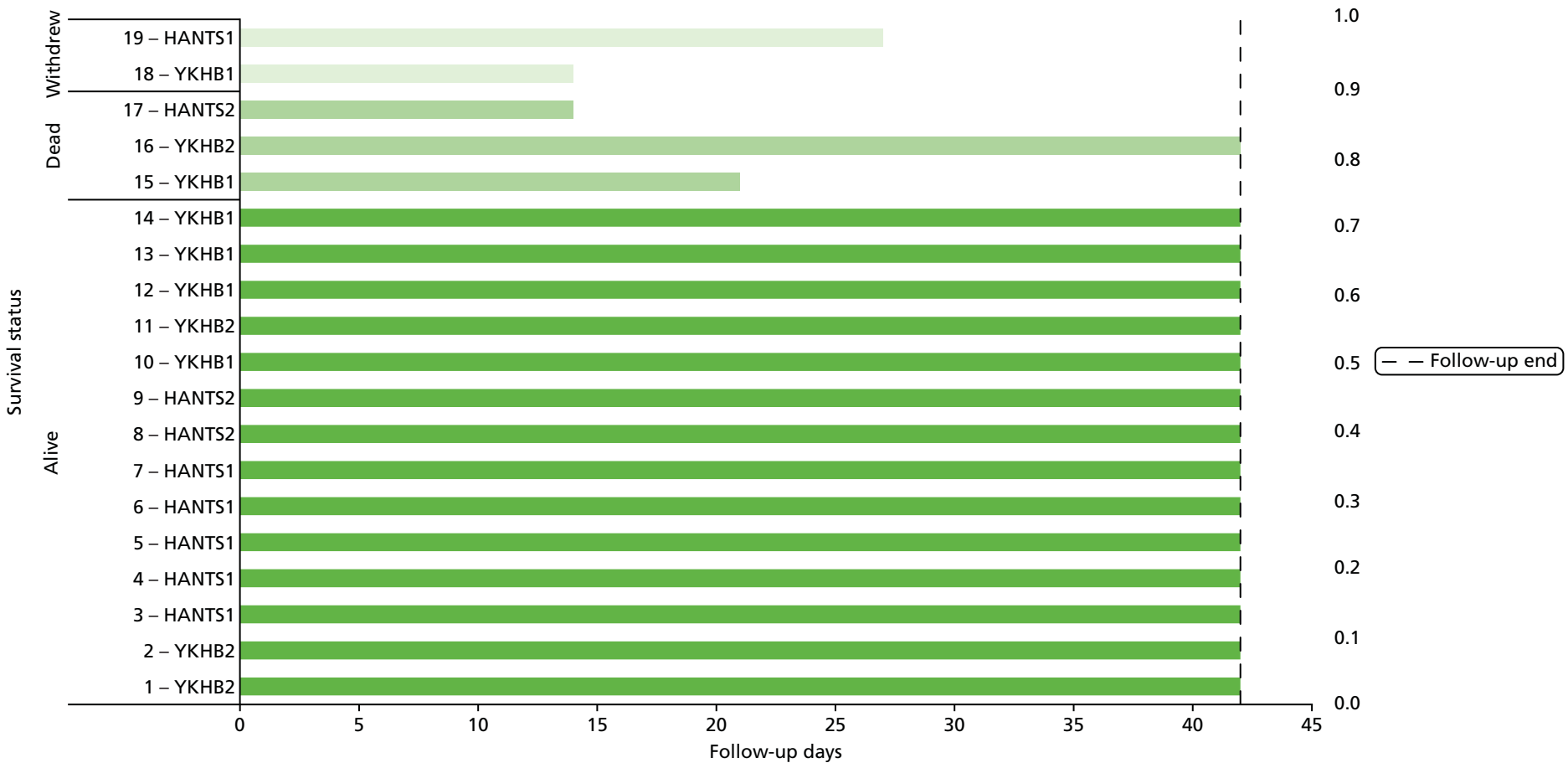

FIGURE 7 Survival (days) for each participant.

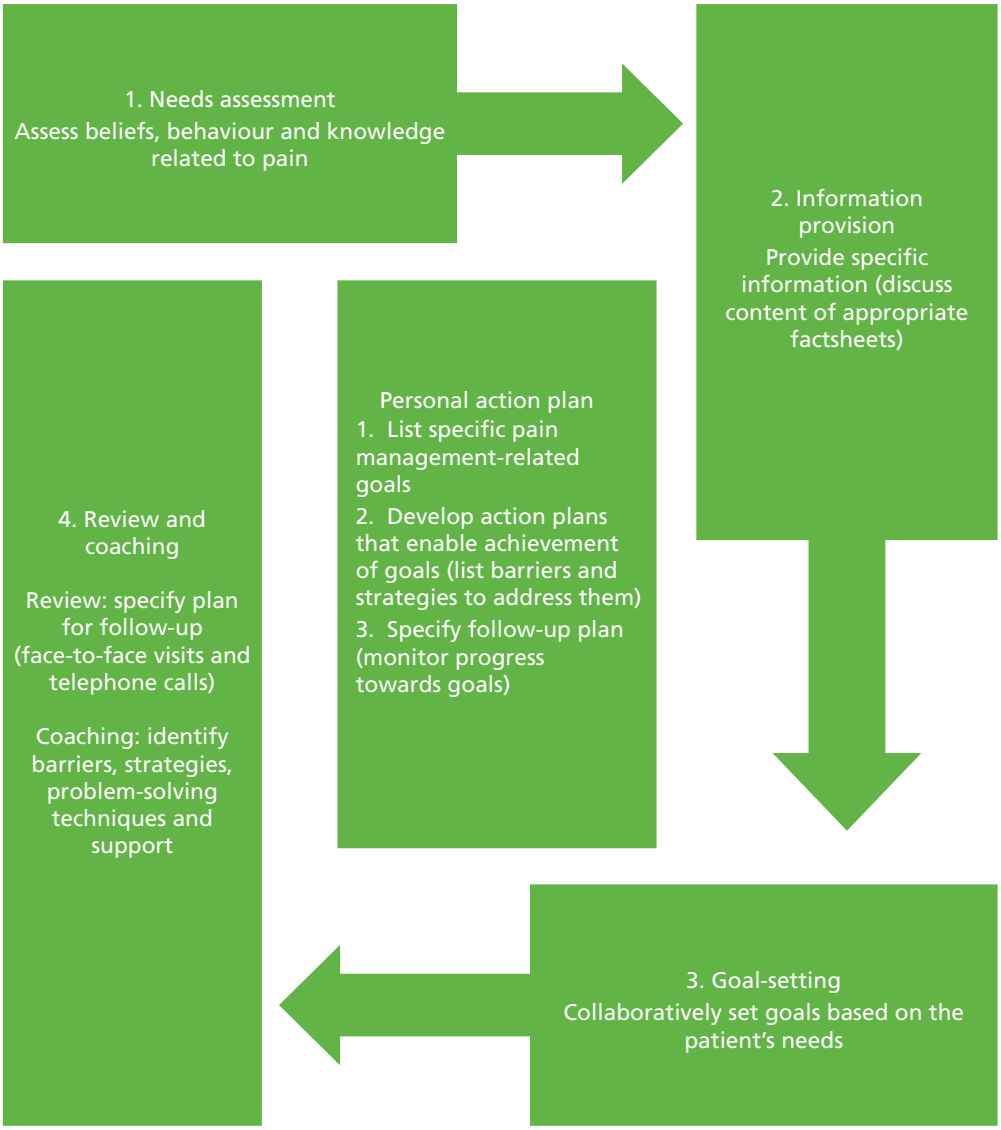

FIGURE 8 Diagram of the SMART four-step educational process.

There was insufficient opportunity during the training workshop for the study nurses to become familiar with the research process, which led to some anxiety during the workshop. This had an impact on time available for role modelling a conversation in practice. Therefore, a future definitive trial should consider providing an opportunity to receive information and ask questions about the research process prior to any training.

Based on our finding of a mixed reception to the self-management ethos, it appears important that nurses process the intervention and rehearse how they deliver self-management-focused conversations that fit their own practice. There are likely to be different timelines regarding adoption of such a focus, and nurses vary in how much they need to practise this before it becomes embedded. Therefore, some form of further training and support for those involved in delivering the intervention is desirable and could be combined with efforts to assure intervention fidelity.

The busy and time-pressured reality of clinical practice for these specialist nurses, who often managed large caseloads, meant that the delivery of ongoing training and support during the course of the trial was often problematic. These issues were captured in the researchers' field notes and included difficulty making appointments to meet the study nurses. Visits usually had to be made at the start of their working day. However, not all the study nurses visited their office before going out to visit patients, and none wanted to make appointments at the end of the day. Furthermore, visits to the study nurses were

complicated by nurses covering weekend working and, therefore, having days off in the week. Once appointments were made, the study nurses were not always subsequently available (because of extended/unexpected patient visits, over-running meetings, their own illness, etc.). Nonetheless, when they were available, they were usually open to discussing their experiences of delivering the intervention (utilising the four-step educational approach), but time devoted to this was always pressured or limited. Over the course of trial, the study nurses were usually visited by the study researchers once a fortnight depending on their availability, which was less often than the weekly frequency originally intended.

To what extent was the intervention delivered by study nurses as planned?

Table 16 summarises the pattern of the intervention delivery for each participant. Overall, there were 52 SMART study nurse visits across all participants, evidenced by completion of study nurse CRFs. When study nurse CRFs were missing, evidence of a SMART intervention visit having taken place was gathered from participants' clinical records, the presence of a goal-setting sheet having been completed (with date) or from researchers' field notes. The final column in *Table 16* groups the participants based on whether they received the intervention as planned (group A), partially (groups B and C) or not at all (groups D and E).

Of the 19 participants who consented, 17 (89%) had a first SMART study nurse visit and started using the intervention (see *Table 16*). From this point, 10 participants (53%) received the intervention as planned (group A). One participant in group A decided not to have the factsheets after reading through them, but did engage with the goal-setting. As the information provision was designed to be tailored to the participants' needs, this still met the criteria for this element of the intervention. Four participants (21%, group B) received the minimum number of SMART study nurse visits, goal-setting, and review and coaching, but the information provision was not staged as they received all the factsheet on their first SMART study nurse visit. This does not necessarily represent inappropriate delivery of the intervention resources; however, it was not clear whether all the factsheets were delivered on the first visit at the participant's request (which would satisfy the criteria for tailored provision of information) or whether the study nurses handed them all over in one go. One participant in group B [identification (ID) 14 – YKHB1; see *Table 16*] withdrew from researcher follow-ups because of uncontrolled pain but continued to engage with the goal-setting and reviewing (steps 3 and 4 of the intervention). Three participants (16%, group C) did receive the intervention materials and the goal-setting, but did not receive the minimum number of SMART study nurse visits. However, in group C one participant died during the first 2 weeks of the study and one participant was lost to follow-up because of rapidly declining health (see *Table 16*). Finally, two participants (10.5%, group D) did not receive any elements of the intervention: one participant died within a week of giving consent and the other did not receive the intervention (because of complex pain management issues that prevented the study nurse from starting the SMART intervention), but did complete all researcher follow-up visits.

The timing of study nurse visits is summarised in *Figure 9*, which shows that participants generally received a SMART study nurse visit once a week or once a fortnight. The average duration of SMART study nurse visits was 57.2 minutes (SD 15.1 minutes), but this covers the whole consultation and not just time spent using the SMART intervention. Interview data with study nurses revealed that they were able to successfully deliver the SMART intervention during their visits and the pattern of delivery was acceptable as it matched their normal visiting pattern. However, in relation to the acceptability of the length of the SMART study nurse visits, the nurses were very conscious of the extra time required for study visits (approximately 30 minutes for the first visit and 15 minutes for each further visit) and the impact this had on their workload. One study nurse responded:

> *We [one study nurse and another study nurse] talked about timekeeping a lot, because in my first couple of SMART study appointments they were really long, partly because the lady I had, it was quite difficult to keep to time with them anyway.*
>
> *H2CNS001*

The study nurses managed to successfully accommodate this additional workload without changes to their usual care patterns, except for one (part-time) study nurse who asked a colleague to follow up some patients

TABLE 16 Pattern of SMART intervention delivery: who got what when

ID – site	Start 7 days?	Number of SMART visits	Average visit time (minutes)	New resources at each follow-up[a]			Number of factsheets received	Number of goal-setting sheets received	Podcast films watched?	Intervention delivered as planned[b]	Complete all follow-up visits?
				Week 2	Week 4	Week 6					
1 – YKHB2	Yes	3	62	1, 5, 7, 10, 11	6, 11	2, 3, 4, 8, 9, 11	10	3	No	A	Yes
2 – YKHB2	Yes	3	60	1, 7, 8, 11	4, 9, 10, 11	2, 3, 5, 6, 11	10	3	Yes	A	Yes
3 – HANTS1	Yes	4	47	2, 3, 7, 11	10, 11	11	4	3	No	A	Yes
4 – HANTS1	Yes	5	44	2, 3, 8, 11	5, 11	11	4	5	No	A	Yes
5 – HANTS1	Yes	4	71	1, 2, 4, 8, 10, 11	3, 7, 11	11	7	4	No	A	Yes
6 – HANTS1	Yes	3	47	1, 2, 11	7, 8, 9, 11	11	5	3	No	A	Yes
7 – HANTS1	Yes	4	55	1, 2, 10, 11	8, 11	11	4	3	No	A	Yes
8 – HANTS2	Yes	3	62	2, 3, 5, 11	11	9, 10, 11	3	3	Yes	A	Yes
9 – HANTS2	Yes	4	52	2, 7, 9, 10, 11	11	11	4	4	Yes	A	Yes
10 – YKHB1	Yes	2	60	11	11	11	0	2	No	A	Yes
11 – YKHB2	Yes	3	45	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	11	11	10	3	No	B	Yes
12 – YKHB1	Yes	3	60	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	11	11	10	3	Yes	B	Yes
13 – YKHB1	No	3	60	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	11	11	10	3	No	B	Yes
14 – YKHB1[c]	Yes	4	22	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	–	–	10	4	No	B	No
15 – YKHB1	No	1	60	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	–	–	10	1	Yes	C	Yes
16 – YKHB2[d]	Yes	2	70	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	–	–	10	1	No	C	No
17 – HANTS2[e]	Yes	1	95	7, 8, 10, 11	–	–	3	1	No	C	No

continued

TABLE 16 Pattern of SMART intervention delivery: who got what when (*continued*)

ID – site	Start 7 days?	Number of SMART visits	Average visit time (minutes)	New resources at each follow-up[a]			Number of factsheets received	Number of goal-setting sheets received	Podcast films watched?	Intervention delivered as planned[b]	Complete all follow-up visits?
				Week 2	Week 4	Week 6					
18 – YKHB1[f]	No	0	0	–	–	–	0	0	–	D	Yes
19 – HANTS1[g]	No	0	0	–	–	–	0	0	–	D	No

a Data from researcher follow-up CRFs: 1, managing pain with opioids; 2, contacts and further information; 3, getting hold of prescriptions; 4, organising medicines; 5, fitting opioids into daily routine; 6, checking opioids are managing pain; 7, common concerns; 8, keeping on top of side effects; 9, pain diary; 10, medication chart; and 11, goal-setting sheet.
b A, received the intervention as planned, i.e. started within 7 days of baseline data collection, received at least a minimum of three SMART study nurse visits, received tailored staged information provision, goal-setting and regular review and coaching; B, received the intervention as planned (minimum of three SMART study nurse visits + goal-setting + review and coaching), but unclear if information provision was tailored to participants needs; C, received goal-setting, review and coaching as planned, but did not receive minimum of three SMART study nurse visits or staged information provision; D, did not received any elements of the intervention.
c Participant withdrew from researcher follow-up after 14 days, but continued to use the goal-setting element of the SMART intervention with study nurse.
d Participant died after receiving two SMART study nurse visits.
e Participant died after receiving one SMART study nurse visit.
f Participant did not receive the intervention from their study nurse, but did complete all follow-up visits with a researcher.
g Participant died before receiving first SMART study nurse visit.

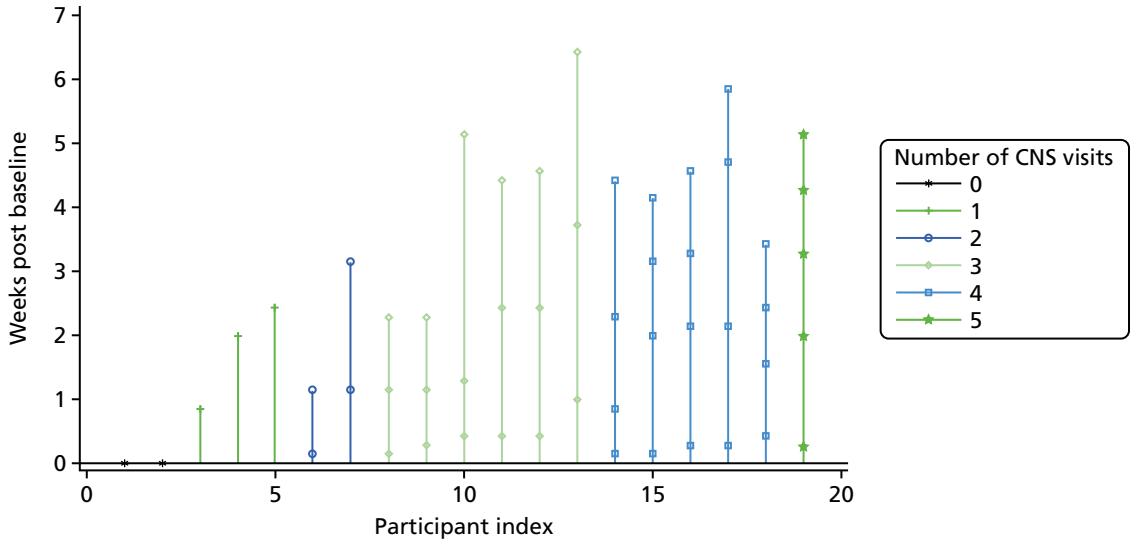

FIGURE 9 Timing of SMART study nurse visits.

on her caseload by telephone on a single day because of a SMART study visit. The extra time required for SMART study nurse visits led the study nurses at the individual sites to discuss this impact with one another.

To what extent were each of the intervention elements implemented as planned?

Overall, the deliverability of the four-step educational approach was initially seen by the study nurses as challenging and required practice. However, they perceived the delivery of the four steps in a therapeutic conversational style, which enabled it to flow naturally and recognised them as being inherently part of what specialist nurse practice looks like. Study nurses responded:

> *The four-step process sort of reflects the nursing process really doesn't it? You know that's what you do, or what you should be doing. But I think having it in your head more concretely and having things that you do at each of those steps just makes it more real.*
>
> *H4CNS003*

> *I followed this process . . . I found that kind of reflected pretty much what we do with that sort of pain assessment and their usage of medication assessment that followed quite well anyway.*
>
> *H4CNS001*

Fully embedding the concept of supported self-management in end-of-life care took time and practice for the study nurses. The reflective patient-led approach to the educational process challenged their desire to go in and immediately 'come up with solutions' (H2CNS002). In addition, all the study nurses were experienced palliative care clinicians and the standardised approach to the four steps challenged their own working style which they had evolved. Consequently, the shift in thinking required for delivery of the self-management ethos within the educational approach was accommodated more successfully by some of the study nurses than by others. For example, one said, 'I need to just take a little step back and let the patient tell me what they want to do a little bit more' (H2CNS002).

The deliverability of the individual elements of the four-step educational approach was mixed. The quality/completeness of evidence for each step varied owing to poor completion of the study nurse CRFs, which were intended to document what had been delivered by the study nurses at each SMART visit (*Table 17*). Undertaking the needs assessment (step 1) was universally recognised by the study nurses as part of their usual practice and did not present as a challenging aspect of the intervention. *Table 17* shows that, based on the study nurse CRFs and the presence of staged information provision and goal-setting (which were predicated on having undertaken a needs assessment), all of the 17 participants who started using the intervention received a needs assessment.

TABLE 17 Evidence of the four-step educational approach

	Step			
ID – site[a]	1: need assessment[b]	2: staged information provision[c]	3: goal-setting[d]	4: review and coaching[e]
1 – YKHB2	Yes	Yes	Yes	Yes
2 – YKHB2	Yes	Yes	Yes	Yes
3 – HANTS1	Yes	Yes	Yes	Yes
4 – HANTS1	Yes	Yes	Yes	Yes
5 – HANTS1	Yes	Yes	Yes	Yes
6 – HANTS1	Yes	Yes	Yes	Yes
7 – HANTS1	Yes	Yes	Yes	Yes
8 – HANTS2	Yes	Yes	Yes	Yes
9 – HANTS2	Yes	Yes	Yes	Yes
10 – YKHB1	Yes[f]	Yes	Yes	Yes
11 – YKHB2	Yes	Unclear	Yes	Yes
12 – YKHB1	Yes[f]	Unclear	Yes	Yes
13 – YKHB1	Yes[f]	Unclear	Yes	Yes
14 – YKHB1	Yes	Unclear	Yes	Yes
15 – YKHB1	Yes[f]	No	Yes	No
16 – YKHB2	Yes	No	Yes	Yes
17 – HANTS2	Yes	No	Yes	No
18 – YKHB1	No	No	No	No
19 – HANTS1	No	No	No	No

a IDs match IDs in *Table 16*, but are presented in order of those with most to least evidence of the four-step educational approach; therefore, not in ascending order.
b Evidence based on CRFs completed by study nurses.
c Evidence based on follow-up CRFs completed by researchers.
d Evidence based on presence of goal-setting sheets in participants CRF at each follow-up time point.
e Evidence based on study nurse CRFs, or evidence of multiple goal-setting if study nurse CRFs were missing.
f Study nurse CRFs not completed; therefore, evidence based on presence of information resources together with goal-setting sheets and support by researcher field notes.

Overall, step 2 (giving information supported by educational resources in a staged and tailored approach) was adhered to for the majority of participants. A total of 10 out of 19 participants (52.6%) received the educational resources as intended (see *Table 16*, group A), whereas four participants received all the factsheets resources at the first SMART visit. It is unclear whether or not this latter method of information provision was at the participant's request; however, one study nurse responded that 'I just handed everything over' (H4CNS001). This type of delivery may have negatively influenced the acceptability of the factsheets for these participants. The following argument for giving all the factsheets on the first SMART visit was put forward by one study nurse:

> *When somebody's newly started on an opioid . . . you can't kind of pre-guess what they're going to need. And to me the whole point of it is that you are giving them the tools to be able to self-manage . . . they should have all of them [the factsheets] at the beginning so that they've got the information there.*
>
> *H4CNS001*

Table 16 shows that all of the 17 participants who started using the SMART intervention received a goal-setting sheet on their first SMART visit (step 3, resource 11). Subsequently, of the 14 participants who received the intervention and completed a 6-week follow-up visit (see *Table 16*, IDs 1–14), only one did not receive continued goal-setting and regular review and coaching (step 4). The study nurses universally perceived the goal-setting and regular review process as acceptable and deliverable. They identified the goal-setting as a core component of the intervention and perceived value in it because it formalised and evidenced their specialist practice. It also facilitated review and coaching as the previous goals because they were there to 'reflect back on' (H4CNS003). Consequently, goal-setting often became the mechanism by which participants were helped to focus on doing things for themselves (i.e. implementing self-management strategies). Participants and carers also recognised the value of the goal-setting process as focusing on their needs and motivating behaviour change:

> *That's been helpful . . . I think it has made me a bit more explicit about setting goals and saying to [CNS name] 'I'd like to do this, can you help me do this?'*
>
> *H3Pt002*

> *If you set a goal, even if you don't reach it, I still think it's a good thing to do.*
>
> *H4Pt013*

Participants' perceived disadvantages of goal-setting were related to having different expectations of the process, 'sometimes your perception of what they are going to write is just completely different to what they come out with' (H2CNS001). Some participants struggled to think what their goals would be in the context of clinical depression or a degree of memory loss.

In addition to the goal-setting, the only other core factsheet resource was 'contacts and further information' (resource 2), which the CNSs were asked to deliver to the trial patient on their first SMART visit. Thirteen (68%) participants received this factsheet on their first SMART study nurse visit (see *Table 16*). By the 6-week follow-up time point, a further two participants had received this core factsheet.

Overall deliverability of the intervention

A total of 14 out of 19 (74%) participants received the intervention as intended or partially as intended (see *Table 16*, groups A and B). Evidence of the four steps of the intervention having been completed was present for the majority of participants who started using the intervention (see *Table 17*). The end-of-life context provided a complex set of circumstances within which study nurses had to deliver the intervention. Consequently, not all participants were able to fully engage with all elements of the intervention; however, overall the four-step educational approach appears to have been adhered to by the study nurses.

Acceptability of the intervention

Acceptability of the self-management support toolkit components

Overall, the participants found the factsheet resources to be easy to read, clear and not too long. In the case of the few participants who received factsheets and did not read them or just scanned them, the resources were usually read by their carer and were perceived to be of benefit to them. The factsheet 'Contacts and further information' was often poorly delivered (i.e. not completed by nurses), but participants saw it as highly relevant and acceptable: 'all the numbers you need are there, it's a brilliant idea' (H1Pt015-C) and 'it's just reassurance you know, an easy reference, just in case' (H2Pt007).

Other than the core resources, factsheets that were commonly delivered on the first visit were 'Managing pain with opioids' ($n = 11$) and 'Common concerns' ($n = 10$) (see *Table 16*). Both were considered by study nurses to be essential resources as they helped to address concerns and expectations, 'I think that perhaps all patients should have that information [common concerns factsheet] as a standard' (H1CNS001). By the end of 6-week follow-up, 10 participants had received all 10 factsheet resources (see *Table 16*).

The medication chart (resource 10) was delivered to 14 participants (see *Table 16*); however, the frequent non-completion of the medication chart by the study nurses meant that its use and benefit varied. Some nurses provided and completed a simplified one-page medication chart, whereas others helped participants to produce their own versions (either paper based or using a spreadsheet). A number of participants indicated that the medication charts helped them to plan activities away from the home by preparing the necessary medicines to take with them – something that they previously would not have engaged in. Similarly, the medication chart also facilitated carer involvement as it allowed for pre-emptive planning for deterioration of the participant (i.e. carers were able to familiarise themselves with the medication chart and respond appropriately if the participant was unable to).

The pain diary (resource 9) was successfully delivered to 11 participants (see *Table 16*) who viewed it as acceptable, with the majority using it regularly. Participants and carers responded during the end-of-study interview that the pain diary formalised and recorded information about the timing, intensity of pain and outcome of analgesia comprehensively. Participants also responded that it helped with managing breakthrough opioid medication because it enabled them to monitor pain intensity rating throughout the day. The study nurses universally saw the pain diary as a helpful tool to monitor pain and evaluate the effectiveness of analgesic medication and non-drug pain relief strategies (e.g. distraction or hot bath). Overall, participants reported that the pain diaries helped them to keep track of the effectiveness of their medicines by recording when a pain episode occurred, what action was taken and the response. This had the effect of relieving the pressure and anxiety of having to remember these details. In addition, it made participants, carers and study nurses aware of the pattern of pain events throughout the day and stimulated conversations around adjustments to medicines and pain management in general.

The podcast films were watched by five participants who perceived them to be acceptable and:

> *. . . reassuring . . . I think the information was very useful, because it did home in on the fact that you're in control . . . that came across very clear.*
>
> *H2Pt019*

Nevertheless, it was noted that the podcast films (as with some of the factsheet resources) would have been of greater use earlier on in participant's experience of managing pain with opioid medicines. For example:

> *I think that would be useful if I was at the start of the process, but now, with all the things that were said in the DVD, I kind of already knew, especially the chap who was managing his prostate cancer, I've been through the same process myself.*
>
> *H3Pt002*

Importantly, participants responded that they valued the authenticity of the subjects in the films (one patient and two specialist palliative care nurses), particularly as they were sharing their experience and self-management strategies. Only one participant who received the podcast films did not watch them, which was in the context of untreated depression. Study nurses responded during the end-of-study interviews that they thought the podcast films were helpful for participants and their carers, and having an alternative to paper-based information suited some people well. However, overall the podcast films were not offered by the study nurses to all participants. This may have been an issue of practicality; for example, one study nurse said that she forgot about them because they were separate from the main file with the factsheet resources, whereas another noted that she did not carry the DVD/memory sticks with them when she visited participants.

Finally, the goal-setting sheets were universally seen by participants, carers and study nurses as acceptable. The study nurses responded during the end-of-study interviews that the goal-setting sheets formalised and evidenced their specialists practice as well as facilitating the review and coaching of previously made goals:

> *I could actually say to you now, with the patients, I'm actually at this point with them . . . we've set these goals and I'm off today to reflect on those and identify any other issue.*
>
> *H4CNS003*

Participants also responded positively to the goal-setting, indicating that the process was manageable and helped them to be more explicit about the things they wanted to achieve. It also helped stimulate participants' thinking around performing the tasks necessary for self-managing medicines such as:

> *. . . right this is what we've got to do now, and get this sorted . . . it's made us more aware to help things along.*
>
> *H1Pt015*

Completion rate for the goal-setting sheets was high: of the 52 SMART study nurse visits that occurred across all participants, there was evidence of goal-setting (or review of goal-setting) at 44 (85%). In the majority of cases, the goal-setting sheets were delivered and completed well, with appropriate patient-focused goals set and action plans made to achieve the goals. One participant who withdrew from researcher follow-ups (due to uncontrolled pain) continued to use the goal-setting sheets.

Overall, the patients, carers and CNSs always perceived some benefit to the SMST. The goal-setting was the most frequently valued element, but often other elements were also liked (e.g. the pain diary). The factsheets often reinforced information provided by the CNSs or that the patients already knew and they stimulated patients and carers to ask further questions. If the factsheets were not read by the patient, then they were often valued by their carer. The CNSs particularly valued the common concerns factsheet. The podcast films were valued by those who had been provided with them.

Overall, there was a range of participant responses to the SMST as a whole from the overtly positive, 'we'll treasure that' (H1Pt001), through to more general, 'it has helped me, definitely' (H3Pt041); a minority of patients did not fully engage with it. Generally, the study nurses viewed the SMST as of value particularly as a resource to support verbal information provision and to refer back to when reviewing self-management progress. For example:

> *It's just a solid piece of evidence, rather than us just trying to explain things to patients and sort of jot things down for them, they've actually got information that we can leave with them that they can use . . . I'd like to be able to use these tools with other people that come onto my caseload. I think they are very useful.*
>
> *H4CNS003*

> *To have all of this to give them, kind of backs up what we say, rather than it's just you talking to the patient, and then the minute you've left the house they've got nothing then to hold on to.*
>
> *H4CNS001*

However, given the complex end-of-life circumstances for some participants, not all were able to engage with the intervention or benefited from it directly themselves. For example:

> *Unfortunately things have gone from bad to worse with him [study patient] deteriorating and [name of carer] not being very well, I think it was just perhaps a bit too much.*
>
> *H1CNS001*

Acceptability of the four-step educational approach

The deliverability of the four-step approach was seen as acceptable to the study nurses, who did not perceive that they needed any additional skills to deliver it; it was viewed as a normal part of the specialist role. Still, study nurses perceived value in the explicit nature of the four-step educational approach as it formalised and gave structure to supporting participants and their carers to self-manage medicines within the complexity of the end-of-life context with frequent deterioration of health and depression.

All participants stated that they derived a benefit from the intervention, but the extent to whch the participants were aware of, or acknowledged, the four-step approach varied. The acceptability of the

delivery of the intervention and resulting benefit were increased for the participants and their carers because of the almost universal value that they placed on contact with their study nurse (particularly when face to face and in their own homes).

The second part of the four-step approach was provision of information tailored to patients' needs. Frequently, delivery of the SMST resources (i.e. the factsheets) by the study nurses was less than ideal, which, as a result, had an impact on the acceptability and benefit of the resources, particularly when they were not discussed or talked through, or when all the factsheets were given all together as a large file. There was also difficulty in providing the intervention at the most appropriate time for participants (and their carers) while they were well enough to engage in it, given the unpredictability of end-of-life context.

Overall, the four-step educational approach helped to stimulate suggestions for self-management strategies and then enabled patients, carers and study nurses to determine which strategies worked for the individual. In addition, the intervention as a whole (see *Box 3*) stimulated appropriate questioning by the patient or carer to the CNS; for example, 'it's been easy to ask questions' (H1Pt001). Participants who were already effective self-managers prior to the trial felt that they would have used the materials more if they had received them earlier (at their first contact with their CNS). For example:

> *I've been doing this for over a year. And a lot of the things in here I knew. And frankly, I'm a very organised person, so I've got all the diaries, and I've got all the prescriptions, and they're all online. Whereas it takes a while to get to that stage, to figure out what you're meant to be doing, how you're meant to be doing it.*
>
> *H3Pt002*

Completion of study nurse case report forms

Study nurses were asked to complete a brief CRF after each SMART visit, documenting what had been delivered. Completion rates were high; study nurses' CRFs were completed in 43 out of 52 SMART intervention visits that were delivered across the whole feasibility study (83% completion rate). For SMART study nurse visits for which study nurse CRFs were missing, information on the date of visit was gathered from participant clinical records and evidence of the four-step educational process and the use of the SMST tool resources (including whether or not goal-setting sheets had been completed) was gathered by researchers at follow-up visits. For four participants [all from the same site in Yorkshire and the Humber (YKHB1)] no study nurse CRFs were completed.

Participant self-reported outcomes

Exploratory analysis of participant self-reported outcomes

Descriptive statistics (mean and 95% CIs) of the participant self-reported outcome measures at each time point and at 6 weeks compared with baseline (difference) are presented in *Table 18* and summarised overall by time point. Owing to the small number of participants taking part, further outcome summaries by potential confounders such as disease state, age, sex, level of support and recruitment site, were not undertaken.

This study was not powered to detect any changes in outcome measure score, and there was no change in average pain scores; however, there was a slight reduction in interference from pain (–1.6, 95% CI –2.8 to –0.4) and a modest increase (0.7, 95% CI 0.3 to 1.2) in self-efficacy scores (see *Table 18*). There was no overall change in the intensity of common end-of-life symptoms (ESAS), health-related quality of life [EuroQol-5 Dimensions (EQ-5D)] or satisfaction with information about medicines (SIMS).

Figures 10–12 present histograms of the change in average pain, pain interference and self-efficacy scores, respectively. These histograms show that, for the majority of participants, average pain intensity worsened over the study period (i.e. scores of > 0), whereas there was greater stability or improvement across the

TABLE 18 Descriptive analysis of participant self-reported outcomes

Participant-reported outcome	Study time point				
	Baseline	Week 2	Week 4	Week 6	Difference[a]
BPI (scale 0–10)					
Average pain	4.3 (3.1 to 5.6)	3.3 (2 to 4.6)	4.1 (2.4 to 5.7)	3.5 (2.3 to 4.8)	–0.2 (–1.5 to 1.1)
Pain interference	4.3 (3.1 to 5.5)	3.5 (1.8 to 5.2)	2.7 (2.4 to 5)	2.5 (1.4 to 3.6)	–1.6 (–2.8 to –0.4)
Worst pain	6.1 (4.5 to 7.6)	5.3 (3.4 to 7.2)	5.9 (3.9 to 7.8)	5.4 (3.6 to 7.2)	–0.1 (–1.5 to 1.4)
Least pain	2.8 (1.4 to 4.2)	2 (0.7 to 3.3)	2.7 (1.2 to 4.2)	2.5 (1.1 to 3.8)	0.1 (–1.1 to 1.3)
Present pain	2.9 (1.8 to 4.1)	2.7 (1.5 to 3.8)	3.5 (1.8 to 5.1)	3.7 (1.9 to 5.5)	0.8 (–0.8 to 2.4)
SES (scale 0–10)					
Total score	7.1 (6.3 to 7.9)	7 (6.2 to 7.8)	7.5 (6.5 to 8.5)	7.7 (6.7 to 8.6)	0.7 (0.3 to 1.1)
ESAS (scale 0–10)					
Total score	2.3 (1.7 to 2.9)	2.6 (1.6 to 3.6)	2.9 (2.3 to 3.5)	2.7 (1.9 to 3.5)	0.1 (–0.5 to 0.7)
EQ-5D (scale 0–1)					
Health status	0.52 (0.4 to 0.63)	0.56 (0.44 to 0.68)	0.52 (0.4 to 0.63)	0.58 (0.44 to 0.7)	0.05 (–0.11 to 0.21)
SIMS (scale 0–17)					
Total score	11.7 (9.7 to 13.8)	13.8 (11.4 to 16.2)	13.4 (11.4 to 15.4)	13.7 (7.5 to 20)	1.7 (–4.5 to 7.8)

a Differences were calculated as the mean difference between baseline and 6-week follow-up time points.

Notes

Data are presented as mean (95% CIs).

An intention-to-treat approach was taken, therefore the denominator at baseline was $n = 19$ and at all follow-up time points was $n = 15$.

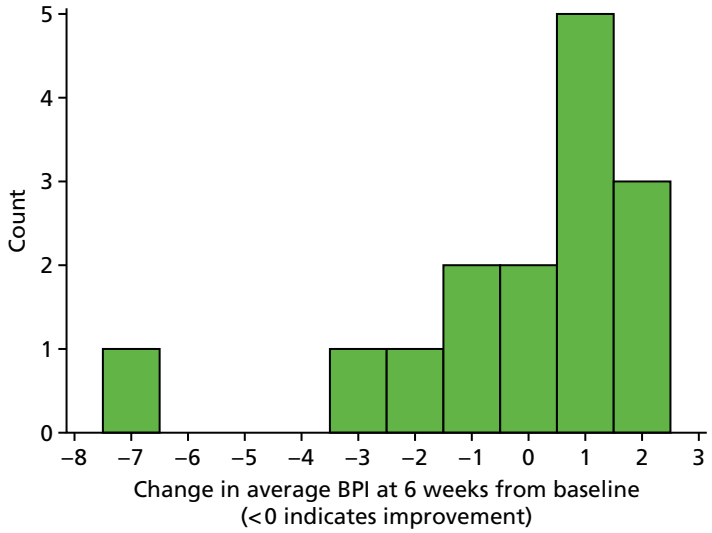

FIGURE 10 Histogram of change in BPI average pain intensity scores. N.B. change scores calculated week 6 score minus baseline score.

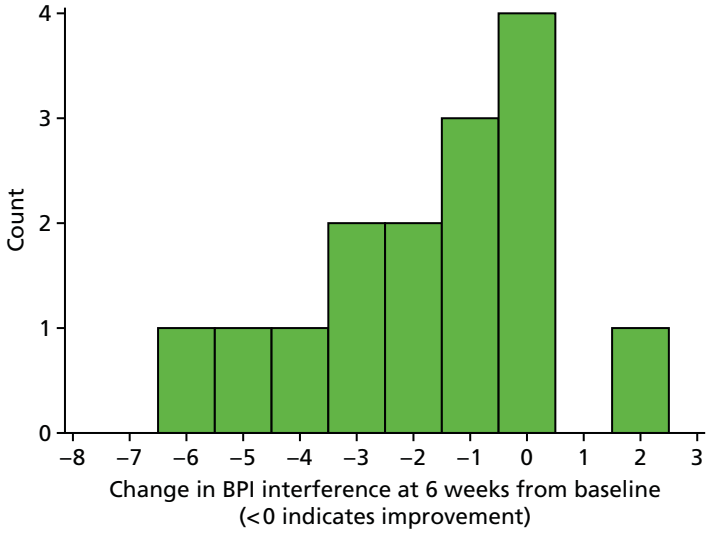

FIGURE 11 Histogram of change in BPI pain interference score. N.B. change scores calculated week 6 score minus baseline score.

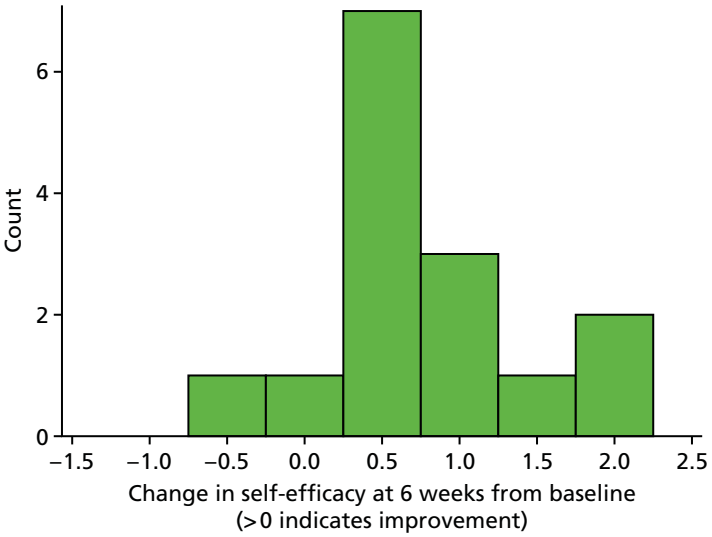

FIGURE 12 Histogram of change in SES score. N.B. change scores calculated week 6 score minus baseline score; > 0 indicates improvement.

board on BPI pain interference (i.e. scores of ≥ 0) and, largely, there were improvements for all participants on the self-efficacy scale (i.e. scores of > 0). *Table 19* presents the variability (SD) with 95% CI for candidate primary outcome measures, along with the estimated effect size for the change in average pain, pain intensity and self-efficacy at 6 weeks compared with baseline.

The number, proportion and 95% CI around the proportion of participants with clinically meaningful reduction in average pain and pain interference are summarised in *Table 20*. These data show that at follow-up weeks 2 and 6 there were more responders based on pain interference than average pain intensity.

TABLE 19 The SDs and 95% CIs for candidate primary outcome variables for a definitive trial

	Candidate primary outcome variable, SD (95% CI)		
Time point	BPI average pain	BPI pain interference	SES
Follow-up week 2	2.6 (1.9 to 3.8)	2.5 (1.9 to 3.7)	1.6 (1.2 to 2.4)
Follow-up week 4	2.4 (1.7 to 3.7)	3.1 (2.2 to 4.8)	1.4 (1.0 to 2.2)
Follow-up week 6	3.0 (2.2 to 4.7)	2.4 (1.7 to 3.8)	1.8 (1.3 to 2.9)

TABLE 20 Responders based on reductions in average pain intensity and pain interference at each follow-up

	Responders					
	BPI average pain			BPI pain interference		
Time point	Number of responders	%	95% CI	Number of responders	%	95% CI
Follow-up week 2	4	26.7	7.8 to 55.1	6	40.0	16.3 to 67.7
Follow-up week 4	3	20.0	4.3 to 48.1	3	20.0	4.3 to 48.1
Follow-up week 6	3	20.0	4.3 to 48.1	7	46.7	4.3 to 48.1

Notes
The denominator at all follow-ups was $n = 15$.
Responders were classified as participants reporting a $\geq$ 2-point or $\geq$ 30% reduction in average pain score or a $\geq$ 1-point reduction in pain interference at each follow-up time point compared with baseline.

Participant acceptability of self-reported outcomes

Generally, participants' experience of completing the self-reported outcome measures was acceptable; however, there were some limitations related to the wording of some questions given the end-of-life context (e.g. 'normal work' and 'enjoyment of life' on the interference subscale of the BPI). A small number of participants criticised the 'duplicity' (H4Pt001) of some questions, given the combination of five different measures. Overall, there was dislike for the SIMS as many participants experienced difficulty remembering specific information that they had received about their medicines over the preceding 2 weeks.

Overall, completion rates for the questionnaire packs were high: all questionnaires were completed by participants with a researcher at each time point. The proportion of missing data at individual item level was very low (*Table 21*) and did not prevent any summary scores from being calculated at any time point. The proportion of missing data was < 3% for all participant self-reported outcome measures at all time points, except for BPI at the week 4 follow-up (3.9%). The most commonly missing item on the BPI was the final item about the extent to which pain interferes with enjoyment of life (missing in three cases from the same participant); a number of participants responded that they felt that this question was inappropriate for people approaching the end of life. Similarly, for the EQ-5D, one response to the final item asking respondents to rate their overall health from best to worst was missing at all time points (from the same participant in each case). The field notes kept by the researchers identified a general lack of acceptability of this question by participants. One participant responded during the end-of-study interview, 'it's a stupid question to ask people in palliative care' (H1Pt011-C), when asked specifically about this response item. The SIMS was least liked by the participants; nevertheless the proportion of missing data was extremely low.

TABLE 21 Missing data level from participant self-reported outcome measures

Study time point	Outcome measure	Number of items overall (all participants)	Number of (%) missing items
Baseline ($n = 19$)	BPI[a]	228	2 (0.9)
	SES[b]	114	0 (–)
	ESAS[c]	190	3 (1.6)
	EQ-5D[b]	114	2 (1.8)
	SIMS[d]	323	0 (–)
Week 2 follow-up ($n = 15$)	BPI[a]	180	4 (2.2)
	SES[b]	90	1 (1.1)
	ESAS[c]	150	2 (1.3)
	EQ-5D[b]	90	1 (1.1)
	SIMS[d]	255	1 (0.8)
Week 4 follow-up ($n = 15$)	BPI[a]	180	7 (3.9)
	SES[b]	90	0 (–)
	ESAS[c]	150	4 (2.7)
	EQ-5D[b]	90	1 (1.1)
	SIMS[d]	255	0 (–)
Week 6 follow-up ($n = 15$)	BPI[a]	180	5 (2.8)
	SES[b]	90	0 (–)
	ESAS[c]	150	2 (1.3)
	EQ-5D[b]	90	1 (1.1)
	SIMS[d]	255	0 (–)

a A total of 12 items.
b A total of 6 items.
c A total of 10 items.
d A total of 17 items.

Primary outcome measure for a definitive trial

The level of missing data for the BPI average pain, BPI pain interference and SES was negligible (see *Table 21*). There were no ceiling or floor effects for the BPI average pain (maximum score = 10, reported by $n = 0$; minimum score = 0, reported by $n = 1$). For BPI pain interference, no ceiling effects were found (maximum score = 10, reported by $n = 0$); however, marginal floor effects were observed (minimum score = 0, reported by $n = 4$). No floor or ceiling effects were found on the SES (maximum score = 10, reported by $n = 0$; minimum score = 0, reported by $n = 0$). There was greater stability or improvement by 6-week follow-up across the board on BPI pain interference (i.e. scores of ≤ 0) compared with BPI average pain intensity and, largely, there were improvements for all participants on the self-efficacy scale. Taking account of the variability in participants' change in scores from baseline to 6 weeks (based on the upper limit of the 95% CI for the SD), a large effect size of 0.65 was observed on the SES and 0.46 on the BPI pain intensity scale, whereas a negligible effect size of 0.05 was observed on the BPI average pain scale (*Table 22*).

The results suggest that the SES and BPI pain interference scale are more responsive to change and should be considered for the primary outcome for a definitive trial. Estimates of mean scores, variability and effect sizes are provided in *Tables 18*, *19* and *22* to inform future sample size calculations.

TABLE 22 Summary statistics and estimated effect sizes for the difference in scores for candidate primary outcome measures at 6 weeks compared with baseline

		Difference at 6 weeks compared with baseline			
Outcome	*n*	Mean difference (95% CI)	SD (95% CI)	Effect size (mean/SD)	Effect size (mean/SD upper limit)
BPI average pain	15	–0.2 (–1.5 to 1.1)	2.4 (1.8 to 3.8)	0.2/2.4 = 0.082	0.2/3.8 = 0.05
BPI interference	15	–1.6 (–2.8 to –0.4)	2.2 (1.6 to 3.5)	1.6/2.2 = 0.73	1.6/3.5 = 0.46
SES	15	0.7 (0.3 to 1.1)	0.7 (0.5 to 1.1)	0.74/0.72 = 1.03	0.74/1.14 = 0.65

Assessing contamination of non-study nurses

The survey assessing contamination of non-study nurses was sent to all non-study CNSs working at the four recruitment sites ($n = 37$). The demographics and responses are summarised in *Table 12*. The overall response rate was 41% ($n = 15$) and, like the study nurses, non-study nurses were all female, of a similar age and had worked in specialist palliative care services for a similar length of time. However, fewer non-study nurses were independent prescribers.

The responses to the non-study nurse survey are summarised in *Table 23*. A general awareness of the presence of the SMART study was high among non-study nurses. Of the 15 respondents, only one (7%) was unaware of the SMART study and, of the remaining 14 responders, nine (64%) were aware of what the SMART study was about in a general sense. One non-study nurse responded: 'not aware of what it involves or spoken to my colleagues about it. Just from the title that it is a study about patients having more control in managing their medication' (NSN004).

TABLE 23 Non-study nurse survey responses

Non-study survey questions	*n* (%)
Aware of SMART study?	
Yes	14 (94)
No	1 (6)
Aware of what the SMART study is about?	
Yes	9 (60)
No	6 (40)
Discuss SMART study with a study nurse?	
Yes	1 (6)
No	14 (94)
Influenced or changed practice?	
Yes	0 (–)
No	15 (100)
Have you seen a SMART participant?	
Yes	2 (13)
No	13 (87)

In terms of direct communication about the study, only one respondent (7%) had discussed the SMART study with one of the study nurses. Concerning contamination of non-study nurse usual practice, all respondents indicated that their own practice was not influenced or changed as a consequence of working in a team in which their colleagues were using the SMART intervention. Two respondents indicated that they had each seen one SMART participant when covering for a study nurse: one during a hospital admission and one in an outpatient clinic.

Adverse events

There were no serious adverse events attributed to the trial intervention or trial processes. Two participants were admitted as inpatients (one to a hospice and one to a hospital) for symptom control.

Conclusions

In conclusion, the feasibility study of the SMART intervention was a single-arm trial in which 19 participants were recruited over 4 months from four community palliative care services via 12 palliative care CNSs who were trained in the delivery of the intervention. In total, 17 participants commenced the SMART intervention with a trained study nurse and 15 were followed up at 2, 4 and 6 weeks following baseline assessment. Through this study we have demonstrated that our research process, study nurse training schedule and intervention delivery strategy are feasible and acceptable within a sample of community-based individuals approaching the end of life, their carers and palliative care CNSs. A total of 74% of participants received the intervention as intended (or partially as intended), with flexibility of delivery necessary to allow for the complex circumstances of managing symptoms at the end of life. The follow-up rate was 79% at 6 weeks, higher than follow-up rates observed in previous trials of similar community-based populations.

Although the analysis of participant self-reported outcome was exploratory, the data overall tended to favour improvements in pain interference and self-efficacy over improvements in pain intensity. The results of the feasibility study were used to determine which outcome should be considered as the primary outcome for a future definitive RCT and to estimate the sample size required for such a trial. The next chapter demonstrates the feasibility of conducting a health economic evaluation of the SMART intervention.

Chapter 4 The SMART health economics: feasibility of economic evaluation and preliminary cost-effectiveness

Introduction

Before investment in new health-care interventions can be made, convincing evidence of the value for money of those interventions must be provided. The SMART feasibility study included resources for health economic research to be conducted that would help determine both the feasibility of an economic evaluation in this patient group and setting and whether or not there is the potential for the SMART intervention to be cost-effective.[80]

Aims and objectives

The overall aim of the health economic research was to establish the feasibility of an economic evaluation of SMART and preliminary estimates of cost-effectiveness. Specific objectives were to:

- determine acceptability and completeness of resource use and utility measures in this setting
- establish the cost of the SMART intervention
- develop a decision-analytic model that would permit the generation of cost-effectiveness estimates
- employ the model to test effectiveness scenarios
- employ the model to estimate the value of further research.

Feasibility

The SMART feasibility study was used to test the acceptability of the data collection forms. Acceptability is evidenced by the level of missing data. The completeness of the data collected in the outcome measures pack was recorded using descriptive statistics, detailing the number and percentage of questionnaires returned and the number and percentage of missing items within the returned questionnaires.

Resource use

Data collection forms to identify the health and social care services that individuals used were completed by researchers using clinical records. The form, which was adapted from one used in the IMPACCT study, is included in *Appendix 3*.

Quality of life (utility)

In order to calculate quality-adjusted life-years (QALYs), it is necessary to collect data on health state utility. The EQ-5D is NICE's preferred measure of health state. The feasibility of using the new EQ-5D-5L was explored.[81] The EQ-5D-5L formed part of the interview-administered questionnaire and was scored using a newly developed UK tariff.[82]

The small sample size and absence of a control group meant that an economic evaluation based on patient-level analysis of the data was not possible. Thus, estimates of cost-effectiveness were based on a decision-analytic modelling (DAM) approach.

Cost-effectiveness and decision-analytic model

We conducted a preliminary economic evaluation of the SMART intervention plus standard care compared with standard care alone following the NICE reference case.[83] Outcomes were expressed as QALYs and costs calculated from the perspective of the NHS and Personal Social Services (PSS). A DAM developed for the NIHR-funded IMPACCT project was adapted for use here. In the absence of trial data, the DAM allows us to estimate the cost-effectiveness of the SMART intervention and explore, through sensitivity and scenario analyses, the levels of effectiveness and costs that would yield acceptable value for money metrics for the intervention. The DAM is a simplified representation of the patient pathway describing the major health and cost events that occur over a relevant time period.

Model structure, cycle length and time horizon

The SMART DAM (*Figure 13*) was adapted from the IMPACCT DAM and is a Markov model with weekly cycles that runs for a time horizon of 52 weeks. The model structure, time horizon, cycle length and parameters were developed using the findings from a model literature review and expert and patient opinion. The model was developed in line with current best-practice standards.[84,85]

The DAM comprises health states based on level of pain severity (no/mild pain, moderate pain, severe pain) and death (see *Figure 13*). Within each of the pain health states, the occurrence of side effects (i.e. constipation, drowsiness and nausea) was permitted.

In the DAM, a cohort of hypothetical patients (mean age 72.4 years) who have advanced cancer and pain move (or transit) through the health states in accordance with specified transition probabilities. Each health state has a mean cost and utility value associated with it so that the cohort members accrue QALYs and costs as the 52 weeks pass. Patients can move between pain states and between pain states and death. Side effects are not represented as separate health states.

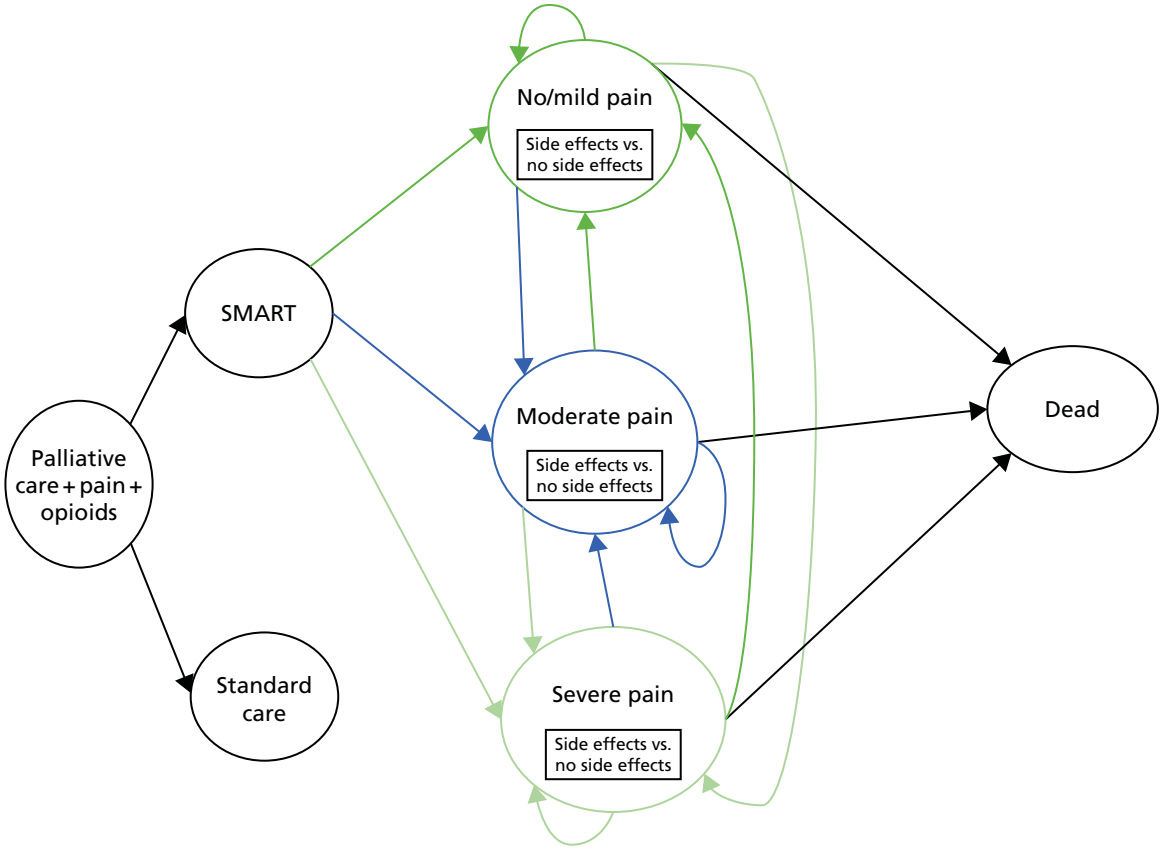

FIGURE 13 Diagram of the SMART DAM.

Model parameters

The model parameter values are described in *Tables 19* and *21*. They were derived from a number of sources, including the IMPACCT patient survey data, data from the literature, analysis of palliative care patient survival data and analysis of a previous advanced cancer trial.[86]

Cost and utility parameters

The model uses resource use and utility data collected from participants during the NIHR-funded IMPACCT study. Between August 2013 and June 2014, 248 patients were recruited to the study and completed a survey. Community-based patients with pain from advanced cancer who were aged ≥ 18 years were eligible for the study. Patients with advanced cancer were defined as those patients with metastatic cancer (histological, cytological or radiological evidence) and/or those receiving anticancer therapy with palliative intent. Patients with pain were defined as those receiving analgesic treatment for cancer symptom-related and/or therapy-related pain. Patients had to be able to complete the questionnaires and provide informed consent to participate. Thirteen palliative care services across England recruited patients to the study. The participants completed a resource use questionnaire capturing health-care use, pain rating scales, the EuroQol-5 Dimensions, three-level version, and additional utility measures: the European Organisation for Research and Treatment of Cancer 8 Domains (EORTC-8D)[87] and ICEpop CAPability measure for Adults (ICECAP-A).[88]

The resource use questionnaire asked participants to recall use of primary and community care (e.g. GP visits and nurse contact) and secondary or hospital care (e.g. visits to accident and emergency and hospice stays) in the previous 4 weeks. Unit costs were assigned to the data in order to estimate the average cost of health and social care service use for the sample. Unit costs were obtained from national sources including the Personal Social Services Research Unit (PSSRU) *Unit Costs of Health and Social Care 2015*,[89] *NHS Reference Costs 2014–2015*[80] and the *British National Formulary*.[90]

Mean cost and utility estimates (with variance) were estimated for each of the model pain health states (*Table 24*). Individuals were classified into pain health state using a 0–10 pain severity rating scale, where:

- 0–4 = no/mild pain
- 5–6 = moderate pain
- 7–10 = severe pain.

The impact of side effects (nausea, constipation and drowsiness) were estimated using a previous trial data set that included EQ-5D, cost and side effect data. COUGAR II[86] was a trial of chemotherapy compared with active symptom control for those with refractory oesophagogastric adenocarcinoma.[92] These data were thought appropriate as the participants were at the end of life and had similar characteristics to those in the survival estimation and IMPACCT survey samples.[91] A regression model was run predicting, in turn, EQ-5D and costs, and using side effect identifiers based on European Organisation for Research

TABLE 24 Utility parameter values

Parameter	Mean	SD	Source
No/mild pain	0.526	0.282	IMPACCT patient survey[91]
Moderate pain	0.423	0.296	IMPACCT patient survey[91]
Severe pain	0.149	0.321	IMPACCT patient survey[91]
Decrement for nausea	–0.084	0.028	COUGAR II trial data[86]
Decrement for constipation	–0.052	0.027	COUGAR II trial data[86]
Decrement for drowsiness	–0.222	0.022	COUGAR II trial data[86]

and Treatment of Cancer – Quality of Life Questionnaire C30 (EORTC-QLQ C30) questions as predictors. The beta coefficients on each of the predictors denote the utility decrement or cost impact associated with each side effect. These were applied in an additive way in the model.

The development and implementation of the new tool were costed following consultation with the SMART study researchers. In addition to the participant-completed data, the resources associated with development and delivery of the SMART intervention were recorded based on routine data, such as administrative records and participant records, as well as a detailed description of the intervention costs. The costs of material development, printing and nurse training are included in *Table 25*.

Survival parameter

Although it was assumed that neither of the interventions compared in this evaluation influences mortality, it was necessary still to estimate background survival in this population. The survival of the hypothetical model cohort was estimated using a parametric regression, which was fitted to data gathered in another IMPACCT workstream. The data ($n = 4638$, of whom 84% of patients had a cancer diagnosis and 16% a non-cancer diagnosis) were retrospectively collected on all patient referrals to specialist palliative care services in the city of Leeds, West Yorkshire, over a 2-year period (2012–14) and contained variables on date of referral to palliative care, age, sex and date of death. The characteristics of the sample are described in *Table 26*. There was no censoring of death and a Kaplan–Meier (K–M) curve was estimated for the time between referral and death. Negative numbers were assumed to be errors and, where they occurred, resulted in the cases being dropped.

A number of models were applied to the data, including exponential, Weibull and Gompertz. Visual comparison of the modelled survival curve with the K–M curve and the Akaike information criterion were used to judge model quality. Weibull had the lowest Akaike information criterion (16,891.5 vs. 17,760.15 for exponential and 16,891.5 vs. 17,138.03 for Gompertz functions) and had good fit with the observed K–M curve. Age and sex covariates were tested in the models but only age was found to be significant. The results of the Weibull regression are shown in *Table 27* and *Figure 14*. As the gamma factor was significant, the use of the Weibull model is justified as this indicates a non-constant (and declining) hazard function. The same

TABLE 25 Cost parameter values

Parameter	Mean (£)	SD (£)	Source
No/mild pain	531.49	1021.82	IMPACCT patient survey[91]
Moderate pain	720.55	1038.83	IMPACCT patient survey[91]
Severe pain	1089.12	1455.65	IMPACCT patient survey[91]
Increment for nausea	93.93	47.32	COUGAR II trial data[86]
Increment for constipation	33.23	46.60	COUGAR II trial data[86]
Increment for drowsiness	81.04	36.97	COUGAR II trial data[86]
Cost for SMART intervention	320.25	–	SMART – see *Table 33*

TABLE 26 Sample for the survival analysis

Parameter	*n* (%) (*N* = 4638)	Mean	SD	Range
Female	2372 (51)	–	–	–
Age (years)	4638 (100)	72.44	13.54	17–108
Survival (days)	4638 (100)	80.77	117.81	0–933

TABLE 27 Weibull survival analysis[a]

Parameter	Coefficient	SE	*z*	*p* > *z*	95% CI	Hazard ratio
Gamma (_ln/p)	–0.306	0.011	–27.220	0.000	–0.328 to –0.284	0.737
Constant	–2.019	0.083	–24.330	0.000	–2.182 to –1.857	0.133
Age	0.005	0.001	4.640	0.000	0.003 to 0.007	1.005
p	0.737	0.008			0.721 to 0.753	
1/p	1.358	0.015			1.328 to 1.388	

SE, standard error.
a Survival per week from referral to palliative care.

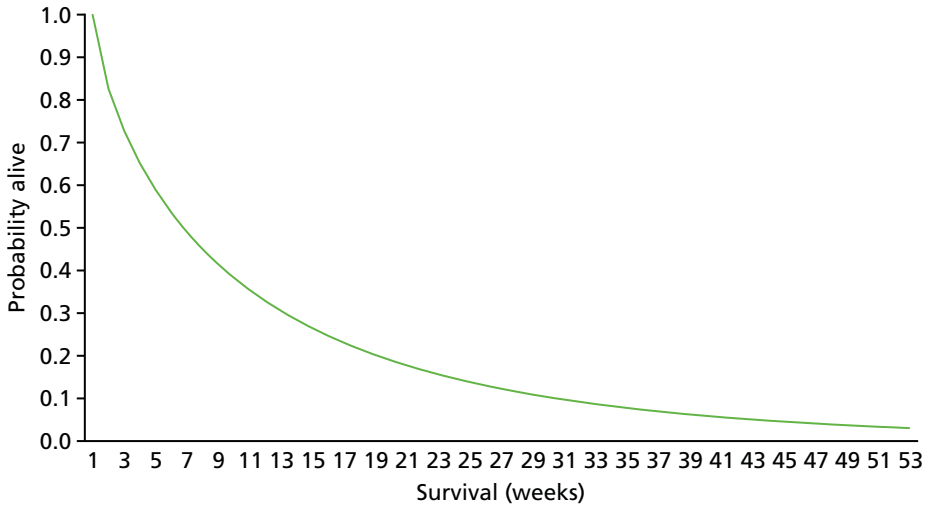

FIGURE 14 Weibull estimated survival (weeks after referral to palliative care).

risk estimates from this analysis were applied to all health states and the Markov model was relaxed to allow these risk estimates to vary over time. The survival model estimates were permitted to vary in the probabilistic sensitivity analysis following Cholesky decomposition for correlated regression parameters. During the 52-week model time horizon, 97% of the cohort were expected to have died. Survival was assumed to be unrelated to pain, and thus the mortality rate was the same for all pain health states.

Transition probability parameters

Table 28 summarises the transition probabilities used in the model. The starting proportions of those in each pain health state and of those with each of the three side effects were taken from the IMPACCT patient survey, but allowed to vary in sensitivity analyses. Data from the feasibility study could not reliably inform on the effectiveness of SMART as the study was not powered to do so. In the absence of effectiveness data on the impact of the SMART intervention on pain and side effect management, we relied on expert opinion on the likely effectiveness of the intervention (Professor Michael Bennett, University of Leeds) and on a review of the literature. Given the uncertainty over the intervention effectiveness, we explored scenarios in the model which assumed, for example, that the SMART intervention led to an overall reduction in the proportion of people with side effects of 5% and a weekly reduction in pain status (from moderate and severe to no/mild) of 1% per week. The baseline pain and side effect levels and pain progression were assumed equivalent to those estimated in the standard care arm. To help inform model parameter estimation, literature searches were conducted in June and July 2016 across the databases MEDLINE, MEDLINE In-Process & Other Non-Indexed Citations, EMBASE and The Cochrane Library to identify economic models of behavioural and educational self-management interventions for patients to manage pain and side effects of medications at the end of life.

TABLE 28 Transition probability parameters

Parameter	Mean (£)	SD (£)	Source
Background survival	See *Table 26*	N/A	Palliative care referral data
Starting proportions			
No/mild pain	0.439	N/A	IMPACCT patient survey[91]
Moderate pain	0.305	N/A	IMPACCT patient survey[91]
Severe pain	0.256	N/A	IMPACCT patient survey[91]
Nausea	0.212	N/A	IMPACCT patient survey[91]
Constipation	0.331	N/A	
Drowsiness	0.773	N/A	
Pain progression	See *Table 26*	N/A	COUGAR II trial data[86]
Effectiveness			
Standard care: pain	0		No change in pain progression – assumption
Standard care: side effects	0		No change in side effects – assumption
SMART intervention: pain	–0.001		Weekly transitions: moderate to no pain and severe to moderate – assumption
SMART intervention: side effects	–0.05		Assumption

N/A, not applicable.

The change in pain status in standard care was modelled using the COUGAR II trial data set.[86] In COUGAR II, patients completed the EQ-5D measure at 3- and 6-weekly follow-ups during the trial, meaning that a substantial number of longitudinal data were available for this group. The EQ-5D pain and discomfort item response options were considered to be equivalent to the health states in the model defined by the numeric pain scale categories. Thus, the EQ-5D responses 'I have no pain or discomfort', 'I have moderate pain or discomfort' and 'I have extreme pain or discomfort' were assumed roughly equivalent to the pain rating categories of 0–4, 5–6 and 7–10, respectively. Hence, by observing changes in EQ-5D pain item responses over time, we were able to estimate the change in pain status over time at the end of life.

The EQ-5D pain item response was predicted in a multinomial regression with study week number and survival included as covariates. Thus, the coefficient on the week covariate indicates the likelihood of change in pain item response as time progresses, after controlling for survival. The results of the regression are shown in *Table 29* and indicate an increase in pain level over time, albeit a small one. Marginal effects were used to estimate the transition probabilities for pain progression using the multinomial results. These results inform only on the change in proportions over time (and not all the possible transitions between health states), and the COUGAR data were insufficient to inform on all possible pain health state transitions. Therefore, we assumed that transitions occurred only from the 'no pain' group to moderate and severe pain groups. This background pain progression at the end of life was assumed to be the same in both arms, but the scenario analyses allowed for improvements in health status in the SMART intervention arm.

Cost-effectiveness analysis

The economic evaluation follows the NICE reference case and hence a cost–utility analysis was conducted with a cost per incremental QALY presented from UK NHS and PSS perspectives. The costs are reported in 2015 prices and patient health is measured in terms of QALYs. Cost-effectiveness was assessed using the incremental cost-effectiveness ratio (ICER) and net monetary benefit (NMB) values, and a range of sensitivity analyses were conducted to explore the impact of key model assumptions and parameter uncertainty on the results.

TABLE 29 Pain progression over time

Model parameter						
n	639					
Log-ratio $\chi^2(4)$	30.99					
Probability > χ^2	0.0000					
Pseudo-R^2	0.0299					
Log-likelihood	–502.644					
Pain parameter	**Coefficient**	**SE**	***z*-value**	***p*-value**	**Lower CI**	**Upper CI**
No pain (base)						
Moderate pain						
Week	0.0270	0.0092	2.9500	0.0030	0.0091	0.0450
Survival	–0.0031	0.0006	–4.9600	0.0000	–0.0043	–0.0019
Constant	1.2037	0.1617	7.4500	0.0000	0.8868	1.5205
Extreme pain						
Week	0.0524	0.0170	3.0800	0.0020	0.0191	0.0858
Survival	–0.0029	0.0015	–2.0200	0.0440	–0.0058	–0.0001
Constant	–1.6192	0.3482	–4.6500	0.0000	–2.3017	–0.9368

SE, standard error.

The ICER is calculated by dividing the difference in mean costs between two arms by the difference in mean QALYs between the two arms:

$$\text{ICER} = \frac{C_{SMART} - C_{UC}}{E_{SMART} - E_{UC}} = \frac{\Delta C}{\Delta E}, \quad (1)$$

where C_{SMART} and E_{SMART} are the expected cost and effectiveness of the intervention (i.e. SMART) and C_{UC} and E_{UC} are the expected cost and effectiveness of the usual care arm. The incremental cost and effect of the SMART arm compared with usual care arm are represented by ΔC and ΔE, respectively. The NICE willingness to pay per incremental QALY threshold [$(\lambda) = £20{,}000$] was used to define cost-effectiveness. ICERs < £20,000 are usually indicative of cost-effectiveness. It was assumed that the NICE end-of-life criteria were not met as these require an intervention to deliver an average increase in survival of 3 months over usual care.

We account for parameter uncertainty in non-linear models by assigning probability distributions to each of the input parameters and randomly drawing from these probabilities over the 10,000 Monte Carlo simulations. This probabilistic sensitivity analysis allows the calculation of 10,000 ICERs and informs on the level of uncertainty in the model. The probabilistic sensitivity analysis results were plotted on the cost-effectiveness plane and NMB estimates used to generate the cost-effectiveness acceptability curve (CEAC).[92] The CEAC illustrates the probability that each intervention would be cost-effective given a range of willingness-to-pay thresholds per incremental QALY.

The NMB was derived thus:

$$\text{NMB} = (\lambda \times \text{QALYs}) - \text{costs}. \quad (2)$$

Discounting was not required as all costs and benefits were experienced within 1 year. A half-cycle correction was applied to account for the likelihood that model health state transitions occur half-way through the model cycles. All analyses were conducted in Stata software (version 14) and Excel® (2013; Microsoft Corporation, Redmond, WA, USA).

Feasibility results

Resource use

Full resource use data for 6 weeks were collected for 15 of the 19 participants (78.9%). Four participants (21.1%) were lost to follow-up and, therefore, their patient records were not accessed. It was of note that use of health-care services outside the GP practice, for example by the community team, was often not recorded. Further investigation of how these services may be captured is required. Despite these challenges, the researcher-completed outcome measure packs were completed.

There were 164 recorded instances of health-care service use for 15 participants over the 6-week study period. As seen in *Table 30*, community nurse and palliative care CNSs were the services most frequently accessed.

In order to calculate mean cost of care for each participant over the 6-week period, we assigned unit costs to each service use (see *Appendix 26* for unit costs). Cost data were completed for 15 participants. As seen in *Table 31*, with unit costs applied to service use it can be observed that the main drivers of cost are GP, CNS and district nurse home visits.

The questionnaire also included space to record prescribed medications. These data were collected for the final 2 weeks for 15 patients and included only prescribed medications and not over-the-counter medications and treatments the patient may have paid for themselves. These data have not been included in the descriptive analysis.

Quality of life

In respect of assessment of quality of life, of the 19 participants in the study, 15 had complete information for calculation of EQ-5D-5L. The four participants who were lost to follow-up had missing data for this part of the questionnaire. Mean change from baseline to week 6 was 0.1079. *Table 32* provides a summary of the EQ-5D-5L.

TABLE 30 Recorded service use for 15 participants

Service	Outpatient/day hospice	Home	Inpatient admission	Telephone	Total
GP	3	15	0	6	24
CNS palliative care	5	21	7	16	49
Doctor palliative care	3	2	0	4	9
Community nurse	20	29	0	8	57
Secondary care	7	0	3	0	10
Nurse other	6	3	0	6	15
Total	44	70	10	40	164

TABLE 31 Mean resource use and costs

Service	Type	*n*	Number of uses	Mean cost (£)	SD (£)	Minimum (£)	Maximum (£)
GP	Outpatient/day hospice	1	3	132.00	0.00	132.00	132.00
	Home	8	15	168.75	89.19	90.00	360.00
	Telephone	4	6	40.50	15.59	27.00	54.00
CNS palliative care	Outpatient/day hospice	3	5	62.10	21.51	37.26	74.52
	Home	8	21	97.81	59.54	37.26	223.56
	Inpatient admission	2	7	130.41	131.73	37.26	223.56
	Telephone	8	16	33.06	17.67	16.53	66.12
Doctor palliative care	Outpatient/day hospice	1	3	501.00	0.00	501.00	501.00
	Home	2	2	167.00	0.00	167.00	167.00
Community nurse	Outpatient/day hospice	4	20	186.30	80.49	74.52	260.82
	Home	6	29	180.09	211.32	37.26	596.16
	Telephone	5	8	26.45	9.05	16.53	33.06
Secondary care	Outpatient/day hospice	7	7	167.00	0.00	167.00	167.00
	Inpatient admission	1	3	501.00	0.00	501.00	501.00
Total cost (£)				536.07	513.04	90.00	1998.77

TABLE 32 THE EQ-5D-5L utility values by time point

Time point	Observed	Missing	Mean	SD	Minimum	Maximum
Baseline	19	0	0.564	0.227	0.122	0.927
Week 2 (follow-up 1)	15	4	0.679	0.196	0.193	0.942
Week 4 (follow-up 2)	15	4	0.603	0.206	0.184	0.942
Week 6 (follow-up 3)	15	4	0.672	0.223	0.108	0.942

Intervention costs

Intervention costs were calculated and included for SMART. The total intervention cost is estimated at £320.25 per patient (*Table 33*). Development costs were also estimated; this included material development (printing SMST resources), training sessions for nurses and researchers and time to deliver intervention (*Table 34*).

Cost-effectiveness results

Results for the base-case cost-effectiveness analysis of SMART compared with usual care are presented in the *Table 35*. Based on the model assumptions regarding pain progression and SMART intervention impact, it can be seen that SMART is more effective and less costly than usual care. SMART can be said to dominate usual care, indicating that there are cost savings to be made from the introduction of SMART.

TABLE 33 Intervention costs

Resource type	Unit cost (£)	Mean number of visits	Time (minutes)	Cost (£)
Sessions with CNS[a]	91 (per hour of face-to-face contact)	3.25	55	271.10
SMART toolkit contents (see *Appendix 9* for more detail)	43.87	N/A	N/A	43.87
DVD pressing	3.60	N/A	N/A	3.60
Memory sticks	1.68	N/A	N/A	1.68
Total				320.25

N/A, not applicable.
a Development costs were estimated. This included material development (printing and patient boards), training sessions for nurses and researchers.

TABLE 34 Development costs of SMART

Item[a]	Total cost (£)
Intervention toolkit folders	2293.55
SMART DVDs	949.44
Seven × nurse[b] training	3276.00
Trainer expenses	2220.00
Researcher preparation and delivery time	354.60
Total	9093.59

a See *Appendix 26* for detail.
b Reference: Curtis[89] page 17.

TABLE 35 Results of cost-effectiveness analysis SMART vs. usual care

Strategy	Total cost (£)	Total QALY	Incremental cost (£)	Incremental QALY	ICER	NMB (£)	Net health benefit
SMART	8921	0.0473	–175	0.009	SMART dominates	5	0.0025
Usual care	9096	0.0387					

The results of the one-way sensitivity analyses conducted for SMART compared with usual care are given in *Table 36*. Assuming that there was a 2.5% reduction in side effects and a 0.005% reduction in pain led to a drop in QALY gain of 0.0041. This meant that costs for SMART were now higher than for usual care, but with an additional health benefit of 0.0045 QALYs per patient. This results in an ICER of £11,977 per additional QALY, which still indicates cost-effectiveness. Sensitivity analyses were conducted using different utility values, the EORTC-QLQ C30 and the ICECAP-A quality-of-life measures. The results of both of these analyses were similar, with SMART once again dominating standard care alone.

With costs of SMART increased 100%, it can now be seen that SMART becomes a more expensive intervention. However, the ICER of £16,778 remains below the NICE cost per QALY threshold of £20,000. One assumption that could be made is that nurse visits to the patient do not increase because of SMART. This extra visit cost was removed, leading to an intervention cost of £49.15. This decrease in incremental cost served to make SMART more cost-effective. With the costs of cancer for each pain severity group halved, SMART becomes a more expensive intervention; however, again, with an ICER of £1830, this remains below the NICE cost per QALY threshold.

TABLE 36 Results of one-way sensitivity analysis

Sensitivity analysis	Strategy	Total cost (£)	Total QALY	Incremental cost (£)	Incremental QALY s	ICER (£)
Reducing effectiveness by 50%	SMART	9151	0.0432	55	0.0045	11,977
	Usual care	9096	0.0387			
Using ICECAP-A utility values	SMART	8921	0.0847	–175	0.0055	SMART dominates
	Usual care	9096	0.0792			
Using EORTC utility values	SMART	8921	0.1000	–175	0.0054	SMART dominates
	Usual care	9096	0.0946			
Increasing SMART intervention costs by 100%	SMART	9241	0.0473	145	0.0086	16,778
	Usual care	9096	0.0387			
Assuming no extra visit costs for SMART	SMART	8650	0.0473	–446	0.0086	SMART dominates
	Usual care	9096	0.0387			
Halving the costs of the cancer for each severity group	SMART	5073	0.0473	16	0.0086	1830
	Usual care	5057	0.0387			
Scenario where side effect costs and utility decrement are halved	SMART	8468	0.0670	–119	0.0068	SMART dominates
	Usual care	8587	0.0602			

EORTC, European Organisation for Research and Treatment of Cancer.

The uncertainty around the model results can be seen in *Figure 15*, the cost-effectiveness plane. The results vary widely, with ICERs scattered across the cost-effectiveness plane. As the spread of ICER cloud is greater vertically than horizontally, there appears to be greater uncertainty in the costs than in the QALYs.

The uncertainty around the cost-effectiveness is further represented in the CEAC in *Figure 16*. The CEAC shows the likelihood that SMART will be acceptable to a decision-maker, given a particular threshold. SMART has a 68.9% probability of being cost-effective at a £20,000 per QALY threshold, increasing to 78.3% at a £50,000 per QALY threshold.

Feasibility of conducting a cost-effectiveness evaluation of SMART

An economic evaluation was conducted to assess the feasibility of estimating cost-effectiveness of SMART compared with usual care in patients at the end of life who receive opioids. The feasibility of a trial-based evaluation was also explored. The evaluation consisted of an economic decision-analytic model, in which cost-effectiveness was assessed for the remaining survival time of patients from a NHS and PSS perspective over 1 year.

The costs of developing and implementing the SMART intervention are relatively modest and, in this analysis, these costs are recovered in savings brought about by improved management of pain and opioid side effects. Given the assumptions made relating to effectiveness, the SMART intervention led to cost savings and yielded incremental QALYs in our base case and many of the deterministic sensitivity analyses. These QALY gains are small, although this is to be expected as this population has a limited survival time in which to benefit. In general, the results are robust to one-way parameter changes and SMART appears to be cost-effective compared with standard care alone.

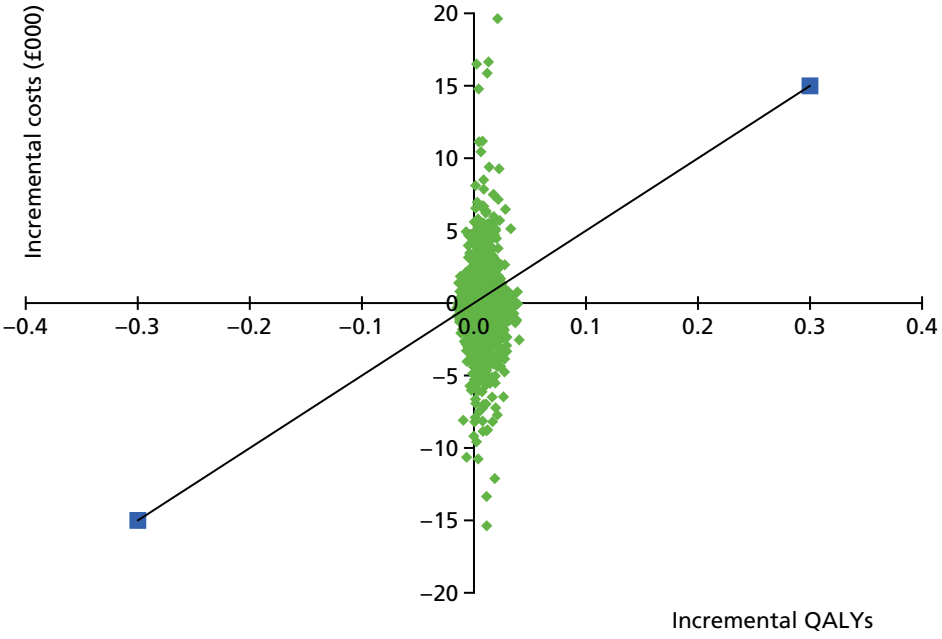

FIGURE 15 Cost-effectiveness plane.

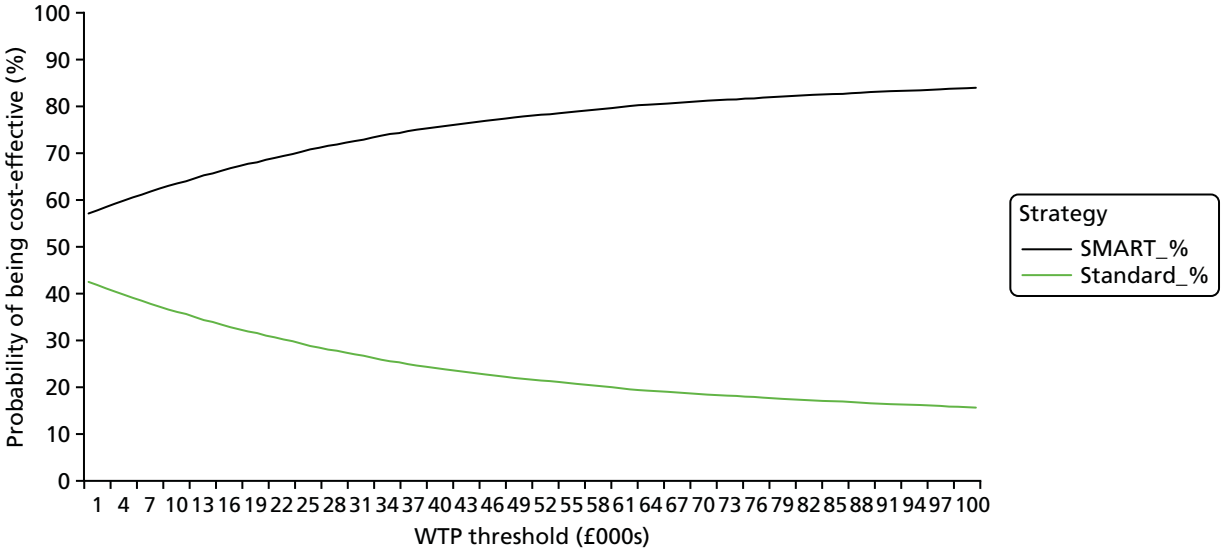

FIGURE 16 Cost-effectiveness acceptability curve: SMART vs. usual care. WTP, willingness to pay.

The probabilistic sensitivity analysis highlights moderate uncertainty in the model as the SMART intervention has a 69% chance of being cost-effective. Given the uncertainty around the cost-effectiveness and data highlighted above, and as effectiveness parameters were based on plausible scenarios, the results should be treated with caution. However, the results indicate that a low-cost intervention such as SMART could be cost-effective in this population even if the impact on pain and side effect management were modest and suggests that further research is warranted.

A full economic evaluation of patient-level data from a RCT is required to allow confidence in decision-making. The feasibility aspects of this study suggest that this should be possible. Although missing data on the utility measures were minimal, greater effort may be required in the collection of cost data and access to centrally held health-care use records may be optimal.

Chapter 5 Discussion and conclusions

We have shown that the evaluation of a supportive self-management intervention for patients requiring analgesia, and who are approaching the end life, is feasible.

Summary of specific feasibility study outcomes

Developed a construct of supported self-management in palliative care in relation to analgesic medicines

This was derived through a synthesis of our existing research and literature reviews of patient needs, behaviour change theory, existing interventions and ways to optimise the context in which HCPs can provide support. The development of the supportive self-management concept included key contextual factors in end-of-life care pain management, patients' concerns about analgesia and the roles and responsibilities of patients, carers and professionals that we represented on a continuum in relation to self-management behaviours.

Developed and refined an intervention consisting of a self-management toolkit and a four-step education approach

We explored and refined our concept of supported self-management with 11 patients, eight carers and 19 HCPs though interviews and focus groups, informing the development of our intervention. From these data, we developed a four-step education approach that consisted of a needs assessment, including capacity for self-management, provision of information, goal-setting and review and coaching. We supported this approach with a self-management toolkit that comprised information factsheets, a pain chart and medication diary, goal-setting sheets and two 5- to 6-minute podcasts. We mapped data from our literature review and interviews against target behaviours and techniques to enhance self-efficacy to ensure that the toolkit and education approach would address the needs of patients, would be based on sound theoretical principles of enhancing self-management and would therefore be more likely to be effective in practice.

Developed and delivered a brief training programme for clinical nurse specialists in palliative care

The intervention was designed to be delivered to patients by community-based CNSs in palliative care. We engaged an expert nurse educator to design and deliver the training, which modelled the four steps within a clinical encounter and was based on a therapeutic conversational process between the specialist nurse and patient. This training included reflection, experiential learning and the development of a modelled self-management-focused conversation between two nurse educators.

Conducted a feasibility study of the intervention to inform the design of a future randomised controlled trial

This tested the recruitment and follow-up rates, fidelity of treatment delivery and suitability of outcome measures. We trained 12 CNSs from four UK hospices in the delivery of the intervention. During the 4-month study period, we identified 103 eligible patients from 417 who were screened. The most common reasons for ineligibility were patients not treated with a strong opioid (53%) and expected survival of < 6 weeks (19%). Of the 103 eligible patients, 37 (36%) were approached, of whom 19 (51% of those approached) agreed to participate and 15 completed the 6-week follow-up period. We found that 13 out of these 15 patients received all components of the intervention. Most patients (13/15) received a minimum of three visits during the 6-week study period. Rates of missing data for our outcome measures were very low. Although we observed no changes in our measures of pain intensity, we did observe improvements in our measures of interference from pain and in enhancing self-efficacy, which our evidence synthesis and interview data highlighted as being more important outcomes to patients than pain intensity alone.

Acceptability of intervention

Through qualitative interviews with patients and CNSs who participated in our feasibility study, we were able to understand the acceptability of the intervention and potential challenges within a large RCT. Patients and carers perceived that they all derived some benefit to them from the SMST, but the degree and nature of this benefit was variable and dependent on individual circumstances and preferences. The goal-setting sheets were the most frequently valued element; however, there were often other elements that were liked (e.g. the pain diary). The value of the factsheets to patients and carers appeared to be in reinforcing information that they had already been provided with by their CNS. Nurses reported that, although some patients found the concept of supported self-management more difficult to grasp, in general they felt that the educational approach was in keeping with their usual practice. All of them valued the training and materials. The busy and time-pressured reality of clinical practice for these specialist nurses, who often managed large caseloads, meant that the delivery of the intervention per protocol during the course of the trial varied. Patients perceived that the intervention was most effective when nurses delivered the factsheets according to need, completed contact information sheets, reviewed patients' diaries and set goals. We assessed the potential for contamination of nurses not involved in the study by those nurses who were. We found that, although there was a general awareness of the study, there was no evidence that practice had changed or that the intervention was used by nurses who were not involved in the study.

Health economic analysis

We estimated cost-effectiveness of the SMART intervention within this feasibility study using a DAM approach because of the small number of patients and the lack of a control arm. We demonstrated that it was feasible to collect information to inform a full economic evaluation within a definitive RCT. The cost–utility analysis suggested that the SMART intervention appears to be cost-effective compared with standard care alone and could lead to cost savings. The SMART intervention yielded QALY gains and cost savings in our base case and many of the deterministic sensitivity analyses.

Success criteria and key learning points

Ultimately, we aimed to establish the acceptability and uptake of the SMART intervention and determine the feasibility of evaluating this intervention within a definitive trial. In order to judge whether or not we had achieved our aims, we agreed our success criteria beforehand (see *Chapter 1*, *Success criteria*). Here we review the extent to which we have met these criteria.

Phase I

Establishment of patient and public involvement panel

This was achieved within 3 months of starting the SMART project. The PPI panel consisted of carers and bereaved carers of patients who had received palliative care in the community. PPI panel members were invited to quarterly PPI meetings as well as the biannual investigators meeting and Study Steering Group meetings. PPI panel members were involved in reviewing our initial concept of self-management and the components of our prototype SMART intervention prior to the modelling focus groups. A PPI panel member reviewed participant study materials (e.g. information sheets) and contributed to interpreting the results of the feasibility trial during the investigator meetings.

Development of a concept of usual care based on literature review and clinical practice observations

This was achieved by reviewing the contextual policy literature on delivering end-of-life care in the community (see *Chapter 1*) and during interviews with CNSs, GPs and consultant palliative care clinicians working in hospice and community palliative care services (see *Chapter 2*).

Development components of a prototype SMART intervention and delivery strategy

This was achieved throughout the first phase of the SMART project, during which the literature was reviewed on supported self management of chronic diseases and end-of-life care. The literature scoping work informed the theory-driven development of a prototype SMART intervention based on the theories of self-efficacy and behaviour change that were best suited to the developing intervention.[39,54]

Phase II

Establish members of focus groups

Recruitment of patients, carers and HCPs to the Phase II focus groups was achieved through community palliative care services. The Phase II methodology was amended to allow patients to take part in a interview format if they were to unwell or preferred not to attend a focus group but still wished to participate.

Development of refined intervention materials and delivery strategy

This was achieved through an iterative process involving patients, carers, HCPs, the research team, expert advice from the study co-applicants, the PPI panel and the Study Steering Group.

Phase III

Recruit three participants per month per each site within 4-month recruitment period

The observed recruitment rate was 1.2 participants per month per site for 4 months. Our initial recruitment strategy was an estimate based on the caseloads of all CNSs working within community services at the four sites. We recruited approximately one-third of all full-time equivalent CNSs working within the recruitment sites. The observed new referral rate was approximately what we had expected (4.2 patients per month per site vs. 3 patients per month per site, respectively); however, we overestimated the proportion of patients that we expected would be prescribed strong opioids for pain, which led to a screening failure rate of 53.5%. Therefore, to increase the recruitment rate to three participants per month per site, a future definitive trial should consider recruiting all full-time equivalent CNSs within community palliative care services at each of the sites and increase the range of the intervention (and consequently the eligibility criteria) to include patients on weak opioids.

Feasibility of data collection

The overall level of missing data for the participant self-reported outcomes and the measures of health-care resource use was very low. These findings indicate that the deliverability of data collection methodology was feasible through face-to-face researcher visits. Data from our previous research (IMPACCT) indicate that follow-up data collection rates would be far worse if data were not collected face to face. Participant acceptability and preferences of the self-reported outcomes were assessed by evaluating the level of missing data for each outcome measure and the post-study interviews with participants.

Estimating primary study end point

Owing to the low level of missing data, we were able to evaluate the variability in the participant self-reported outcome measures across the follow-up time points. We identified that the BPI pain interference scale and SES are the measures most likely to be sensitive to change over the defined follow-up period. This fits with the mechanisms of impact of the intervention outlined in the logic model presented in *Chapter 2*, which identified that the SMART intervention would lead to improvements in participants' self-confidence (self-efficacy) in managing analgesic medication and consequently reduce the impact of pain on activities of daily living within the context of declining health. The self-efficacy scale was most acceptable to participants (some participants did not like the final question on the BPI interference scale) and demonstrated the largest potential effect size.

Participant, carer and study nurse acceptability of the study experience

Participants and their carers universally indicate that their overall experience of the study was positive and they had sustained use of the intervention resources over the 6-week follow-up time point. The study nurses also indicated that the study process was acceptable; however, ongoing training and support throughout the trial period were necessary to improve the fidelity of delivery of the intervention and a future definitive trial should consider implementing a sustained programme of 'top-up' training sessions for study nurses.

Limitation of feasibility and considerations for a future definitive randomised control trial

To inform the design of a future definitive RCT of the SMART intervention, we have identified the key learning points and highlighted opportunities to address them.

Recruitment

Limitation

The feasibility study was limited by the lower than anticipated recruitment rate.

Solution

Extend the range of eligible participants to include people prescribed weak opioids. Research field notes identified that many patients who were screened as ineligible because they were not prescribed strong opioids were in fact prescribed weak opioids for pain. Recruited patients already taking strong opioids reported that they would have benefited from the intervention before or at the point of commencing strong opioids.

Intervention content

Limitation

The content of the intervention was focused on strong opioids only.

Solution

Modify the content of the SMST resources and CNS training manual to include information about weak opioids. This process should include further stakeholder input (i.e. patients, carers and HCPs) to ensure that the content of the SMST resources remains relevant and acceptable to individuals prescribed weak opioids.

Intervention delivery

Limitation

The fidelity of intervention delivery was limited by the need for ongoing training and support throughout the trial period.

Solution

Modify training and support for CNSs to ensure that the research process is more clearly articulated and that the concepts of self-management and means to support this by nurses are better understood to reduce variations in the fidelity of intervention delivery.

Trial support

Limitation

Sites where CRN support was not secured had lower recruitment rates.

Solution

Securing CRN support at each site to assist researchers with screening, recruitment, follow-up visits and final data collection, and to assist study nurses with completion of CRFs relevant to the delivery of the intervention.

Trial processes

Limitation
The process for recording withdrawal was not sufficiently detailed.

Solution
Clear reporting of withdrawal procedures with levels of withdrawal to capture patients who withdraw from researcher follow-up (because of the burden of continuing with these visits), but continue to use the intervention with the study nurse.

Outcomes and outcome measures

Limitation
The number of follow-up visits was considered burdensome for some participants.

Solution
Reduce the number of follow-up visits from three to two (weeks 3 and 6 following baseline). Data from participant self-reported outcome measures indicated little change in the variables between weeks 2 and 4. Based on the acceptability to participants and large potential effect size, we recommend that the primary outcome measure for a further definitive trial would be the SES. Consider using interference from pain as a second primary outcomes rather than pain intensity.

Trial design

Limitation
The feasibility trial did not have a control arm or assess the feasibility of randomisation processes.

Solution
Contamination of non-study nurses was low at participating sites; therefore, a parallel design could be considered for this reason. However, this design would be feasible only if patients allocated to the control arm were seen by untrained nurses and those allocated to intervention arm were seen by trained nurses. Current services are delivered by nurses with geographically based caseloads and so their eligible patients could be allocated to either arm. A cluster design with nurse as the cluster would lead to the most efficient trial design, while accounting for nurses' geographically aligned caseloads. If nurses within a service are willing to be randomly allocated to either intervention or the control, then all eligible patients within a service could still be considered for recruitment, maximising accrual rate while increasing the number of clusters of participants. In addition, having intervention and non-intervention nurses within each site further minimises between-site differences. Therefore, we recommend a cluster trial design at the level of the nurse for a future definitive trial, as we have shown that there is little contamination of nurses within a site and it allows participants to be seen by their geographically aligned nurse without having to cluster at the site level. Furthermore, we recommend that a future definitive trial would have an internal pilot study to evaluate the feasibility of randomisation processes and generate pilot data required to inform the sample size for a definitive trial.

Conclusion

We have shown that the evaluation of a supportive self-management intervention for patients requiring analgesia, and who are approaching the end life, is feasible. Our success criteria were largely met and, for those that were not, we have identified clear means to succeed within a future trial through a detailed process evaluation of our feasibility study. The key considerations in the design of future definitive trial have been identified, which we believe is now feasible to undertake.

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Contributions of authors

Professor Michael I Bennett, St Gemma's Professor of Palliative Medicine, led the research as chief investigator. He led the design of the overall study, co-ordinated the funding proposal application, had overall supervision of the research, facilitated the Project Advisory Group meeting, reviewed the content of the SMART intervention and study materials and wrote the final report.

Dr Matthew R Mulvey, Research Fellow, University of Leeds, contributed to the design of the overall study and wrote the funding proposal application, project managed and co-ordinated the day-to-day running of the research, facilitated the PPI panel meetings, completed the literature scoping in Phase I, facilitated the focus groups and interviews for Phases I and II, developed the content and format of the SMART intervention resources and study materials, led the NHS REC approval applications, co-ordinated the site site-up, patient recruitment and data collection for the feasibility study sites in Yorkshire and the Humber, facilitated the study nurse training workshops, performed the quantitative analysis of the feasibility study data, interpreted in the finings from the feasibility study and led the writing of the final report.

Dr Natasha Campling, Research Fellow, co-ordinated the delivery of the research at the Hampshire sites, facilitated the focus groups and interviews for Phase II, performed the qualitative analyses of data from Phases I and II, developed the framework of supported self-management within palliative care services, developed the content and format of the SMART intervention resources, developed a bespoke training package and learning resources for the study nurses, led the development and production of the podcast films, co-ordinated the site set-up, patient recruitment and data collection of the feasibility study in

Hampshire, performed the qualitative analyses of the data of the feasibility study, interpreted in the finings from the feasibility study and wrote the final report.

Professor Sue Latter, Professor of Nursing, contributed to the design of the overall study and writing of the funding proposal application, supervised the research in Hampshire, reviewed the content of the SMART intervention and study materials and contributed to the writing of the final report.

Professor Alison Richardson, Clinical Professor in Cancer Nursing and End-of-Life Care, contributed to the design of the overall study and writing of the funding proposal application, supervised the research in Hampshire, reviewed the content of the SMART intervention and study materials and contributed to the writing of the final report.

Professor Hilary Bekker, Professor of Medical Decision-Making, contributed to the design of the overall study and the writing of the funding proposal application and helped to develop the content of the SMART intervention resources by providing expertise in health literacy.

Professor Alison Blenkinsopp, Professor of Pharmacy Practice, contributed to the design of the overall study and interpretation of study findings.

Mr Paul Carder, Research Manager, contributed to the design of the overall study and interpretation of study findings.

Professor Jose Closs, Professor of Nursing Research, contributed to the design of the overall study and interpretation of study findings.

Professor Amanda Farrin, Professor of Clinical Trials and Evaluation of Complex Interventions, contributed to the design of the overall study and interpretation of study findings with a focus on the requirements for a future definitive trial.

Dr Kate Flemming, Senior Lecturer, contributed to the design of the overall study, interpretation of study findings and provided expert advice on the literature reviewing activities in Phases I and II.

Ms Jean Gallagher, PPI Co-applicant, contributed to the design of the overall study, reviewed SMART intervention resources and study materials (including participant information sheets and questionnaires) and helped to interpret the results of the feasibility trial.

Dr David Meads, Lecturer in Health Economics, helped design the overall study and led the health economic feasibility evaluation and modelling.

Professor Stephen Morley, Professor of Clinical Psychology, contributed to the design of the overall study, development of the framework of supported self-management and interpretation of the study findings.

Mr John O'Dwyer, Research Fellow in Health Economics, conducted the health economic feasibility evaluation and modelling.

Ms Alexandra Wright-Hughes, Senior Medical Statistician, contributed to the design of the overall study, helped to develop the protocol and analysis plan for the feasibility study and contributed to the quantitative analysis and interpretation of the feasibility study data and writing of the final report.

Ms Suzanne Hartley, Head of Trial Management, contributed to the content and development of the feasibility study protocol and development of the study materials.

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Data sharing statement

Data collected as part of the SMART study are held securely at the University of Leeds. The research team will consider applications to share data provided sufficient governance procedures and approvals are in place. Enquires should be made to the corresponding author Professor Michael Bennett (m.i.bennett@leeds.ac.uk).

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Appendix 1 National Institute for Health Research Health Technology Assessment programme commissioning brief

Health Technology Assessment Programme

NHS National Institute for Health Research

HTA no 12/188

Self-management of pain relief, nausea and constipation for patients approaching the end of life

Introduction

The aim of the HTA programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Research Question:

Can a patient support tool improve the self-management of medication for pain, nausea and constipation in patients approaching the end of life?

1. **Technology:** Patient support tool, appropriate for use in the NHS and tailored to the patient group, to help self-management through medication of pain relief, nausea and constipation - to be delivered in addition to usual care. Applicants should consider the extent to which healthcare professionals should be involved in the use of the support tool.
2. **Target Group:** Patients suffering from significant pain approaching the end of life, being cared for in their own home, and their family carers – exact inclusion criteria to be defined by applicants. Consideration should be given to the cognitive abilities of the patients.
3. **Setting:** Community.
4. **Control or comparator treatment:** Usual care – to be defined by applicants.
5. **Study design:** Feasibility study to develop and manualise the intervention and to define appropriate standard care. If appropriate, the intervention could be adapted from existing evidence based self-management aids. Researchers should assess the acceptability and uptake of the intervention.
6. **Important outcomes:** Development of a manualised intervention; change in use of medicines; improved symptom relief; confidence.
   Other outcomes: Health related quality of life; patient, carer and healthcare professional acceptability; place of death; hospital admissions.
7. **Minimum duration of follow up:** Remainder of life.

Background information for potential applicants:

Enhanced patient-family health decision making can improve the overall quality of end of life care. As life-limiting illnesses progress, the number of disease related symptoms typically increases. Medication regimens can be complex and pain, nausea and constipation are among the common symptoms that often fluctuate and may be appropriate for self-management by patients and their family carers.

Patient decision aids have been shown to be effective in facilitating informed decision making and it may be that a self-management aid could help patients and their families to manage their medication regimens to improve pain, nausea and constipation symptom control. A feasibility study is needed to develop a support aid and to assess its acceptability.

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Notes to Applicants

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland, NISCHR in Wales, and the Public Health Agency in Northern Ireland. Researchers from Northern Ireland and Scotland for certain NICE related calls should contact NETSCC to discuss their eligibility to apply.

For many of the questions posed by the HTA Programme, a randomised controlled trial is likely to be the most appropriate method of providing an answer. However, there may be practical or ethical reasons why this might not be possible. Applicants proposing other research methods are invited to justify these choices.

Applicants are asked to:

1. Follow the Medical Research Council's Good Clinical Practice guidelines (http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416) when planning how studies, particularly RCTs, will be supervised. Further advice specific to each topic will be given by the HTA Programme at full proposal and contract stages.

2. Note that trials involving medicinal products must comply with "The Medicines for Human Use (Clinical Trials) Regulations 2004". In the case of such trials, the DH expects the employing institution of the chief investigator to be nominated as the sponsor. Other institutions may wish to take on this responsibility or agree co-sponsorship with the employing institution. The DH is prepared to accept the nomination of multiple sponsors. Applicants who are asked to submit a full proposal will need to obtain confirmation of a sponsor(s) to complete their application. The DH reserve the right to withdraw from funding the project if they are not satisfied with the arrangements put in place to conduct the trial.

The MHRA (info@mhra.gsi.gov.uk, http://www.mhra.gov.uk) can provide guidance as to whether your trial would be covered by the regulations. The DH/MRC website (http://www.ct-toolkit.ac.uk/) also contains the latest information about Clinical Trials regulations and a helpful FAQ page.

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/#

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early a stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service (http://www.nihr.ac.uk/infrastructure/Pages/infrastructure_research_design_services.aspx) can advise on appropriate NIHR programme choice, and developing and designing high quality research grant applications.

Clinical Trials Units are regarded as an important component of any trial application and can advise and participate throughout the process from initial idea development through to project delivery and reporting. NETSCC CTU Support Funding (http://www.netscc.ac.uk/supporting_research/CTUs) provides information on the units receiving funding from the NIHR to collaborate on research applications to NIHR programmes and funded projects. In addition UKCRC CTU (http://www.ukcrc-ctu.org.uk) provides information and searchable information resource on all registered units in the UK.

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Research networks

The HTA Programme expects, where appropriate, that applicants will work with the relevant research network.

Making an application

If you wish to submit an outline proposal on this topic, complete the on-line application form at http://www.hta.ac.uk/funding/standardcalls/index.shtml and submit it on line by **2nd May 2013**. Applications will be considered by the HTA Commissioning Board at its meeting in **July 2013**. For outline applications, if shortlisted, investigators will be given a minimum of eight weeks to submit a full proposal.

Applications received electronically after 1300 hours on the due date will not be considered.

Please see GUIDANCE ON APPLICATIONS overleaf.

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Guidance on applications

Required expertise

HTA is a multidisciplinary enterprise. It needs to draw on the expertise and knowledge of clinicians and of those trained in health service research methodologies such as health economics, medical statistics, study design and qualitative approaches. The HTA programme expects teams proposing randomised controlled trials to include input from an accredited clinical trials unit, or one with equivalent experience. Applicants are also expected to engage a qualified Trial Manager for appropriate projects. A commitment to team working must be shown and applicants may wish to consider a collaborative approach between several institutions.

Public involvement in research

The HTA programme recognises the benefit of increasing active involvement of members of the public in research and would like to support research projects appropriately. The HTA programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal *could* be improved by involving members of the public. Examples of how this has been done for health technology assessment projects can be found at http://www.hta.ac.uk/PPIguidance/. Research teams wishing to involve members of the public should include in their application: the aims of active involvement in this project; a description of the members of the public (to be) involved; a description of the methods of involvement; and an appropriate budget. Applications that involve members of the public will not, for that reason alone, be favoured over proposals that do not but it is hoped that the involvement of members of the public will improve the quality of the application.

Outcomes

Wherever possible, the results of HTA should provide information about the effectiveness and cost-effectiveness of care provided in its usual clinical setting and for the diverse subjects who would be eligible for the interventions under study. The endpoints of interest will in most cases include disease specific measures, health related quality of life and costs (directly and indirectly related to patient management). Wherever possible, these measurements should be made by individuals who are unaware of the treatment allocation of the subjects they are assessing. We encourage applicants to involve users of health care in the preparation of their proposal, for instance in selecting patient-oriented outcomes. Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established. A period of follow up should be undertaken which is sufficient to ensure that a wider range of effects are identified other than those which are evident immediately after treatment. These factors should guide applicants in their choice of subjects, settings and measurements made.

Sample size

A formal estimate should be made of the number of subjects required to show important differences in the chosen primary outcome measure. Justification of this estimate will be expected in the application.

Communication

Communication of the results of research to decision makers in the NHS is central to the HTA Programme. Successful applicants will be required to submit a single final report for publication by the HTA programme. They are also required to seek peer-reviewed publication of their results elsewhere and may also be asked to support NETSCC, HTA in further efforts to ensure that results are readily available to all relevant parties in the NHS. Where findings demonstrate continuing uncertainty, these should be highlighted as areas for further research.

Timescale

There are no fixed limits on the duration of projects or funding and proposals should be tailored to fully address the problem (including long-term follow-up if necessary). Applicants should consider however that there is a pressing need within the NHS for this research, and so the duration of the research needs to be timely.

Feasibility and Pilot studies

We expect that when pilot or feasibility studies are proposed by applicants, or specified in commissioning briefs, a clear route to the substantive study will be described. This applies whether the brief or proposal describes just the preliminary study or both together. Whether preliminary and main studies are funded together or separately may be decided on practical grounds.

Feasibility Studies are pieces of research done before a main study. They are used to estimate important parameters that are needed to design the main study. Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study. If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.

For a full definition of the terms 'feasibility study' and 'pilot study' visit the NETSCC website glossary page http://www.netscc.ac.uk/glossary/

Diagnostics and Imaging

In evaluating diagnostic and imaging techniques, the emphasis of the HTA programme is to assess the effect on patient management and outcomes (particularly where changes in management can be shown to have patient benefits). Improvements in diagnostic accuracy, whilst relevant, are not the primary interest of this commissioned research programme. Applicants should justify where they consider improvements in diagnostic accuracy to be relevant to these objectives. Where there is poor evidence to link diagnostic improvements to patient benefits, part of the primary research may be to assess the effects of such changes on patient outcome.

An assessment should also be made of changes in other resources (particularly other subsequent therapies) used as a result of changes in diagnostic methods.

Appendix 2 The content and form of previous interventions to improve pain management

West CM, Dodd MJ, Paul SM, Schumacher K, Tripathy D, Koo P, *et al.* The PRO-SELF(c): Pain Control Program – an effective approach for cancer pain management. *Oncol Nurs Forum* 2003;**30**:65–73.[58]

PRO-SELF: a pain control programme for cancer pain management	
Time period	**Intervention**
Week 1	Nurses meet patients and family caregivers in their homes
	Conduct an in-depth assessment session, identifying areas of knowledge deficit
	Review answers to questions on the knowledge and attitude questionnaire
	Review the PRO-SELF: pain control booklet and use the teaching guide to enhance information in the booklet
	Review baseline pain scores and pain pattern
	Review pain medicines and drug administration schedule
	Educate patients regarding optimal administration of pain medications, set up medicines in the dosette box
	Instruct patients on how to complete a daily pain management diary
	Review side effects checklist and discuss prevention and management of side effects
	Educate patients on how to discuss with their HCPs the need for change in the pain management plan if appropriate
	Review how to contact nurses for pain management questions
Week 2	Nurses telephone patients and family caregivers
	Review pain scores and medication use during the previous week
	Reinforce teaching about use of analgesics, side effects management and concerns about addiction if needed
	Determine if patients had to see HCPs for pain management or if analgesic prescription changed during the previous week
	Answer questions about pain management
Week 3	Home visit: same as week 2
Week 4	Telephone call: same as week 2
Week 5	Telephone call: same as week 2
Week 6	Home visit: same as week 2

Fahey KF, Rao SM, Douglas MK, Thomas ML, Elliott JE, Miaskowski C. Nurse coaching to explore and modify patient attitudinal barriers interfering with effective cancer pain management. *Oncol Nurs Forum* 2008;**35**:233–40.[59]

Coaching intervention: nurse teaching to explore and address patient attitudinal barriers interfering with effective cancer pain management.

Four telephone calls over 6 weeks:

1. greeting – initiate call by listening and outlining plan for the session
2. current issue – consider and explore attitudinal barriers; promote patient's recognition of attitudinal barriers interfering with adequate pain management
3. problem – help patient describe and consider the nature and extent of problem that is interfering with better pain management
4. problem impact – explore specifics about how the problem (and related beliefs and behaviours) is affecting the patient
5. short-term goals – encourage identification of short-term goals and promote exploration of specific behaviours that might help the patient reach goals
6. strategies – list strategies and options for overcoming the barriers
7. tasks – select tasks that will support the removal of attitudinal barriers, enhance self-confidence and improve pain management
8. summary – summarise the discussion and allow for questions.

Ward S, Donovan H, Gunnarsdottir S, Serlin RC, Shapiro GR, Hughes S. A randomized trial of a representational intervention to decrease cancer pain (RIDcancerPain). *Health Psychol* 2008;**27**:59–67.[60]

RIDcancer PAIN +: an intervention to decrease cancer pain.

Seven elements:

1. Patients asked to describe their beliefs about their pain in terms of cause, timeline, consequences and control (assessment interview). The intervener listened carefully for mention of barriers to pain management such as fears of addiction or concerns about side effects.
2. Gaps, confusions and misconceptions about reporting pain and using analgesics were identified and discussed.
3. Creating conditions for change – patients discussed the losses that result from the misconceptions.
4. Intervener provided information to fill the gaps and replace confusions that had been identified. An educational message had been prepared for each of the common attitudinal barriers (fatalism about cancer pain management, exaggerated fear of addiction, worry about developing tolerance, concern about side effects, fear of being a complainer and worry about masking changes in disease status). The messages were developed from evidence in the literature and had been used previously.
5. Summary and discussion of the benefits of adopting this new information.
6. The patient created a plan for changing the way he/she managed pain.

The first six elements were covered in a single session that lasts from 20 to 80 minutes, depending on the number of misconceptions that were identified.

7. Evaluation of coping plans – took place during follow-up telephone calls that occurred 2 and 4 weeks after the first session. The intervener reviewed the plan with the patient to work out if the patient was meeting their goals, to determine which coping strategies had been most useful and to revise the plan. These follow-up calls lasted approximately 5–10 minutes.

Cagle JG, Zimmerman S, Cohen LW, Porter LS, Hanson LC, Reed D. EMPOWER: an intervention to address barriers to pain management in hospice. *J Pain Symptom Manage* 2015;**49**:1–12.[61]

EMPOWER: an intervention to address barriers to pain management in hospice patients.

Components:

1. Staff training

    i. an overview of barriers to pain management in hospice
    ii. an in-depth discussion of common barriers and suggestions for addressing patient and family fears and misconceptions
    iii. instructions on use of the EMPOWER screen
    iv. strategies to improve patient caregiver medication management
    v. presentation of case examples
    vi. distribution of written material outlining the components of the intervention.

2. The EMPOWER screen

    i. Hospice nurses were instructed to screen family caregivers and, if possible, the patient, using the EMPOWER screen during admission. The screen consisted of eight yes/no questions to identify common concerns related to pain and pain management. The concerns included addiction, side effects, pain as a sign of weakness, being perceived as drug seeking, being a bother, building a tolerance, taking/giving too much and that the medicines would not work.

3. Tailored education using the EMPOWER brochure

    i. If any of the eight barriers to pain management were identified, hospice staff gave the patient/family member the EMPOWER brochure, which included evidence-based statements, and reviewed its content. The statements were written to address common fears and misinformed beliefs while aiding communication between patients, caregivers and hospice providers. For example, to address concerns about tolerance the statements say –

        – 'It is normal for your body to adjust to the pain medication. Your dose can be increased if necessary so the medication keeps working'
        – 'Using medication now will not prevent it from working in the future'.

    ii. When no barriers were identified during the screen, families still received the brochure, but there was no discussion of its content.

4. Follow-up

    i. Staff were instructed to document patient and family concerns in the medical chart and discuss identified concerns during team meetings.

Appendix 3 Summary of learning Cancer Carer Medicines Management

A Phase I/II feasibility trial of Cancer Carer Medicines Management: an educational intervention for carer management of pain medication in cancer patients at end of life (research data available to the team)

The Phase I systematic review and Phase II patient and carer interviews

Beliefs

- Evidence of beliefs that initially hindered, reduced or delayed pain control.
    - Fears of addiction/dependency (not being able to come off it if started).
    - Fears of having to rely on morphine.
- Patients self-managing to avoid 'crises' (i.e. pre-empting emergencies and seeking to avoid hospital admissions).
- Fear of side effects (e.g. reluctance to increase baseline pain medicines for fear of drowsiness); therefore, use of pro re nata medication instead.
- Concern about out-of-hours care and treatment.
- Common wish to take the minimum medication possible – often underpinned by rationale 'so that they can have more later'.

Skills

- Carer often acts as the person who reminds the patient to take medicines, helping when patients become confused or forgetful, ensuring that medicines taken at appropriate times.
- Development of routines to suit home life (e.g. to prepare medicines in evening for next day or week).

Recurrent contextual issues

- Lack of in-depth conversations with patient and carer regarding pain medications across control group.
- Problems with 111 service in a crisis.

Value of intervention

- Most found some aspects of it helpful.
- Carers commented on the value of CCMM resources in the toolkit, particularly for information, reassurance and supporting problem-solving.
- Some positive changes in medicines management (e.g. increased acceptance of the need for opiates), knowledge being reinforced or enhanced, and behavioural change (e.g. responding more readily to patients' requests for pain relief and improved systems in place for giving and recording medicines).

Nurse data

- Only some aspects of the intervention were perceived as distinct from current practice.
- The toolkit (e.g. the information about opioids was seen as a new and useful resource).
- The structured conversational process was considered to be similar to nurses' routine practice.

- Value of having written materials about opioids and introducing more systematic techniques for managing pain medication.
- Positive experiences of training helped nurse engagement.
- Nurses' accounts emphasised the diversity of patient and carer circumstances, experiences and needs. The adaptability of the intervention, the extent to which nurses could individualise its delivery was perceived as crucial to its usefulness.
- Nurses did not fully exploit the adaptability of the toolkit. Although some nurses introduced the toolkit resources selectively, there was a tendency to use the toolkit as a package that they gave to carers in its entirety with the expectation that they would decide for themselves which tools would be useful.
- The focus on pain was seen by some nurses as limiting its usefulness. They argued that carers typically managed multiple medications for a range of symptoms at end of life so broadening the intervention to accommodate that would increase its applicability and acceptability to carers. Nurses were critical of some written resources, which they felt should be comprehensive (all medicines for cancer) rather than pain specific (e.g. the medicines chart).
- Most argued that introducing the intervention earlier in the course of a patient's illness would be easier, more appropriate and of greater benefit. They gave examples of carers who were unable to engage with the intervention because they were overwhelmed and distressed.
- The nurses reported that the intervention had facilitated communication and relationship building.
- Most found value in the intervention and identified advantages in offering carers written information about analgesics and simple formats for documenting pain and medication. Some thought the intervention had influenced their practice: they would be more likely in future to include carers in discussions and encourage them to keep records.

Carer need literature

Lau et al.[93]

- Interviews with informal caregivers ($n = 23$) and hospice providers ($n = 22$).
- Caregivers' life experience and self-confidence facilitated medication management.
- Caregivers' negative emotional states, cognitive and physical impairments, low literacy, other competing responsibilities, as well as patients' negative emotional states and complex medication needs were limiting factors.

Kimberlin et al.[94]

- Focus groups and interviews with cancer patients ($n = 22$) and family caregivers ($n = 16$).
- Seven themes emerged suggesting improvements that are needed in the communication process. These included (1) improving the process of information exchange, (2) increasing active participation of patient and caregiver in the care process, (3) improving provider relationship-building skills, (4) overcoming time barriers, (5) addressing fears regarding use of pain management medications, (6) fostering appropriate involvement of family and caregivers in the communication process and (7) improving co-ordination of care among providers.

Mehta et al.[95]

- Grounded theory study of family caregivers ($n = 24$).
- Derived an explanatory model of how family caregivers manage the pain of cancer patients at home involving four main processes: 'drawing on past experiences'; 'strategizing a game plan' (accepting responsibility for pain management, establishing relationships with patients and health-care team and seeking information on pain and pain management); 'striving to respond to pain' (including implementing strategies for pain relief, determining the characteristics of pain and verifying the degree to which pain relief strategies are successful); and 'gauging the best fit' (a decision-making process that links all the processes, recognising parameters and limitations, and then joins the pieces together).

Mehta et al.[96]

- Grounded theory study of family caregivers ($n = 24$).
- Family caregivers are not always well prepared and require appropriate support to ensure optimal pain control.
- Understanding that family caregivers are continuously engaged in specific processes as they prepare for and implement pain management strategies can help HCPs tailor their interventions.

Mehta et al.[97]

- Grounded theory study of family caregivers ($n = 24$).
- Caregivers assessed different types of pain and, therefore, were experimenting with different types of interventions. Not all family caregivers were able to distinguish between the different pains afflicting patients and, consequently, were not selecting the most appropriate interventions. This often led to poorly managed pain and frustrated family caregivers.

Schumacher et al.[98]

- Transcribed interactions between intervention nurses and patients ($n = 52$) and their family caregivers ($n = 33$).
- Describes the difficulties with pain management that patients and family caregivers bring to a nurse's attention during a teaching and coaching intervention. Found patients had difficulty in seven areas when they attempted to put a pain management regimen into practice, namely (1) obtaining the prescribed medication(s), (2) accessing information, (3) tailoring prescribed regimens to meet individual needs, (4) managing side effects, (5) cognitively processing information, (6) managing new or unusual pain and (7) managing multiple symptoms simultaneously. The findings suggest that the provision of information about cancer pain management to patients and their family caregivers is not sufficient to improve pain control in the home care setting.

Appendix 4 Summary of learning IMPACCT

Meta-review[57] (of six reviews and two papers) describing the optimal components for an educational intervention for advanced cancer pain using Michie *et al.*'s[39] behaviour change wheel as theoretical underpinning.

Information on pain management

- Providing education to patients approaching the end of life to self-manage their pain is known to reduce pain.
- Include name and type of medication, routes of administration, around the clock/as needed, schedule and dosing.
- Patients with cancer pain should routinely be provided with patient-based education to improve knowledge on managing pain and analgesia.
- Provide consistent screening for misunderstandings about pain and analgesia prior to commencing analgesic therapy. Address these aspects through clear advice and information.
- Written or audio-visual material supporting the advice should be given to the patient to take away.

Cognitive barriers to pain management

Includes concerns about tolerance, addiction, fatalism, religious fatalism, being a good patient, side effects of medication are inevitable and unmanageable, masking signs of disease progression, distracting clinicians from treating the disease, harming the immune system, injections and respiratory depression. Patients and carers view pain as a referent for disease status (i.e. worsening pain = worsening disease). Morphine use has particularly strong symbolism of addiction and tolerance and its introduction into a patient's life is seen/interpreted as a signal of impending death.

Information on how to implement self-management strategies

- It is not known which aspects of self-management education interventions are most effective (content, timing, frequency, mode of delivery).
- Information and advice should be so that a lay person could improve his/her knowledge of pain management.
- Behavioural instructions on how to perform the desired behaviour means skill building via instructions, so that a lay person could actually perform desired pain management.
- Skills-based interventions showed greater effectiveness compared with education approaches in reducing pain severity (not statistically significant, but considered a promising finding). Skills-based interventions defined as 'changing patients' dysfunctional beliefs about pain and promote the use of specific skills to manage it (e.g. distraction, relaxation). Specific components varied, targeting all three attributes of knowledge, skills, attitudes of cancer pain and its management.
- Specialist nurses and pharmacists might be the most appropriate HCPs to deliver pain management advice.

Contextual factors that need to be addressed in an intervention to support self-management of cancer pain

- Patient/carer level (intrinsic): psychological and physical capability to engage with an intervention; reflective processes around planning and managing cancer pain.
- HCP level (extrinsic): appropriate education/training of the HCP to deliver education (the intervention) to patients; the HCP requires protected time to deliver education (the intervention) to patients (written material and face-to-face educational session of not less than 15 minutes); multidisciplinary involvement.

Themes from qualitative studies

Control, knowledge, meaning of morphine, adherence, impact of pain and trust. Qualitative research evidences indicates that patients constantly make a trade-off between the impact of pain against the impact from analgesia on physical and cognitive function.

Intervention components are those activities that should be included in an educational intervention in order to change the behaviour of individuals. The authors identified five out of the nine behaviour change wheel intervention functions and suggest that these should be included in any educational intervention promoting self-management of advanced cancer pain:

1. education, for example providing written information about pain management, including analgesic and non-pharmacological approaches
2. training, for example providing instruction, demonstration and coaching of new skills (techniques for managing daily drug regimes, relaxation techniques)
3. enablement and persuasion, for example overcoming cognitive and emotional barriers to pain management through addressing concerns about tolerance or addiction
4. environmental restructuring and resources, for example incorporating the delivery of education for self-management into the usual care provided by specific health professionals, such as specialist nurses, primary care practice nurses and community pharmacists
5. modelling, for example patients talking to other patients about their successful use of various pain management strategies.

Appendix 5 Focus group topic guide/interview guide: patients/carers

THE CONTEXT OF SELF-MANAGEMENT OF MEDICINES for pain and related nausea, constipation & drowsiness

INTRODUCTION

- National study
  - We are developing a toolkit - package of resources to help patients self-manage their pain medicines and related side-effects. Patients would be instructed to use the resources by a CNS. The overarching intervention will be more than just a toolkit but a process too that the nurses can use to help assess and educate patients to make appropriate everyday choices regarding their medicines.
  - We will go on to run a trial, to see how well it might work in practice
  - So, we'd like your help to discuss with us the issues for you in managing your pain medicines and related side-effects and to provide suggestions about the package of resources, so that we can shape it to meet your needs
- Context
  - Helping individuals to successfully self-manage medications in the community
  - Self-management of pain medicines may lead to better pain and side-effect control
  - We know carers need information regarding medicines too, and some are heavily involved in helping with medicines, which is why we have actively sought their views too

SELF-MANAGEMENT SUPPORT IN RELATION TO MEDICINES

Our study focuses on self-management of pain medicines and the related side-effects of nausea, constipation and drowsiness. We are looking at the strong painkillers called opioids, some examples are morphine, oxycodone, buprenorphine and fentanyl.

I'm here understand the day-to-day difficulties and decisions that individuals (and their carers) have to make when dealing with their pain medicines.

We have been working to the following definition of self-management support as:

Assessing, planning, and implementing care to support the individual to be given the means to deal with their illness or its effects. With self-management of pain medicines this may require helping the individual with things like getting prescriptions and supplies, storing medicines, administering them, monitoring symptoms and adjusting doses. When self-management is supported by nurses, individuals can face these practical difficulties and identify areas where they need further support. So it's about being provided with the means to master or deal with problems, by learning new skills, rather than giving up control of them to others.

ROLE

What role do you play in managing your medicines?

- Could you tell me about how you like to participate?
- What are the things that you expect to have to do so that your pain and any side effects of pain medicines are well managed?
  - What do you choose to do, and what do you choose not to concentrate on?

What are the things people do to help you with your medicines? (What role does your carer play?)

- Do any of your family or friends help?
- What specific help do they provide?

How helpful have your palliative care specialists been in educating you about your medicines?

- What has been helpful?
- What hasn't been helpful?
- Is anything missing?

Do you need any additional help at all?

- What should this help look like?

PRACTICAL DIFFICULTIES

From the literature we know that the issues on these cards have been problems for some people. Getting prescriptions, obtaining medicines, understanding, organising, storing, scheduling, remembering, administering, monitoring.

- Could you pick any that are important to you and provide some examples of the problems you've encountered?
- What are the kinds of things that would better support you for dealing with those problems?

DEVELOPMENT OF THE INTERVENTION

The kinds of things we know that are helpful from the research are:

1. Initial assessment – understanding of what's being taken and why, side-effects, offsetting of intended vs unintended effects of medicines, assessment of fears regarding medicines taking (educational messages to address these barriers)
2. Information giving – verbal, written and DVD, when and where to go for advice/support if things aren't working
3. Joint planning between nurse, patient and carer - setting of short term goals (e.g. improved pain control at night) and planning of ways to achieve the goals
4. On-going support - weekly phone calls or visits by a CNS over approximately 4 to 6 weeks, including practical support regarding getting and maintaining supplies of medicines

What we are thinking is if we develop an intervention (with the specialist healthcare professionals) that combines all these elements then we may be able to better prepare individuals to manage their medicines.

- What do you think?
    - What do you think would be the most important elements for you?
- Recognising that time with specialist nurses can be limited what are the most important things that you would want to talk though with him/her as opposed to being left written materials on, so that you are better prepared to deal with your pain and the side-effects?

Thank you so much we've had a really useful discussion on your experiences of self-management of pain medicines and related side-effects. We will take your information and merge it with the information we gain from specialists to tailor the toolkit to meet patient and carer needs. Is there anything that you would like to add that you feel has not been discussed already?

Appendix 6 Card pack used in the patient/carer interviews and focus group

1. Getting prescriptions
- Obtaining a prescription from a clinician
    - Getting the initial prescription
    - Getting repeat prescriptions
- The frequent need for new prescriptions can be problematic – due to tailoring of pain medicines to meet individual needs
- Prescribing by multiple clinicians?
- Need to physically collect the prescription?

2. Obtaining medicines
- Having to get to the pharmacy?
- Carer or someone else going on individual's behalf?
- Delay in "filling" the prescription as the pharmacy may not stock the medicine or the prescribed dose
- Need to establish a relationship with the pharmacist
- Medicines via a delivery service?
- Any dispensing errors?

3. Understanding
- Individuals are faced with understanding the medicines collected
- Individuals usually receive information about their medicines but this may not be to the extent needed or in a helpful form
- Lack of understanding can result in uncontrolled pain
- Confusion because of long drug names, drugs with similar sounding names, abbreviations, maximum dose limits and intervals between taking drugs
- Medicines may be recognised by their appearance rather than name
- Information printed on labels or leaflets may be too small
- Confusion because of the wide variety of information sources – doctors, nurses, pharmacists, leaflets, the pack, the internet etc.

4. Organising
- Orderly arrangement of medicines so they can be easily remembered and kept track of
- Often an issue because of the sheer number and various forms of medicines prescribed for regular and as needed use – pain management regimes often include patches, lozenges and liquids as well as pills
- Leads individuals to set up their own organisational strategies e.g. bags, tool boxes, vegetable racks
- Filling of a dosette box – who does this and what medicines can go in it?

5. Storing
- Safe storage - putting medicines safely away
- Storage of old medicines – many individuals describe keeping out-dated prescription medications to hand with no particular plan to dispose of them
- Storage may involve hiding medicines e.g. from grandchildren

6. Scheduling
- Scheduling medicines according to the best time to take them in relation to an individual's daily lifestyle
- Requires understanding of which medicines provide maximum benefit with a fixed schedule and which can be tailored to changing needs
- Often complicated by a mind-set of taking medicine only when the symptom is present
- Some link their schedule to activities such as mealtimes
- Others schedule medicines at easy to remember times e.g. 8am and 8pm

7. Remembering
- Remembering to take the pills
- Problems arise when daily routines change e.g. with visitors
- Drowsiness, forgetfulness or fatigue lead to medicines not being taken
- Family carers can play a key role in reminding individuals to take their medicines
- Others may set alarms to remind themselves to take their medicines

8. Taking
- Nausea makes taking medicines problematic
- There may be trouble swallowing large pills or trouble opening medicine bottles etc.
- Forgetfulness/drowsiness – have the medicines been taken already?
- Are the medicines being taken appropriately e.g. are sustained release pills being split in half?

Appendix 7 Focus group topic guide/interview guide: health-care professionals

THE CONTENT OF A SELF-MANAGEMENT SUPPORT TOOL FOR PAIN MEDICINES MANAGEMENT AND RELATED NAUSEA, CONSTIPATION & DROWSINESS

SELF-MANAGEMENT SUPPORT IN RELATION TO MEDICINES

Our study focuses on self-management of the opioid medicines for pain (and the related side-effects of nausea, constipation and drowsiness).

SLIDES 1&2

We want to know what the things are that you have to do to put supportive pain management into practice so that it can be systematised, whilst also tailored to individuals.

- **If you think about a patient you've looked after in the last 2 weeks, what did you do to help them manage their pain and any side effects?**
    - What are the things that you do for patients to help them stay in control?
    - How do you help patients make everyday decisions regarding their medicines?

SLIDE 3

Patients say there are particular practical issues for them around: getting prescriptions, obtaining medicines, understanding, organising, storing, scheduling, remembering, administering.

- **What are the things that you do to help patients cope with these issues?**

SLIDE 4

PROFESSIONAL ROLES IN SELF-MANAGEMENT SUPPORT

It is argued that there are 8 professional roles in relation to supported self-management. We have sought to define these for supported self-management of pain medicines.

Could you give us examples of things that you've done within these roles to promote self-management of opioids?

- What are the conversations or behaviours that you use within these roles with regards to pain management?
- Which of these roles can be difficult?
- What are the things that patients and carers often struggle with?

What would be helpful to improve supportive self-management practice in this area?

- Is there anything you wish you had?
- What resources would help you systematise your practice?

We have some examples of previous interventions that have been shown to be useful. We would like to see what you think of them and what might be helpful.

Let's look at the details of the previously used interventions. We have these summarised on A3 sheets.

- What are the elements that you like in any of the interventions?
- What are the elements that you don't like? Why?
- Some of these interventions involve various types of information - what is helpful to most patients?
    - Verbal?
    - Written? Content and form – leaflets or booklets?
    - Visual?
- Would the PRO-SELF schedule fit with your practice?
    - Intervention for 4-6 weeks?
    - Contact every week – alternating face to face and telephone

Thank you so much we've had a really useful discussion based on all of your expertise helping patients' self-manage medicines for pain and related side-effects. We will take the information you have provided to blend current best practice, the best parts of previous research and information from patients and carers to tailor the toolkit to meet professional, patient and carer needs.

Is there anything that you would like to add as final points that you feel has not been discussed already?

Appendix 8 Card pack used in the health-care professional interviews and focus groups

1. Self-management support in palliative care

…Assessing, planning, and implementing appropriate care to support the patient to be given the means to master or deal with their illness or its effects. Supported self-management in advanced disease, by nurses, can, empower people to acknowledge the impact of their condition on their life, and enable them, where possible, to face the range of challenges they may have, and identify areas where they need further support, help or care. Therefore, for individuals it's about being provided with the means to master or deal with problems rather than relinquish them to others… (Johnston et al 2014)

2. Self-management support in relation to opioids and their side-effects

- Understand what you see as the everyday challenges that patients have in managing their opioids and related side-effects
- Picture the conversations and actions you take or would like to take to put patients in better positions to manage their opioids and related side-effects

3. Practical issues for patients

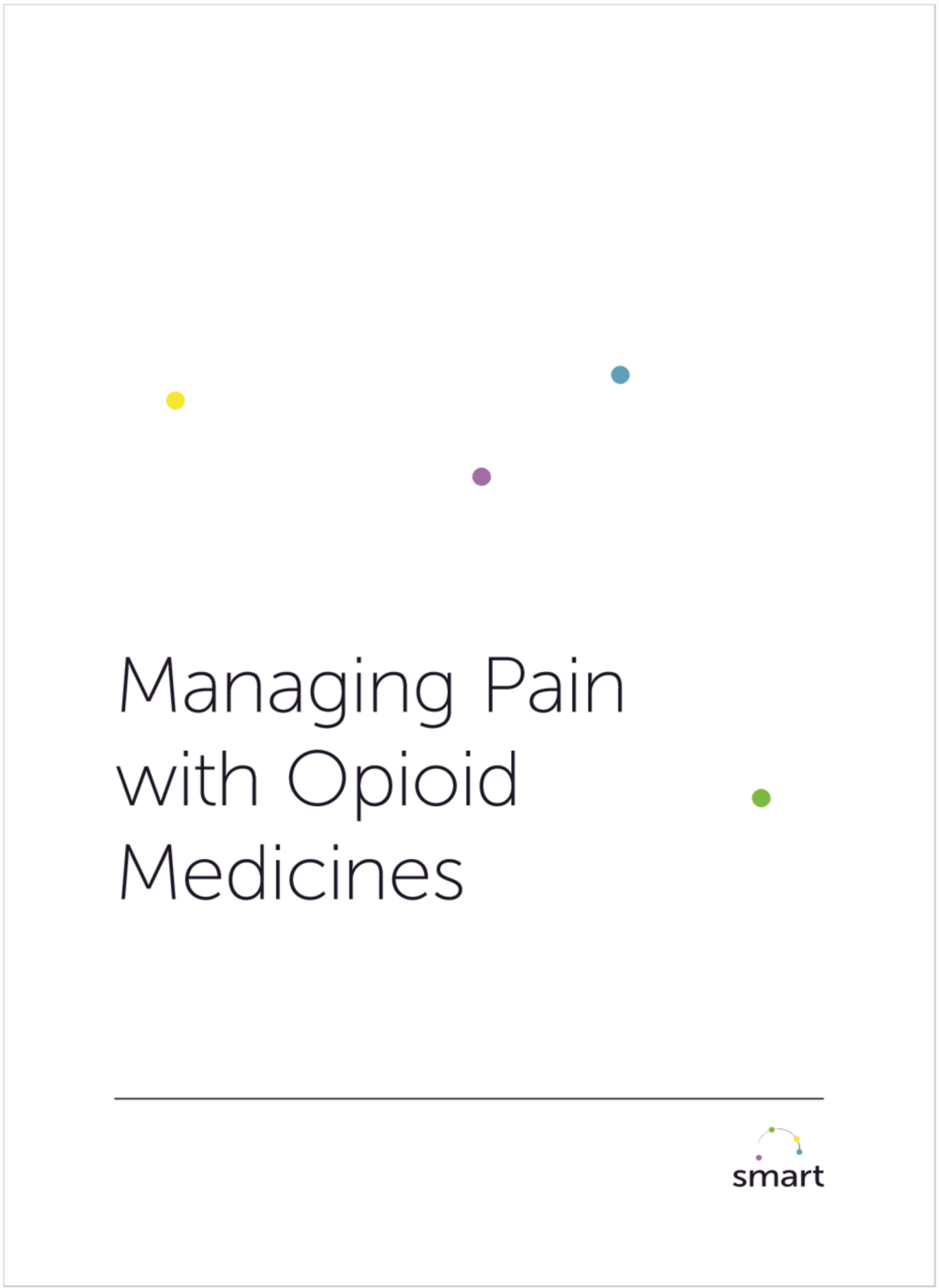
- Getting prescriptions
- Obtaining the medicines
- Understanding
- Organising
- Storing
- Scheduling
- Remembering
- Taking

(Schumacher et al 2014)

4. Self-management support: professional roles

- **Advocate** – To support self-management and the right of palliative patients to receive appropriate medicines to meet their symptom control needs
- **Educator** – To provide instruction regarding medicines to allow patients to self-manage
- **Facilitator** – To promote relationships between healthcare professionals and patient/carer to enable effective access to and use of medicines
- **Problem solver** – To use expertise (underpinned by robust needs assessment) to work out whether current medicines and dosages are appropriate, or whether they should be altered
- **Communicator** – To facilitate communication between individuals e.g. encouraging a patient to discuss their pain with their carer
- **Goal setter** - To identify specific goals that the patient wishes to achieve, and the methods to achieve the goals. This is motivational and enhances self-management performance
- **Monitor** – To observe and constantly re-assess self-management of medicines over time. This requires evaluation of an individual's capacity to self-manage vs. their willingness to engage and compliance
- **Reporter** – To gather information and report it e.g. at multidisciplinary team meetings

Appendix 9 SMART self-management support toolkit factsheets



Introduction

This factsheet is about opioid medicines and how they help people control pain.

People's experience of medicines and pain change over time. The prompts and spaces below are for people to note their experiences of taking opioid medicines and any questions they may want to ask their doctor, specialist nurse or pharmacist about managing pain with opioid medicines.

Pain and health professionals

People experience pain when tissue inside their bodies is damaged. The tissue inside people's bodies can be damaged by illness (e.g. cancer). The damage to tissues is picked-up by nerves which send pain messages to the brain. When the brain gets enough messages, people feel pain.

Health professionals help people to manage pain caused by ongoing illness such as cancer. Health professionals that do this are the GP, a hospital or hospice doctor, a specialist palliative care nurse (sometimes called a Macmillan Nurse) or pharmacists. These professionals help to manage pain at all stages of someone's life, including when people have an illness that cannot be cured (palliative care).

Opioid medicines and pain control

Opioid medicines are given by health professionals to people with pain when other pain-relief medicines have not helped or have not been strong enough. People are given a prescription for opioid medicines by a doctor or specialist nurse. Some examples of opioids are morphine, oxycodone, buprenorphine and fentanyl. The types of pain-relief medicines that don't need a prescription (over-the-counter) are paracetamol, aspirin and ibuprofen.

Opioid medicines work by stopping pain messages from traveling along the nerves in the spinal cord to the brain. People feel less pain because the brain gets fewer pain messages.

Opioid medicines control two types of pain:

- Background pain is the pain people feel over a long time. It is controlled with slow-release medicines.
- Breakthrough pain is a burst of intense pain people get when coping with background pain. It is controlled with fast-release medicines.

To control background pain, people take regular doses of slow-release opioid medicines every day.

To control breakthrough pain, people take a fast-release opioid medicine. The fast-release opioid medicine is an extra dose on top of the slow-release medicines. It is taken to control the sudden burst of breakthrough pain. The person will keep taking their slow-release opioid medicine to control the background pain.

Taking opioid medicines for pain

Slow-release opioid medicines give out a steady amount of opioid over several hours to provide long lasting pain control. To control background pain means taking a dose of slow-release opioids by mouth usually twice a day, every day. Sometimes slow-release patches on the skin are used which can be changed every 3 or 7 days. After taking a dose of slow-release opioids by mouth it takes about 1-2 hours before a person starts feeling their background pain is being reduced.

- The usual slow-release tablets are morphine (called morphine sulphate tablets) or oxycodone (called OxyContin). The usual slow-release patches are buprenorphine (called Butrans) or fentanyl (called Duragesic).
- Fast-release opioid medicines give out all the opioid quickly. They start working after about 15-20 minutes and wear off after 3-4 hours. Fast-release medicines are sometimes called fast-acting or immediate-release medicines.
- Fast-release medicines are taken by mouth in tablet, capsule or liquid form. The usual fast-release tablets are morphine (called Sevredol). The usual fast-release liquid form of morphine is called Oramorph. There is also a fast-release form of oxycodone called OxyNorm which comes in tablet or liquid form.

Tips for managing breakthrough pain

- Sometimes people feel a burst of intense pain even if they have taken their regular doses of slow-release opioid medicine.
- To control this breakthrough pain people take a dose of their fast-release opioid.
- People wait at least an hour to give it time to start working before taking a second dose of fast-release opioid.
- If you find you need to take 3-4 fast-release doses in 24 hours to control your breakthrough pain you should contact your specialist nurse and ask them to review your pain control.
- Before going to bed at night, some people find it useful to prepare a dose of their fast-release opioid in case they wake at night in pain.

Managing Pain with Opioid Medicines

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Experiences of taking opioid medicine

People have different experiences when taking opioid medicines. People's experience depends on the type of illness they have, the opioid-medicine they take, other health issues, other medicines, and their size, weight, and age. Studies of patients' experiences show:

- About 70% of people say that taking opioid medicines helps control their pain. Most people find their pain becomes manageable. For some people, there are times when they feel no pain.
- People find that it is easier to keep on top of pain by taking regular doses of their slow-release opioid medicine.
- When pain is manageable, people can do more of what they like doing, such as seeing friends and family, reading or getting out.
- Getting on top of pain can help with sleeping.
- Some people get other symptoms like being constipated, feeling sick or tired when they take opioid medicines. Health professionals talk to their patients about these side-effects of opioid medicines and can help to find the right dose to manage pain with fewer side-effects.

Starting my opioid medicines

Nurses and doctors help people to fit taking opioid medicines into their daily routine by talking about their experiences of pain and the medicines. Writing down what opioid medicines you are taking helps start this conversation. Your specialist nurse can help with writing the information below:

	Name	Dose	Number of doses per day	Date Started
Slow-Release Opioid				
Fast-Release Opioid				

Managing Pain with Opioid Medicines

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It can take time to find an opioid medicine at a dose that controls pain with manageable side-effects. Some people find it helpful to keep a diary of pain, the medicines and any side-effects. Nurses and doctors can use this information to make a plan about your opioid medicines with you.

The questions below are ones that other people have asked when they started taking opioids. There is space below to note down your own questions.

- How long will the pain relief last for?
- How and when do I take my opioid medicines?
- How can I store opioids safely?
- How much pain relief will I get from taking opioid medicines?
- What are the side effects that I might get?
- How and when will I get my next prescription?
- Who can I contact outside of surgery hours if I have any problems?
- Can I still drive if I'm taking opioid medicines?

Your questions:

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Notes page

Managing Pain with Opioid Medicines

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Notes page

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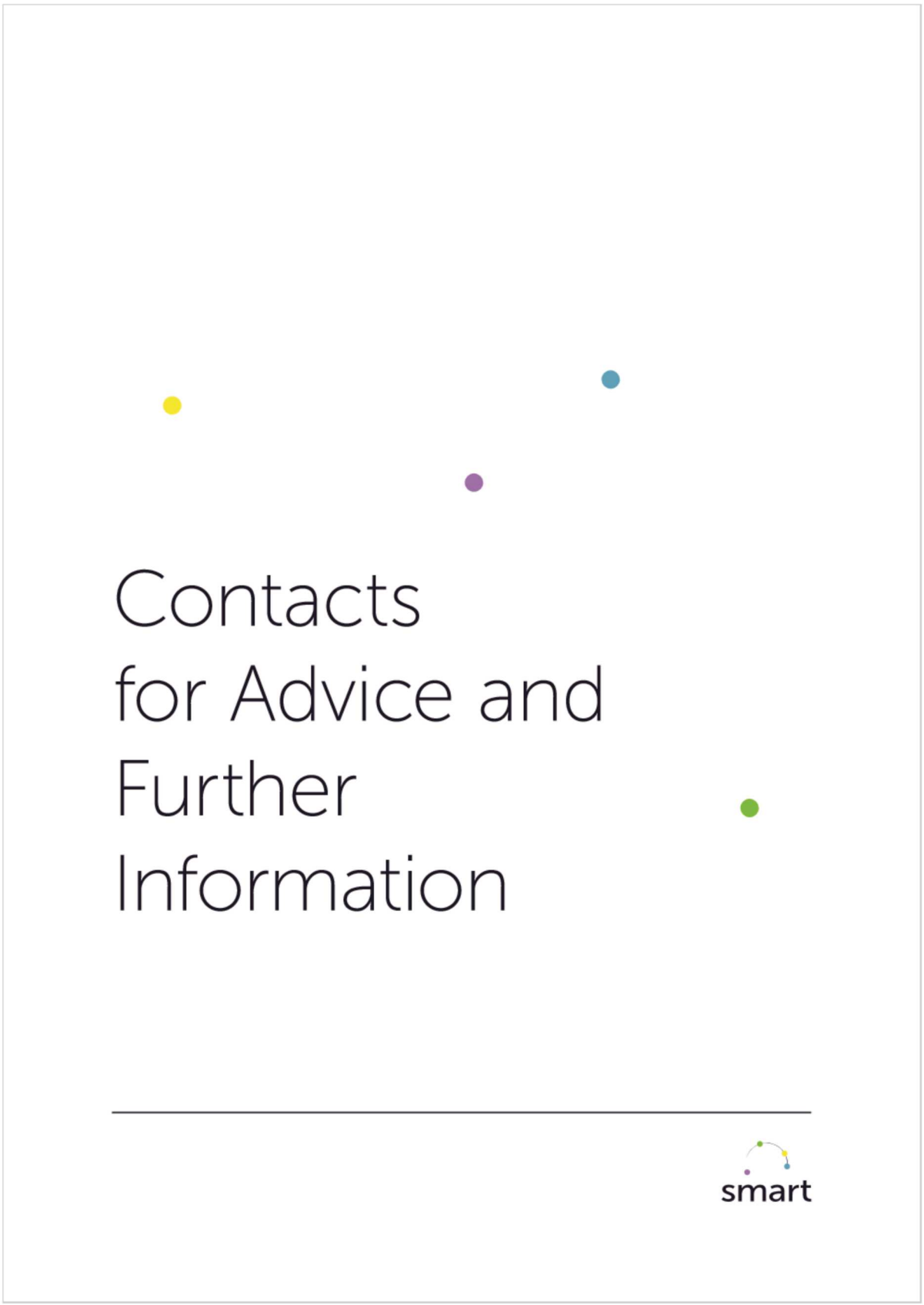
Contacts
for Advice and
Further
Information
smart

Introduction

Nurses and doctors are here to help when people want advice about managing their pain. The spaces below can be used to note down the contact numbers you might need. Your specialist nurse can help with finding the right contact information.

People find it useful to keep these contact numbers to hand, e.g. by their landline phone or stored in their mobile phone. Sometimes people need to contact a doctor or nurse outside of normal working hours. It can be helpful to discuss with a specialist nurse or doctor what 'out of hours' services are available.

Community palliative care service

A specialist nurse is often the best initial person to speak to about medicines or symptoms.

Name of community palliative care service	
Contact number	

GP

If you need medical advice or have an urgent query contact your GP. Try to contact your GP as early in the day as possible.

Name of GP or Surgery	
Contact number	

Out of hours services

Sometimes people need advice about managing pain and their medicines outside of normal working hours. Your specialist nurse will be able to tell you how to access your local out of hours services.

Name of out of hours service	
Contact number	

Contacts for Advice and Further Information

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Community nurses

Some people are also visited by a community nurse. This may be for skin care, help with catheters or to receive medicines. If you have a problem with something you would normally see a community nurse about they may be your best point of contact.

Name of community nurse service	
Contact number	

Community Pharmacist

Pharmacists are a good source of information about medicines, particularly the different forms that medicines come in.

Name of community pharmacist	
Contact number	

Websites for Further Information

After speaking to a nurse or doctor about opioid medicines, some people find that they want to understand more about pain and their medicines, as well as how to manage them. There are websites on the internet that some people may find helpful.

We have suggested words to search for on each of the websites to bring up information about managing pain and opioid medicines.

National Institute of Health and Care Excellence (NICE)

NICE are part of the NHS. They provide guidance to health professionals and the public about health and social care.

Web address: www.nice.org.uk

Q **Search for:** Opioids in palliative care – information for the public

NHS Choices

NHS Choices is a source of information about health, treatments and conditions for patients.

Web address: www.nhs.uk

Q **Search for:** Controlling pain and other symptoms (end of life care)

Contacts for Advice and Further Information

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Patient.co.uk

This is a website with medical information and support for patients.

Web address: www.patient.co.uk

Search for: Strong painkillers (opioids)

HealthTalk

HealthTalk is a website with information and support for a range of health issues. Most of the information is from videos and audio-recordings of people's real life experiences.

Wed address: www.healthtalk.org

Search for: Pain and pain control (living with dying)

Marie Curie

This website provides information about care and support for those with a palliative diagnosis.

Web address: www.mariecurie.org.uk

Search for: Pain relief and common side effects, Controlling pain, Managing medications

For further information specific to cancer:

The British Pain Society

The British Pain Society is a website for health professionals who care for those with pain. There is a document written for patients about living with chronic pain and pain from cancer.

Web address: www.britishpainsociety.org

Search for: Managing cancer pain – information for patients

Macmillan Cancer Support

Macmillan provide support and advice to people going through cancer.

Web address: www.macmillan.org.uk

Search for: Side effects and symptoms - pain, Common questions about painkilling drugs, Storing and remembering your medicines

Cancer Research UK

Cancer Research UK is a charity which funds research projects on cancer

Web address: www.cancerresearch.org

Search for: Cancer and pain control, Types of painkillers, Barriers to treating pain, Taking medicines

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Contacts for Advice and Further Information

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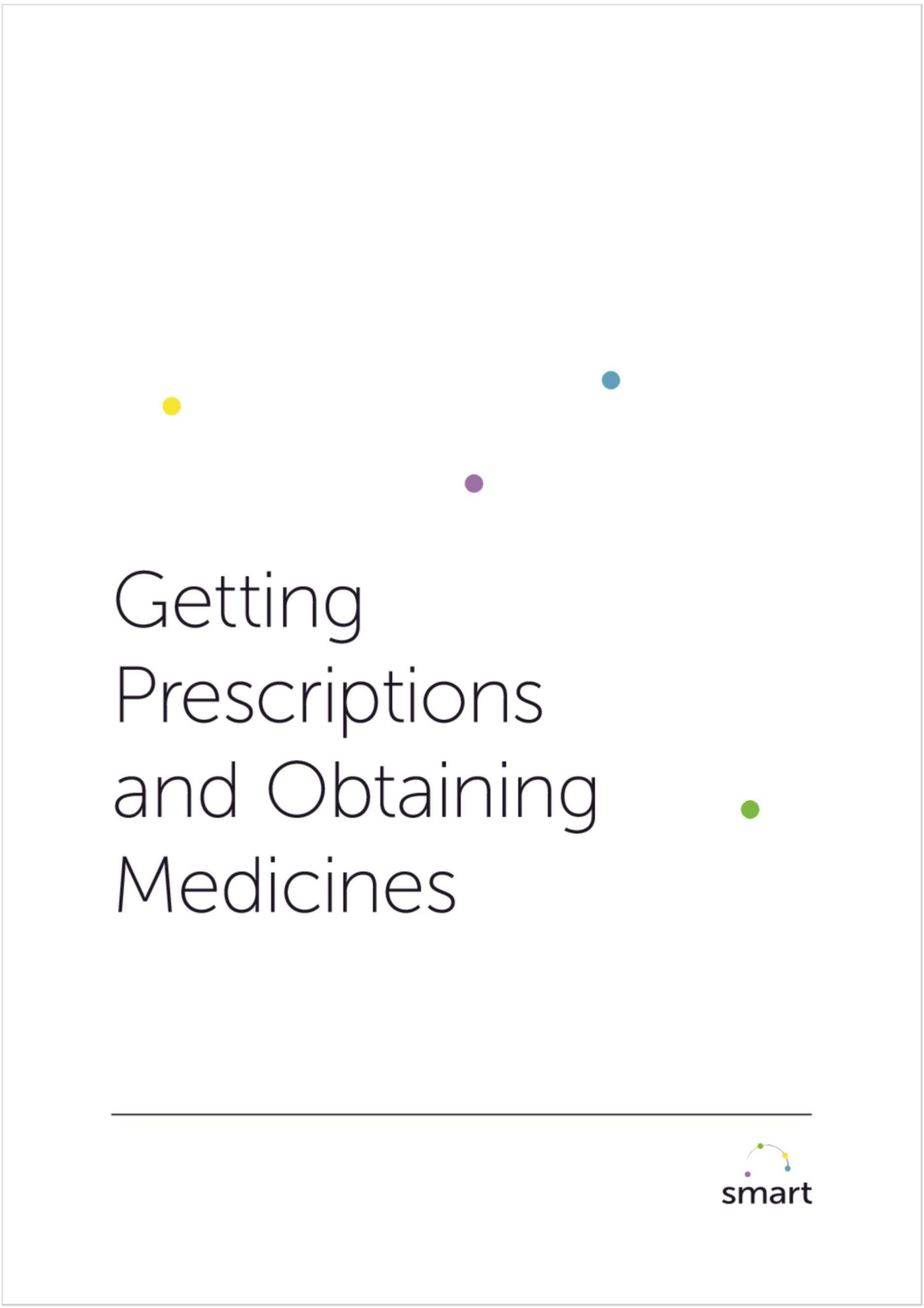
Getting
Prescriptions
and Obtaining
Medicines
smart

Introduction

This fact sheet has information and tips about getting a prescription from a health professional and obtaining medicines from a pharmacy. The prompts and spaces below are for people to note down their experiences and any questions they may want to ask their doctor or specialist nurse about getting a prescription or obtaining their medicines from a pharmacy.

Getting a prescription

Doctors and specialist nurses help people to manage their pain by talking to them about their experiences of pain and making a joint decision about how best to manage it. This may include opioid medicines, in which case the health professional will write a prescription for them. If a specialist nurse is not able to prescribe medicines they will contact the person's GP or hospice doctor and ask them to do it.

Opioid medicines are controlled medicines. This means that there are specific rules about how they are prescribed and extra checks are in place when they are given to you by a pharmacist.

- Once a prescription for a controlled drug, like morphine, has been written it is valid for 28 days.
- A maximum of 30 days' supply of opioid medicine can be prescribed at one time.
- A GP may ask for the prescription to be collected in person by you or a family member/ friend and taken to the pharmacy.

Repeat prescriptions and re-ordering medicines

A repeat prescription is for medication that a health professional has authorised that can be supplied regularly for a period of time without having to see a health professional each time. When people need to reorder medicines they can get their repeat prescription in a number of ways:

- in person at the surgery by filling out the back sheet of their most recent dispensed prescription
- via the surgery's online (computer) system
- and in some cases by telephoning or emailing the surgery

Your specialist nurse can help to find the most convenient method for you. Whatever the method used most GP surgeries usually need 48 hours to generate the prescription. Some GP surgeries can email or fax a prescription directly to a local pharmacy.

Getting Prescriptions and Obtaining Medicines

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Planning ahead

After a person has requested a new or a repeat prescription it can take up to 2 days for a it to be ready to collect from the GP surgery. Once this prescription has been taken to the pharmacy it can take up to another 2 days to dispense the medicines, if they don't have them in stock. If people wait until they have run out of their medicines before re-ordering more there can be a few days without their medicines until the new supply arrives.

So that people don't run out of their medicines they keep track of how many days' supply they have left. When they have one week's supply of a medicine left they re-order them using a repeat prescription or contact their doctor or specialist nurse for a new prescription. Your specialist nurse can help with checking your medicines supply and making a plan for re-ordering more.

Obtaining medicines

Doctors and specialist nurses can help to work out the best way to get your medicines to you. People find it helpful to talk with a specialist nurse about which pharmacies in their local area stock the drugs they need and whether a friend or family member can collect the medicines for them.

Many people find it helpful to get to know the pharmacist in their local pharmacy so they can help with supplying the medicines they need. If a pharmacy doesn't routinely stock a medicine people ask the pharmacist if they can start doing so – often they can. When you collect your medicines, or someone collects them for you, a pharmacist may ask for proof of identity (such as a driving license or passport).

Some pharmacies have longer opening hours and some provide a delivery service, where they bring the medicines to your home address. Ask your specialist nurse which pharmacies in your area provide this.

When people get their medicines they usually check that everything they need is there. For example:

- Has everything been dispensed?
- Is there enough?
- Is it in the form you expected e.g. capsules or liquids?
- Is it the right dose?

Top tips for getting prescriptions and ordering medicines

- Checking your stock levels regularly can help to see what you are going to run out of in the next week or fortnight.
- Some people fill up two weekly pill boxes so that they can check that they have enough for a fortnightly period.
- Others manually check the medicine boxes and leave out the ones that are running low to prompt them to re-order them.
- Putting in a repeat prescription request a week in advance of running out means there is time for the prescription to be written by a health professional, for it to be sent or taken to the pharmacy and for the medicines to be dispensed before your current supply runs out.
- Pharmacies may need up to 48 hours to dispense a prescription if they don't have the medicines in stock.
- If someone living with you also needs prescription medicines, it can help to put the prescriptions in at the same time and use the same pharmacy.

The space below can be used to note down any questions you have about getting hold of a prescription or obtaining your medicines from a pharmacy. It can be helpful to note down which local pharmacies stock the drugs you need, which are open late and whether they can deliver the medicines to your home.

Getting Prescriptions and Obtaining Medicines

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The Prescription and Dispensing Process:

A doctor or specialist nurse makes a change to your prescription or you make a request for a repeat prescription. It can take up to 48 hours for the prescription to be ready, unless you see your GP in person or your specialist nurse is able to prescribe medicines for you.

With your specialist nurse, work out the best way for the prescription to get to the pharmacy of your choice - many GP surgeries can do this electronically for you.

- Check that your local pharmacy stocks the medicines you need or ask your GP or specialist nurse to speak to the pharmacy on your behalf.
- You can ask your pharmacy to order them if they don't have them in stock.

Once the prescription has been sent to the pharmacy it can take a further 48 hours for the medicines to be ready for collection

- You can ask a friend or family member to collect your medicines for you (they may need identification and to sign for them) or some pharmacies can deliver your medicines to your home.

Getting Prescriptions and Obtaining Medicines

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Notes page

Getting Prescriptions and Obtaining Medicines

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Notes page

Getting Prescriptions and Obtaining Medicines

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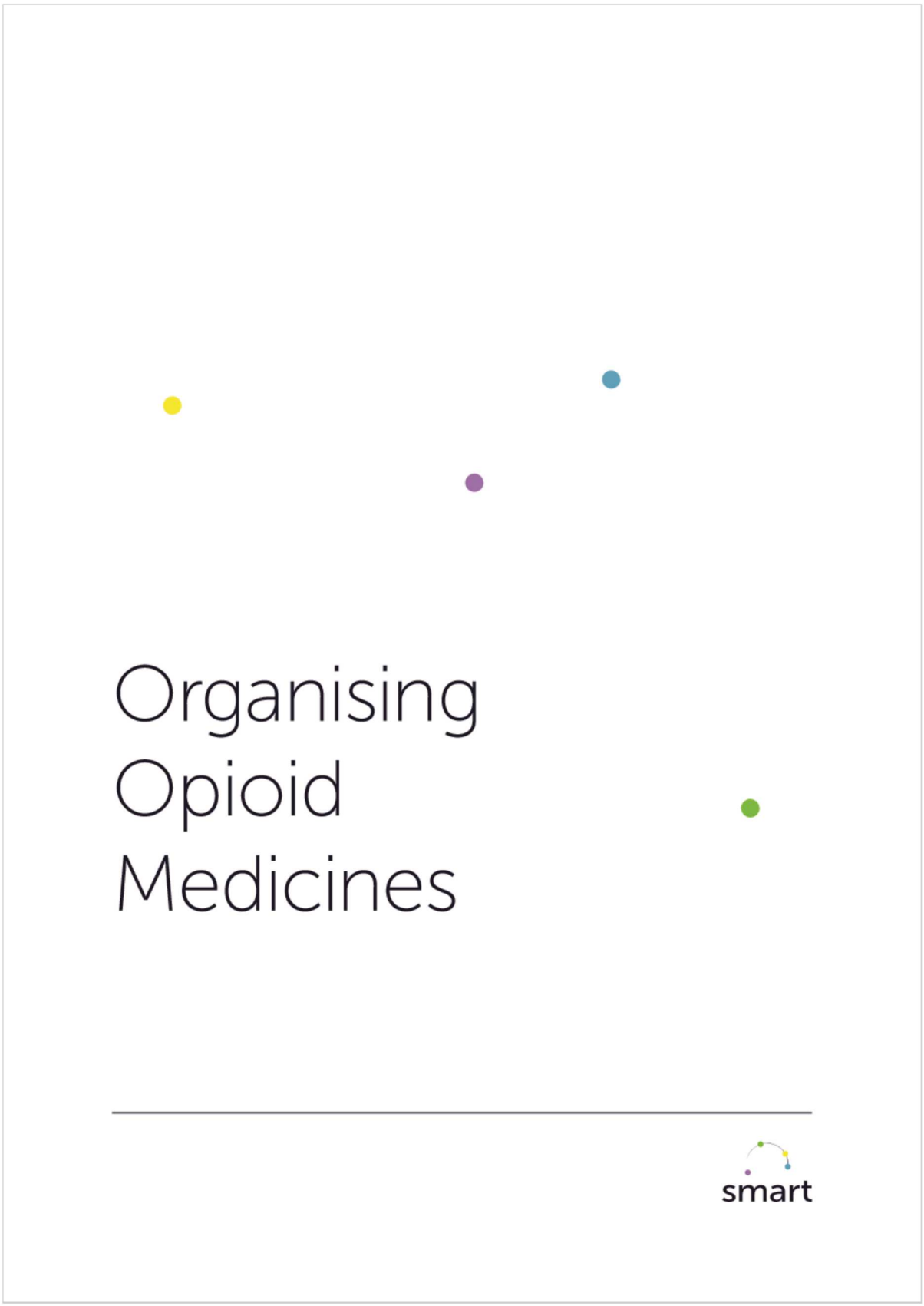

Introduction

This factsheet contains information about organising opioid medicines. The space below is for people to note down any questions they may want to ask their doctor, specialist nurse or pharmacist about organising and storing their opioid medicines at home.

Understanding opioid medicines

Doctors, specialist nurses and pharmacists help people to fit taking opioids into their daily routine by talking about what is important to them and finding ways to organise their medicines. People find that getting to know the names of their medicines and what they are for helps start this conversion and it can also help with re-ordering them. People often ask their specialist nurse or pharmacist if their medicine has abbreviations (letters such as SR) on them if they are unclear what they mean.

From time to time people find that their medicines may be dispensed in different looking boxes to the last time they were dispensed. This happens when different drug companies supply the same medicine to a pharmacy. If this happens people find it helpful to discuss this with their pharmacist or specialist nurse to double check that it is the same medicine.

Organising and storing

Most people find it useful to work out their own strategies for organising and storing their medicines. A specialist nurse can help with this. Some people find it's helpful to use a set of drawers to organise their medicines. For example, morning medicines in the top drawer, lunchtime medicines in the middle drawer and evening medicines in the bottom drawer. Other people find that it helps to remember what the medicines are for if they organise them according to the purpose of the medicines.

The space below can be used to note down any questions you may have about organising medicines. These notes are helpful in conversations with your specialist nurse who can help to make a plan to organise your medicines at home.

Organising Opioid Medicines

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Some people find weekly pill boxes a useful way to organise their medicines. Pill boxes can be purchased from a pharmacist who is also a good source of information about organising medicines. Pharmacists can arrange for medicines to be dispensed in a weekly pill box, which they fill for you.

Unless people are using pill boxes to organise their medicine, it is important to keep medicines in their original packets with the pharmacy labels on them so they can be easily identified. People store their medicines in a cool, dry, safe place out of the reach of children. Some medicines may need to be kept in the fridge. Read the labels to check or your pharmacist will be able to provide advice.

Organising Opioid Medicines

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Fitting Pain Control into My Daily Routine

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Introduction

People find it useful to think about what activities they do each day when fitting pain-control around their routine. There are prompts and spaces in this factsheet to note down any activities people want to do when taking opioid medicines. These notes are helpful in conversations with health professionals. Specialist nurses, doctors and pharmacists use these notes to plan with people times during the day when it is best for them to take their medicines. This planning is called scheduling.

Scheduling

Health professionals help people to make a plan about when to take their medicines that suits their needs. It can help to think about which medicines need to be taken at certain times of the day or which medicines need to be taken with or before food. With a specialist nurse work out which medicines need to be taken:

With food or before food .....
In the morning, lunchtime, evening or bedtime .....

It can be helpful to think about the gaps between doses when planning medicines around your daily activities. With a specialist nurse work out which medicines:

Do not need a 4 hour gap before the next dose .....
Need to be taken at the next scheduled time .....

For some people using a medication chart can help them to plan taking their medicines around their daily routine. There is an example of a medication chart at the end of this factsheet. People find it helpful to note on the medication chart:

The medicine name and dose .....
Instructions of when to take it .....
What it is for .....

Ask your specialist nurse to fill out a medication chart with you if this would help. Some people keep this on their fridge so that they and their family can easily refer to it. A pharmacist is also a good source of information when planning when to take medicines and how to fit taking them around your daily routine.

Smart Factsheets
Fitting Pain Control into My Daily Routine

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Remembering

For some people feeling tired or changes to their daily routine can affect whether they remember to take their medicines. Some people ask others they live with to remind them when to take their medicines. Alternatively, setting reminder alarms on a mobile phone or storing medicines somewhere obvious, like next to the kettle, can help with remembering to take them. If people are using a medication chart, keeping it close at hand and crossing off the doses when the medicines have been taken can help people keep track of their medicines.

With a specialist nurse find ways to remember to take medicines and check that they have been taken:

- Using phone, watch and clock alarms
- Filling up weekly pill boxes
- Putting pills in a place people see often, like near the kettle or radio
- Using a daily list or medication chart and crossing off when medicines are taken

Taking medicines

Specialist nurses, doctors and pharmacists talk to people about the different forms their medicines come in. This helps to make a plan about what suits them best. Most medicines can be prescribed in a liquid form which for some people is easier to swallow. If people are feeling sick (nauseous) taking an anti-sickness medicine can help with taking their other medicines.

Below are some things to consider that other people have asked their specialist nurse, doctor or pharmacist for advice about:

- Opening child proof tops on bottles
- Pushing tablets out from blister packs
- Measuring liquid medicines with syringes
- Reading small print labels – pharmacists can make larger print labels

With a specialist nurse check if there is a better way to take the medicine:

Tablets .....
Capsules .....
Liquids .....
Patches .....
Other .....

Note down any questions you have about scheduling your opioid medicines, remembering when to take them and if having them in a different form (like a capsule or liquid) would help with taking them:

Fitting Pain Control
into My Daily Routine

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Example of Medication Chart

Start date: Monday 10th August		Week of: 10th August							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
Medicine name and dose Amitriptyline 25mg	Breakfast																												
Instructions Take 1 tablet every evening	Lunch																												
What it is for For nerve pain	Evening meal																												
What it looks like Round blue pill	Night/ Bed	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Notes																													

Always take at night

Fitting Pain Control into My Daily Routine

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Checking Opioid Medicines are Managing Pain

Introduction

This factsheet has information on checking how well opioid medicines are managing a person's pain, what side-effects they have, and when side-effects go away. Keeping a track of pain control and side-effects can help health professionals find the right balance of opioid medication that best suits you.

Keeping track of how opioid medicines are working

For some people, their pain is controlled better by opioid medicines than other types of pain-relief. To keep on top of their pain, people take regular doses of slow-release opioid medicine, every day. Keeping track of how well your pain is controlled can help you and your healthcare team work out which medicines suit you best and in what circumstances.

Health professionals usually give people a starting dose of opioid medicine and check if this starting dose helps manage their pain. Each person's experience of taking opioid medicines is different. The starting doses of opioid medicines may not be right straight away. Health professionals review a person's pain control by talking to them about their experience of opioid medicines.

It can be helpful to think about:

- Which medicines are controlling your pain and in what circumstances?
- Do you experience any side-effects, like constipation, nausea (feeling sick) or drowsiness?
- Do the medicines work a little or a lot? If you think one of the medicines takes the edge off the pain but is not controlling it, speak to your specialist nurse about this.
- What works well together? This could be heat pads, distraction and massage, in combination with the opioids.

When health professionals review someone's pain control they ask questions about the person's pain and how taking opioid medicines fits into their daily routine. These details help health professionals' judge if a dose and strength of medicine is right for them, at this time. If the prescribed opioid medicine is not controlling a person's pain, health professionals can change its dose and strength.

Checking Opioid Medicines are Managing Pain

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Monitoring pain

To keep track of pain and how well opioid medicines are managing it, some people note down what opioid medicines they have taken each day or keep a pain diary. These notes can help you and your health professional talk about how opioid medicines are managing your pain and work out the best dose for you that fits into your daily routine.

Here is an example of recording slow-release and fast-release doses of opioid medicines for one day.

Date	Time	Opioid Name and Dose	Notes
14 July	10am	MST 15mg	Slow-release dose (background pain)
14 July	1pm	Oramorph 5mg	Fast-release dose (breakthrough pain)
14 July	8pm	Oramorph 5mg	Fast-release dose (breakthrough pain)
14 July	10pm	MST 15mg	Slow-release dose (background pain)

Here is an example of a pain diary. Many people create their own pain diary, including information on:

- When a pain starts
- Where the pain is
- How strong the pain is
- Whether anything causes the pain to start
- Medicines taken for the pain and whether they helped
- Any side-effects

There is no set way to record this information, but people think about what they have tried, what worked and what didn't, and how long the pain lasted.

Time of day						
Where was the pain?						
What was the pain like?						
Level of pain (0-10 rating)						
Name and amount of medicine taken/other pain control methods used						
What worked and what didn't?						
How long did the pain last?						

Checking Opioid Medicines are Managing Pain

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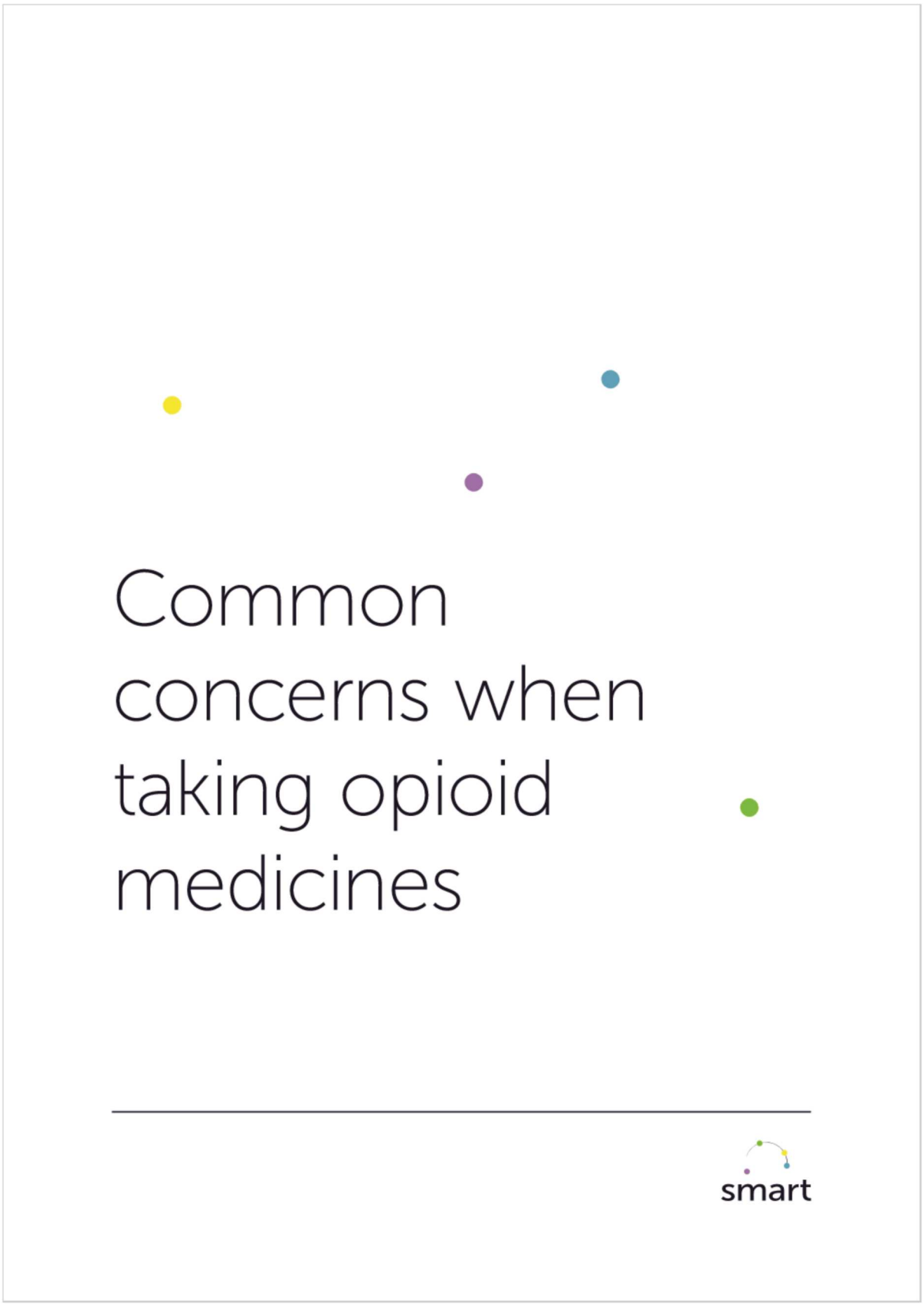
Common concerns when taking opioid medicines
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Introduction

This factsheet has information about some of the concerns people have when they start taking opioid medicines or their dose is changed. By talking about concerns people have when taking opioid medicines, health professionals can help people make a plan to manage their pain.

When are opioids used to control pain

Doctors and some specialist nurses prescribe opioid medicines to control pain when other types of pain-relief medicine do not help or are not strong enough. Opioid medicines are used to control pain caused by illness (e.g. cancer) but also for other causes of pain, like surgery.

Being offered opioid medicines to control pain can happen at any stage of a person's life or at any time during the course of a person's illness. Taking opioid medicines for pain does not mean that people are close to the end of their life. For many people, taking opioid medicines helps to control their pain. When pain is manageable, people can do more of what they like doing, such as seeing friends and family, reading or getting out.

Missing a dose of opioid medicine

People find that fitting regular doses of opioid medicines in with their daily activities helps them to keep on top of their pain while still being able to do the things they want. When people miss a dose it is harder for them to keep control of their pain. It is helpful to talk to a doctor or specialist nurse when people are worried that feeling drowsy will stop them from doing something they want to do. Feeling sleepy or drowsy should wear off after a week of starting a new dose of opioids. If you continue to feel sleepy talk to your specialist nurse or doctor who will find ways to help you.

Finding the right dose

Some people find that their pain gets worse and they may need a higher dose of their opioid medicine. For others, pain can improve and the dose of opioids can be lowered. When people start taking an opioid it is usual for a doctor or nurse to adjust the dose up or down until they find the right dose that controls pain with the minimum amount of side-effects. Your doctor or specialist nurse will work with you to adjust the dose of your opioid medicine to get to right dose for your pain.

Some people find that once they are on the right dose of opioids for their pain, they stay on that dose for some time.

Common concerns when taking opioid medicines

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Taking extra doses of medicine to control breakthrough pain

Sometimes when people are taking their regular dose of slow-release opioid medicines they can experience a burst of intense pain. This is called breakthrough pain. People take a dose of fast-release opioid medicine to control breakthrough pain without fear of overdosing if they follow the advice given to them by their health professional.

Specialist nurses and doctors should explain the breakthrough dose that you have been prescribed and that you can take it when you need it. After taking a breakthrough dose you should feel it starting to work within 30 minutes. If you still have pain after an hour of taking a breakthrough dose, then it is safe to take another breakthrough dose. However, if you still have pain an hour after taking the second breakthrough dose, then you should seek help from your GP or specialist nurse before taking more breakthrough medicine. If you need 3-4 breakthrough doses over 24 hours it may be that your pain is not being managed by your slow-release dose of opioid medicines. You should speak to your specialist nurse so they can review your pain management with you.

Driving and opioid medicines

A person's ability to drive depends on many different factors, including what medicines they may be taking and what car insurance companies will accept. People tell their car insurance company about any serious illness they have to make sure that they are covered in the event of an accident.

With regard to opioids, people may be able to drive when taking the same dose of medicines for a few days or more. If people feel sleepy or the side effects are bothering them, often they won't drive. Drowsiness is more likely to occur when someone starts taking opioid medicines, or when their dose is increased. However, when people have been on the same dose for a while and they feel alert, driving may be possible. If in doubt, speak to your specialist nurse or GP. UK law states that it is your responsibility to consider whether you believe your driving may be impaired (by feeling sleepy) because of any medicines you take.

Concerns about long terms effects

Opioid medicines control pain by blocking the pain messages sent by nerves in the body reaching the brain. People taking opioids can sometimes worry that if they continue to take them for a while they will stop working. The way opioid medicines work means that they will continue to block pain message reaching the brain even if they are taken every day for a long time.

When opioids are used for pain management there is very little risk of addiction. If people feel that their pain has decreased they talk about this with their specialist nurse and discuss whether the dose of opioid medicines they take can be reduced. You should not suddenly stop your pain medicines.

Common concerns when taking opioid medicines

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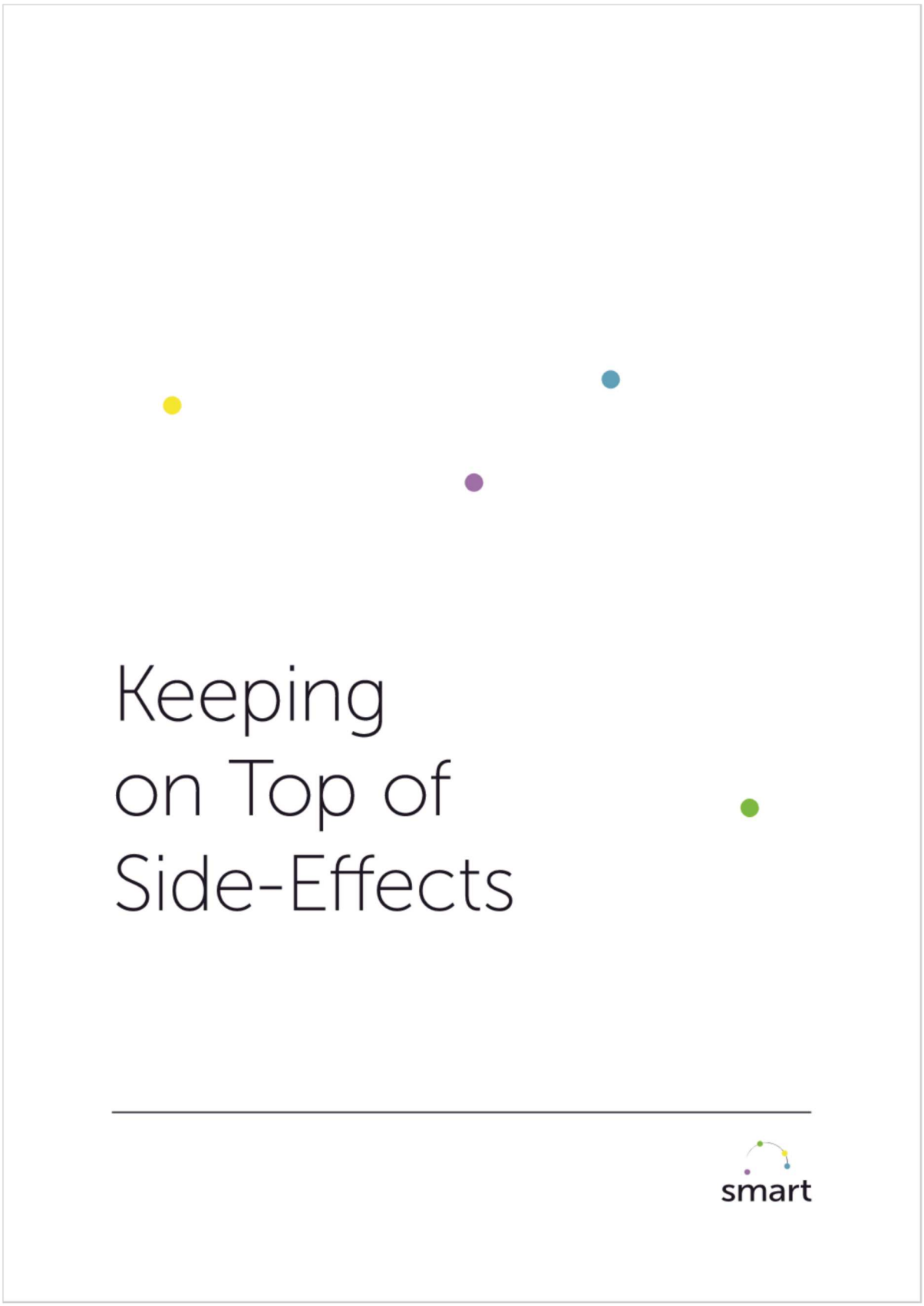

Introduction

This factsheet has information about the side-effects of opioid medicines. People have different experiences of taking opioids and the side-effects of these medicines. Talking to a specialist nurse, a pharmacist or doctor about managing pain and side-effects helps people to make a plan to fit taking opioids into their daily routine.

Understanding side-effects

When people start taking opioid medicines or their dose is changed it can take time for their bodies to get used to them. During these few days, some people have other symptoms like feeling sick or tired. These other symptoms are called side-effects and are caused by the opioid medicines. Most people find that after a few days of getting into the habit of taking opioid medicines, their pain is manageable and these other symptoms get less.

For some people, the side-effects do not go away after a few days. Health professionals talk with their patients about any symptoms they get when taking opioid medicines. There are different types of opioid medicines that can be used to control pain. Some may suit people better than others. If side-effects are a problem, health professionals can adjust the dose or suggest a different opioid medicine which may have fewer side-effects. They also talk about tips that other patients have tried.

The common side-effects from opioid medicines include constipation, feeling sick (nausea) and feeling tired (drowsiness).

Constipation happens to nearly everyone taking slow-release or fast-release opioid medicines. It means people do not have their usual bowel movements and stools (faeces) block up the gut. It can be painful and upsetting. A diet high in fibre is not usually sufficient to prevent opioid related constipation. Health professionals give laxative treatments to people when they are taking opioid medicines. Laxative treatments are usually tablets or liquids taken by mouth to help the body pass out stools. Laxatives which are taken by mouth usually take a few days to take effect, so people taking opioid medicines take laxatives each day. Some laxatives soften stools and make them easier to pass, while others stimulate the bowel to push the stools along more quickly. A combination of these two types is often best at preventing constipation.

People find that taking laxatives each day for as long as they are taking opioid medicines helps them to manage constipation. When people wait to take laxatives once they are already constipated they find it more difficult treat and may require additional treatments, like suppositories and enemas.

With help from their health professionals, people work out which laxatives work best to prevent constipation, when to take them and how to adjust them. There is space at the end of this factsheet to make notes about which laxatives work best for you and plan when to take them and how to adjust them.

Nausea or feeling sick happens to some people when they start taking opioid medicines or their dose changes. For most people, feeling sick or nauseous goes away after a few days. Health professionals can give anti-sickness tablets to people whose nausea symptoms do not go away after a few days.

Tiredness or feeling drowsy happens when people start taking opioid medicines or their dose changes. Some people experience problems concentrating, for example when reading a book or watching TV. Feeling drowsy usually wears off after a week. If feeling tired or drowsy does not go away or gets worse people talk to their specialist nurse or doctor about it. They may suggest changing the dose of slow-release opioid medicine or trying a different one. There are usually alternative options that your specialist nurse of doctor can suggest if feeling tired or drowsy is a problem.

For some people drinking alcohol can increase the feeling of drowsiness. If people drink alcohol, cutting down for a while can help their body get used to the new dose of opioid medicine. If people are planning to drive they check with the person prescribing their medicines that they are safe to do so. Don't drive if you don't feel fully alert or if your reactions are slowed.

The space below is for people to note down any questions they have about managing the side-effects of their opioid medication. These notes can help your specialist nurse or doctor make a plan with you that suits your needs.

Keeping on Top of Side-Effects

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Appendix 10 Topic guide for structured patient podcast

The Practical Issues of Managing Medicines (From checking stock to ordering, collecting and taking them)

Recap about the study

Start filming

Would you be able to guide me through the practical experiences of managing your pain medicines on a day-to-day basis? You have learnt much about this process through trial and error and picked up many pearls of wisdom along the way.

If we start with your experience of getting repeat prescriptions what have you found works for you?

- How do you do this? Online system for GP surgery - your experiences of using it
- When and how do you check your supplies, so you know when to put in a request for a repeat prescription? Fills 2 weekly pill 'dosette' boxes (show on film) so knows has enough supplies for a fortnight
- What's your routine for putting a repeat prescription request in? Puts repeat prescription request in on a Sunday – 5 working days for prescription to be generated, sent to pharmacy, and then prescription to be filled at the pharmacy

In terms of collecting the medicines from the pharmacy has this been an issue for you?

- When do you collect your medicines from the pharmacy? On a Friday, when pharmacist is there. What's important about this relationship?
- Do you then check what is in the bag? What do you look out for?
- Have you had any problems with the pharmacy not stocking any medicines you require? How did you get round this?

You've learnt to understand your medicines in terms of knowing all their names, what they are for and how best to take them. What did you do initially to help with this?

- Did you write anything down? For example, in a medicines chart?
- Who did you find it helpful to discuss the medicines with?
- What have been the benefits of understanding your medicines?

If we move on to thinking about organising and safely storing your medicines, what system have you found works for you?

- Uses 2 drawers – 1 with medicines currently taking, and another for back up supplies

How have you worked out when it's best to take the various medicines to fit around your daily routines?

- When do you prefer to take certain medicines, for example laxatives?
- If you go out or away what do you do?

Taking your medicines has become second nature to you but initially did you do anything to remind yourself to take them?

Finally, what top practical tip, or tips, would you give to someone just starting out on pain medicines?

Thank you

Appendix 11 Topic guide for structured health-care professional podcast

Structured Healthcare Professional Podcast - Monitoring the Effectiveness of Medicines

Recap about the study

Start filming

Could you begin by explaining why it's helpful for individuals to monitor the effectiveness of their medicines for pain and any for the related side effects of constipation and nausea?

Why is this helpful for the particular individual concerned?

- Increases understanding, control over medicines taking and subsequent control over the symptoms of pain, nausea and constipation
- Helps in the fine tuning of the medicines they are on regarding the right doses

Why is this monitoring by the individual helpful for specialist healthcare professionals working with them?

- Helps in understanding how well the medicines are working:
    - understanding any changes in pain or in the effectiveness of meds,
    - whether doses need to go up or down or be altered in terms of when in the day the medicine is taken,
    - or whether an alternative medicine is required
- Helpful to improve the communication between the individual and HCP, so the HCP can understand the individual's experience and together they can discuss any necessary changes

So, what is it a good idea to monitor?

- Which medicines are helping and in what circumstances. For example is something working well in combination with another pain control method?

You have years of experience helping individuals monitor the effectiveness of their pain medicines. How do you aid an individual's initial understanding of their medicines, in terms of what they are taking and why?

- Medicine charts (edit an example into the film) – crossing off what has been taken and noting down any as needed medication taken especially for breakthrough pain

Helping to educate individuals to monitor the effectiveness of their medicines is obviously an on-going process. What level of understanding are you aiming for?

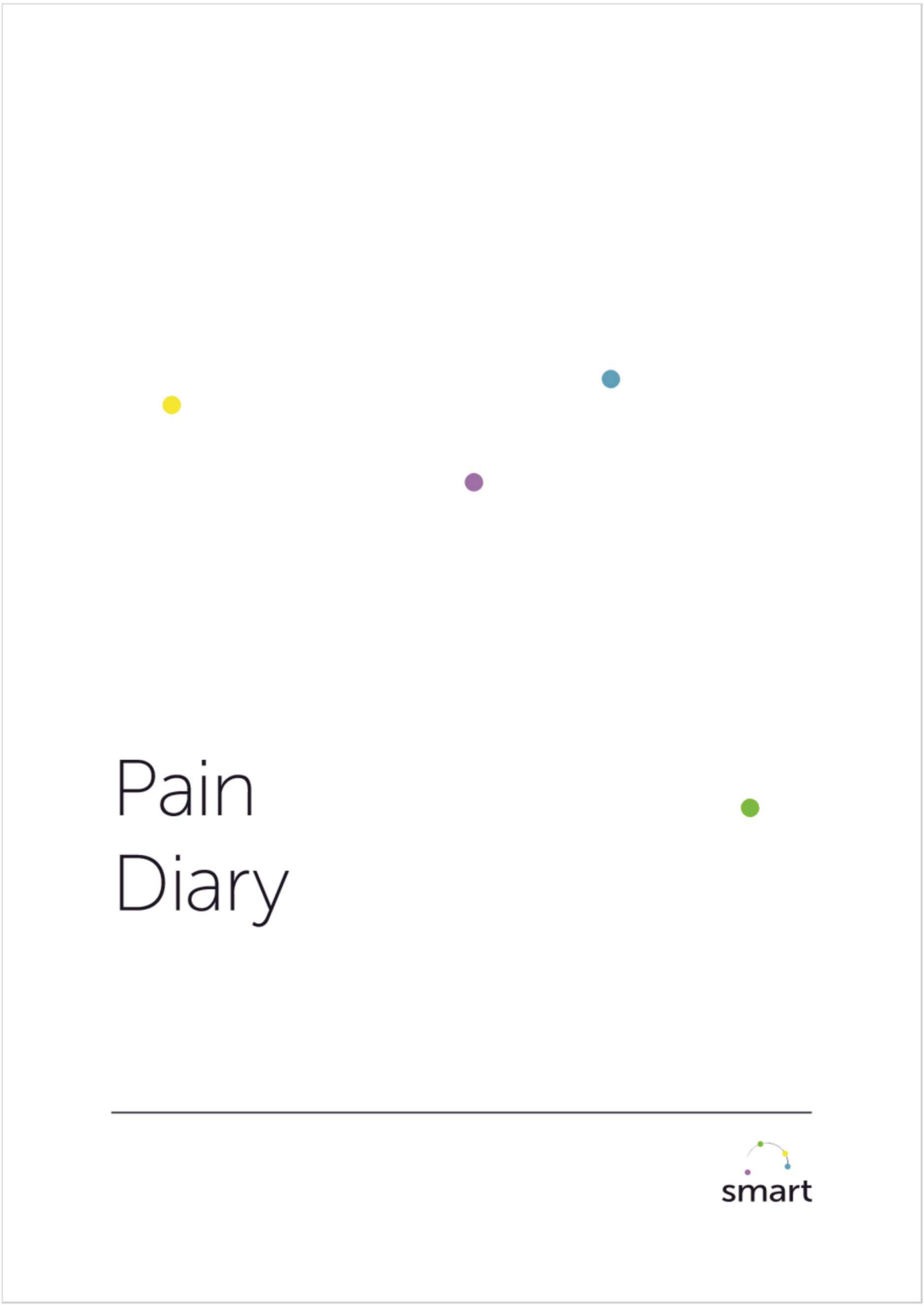
- Understanding of the effects of the medicines on the individual – balancing the intended effects and side effects at the right level for them

In your experience, what have you found helps individuals to achieve this level of understanding?

- Pain diary (edit an example into the film) – recording when a pain starts, where is it, how strong the pain is, whether anything causes the pain to start, the medicines taken for the pain and whether they helped. Did they work a little or a lot? The importance of knowing this.

Thank you

Appendix 12 Pain diary



Time of day	Where was the pain?	What was the pain like?	Level of pain (0-10 rating)	Name and amount of medicine taken/ other pain control methods used	What worked and what didn't?	How long did the pain last?

Pain Diary

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Time of day	Where was the pain?	What was the pain like?	Level of pain (0-10 rating)	Name and amount of medicine taken/ other pain control methods used	What worked and what didn't?	How ong did the pain last?

Pain Diary

smart

Time of day	Where was the pain?	What was the pain like?	Level of pain (0-10 rating)	Name and amount of medicine taken/ other pain control methods used	What worked and what didn't?	How ong did the pain last?

Pain Diary

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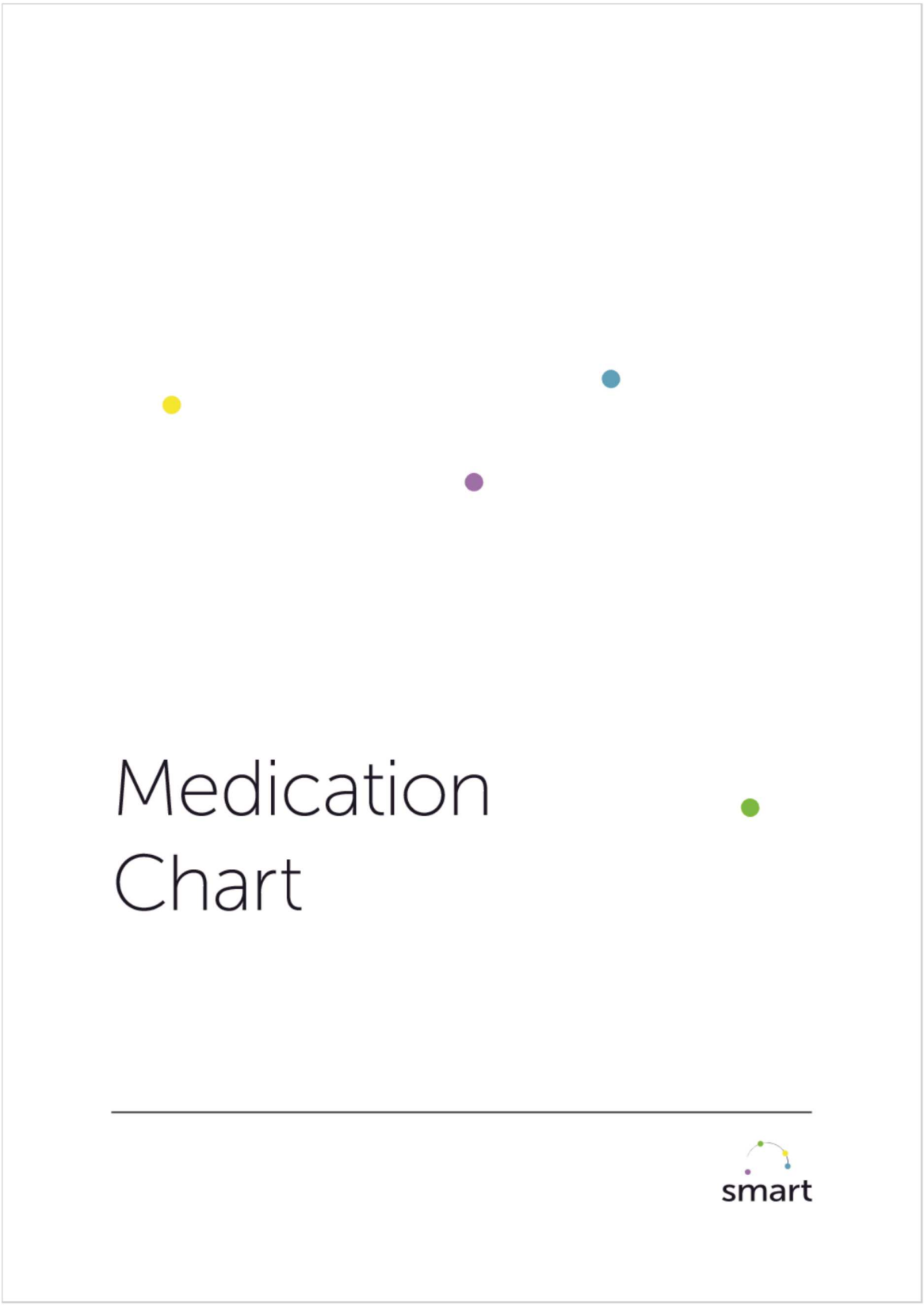
Appendix 13 Medication chart



Start date:		Week of:							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
	Lunch																												
	Evening meal																												
	Night/Bed																												
Notes																													

Start date:		Week of:							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
	Lunch																												
	Evening meal																												
	Night/Bed																												
Notes																													

Medication Chart

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Start date:		Week of:							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
	Lunch																												
	Evening meal																												
	Night/Bed																												
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Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
	Lunch																												
	Evening meal																												
	Night/Bed																												
Notes																													

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Medication Chart

Start date:		Week of:							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
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Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
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Medication Chart

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Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
	Lunch																												
	Evening meal																												
	Night/Bed																												
Notes																													

Start date:		Week of:							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																												
	Lunch																												
	Evening meal																												
	Night/Bed																												
Notes																													

Medication Chart

Start date:		Week of:							Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
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Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
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Medication Chart

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Start date:		Week of:							Week of:							Week of:						
Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
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Medicine		M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
	Breakfast																					
	Lunch																					
	Evening meal																					
	Night/Bed																					
Notes																						

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Medication Chart

Appendix 14 Goal-setting sheets

Introduction

People find it useful to agree one or two goals each time they see their specialist nurse. This helps with planning how to manage their pain with opioid medicines. Setting goals and writing a plan to achieve these goals allows you and your specialist nurse to be clear about what you are aiming to achieve. The goals people choose depend on what is most important to them.

Things I would like to achieve:

Example: To sleep better at night with less pain

What I will do to help me get there:

Example: To take my MST (morphine tablets) at 7pm so that it has time to be working by 10pm

Today's Date:

My Signature: Specialist Nurse's Signature:

The space below can be used to note down what went well with the plan and what worked, as well as things that were difficult to do or didn't go to plan. These notes can help you and your specialist nurse review these goals and make a new plan if needed.

Things I would like to achieve over the next week

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Appendix 15 Communication with the Research Ethics Committee

The Research Ethics Committee's amendment notification and amendment approval letter

Notice of Amendment IRAS Version 5.1.0

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
SMART Feasibility Study

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
(●) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (●) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (●) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

188663/877913/13/454/47477

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- (•) England
- ( ) Scotland
- ( ) Wales
- ( ) Northern Ireland
- ( ) This study does not involve the NHS

4. Which review bodies are you applying to?

- [ ] HRA Approval
- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] Research Ethics Committee
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

5. Will any research sites in this study be NHS organisations?

(•) Yes ( ) No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

( ) Yes (•) No

If yes and you have selected HRA Approval in question 4 above, your study will be processed through HRA Approval.

If yes, and you have not selected HRA Approval in question 4 above, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

(•) Yes ( ) No

If yes, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before submitting other applications. If you have selected HRA Approval in question 4 above your study will be processed through HRA Approval. If not, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

6. Do you plan to include any participants who are children?

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

188663/877913/13/454/47477

Notice of Amendment IRAS Version 5.1.0

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Michael	Bennett
Work Address	[redacted]		
PostCode			
Email			
Telephone			
Fax			

Full title of study:	Self-Management of Analgesia and Related Treatments in palliative care - Feasibility Study
Lead sponsor:	University of Leeds
Name of REC:	North West - Lancaster
REC reference number:	15/NW/0797
Name of lead R&D office:	University Hospital Southampton NHS Foundation Trust
Date study commenced:	23 November 2015
Protocol reference (if applicable), current version and date:	SMART phase 3 protocol version 1 21 September 2015
Amendment number and date:	Amendment number 1 05 November 2015

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Revised protocol attached. Version 2, date 05 November 2015. All changes to the protocol have been tracked

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Notice of Amendment IRAS Version 5.1.0

using track-changes

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

◉ Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

The information sheets and consent forms listed in section "List of enclosed documents" have been amended with new version numbers, dates and changes tracked using track-changes.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

The changes outlined below were made following consultation with patient and carer representatives and the study steering committee at the recent SMART project meeting in October 2015. These changes do not significantly alter the research design or methodology, rather they are intended to (1) reduce the burden for patients of completing fortnightly questionnaires and (2) improve the assessment of the fidelity of intervention delivery in clinical practice and (3) ensure our patient review procedure more closely reflect usual clinical nurse specialist practice.

1. Changes to patient reported outcome measures:
After consultation with patients, carers and the study steering committee it was felt that the 'Self-management ability scale' (SMAS) was too burdensome for an end of life patient group. It was decided to replace the SMAS with the 'self-efficacy for managing chronic disease scale' which is a short 6 item scale which can be adapted to an end of life context and is therefore more closly aligned to the aims and objectives of the study.

In addition, it was also felt that the Beliefs about Medicines (BMQ) questionnaire was felt to be too burdensome and some questions were inappropriate for patients at the end of life. It was therefore decided to remove the BMQ from the study as it was not direcrlty related to the objectives of the study and many of the domains were already address in the patient interview topic guide.

2. Changes to assessing fidelity of delivering the SMART intervention:
The study steering committee advised the study team that audio recording nurse-patient consultations when the SMART intervention is used is the most appropriate way of assessing the fidelity of delivering the intervention. This data can be used to develop a coding framework which in a definitive trail can be used to evaluate the delivery of the intervention.

Audio recording nurse-patient consultations has been written into the protocol under section 10.7 'Intervention adherence' (page 20). It is intended that each specialist nurse will be asked to audio record their consultation with one patient with whom they use the SMART toolkit intervenor.

The information sheets and consent forms for patients and health professionals have been amended to include audio-recording the consultations during which the SMART toolkit is used. It has been made clear that consenting to audio recording consultations is be voluntary and if either the nurse or patient dose not consent to it, it will not prevent them from taking part in the rest of the study.

3. Change to wording of "weekly" review of patient's progress with goal setting.
Following feedback from specialists palliative care nurses on the protocol it was decided to modify the description of the "weekly nurse-patient review" to "regular nurse-patient review". This has been changed throughout the protocol, as well as the patient and health professional information sheets.

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The reason for this change is because it will allow are study protocol to reflect more closely usual specialist nurse care. Nurse feedback indicated that they often review their patient's progress more or less frequently than once a week. Therefore, so that our protocol reflects this usual practice and to ensure we capture all nurse-patient consultations where the SMART toolkit is used we have modified our protocol accordingly to accommodate this.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
SMART Protocol phase 3	2	05/11/2015
SMART Health Professional Consent Form	2	05/11/2015
SMART Patient Consent Form	2	05/11/2015
SMART Health professional information sheet	2	05/11/2015
SMART Patient Information Sheet	2	05/11/2015

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Professor Mike Bennett on 17/11/2015 16:24.

Job Title/Post: Professor of Palliative Medicine

Organisation: University of Leeds

Email: [redacted]

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mrs Clare Skinner on 17/11/2015 13:24.

Job Title/Post: Sponsors Representative

Organisation: Leeds University

Email: [redacted]

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NHS
Health Research Authority
National Research Ethics Service

North West - Lancaster Research Ethics Committee

[redacted]

23 November 2015

Professor Michael Bennett
St Gemma's Professor of Palliative Medicine
University of Leeds
[redacted]

Dear Professor Bennett

Study title:	**Self-Management of Analgesia and Related Treatments in palliative care - Feasibility Study**
REC reference:	**15/NW/0797**
Amendment number:	**1**
Amendment date:	**17 November 2015**
IRAS project ID:	**188663**

Changes to reported outcome measures, assessing fidelity, change to patient review

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The members had no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	1	17 November 2015

Participant consent form [health professional]	2	05 November 2015
Participant consent form [patient]	2	05 November 2015
Participant information sheet (PIS) [Health professsional]	2	04 November 2015
Participant information sheet (PIS) [patient]	2	05 November 2015
Research protocol or project proposal [phase 3]	2	05 November 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

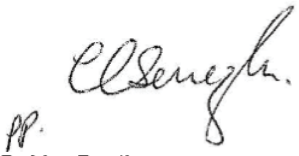
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/NW/0797:	**Please quote this number on all correspondence**

Yours sincerely



Dr Lisa Booth
Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust*
Research Ethics and Governance Admin

North West - Lancaster Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 23 November 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Lisa Booth	Senior Lecturer / Chair	Yes	
Professor Jois Stansfield	Professor of Speech Pathology	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Carol Ebenezer	REC Manager

Appendix 16 Recruitment packs: patients, carers and study nurses

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self management of analgesia and related treatments

Invitation Letter

We are writing to invite you to participate in a research study. The SMART study is aimed at reducing pain and the side-effects of pain medication experienced by patients with advanced disease living in the community. The Chief Investigator for this study is Professor Michael Bennett who is based at the University of Leeds.

Before you decided if you would like to take part in this study, please would you read the enclosed Information Sheet? With your permission, a member of the research team of the University of Leeds will contact you within the next few days to discuss the study and answer any questions you may have. This information will be kept strictly confidential.

If you would like more information about this study please do not hesitate to contact:
<<RESEARCHER CONTRACT DETAILS>>

Thank you very much for taking the time to read this information.

Yours Sincerely,

Mike Bennett

Michael Bennett
St Gemma's Professor of Palliative Medicine
Leeds Institute of Health Sciences
University of Leeds

SMART Invitation Letter
Version 1
21 September 2015

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SMART Invitation Letter
Version 1
21 September 2015

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self management of analgesia and related treatments

Patient Information Sheet

A large print version of this sheet is available on request

Invitation to participate in the study

We would like to invite you to take part in the SMART study, funded by the National Institute for Health Research (NIHR). This information sheet tells you the purpose of this study and what your participation would involve. Please take time to read it carefully and talk it over with another person if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information sheet, your Nurse or a member of the Research Team will talk to you about the study again and you can ask any question you like.

How to contact us

If you have any questions about this study, please talk to your Nurse at <<HOSPICE NAME>> (telephone xxxx) or contact a member of the Research Team at:

SMART Patient Information Sheet
Version 2
05 November 2015

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<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet.

What is the purpose of this study?

The SMART study is aimed at reducing pain and the side effects of pain medication experienced by patients with advanced disease living at home. To do this we are asking 30 patients to take part in a pain management educational programme for 6 weeks delivered by specialist palliative care nurses working in the community.

Why have I been invited to take part?

You have been given this information sheet as a person who is receiving hospice or specialist nursing services. Clinical staff providing your treatment and care have identified you as somebody who is living at home and may benefit from pain management support alongside the usual care you receive.

Do I have to take part?

It is up to you to decide to take part in the study. If you decide you do not wish to take part, it will not affect the care you receive in any way. If you do decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you are free to withdraw at any time without giving a reason.

What will happen to me if I agree to take part?

We have designed an educational programme (called the "SMART toolkit") for patients with pain to be used at home in partnership with their specialist nurse. It is designed to help patients increase their understanding of pain and provide skills to help manage pain and the side effects of pain medication more effectively. The SMART toolkit consists of four sections:

1. Identifying problems, fears or concerns about managing pain or opioid medicines
2. Providing information (fact sheets and/or podcast) about managing pain and opioid medicines
3. Setting weekly goals
4. Reviewing goals on a weekly basis

SMART Patient Information Sheet
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05 November 2015

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If you decide to take part you will be asked to meet with your specialist nurse once a week for six weeks to work through the SMART toolkit together.

The first time you use the SMART toolkit with your specialist nurse they will work with you to identify any problems or concerns you may have, or that you anticipate having, about managing your pain or about managing the opioid medicines you take. During this discussion your specialist may provide you with some information sheets (called fact sheets) or podcasts about managing your pain and/or opioid medicines. At the end of this first meeting your specialist nurse will work with you to set one or two goals for the week ahead related to managing your pain and/or opioid medicines. This first meeting should take about 30-60minutes, however you can take as much time as you need.

Following this, your specialist nurse will meet with you over the next 5 weeks to see how you are getting on with the goals you have set. These meetings can be done over the telephone if you prefer, although the majority are likely to be face-to-face. At these meetings your specialist nurse may provide you with additional fact sheets and set new goals with you for the week ahead. These meetings should take between 15-30 minutes, however you can take as much time as you need.

If you decide to take part in the study your specialist nurse may talk to you about whether you are happy to audio record your meetings when you use the SMART toolkit. Just under half of the people who are recruited to the study (about 12 people) will be asked to do this. If you are asked to do this, you can say no without giving a reason. This will not stop you from taking part in the rest of the study. The purpose of audio recording these meetings is so we can understand how people are using the SMART toolkit with their specialist nurse. This information will help us to train other nurses to use the SMART toolkit with their patients.

If you are asked about audio recording your meetings with your specialist nurse and you agree to it, the recordings will be typed up anonymously so you will not be identified.
If you agree to take part in this study, information about you will be collected from your medical records for the duration of the study by a local healthcare professional from the community palliative care team. You will also be asked to complete a questionnaire when you

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enter the study, at 2 weeks, 4 weeks and 6 weeks after this date. These questionnaires can be completed at home with a Researcher from the University of Leeds or they can arrange to call you and complete them over the phone.

We would also like to invite you take part in an informal interview after you have been using the SMART toolkit for a few weeks to find out how you have found using the SMART toolkit. This interview is optional and you do not have to take part in this bit of the study if you prefer not to. It may be that a spouse/partner/other relative or friend is actively involved in helping you to manage your pain. If this is the case, with your permission we would like to approach that person as well, to ask them to take part in the interview also. This is up to you however; if you do not identify such a person or if you do not wish us to approach such a person for whatever reason, we will not do so and it will not affect your participation in the study. If you do agree for us to approach such a person and they do not wish to participate in the study this will not affect your involvement in the study in any way.

The interview will be more like a conversation than a set of questions with fixed responses. It will last for around 30 minutes to an hour and take place at a time and place that is convenient for you. With your permission, we would like to make an audio recording of the interview. This is because we want to get an accurate account of what is said and the researcher can concentrate on what you say without being distracted by having to take too many notes. The interview will then be typed up and you may have a copy of this if you wish by contacting the research team at the address at the end of this sheet – or directly after the interview. If you do not wish for the interview to be recorded in this way, we will of course respect your wishes and take written notes during the interview instead.

If at any point during the study you no longer wish to continue taking part you can withdraw. You don't have to give any explanation – just that you do not wish to continue participating. If during the interview you feel tired or uneasy in any way you can stop the interview at any time, just let the researcher know. If you wish, it will be possible to continue with the interview after a break, or at a later date.

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If you do not wish to continue participating in all or any part of the study the information you have provided up to that point will still make a valuable contribution to the study. If you do decide to stop participating in the study at any point, this will not affect your treatment or support in any way.

How long is the study going on?

The study will last for 6 weeks. Once all our study participants have reached 6 weeks after they entered the study, final data will be collected from your medical records.

What are the disadvantages of taking part?

We do not foresee any disadvantages or risks to you taking part in this study. However you will be asked to give some of your time for taking part. Your routine care will remain the same whether or not you decide to take part.

What are the benefits of taking part?

We hope the information we collect from you will help us improve the care of patients living at home with pain from advanced disease in the future. We hope that patients who take part in this study will benefit from the educational resources that are provided as part of the study.

What happens when the research study stops?

When the study ends the usual care you receive from your specialist nurse will continue. You will be able to keep the SMART toolkit. At the end of the study your specialist nurse will not normally continue using the SMART toolkit with you.

Will my GP be informed of my involvement in the study?

With your permission, your GP, and the other doctors involved in your healthcare, will be kept informed of your participation in this study. Your GP may be contacted at the end of this study for a final collection of data from your medical records.

What will happen to the information we collect from you?

The information we collect from you will be kept confidential and will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act.

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Personal information that contains your name, date of birth and contact details will be kept separate from any of the questionnaires or interview transcripts in a locked filing cabinet at the University of Leeds. Questionnaires, audio files and interview transcripts will have personal identifying information removed and you will be identified with a code number. This information will be kept in a locked filing cabinet and backed up on a password-protected encrypted hard drive. Questionnaires, audio files and transcripts will be seen and heard only by members of the research team.

What if there is a problem?

The Trial Management Group will closely monitor the study on an on-going basis. If there are any problems they will be detected as soon as possible so that the study can be changed or stopped if necessary. If you experience problems, you must report these to your study nurse or doctor.

If you have any concerns about this study, you should contact a member of the research team in the first instance. If you have a problem or concern about the study and you feel that it has not been responded to satisfactorily, you may at any point contact the Patient's Advisory Liaison Service (PALS) at The Patient Experience Team which is part of Harrogate and District NHS Foundation trust. This service is there for patients. You can either ring or email a member of staff at The Patient Experience Team office:

Telephone: [redacted], Email: [redacted]

What will happen if I don't want to carry on with the study?

If you withdraw consent from further study participation, information will still be collected about you and will be included in the final study analysis, unless you request otherwise. If you withdraw consent for further data collection your data collected up to that point will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

Who has reviewed this study?

SMART Patient Information Sheet
Version 2
05 November 2015

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This study has been reviewed by North West - Lancaster Ethics Committee and has been approved by them.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please contact a member of the research team (contact details and the end of this information sheet).

What happens now?

If there are questions you would like to ask about the study before deciding whether or not to take part please contact <<RESEARCHER NAME>> who is coordinating the study (contact details are below). If you decide you would like to take part in this study, please complete the consent form attached. A member of the research team will contact you by telephone in a few days. If you decide you would like to take part in this study, the researcher will arrange a convenient date and time at a place that suits you to meet with you and complete the first set of questionnaire data. You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Contact details of the research team

<<RESEARCH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact me at the address below.

Yours Sincerely,

<< PRINCIPAL INVESTIGATORS NAME, SIGNATURE AND CONTACT ADDRESS>>

SMART Patient Information Sheet
Version 2
05 November 2015

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Self-Management of Analgesia and Related Treatments
SMART
Patient Consent Form

		Initial each box
1.	I confirm that I have read and understand the information sheet for the above study and have been given a copy to keep. I have had the opportunity to consider the information and ask questions and had these answered satisfactorily. I understand why the research is being done and any risks involved.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without any consequences.	☐
3.	I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies or Sponsor in order to check that the study is being carried out correctly.	☐
4.	I understand that all information collected from me for this study will be held securely and in confidence and that my personal details will not appear on any publication of results.	☐
5.	I agree to my GP being informed of my participation in the study. I agree to a copy of this Consent Form being sent to my GP.	☐
6.	I understand that data collected during the study may be looked at by individuals from regulatory authorities or from Leeds University (the study sponsor), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my study records.	☐
7.	I understand that if I decide to withdraw from the study, data already collected would be retained and used in the study.	☐
8.	I agree to take part in this study	☐

Please turn over

SMART Patient Consent Form
Version 2
5 November 2015

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The following is optional
If you agree to take part in this study, you do not have to agree to this section

9. I agree to being contact by a member of the study team to ask me if I would like to take part in an interview to tell them how useful I found the study	☐
10. I understand that this interview will be audio recorded and that all transcripts will be anonymised.	☐
11. I agree that the consultations with my specialist nurse will be audio-recorded and that these recordings will be typed up anonymously.	☐

Patient:
Name (in block letters) .....

Signature.....

Date: ...../...../.....

Investigator:
Name (in block letters).....

Signature.....

Date: ...../...../.....

For office use only	
Patient ID:	Initials:
Date of birth:	NHS/Hospital Number:
ISRCTN: 35327119	Principal Investigator:

The original copy of this Consent Form is to be stored in Investigator Site File.
One copy to be given to the patient.
One copy to be sent to the patient's GP.

SMART Patient Consent Form
Version 2
5 November 2015

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smart
self management of analgesia and related treatments

Carer/Relative Information Sheet

A large-print version of this sheet is available on request

Invitation to participate in the study

We would like to invite you to take part in the SMART study, funded by the National Institute for Health Research (NIHR). This information sheet tells you the purpose of this study and what your participation would involve. Please take time to read it carefully and talk it over with another person if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information sheet, the Nurse looking after the person your care for or a member of the Research Team will talk to you about the study again and you can ask any questions you like.

How to contact us

If you have any questions about this study, please talk to the Nurse looking after the person your care for at <<HOSPICE NAME>> (telephone xxxx) or contact a member of the Research Team (contact details are on the next page).

SMART Carer/Relative Information Sheet
Version 1.1
20 October 2015

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<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet.

What is the purpose of this study?

The SMART study is aimed at reducing pain and the side effects of pain medication experienced by patients with advanced disease living at home. To do this we are asking 30 patients to take part in a pain management educational programme for 6 weeks delivered by specialists palliative care nurses working in the community. In addition, we also want to understand the views of people who care for someone managing pain from advanced disease at home who has used the SMART toolkit.

Why have I been invited to take part?

The person that you are caring for/close to has consented to take part in this study. We have asked their permission to approach you also to take part in the study.

Do I have to take part?

It is up to you to decide to take part in the study. If you decide you do not wish to take part, it will not affect the treatment the person you care for receives in any way. If you do decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you are free to withdraw at any time without giving a reason. It should be noted at this point that your participation is subject to the participation of the person you care for. If they decided not to take part this will prevent you from taking part.

What will happen to me if I agree to take part?

If you decide to take part you will be invited to take part in a face-to-face interview with the person you care for and a trained researcher from the University of Leeds. The interview will be more like a conversation than a set of questions with fixed responses. The purpose of the

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interview is to allow you to talk in your own words about how you and the person you care for have found using the SMART toolkit to manage the pain that they experience. The interview will last for around 30 to 60 minutes. It will be arranged at a time and place that is convenient for you and the person you care for.

With your permission, we would like to make an audio recording of the interview with you and the person you care for. This is because we want to get an accurate account of what is said and the researcher can concentrate on what you say without being distracted by having to take too many notes. The interview will then be typed up and you may have a copy of this if you wish by contacting the research team at the address at the end of this sheet – or directly after the interview. If you do not wish for the interview to be recorded in this way, we will of course respect your wishes and take a written note of the interview instead.

If during the interview you or the person you care for feel tired, uneasy in any way or worried, you can stop the interview at any time – you don't have to give any explanation – just that you do not wish to go on. If you wish, it will be possible to continue with the interview after a rest, or at a later date. If you do not wish to continue with the interview the information you have provided up to that point will still make a valuable contribution to the study. If you do decide to stop the interview at any point, this will not affect your relative/friend's treatment or support in any way.

How long is the study going on?

The person you care for has consented to take part in a study lasting for 6 weeks. However, we are only asking you to take part in a one off face-to-face interview lasting approximately 30 to 60 minutes.

What are the disadvantages of taking part?

We do not foresee any disadvantages or risks to you taking part in this interview. However you will be asked to give some of your time for taking part.

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What are the benefits of taking part?

We hope the information we collect from you will help us improve the care of patients living at home with pain from advanced disease in the future.

What happens when the research study stops?

When the study ends the usual care received by the person you care for will continue.

What will happen to the information we collect from you?

Everything that you say will be kept confidential and the information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act. Personal information that contains your name and biographical details will be kept separate from interview transcripts in a locked filing cabinet at the University of Leeds. Audio files and interview transcripts will have personal identifying information removed and you will be identified with a code number. This information will be kept in a locked filing cabinet and backed up on a password-protected encrypted hard drive. Audio files and transcripts will be heard and seen only by members of the research team.

What if there is a problem?

The Trial Management Group will closely monitor the study on an on-going basis. If there are any problems they will be detected as soon as possible so that the study can be changed or stopped if necessary.

If you have any concerns about this study, you should contact a member of the research team in the first instance. If you have a problem or concern about the study and you feel that it has not been responded to satisfactorily, you may at any point contact the Patient's Advisory Liaison Service (PALS) at The Patient Experience Team. This service is there for patients. You can either ring or email a member of staff at The Patient Experience Team office:

Telephone: [redacted], Email: [redacted]

SMART Carer/Relative Information Sheet
Version 1.1
20 October 2015

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What will happen if I don't want to carry on with the study?

If you withdraw consent for further data collection your data collected up to that point will remain on file and will be included in the final study analysis. In line with Good Clinical Practice guidelines, at the end of the study, your data will be securely archived for a minimum of 5 years. Arrangements for confidential destruction will then be made.

Who has reviewed this study?

This study has been reviewed by North West - Lancaster Ethics Committee and has been approved by them.

What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please ask your doctor or contact a member of the research team.

What happens now?

If there are questions you would like to ask about the study before deciding whether or not to take part please contact your specialists nurse who gave you this information sheet or <<RESEARCHER NAME>> who is coordinating the study (contact details are on the next page). If you decide you would like to take part in this study, please complete the consent form attached. A member of the research team will contact you by telephone in a few days. If you decide you would like to take part in this study, the researcher will arrange a convenient date and time for interview at a place that suits you. You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Contact details of the research team

<<RESEACH TEAM CONTACT DETAILS>>

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Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact me at the address below.

Yours Sincerely,

<< PRINCIPAL INVESTIGATORS NAME, SIGNATURE AND CONTACT ADDRESS>>

SMART Carer/Relative Information Sheet
Version 1.1
20 October 2015

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Self-Management of Analgesia and Related Treatments
SMART
Relative/Carer Interview Consent Form

	Initial each box
1. I confirm that I have read and understand the information sheet for the above study and have been given a copy to keep. I have had the opportunity to consider the information and ask questions and had these answered satisfactorily. I understand why the research is being done and any risks involved	☐
2. I understand that my participation is voluntary that that I am free to withdraw at any time, without giving any reason and without any consequences	☐
3. I understand that all information collected from me for this study will be held securely and in confidence and that my personal details will not appear on any publication of results	☐
4. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from Leeds University (the study sponsor), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my study records	☐
5. I understand that if I decide to withdraw from the study, identifiable data already collected would be retained and used in the study	☐
6. I understand that this interview will be audio recorded for purposes of data collection and all resulting transcripts will be anonymised	☐
7. I agree to take part in this study	☐

Please turn over

SMART Carer Consent Form
Version 1.1
20 October 2015

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Carer: Name (in block letters) ..... Signature..... Date: ...../...../..... **Investigator:** Name (in block letters)..... Signature..... Date: ...../...../.....

For office use	
Carer ID:	Initials:
ISRCTN: 35327119	Principal Investigator:

The original copy of this Consent Form is to be stored in Investigator Site File.
One copy to be given to the carer.

SMART Carer Consent Form
Version 1.1
20 October 2015

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SMART Carer Consent Form
Version 1.1
20 October 2015

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SMART Carer Consent Form
Version 1.1
20 October 2015

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smart
self management of analgesia and related treatments

Health Professionals' Information Sheet

Invitation to participate in the study

We would like to invite you to take part in the SMART study, funded by the National Institute for Health Research (NIHR). This information sheet tells you the purpose of this study and what your participation would involve. Please take time to read it carefully and talk it over with another person if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Once you have read this information sheet, a member of the Research Team will talk to you about the study again and you can ask any questions you like.

How to contact us

If you have any questions about this study, please talk to a member of the Research Team at

<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet.

SMART Health Professionals' Information Sheet
Version 2
5 November 2015

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What is the purpose of this study?

The SMART study is aimed at reducing pain and the side effects of pain medication experienced by patients with advanced disease living at home. To do this we are asking 30 patients to take part in a pain management educational programme for 6 weeks delivered by specialists palliative care nurses working in the community. We want to understand how useful the specialists nurses delivering the education programme found it. Also, we want to understand if specialists nurses working in research active teams but not themselves delivering the educational programme were aware of it and if this influenced their practice in any way

Why have I been invited to take part?

You have been identified as a healthcare professional (clinical nurse specialist, district nurse, community matron, community nurse specialist) who provides care for patients with advanced disease in the community. You have been involved with delivering the SMART study or are working in a team where your colleagues have.

Do I have to take part?

No. It is up to you to decide. If you do decide to take part, we will ask you to sign a consent form. Even if you sign the consent form, you are free to withdraw at any time without giving a reason.

What will happen to me if I agree to take part?

If you decide to take part a member of the research team will contact you to arrange a time and a place convenient to you to conduct an interview lasting approximately 30 to 60 minutes. With your permission, the interview will be audio-recorded. This is because we want to get an accurate account of what is said and the researcher can concentrate on what is being said without being distracted by having to take too many notes. The interview will then be typed

SMART Health Professionals' Information Sheet
Version 2
5 November 2015

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up and you may have a copy of this if you wish by contacting the research team at the address at the end of this sheet – or directly after the interview. If you do not wish for the interview to be recorded in this way, we will of course respect your wishes and take a written note of the interview instead.

If you agree to take part but during the interview you feel tired, uneasy in any way or concerned, you can choose to stop the interview at any time – you don't have to give any explanation – just that you do not wish to go on.

We would also like to ask for your permission to audio record the consultations you have with one of your patients with whom you use the SMART toolkit. The purpose of this is so we can see how specialist nurses and patients use the SMART toolkit and how this develops over the course of the study. We will use this information to design a training package to coach other non-specialist nurses to use the SMART toolkit with their patients. These recordings will be typed up anonymously so neither you or your patient will be identified from the transcripts. The audio recording and transcripts will only be review by members of the research team.

How long is the study going on?

The study is open from November 2015 to March 2016.

What are the disadvantages of taking part?

We do not foresee any disadvantages or risks to you taking part in this interview. However you will be asked to give some of your time for taking part.

What are the benefits of taking part?

The insight you can provide will help us to evaluate our educational programme and assess the feasibility of conducting a future definitive study. Both of these will help to enhance the

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management of pain from advanced disease for patients living in the community. By participating you therefore have the opportunity to potentially help shape the future direction of this area of your professional practice.

What will happen to the information we collect from you?

Everything that you say in either a patient consultation or one-to-one interview with a researcher will be kept confidential. The information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act. Personal information that contains your name and biographical details will be kept separate from interview transcripts in a locked filing cabinet at the University of Leeds. Audio files and interview transcripts will have personal identifying information removed and you will be identified with a code number. This information will be kept in a locked filing cabinet and backed up on a password-protected encrypted hard drive. Audio files and transcripts will be heard and seen only by members of the research team.

What if there is a problem?

If you have any concerns about this study, you should contact a member of the research team in the first instance. If you remain unhappy about any part of this project or any activity of a member of the research team and wish to complain formally, you can do this by contacting

<<RESEACH TEAM CONTACT DETAILS>>

Who has reviewed this study?

This study has been reviewed by North West - Lancaster Ethics Committee Ethics Committee and has been approved by them.

SMART Health Professionals' Information Sheet
Version 2
5 November 2015

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What will happen to the results of the research study?

When the study is complete the results will be published in a medical journal, but no individual participants will be identified. If you would like to obtain a copy of the published results, please contact a member of the research team.

What happens now?

If there are questions you would like to ask about the study before deciding whether or not to take part please contact Dr Matt Mulvey who is coordinating the study (contact details are on the next page). If you decide you would like to take part in this study, please complete the consent form attached. A member of the research team will contact you by telephone in a few days. If you decide you would like to take part in this study, the researcher will arrange a convenient date and time for interview at a place that suits you. You can keep this information sheet. You will be provided with a photocopy of the signed consent form (if you decide to take part).

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact Dr Matthew Mulvey.

Contact details of the research team

<<RESEACH TEAM CONTACT DETAILS>>

Thank you for taking time to read this information sheet and consider this study. If you would like to discuss the study or require further information please contact me at the address below.

Yours Sincerely,

<< PRINCIPAL INVESTIGATORS NAME, SIGNATURE AND CONTACT ADDRESS>>

SMART Health Professionals' Information Sheet
Version 2
5 November 2015

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Self-Management of Analgesia and Related Treatments SMART
Health Professional Interview Consent Form

	Initial each box
1. I confirm that I have read and understand the information sheet for the above study and have been given a copy to keep. I have had the opportunity to consider the information and ask questions and had these answered satisfactorily. I understand why the research is being done and any risks involved	☐
2. I understand that my participation is voluntary that that I am free to withdraw at any time, without giving any reason and without any consequences	☐
3. I understand that all information collected from me for this study will be held securely in confidence and that my personal details will not appear on any publication of results	☐
4. I understand that data collected during the study may be looked at by individuals from regulatory authorities or from Leeds University (the study sponsor), where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records	☐
5. I understand that if I decide to withdraw from the study, identifiable data already collected would be retained and used in the study	☐
6. I understand that this interview will be audio recorded for purposes of data collection and all resulting transcripts will be anonymised	☐
7. I agree to take part in this study	☐

The following is optional
If you agree to take part in this study, you do not have to agree to this section

8. I agree to audio recording the consultations with one patient with whom I use the SMART toolkit and that these audio recordings will be anonymously transcribed.	☐

Please turn over

SMART Health Professional Consent Form
Version 2
5 November 2015

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Health Professional
Name (in block letters) .....

Signature.....

Date: ...../...../.....

Investigator
Name (in block letters).....

Signature.....

Date: ...../...../.....

For office use	
Healthcare Professional ID:	Initials:
ISRCTN: 35327119	Principal Investigator:

The original copy of this Consent Form is to be stored in Investigator Site File.
One copy to be given to the Healthcare Professional.

SMART Health Professional Consent Form
Version 2
5 November 2015

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SMART Health Professional Consent Form
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SMART Health Professional Consent Form
Version 2
5 November 2015

Appendix 17 Feasibility study case report forms

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FORM 01
Page 1 of 2

Screening Log

Screening number

- This CRF is used to record the screening activity at each site. It should be completed by either a member of the healthcare team or the research nurse
- One individual screening log should be completed for each patient that is screened

General

Recruitment site [redacted]

CRF competed by ☐ CNS ☐ CRN

Name of person completing screening log

Screening date Day Month Year

Sex of patient ☐ Male ☐ Female

Age of patient Years

Patient referral status ☐ New referral ☐ Existing patient

Patient Eligibility

Please tick yes/no/missing. If any shaded boxes are ticked, the patient is ineligible.

Inclusion Criteria

	Yes	No
1. Is the patient >18 years old?	☐	■
2. Is the patient living at home	☐	■
3. Has the patient been prescribed opioid analgesia?	☐	■
4. Is the patient cared for by specialist palliative care services?	☐	■
5. Is the patient considered by their clinical team likely to survive beyond six weeks of follow up?	☐	■
6. Does the patient have capacity to provide informed consent to participate?	☐	■

Exclusion Criteria

	Yes	No
1. Does the patient have insufficient literacy, or proficiency in English, to contribute to the data collection required for the research?	■	☐
2. Does the patient lack capacity to provide informed consent to this trial?	■	☐

Eligibility screening outcome ☐ Failure → Reason

☐ Eligible

Completed by Date Day Month Year Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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FORM 01
Page 2 of 2

Screening Log

Screening number

For Eligible Patients Only

Has the patient been approached by the CNS or CRN and given an information pack? ☐ Yes ☐ No

Date patient given information sheet and consent form Day Month Year

Is the patient interested in the SMART study? ☐ Yes ☐ No

Does the patient think the SMART study is acceptable in principle? ☐ Yes ☐ No
☐ Other, please specify

Has the patient agreed for Research Fellow to contact them? ☐ Yes ☐ No

If no, reason

If yes, have contact details been passed to Research Fellow? ☐ Yes ☐ No

Date patient asked about researcher contact Day Month Year

Was a carer information sheet and consent form given? ☐ Yes ☐ No

If yes, date carer given information sheet and consent form Day Month Year

If no, reason ☐ No carer
☐ Other, please specify

Completed by Date Day Month Year Last Page ■

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 03
Page 1 of 1

CNS Recruitment Log

CNS Initials | CNS Study Number

- This CRF is used to document the recruitment process of CNSs to take part in end of study interview
- Completed by Research Fellow or CRN

Name of CNS

Site [redacted] [redacted] [redacted] [redacted]

Sex ☐ Male ☐ Female

Age ☐☐ Years

Length of time working in specialist palliative care services ☐☐ Years ☐☐ Months

Independent prescriber? ☐ Yes ☐ No

Current grade/band

Has CNS been given an information sheet and consent form? ☐ Yes ☐ No

Date CNS given information sheet and consent form Day Month Year

Has a CNS consented to talking part in an interview? ☐ Yes ☐ No

Date CNS consent given Day Month Year

Has the CNS been given a copy of the signed consent form? ☐ Yes ☐ No

Has a copy of the signed consent form been filed in the site file? ☐ Yes ☐ No

Did the CNS complete the interview? ☐ Yes ☐ No

Study numbers of patients linked to this CNS

Completed by Date Day Month Year Last Page ■

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 02
Page 1 of 3

Patient (and Carer) Recruitment Log

Date of Birth (Day / Month / Year) | Patient Study Number

- **This CRF is used to record the recruitment and retention of all patients (and carers where appropriate) who are given a recruitment pack**
- **Completed by Research Fellow or CRN**

Patient Details

Screening log number

Patient sex ☐ Male ☐ Female

Consent

Has the patient consented to participate? ☐ Yes ☐ No

If no, reason

If yes, date patient consent obtained (Day / Month / Year)

Has the patient been given a copy of the signed consent form? ☐ Yes ☐ No

Has a copy of the signed consent form been filed in the site file? ☐ Yes ☐ No

Has the patient given consent to GP contact? ☐ Yes ☐ No

Date GP letter sent (Day / Month / Year)

Completed by | Date (Day / Month / Year) | *Form continues on next page ►►*

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 02
Page 2 of 3

Patient (and Carer) Recruitment Log

Date of Birth (Day Month Year) | Patient Study Number

Recruitment

Day 1

Date of baseline visit with Research Fellow or CRN (Day Month Year)

Has the patient completed the baseline questionnaire? ☐ Yes ☐ No

If yes, how has baseline questionnaire been completed?
- ☐ With the patient (face to face)
- ☐ Over the phone (with patient)
- ☐ By carer

Location of patient when completed baseline questionnaire
- ☐ At home
- ☐ Hospice
- ☐ Other, specify

If yes, patient is **recruited**; study number is

Has the CNS responsible for the patient been informed to commence the first SMART visit? ☐ Yes ☐ No

If yes, date of first SMART visit with CNS (Day Month Year)

Name of CNS completing SMART visits

Date of randomised interview (Day Month Year)

Did the interview take place? ☐ Yes ☐ No

If yes, date of interview (Day Month Year)

If no, reason

Withdrawal

Has the patient made a withdrawal within the 6 weeks study period? ☐ Yes ☐ No

If yes, date patient withdrawn from study (Day Month Year)

What has patient withdrawn from? *(Tick all that apply)*

	Date	Reason
☐ Questionnaire follow-up	Day Month Year	
☐ SMART intervention	Day Month Year	
☐ Final data collection	Day Month Year	

Completed by | Date (Day Month Year) | Form continues on next page ►►

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 02
Page 3 of 3

Patient (and Carer) Recruitment Log

Date of Birth (Day Month Year) | Patient Study Number

Study completion or Loss to Follow-up

Did the patient complete six weeks of follow-up? ☐ Yes ☐ No

If yes, date patient completed six weeks follow-up (Day Month Year)

If no, how may weeks follow-up did the patient complete? ☐ Weeks

Reason for loss to follow-up
- ☐ Death
- ☐ Deteriorating health
- ☐ Withdrawal
- ☐ Other, please specify

Has the patient been sent a thank you letter at the end of 6 week study period? ☐ Yes ☐ No

Carer Recruitment Interview

Has a carer consented to talking part in an interview? ☐ Yes ☐ No

If yes, date carer consent given (Day Month Year)

Has the carer been given a copy of the signed consent form? ☐ Yes ☐ No

Has a copy of the signed consent form been filed in the site file? ☐ Yes ☐ No

Carer study number *(Linked to patient)*

Carer initials

Carer date of birth (Day Month Year)

Carer sex ☐ Male ☐ Female

Relationship to patient
- ☐ Spouse/partner
- ☐ Other relative
- ☐ Child
- ☐ Friend
- ☐ Other, please specify

Does the carer live with the patient? ☐ Yes ☐ No

Date of interview (Day Month Year)

Did the carer complete the interview? ☐ Yes ☐ No

Completed by | Date (Day Month Year) | Last Page ■

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 04
Page 1 of 1

Patient Contact Details

Date of Birth (Day / Month / Year) | Patient Study Number

The CRF is used to record the patient's contact details

Patient Details

Patient name: Title | First Name | Last Name

Postal address

House number/ name
Street
City
Postcode

Telephone number

Home
Mobile

Email address

What is the best method for contacting the patient?
- ☐ Call home phone
- ☐ Call mobile phone
- ☐ Text mobile phone
- ☐ Email
- ☐ Other, please specify

Have contact details been passed to the appropriate Research Fellow? ☐ Yes ☐ No

GP Details

If patient has consent to GP contact, enter GP name and postal address

GP name
Practice name
Street
City
Postcode

Completed by | Date (Day / Month / Year) | Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised (Date / Initials)	Verified/Checked (Date / Initials)

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FORM 05 Baseline Assessment

Page 1 of 2

Date of Birth	Day Month Year	Patient Study Number	

- This CRF is used to record the baseline contact visit between the patient and the researcher or CRN prior to the first CNS SMART visit
- Completed by RF or CRN

General

Date of baseline visit: Day Month Year

Clinical Characteristics

Disease Characteristics

Type of advanced disease

Date of original/clinical diagnosis: Day Month Year

Date of diagnosis of advanced disease: Day Month Year

Date referral to palliative care services: Day Month Year

Reason for referral to palliative care services

Current or Recent Treatments

Is the patient currently (or within the past month) receiving palliative treatment? ☐ Yes ☐ No

If yes, please list current **palliative treatments**

1.
2.
3.
4.
5.
6.

Completed by | Date: Day Month Year | *Form continues on next page ►►*

Return the completed form to SMART Research Fellows

For office use only	*Computerised* Date Initials	*Verified/Checked* Date Initials

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FORM 05
Page 2 of 2

Baseline Assessment

Date of Birth (Day Month Year) | Patient Study Number

Current or Recent Treatments *(Continued)*

Please give details of medications for pain, constipation and nausea

Name of medication	Type of pain medication *(Please use code list below)*	Dose & units	Frequency of dose *(Please use code list below)*
1.	☐		☐
2.	☐		☐
3.	☐		☐
4.	☐		☐
5.	☐		☐
6.	☐		☐
7.	☐		☐
8.	☐		☐
9.	☐		☐
10.	☐		☐
11.	☐		☐
12.	☐		☐

Type of pain medication code
1 = Strong opioid
2 = Weak opioid
3 = Non-opioid
4 = Adjuvant (pain)

Frequency of dose code
1 = OD
2 = BD
3 = TDS
4 = QDS
5 = PRN

Future Randomisation

If the study had been designed so that those taking part would be randomly selected to receive either the intervention or standard care would you *(the patient)* have taken part? ☐ Yes ☐ No

If no, reason for not taking part in a randomised study

Completed by | Date (Day Month Year) | *Last Page* ■

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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FORM 06

Page 1 of 2

CNS SMART Visits (Weeks 1–6)

Date of Birth (Day / Month / Year) | Patient Study Number

- This CRF is used to document visits between the patient and their CNS using the SMART toolkit
- Completed by CRN

General

Date of visit (Day / Month / Year)

Location of visit
- ☐ Patient's home
- ☐ Hospice
- ☐ Other, specify

Length of visit: ☐☐ Minutes

Type of patient contact
- ☐ Face-to-face
- ☐ Telephone
- ☐ Other, specify

Who was present?
- ☐ Patient only
- ☐ Patient and carer
- ☐ Patient and other person (not main carer), specify relationship to patient

Today's SMART Visit

Disease Characteristics

What needs were identified?

What self-management information was discussed verbally?

Which fact sheets were given, discussed or revisited?
- ☐ Managing pain with opioids
- ☐ Contact and further information
- ☐ Getting prescriptions and obtaining medicines
- ☐ Organising opioid medicines
- ☐ Fitting pain control around my daily routine
- ☐ Checking opioids are managing pain
- ☐ Common concerns when taking opioid medicines
- ☐ Keeping on top of side-effects
- ☐ Pain diary
- ☐ Medication chart
- ☐ Goal setting sheet ("Things I Would Like To Achieve Over The Next Week")
- ☐ None

Were the video podcasts given? ☐ Yes ☐ No

Which video podcasts have been watched since the last visit?
- ☐ Patient
- ☐ Healthcare professional
- ☐ Neither
- ☐ N/A, visit 1

Completed by | Date (Day / Month / Year) | Form continues on next page ►►

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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FORM 06
Page 2 of 2

CNS SMART Visits (Weeks 1–6)

Date of Birth (Day Month Year) | Patient Study Number

Were the goals and action plan from previous visit reviewed? ☐ Yes ☐ No ☐ N/A, visit 1

If no, reason

Have any changes been made to the patient's analgesic medications since the last visit? ☐ Yes ☐ No ☐ N/A, visit 1

If yes, describe changes to analgesic medications

Who made the changes to analgesic medications?
- ☐ GP
- ☐ Palliative care doctor
- ☐ Palliative care nurse
- ☐ Other, specify

Additional Contact With Patient

Has there been any contact with the patient between the previous SMART visit and today's SMART visit? ☐ Yes ☐ No ☐ N/A, visit 1

If yes, date of additional contact (Day Month Year)

Type of patient contact
- ☐ Face-to-face
- ☐ Telephone

Reason for additional contact with patient

Completed by | Date (Day Month Year) | Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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FORM 07
Page 1 of 2

Fortnightly Follow-up Visit (Weeks 2, 4 and 6)

Date of Birth (Day / Month / Year) | Patient Study Number

- **This CRF is used to document the follow-up visit conducted by the RF or CRN**
- **Completed by RF or CRN**

General

Date of visit (Day / Month / Year)

Visit Details

Has the patient completed the follow-up questionnaire? ☐ Yes ☐ No

If yes, who completed it?
- ☐ Patient
- ☐ Patient with Research Fellow or CRN
- ☐ Patient with carer

Where was it completed?
- ☐ Patient's home
- ☐ Hospice
- ☐ Over telephone
- ☐ Other, specify

If no, why was it not completed?
- ☐ Patient withdrew
- ☐ Patient died
- ☐ Unable to contact patient
- ☐ Unable to rearrange visit
- ☐ Other, specify

Have the carbon copies of goal setting sheets been collected from the patient folder for the previous week and this week?

Previous week	☐ Yes	☐ No
This week	☐ Yes	☐ No

Has the patient watched the video podcasts? ☐ Yes ☐ No

If yes, which ones? *(Tick all that apply)*
- ☐ Patient
- ☐ Healthcare professional

At what point in the past two weeks did they watch the pocast?

Completed by | Date (Day / Month / Year) | *Form continues on next page ►►*

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 07
Page 2 of 2

Fortnightly Follow-up Visit (Weeks 2, 4 and 6)

Date of Birth Day Month Year | Patient Study Number

What factsheets does the patient have in their toolkit folder?
(Tick all that are present)

- ☐ Managing pain with opioids
- ☐ Contact and further information
- ☐ Getting prescriptions and obtaining medicines
- ☐ Organising opioid medicines
- ☐ Fitting pain control around my daily routine
- ☐ Checking opioids are managing pain
- ☐ Common concerns when taking opioid medicines
- ☐ Keeping on top of side-effects
- ☐ Pain diary
- ☐ Medication chart
- ☐ Goal setting sheet ("Things I Would Like To Achieve Over The Next Week")
- ☐ None

Is the patient still using the SMART toolkit? ☐ Yes ☐ No ☐ N/A, visit 1

Completed by | Date Day Month Year | Last Page ■

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FORM 08
Page 1 of 3

Final Data Collection

Date of Birth (Day Month Year) | Patient Study Number

- This CRF is used to gather together the final data on patients healthcare resource use, medications and date of death
- Completed by Research Fellows

General

Date of final data collection (Day Month Year)

Death

At end of the patient's 6 week study period, is the patient known to have died? ☐ Yes ☐ No

If no, date last known alive (Day Month Year)

At the **end of the SMART study**, is the patient known to have died? ☐ Yes ☐ No

If no, date last known alive (Day Month Year)

If yes to either question above, please record details of death:

Date of death (Day Month Year)

Place of death
- ☐ Home
- ☐ Hospice
- ☐ Hospital
- ☐ Care home
- ☐ Other, specify
- ☐ Unknown

Preferred place of death
- ☐ Home
- ☐ Hospice
- ☐ Hospital
- ☐ Care home
- ☐ Other, specify
- ☐ Unknown

Primary cause of death

How were you informed that the patient had died?
- ☐ Informed by health professional, please specify
- ☐ Informed by family member
- ☐ Clinical notes
- ☐ Other, specify

- Return to SMART Research Fellows within 5 days of becoming aware of participant's death
- Where death is the result of an ongoing Related Unexpected Serious Adverse Event (RU SAE), ensure F10 RU SAE Report is updated and faxed to SMART Research Fellows within 24 hours

Completed by | Date (Day Month Year) Form continues on next page ▶▶

Return the completed form to SMART Research Fellows

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	Date	Initials	Date	Initials

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FORM 08 Page 2 of 3 **Final Data Collection**

Date of Birth	Day Month Year	Patient Study Number	

Healthcare Resource Use – Collected up to 6 Weeks After Study Entry

Date of contact	Type of contact	Reason for attendance	Name of person conducting visit
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		
Day Month Year	☐ Telephone ☐ Day hospice/ outpatient ☐ Home ☐ Inpatient admission → Date of discharge Day Month Year		

Completed by		Date	Day Month Year	*Form continues on next page* ►►

Return the completed form to SMART Research Fellows

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FORM 08
Page 3 of 3

Final Data Collection

Date of Birth	Day Month Year	Patient Study Number	

Analgesic Medication Prescriptions – Collected up to 6 Weeks After Study Entry

Please give details of medications for pain, constipation and nausea

Name of medication	Date of prescription	Type of pain medication *(Please use code list below)*	Dose & units	Frequency of dose *(Please use code list below)*
1.	Day Month Year			
2.	Day Month Year			
3.	Day Month Year			
4.	Day Month Year			
5.	Day Month Year			
6.	Day Month Year			
7.	Day Month Year			
8.	Day Month Year			
9.	Day Month Year			
10.	Day Month Year			
11.	Day Month Year			
12.	Day Month Year			
13.	Day Month Year			
14.	Day Month Year			
15.	Day Month Year			
16.	Day Month Year			
17.	Day Month Year			
18.	Day Month Year			
19.	Day Month Year			
20.	Day Month Year			
21.	Day Month Year			

Type of pain medication code
1 = Strong opioid
2 = Weak opioid
3 = Non-opioid
4 = Adjuvant (pain)

Frequency of dose code
1 = OD
2 = BD
3 = TDS
4 = QDS
5 = PRN

Completed by | Date Day Month Year | *Last Page*

Return the completed form to SMART Research Fellows

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FORM 09
Page 1 of 1

Participant Withdrawal Request

Date of Birth (Day Month Year) | Patient Study Number

- **Complete this form for any participant who requests to withdraw consent to the trial interventions/ follow-up, as detailed in the categories below**
- **Ensure that the form is returned to the CTRU within 7 days of the date of withdrawal**

Date of withdrawal request (Day Month Year)

Has the participant withdrawn consent to the trial interventions?
- ☐ Yes → Has the participant withdrawn prior to receiving the trial interventions?
  - ☐ Yes
  - ☐ No
  - ☐ Not known
- ☐ No

Has the participant withdrawn consent for questionnaire completion **via researcher contact**?
- ☐ Yes
- ☐ No

Is the participant still willing for further data to be collected from their medical records during the trial follow-up period?
- ☐ Yes
- ☐ No

Has the participant given a reason for their withdrawal? ☐ Yes ☐ No

If yes, please provide details *(Please specify if the participant was too unwell)*

Form completed by
- ☐ CNS
- ☐ CRN
- ☐ Research Fellow
- ☐ Other, please specify

Completed by | Date (Day Month Year) | Last Page ■

Return the completed form to SMART Research Fellows

For office use only	Computerised		Verified/Checked	
	Date	Initials	Date	Initials

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RUSAE Report
Relevant Medical History Supplemental Page

Date of Birth	Day Month Year	Patient Study Number	

ONLY RECORD THE PARTICIPANT'S RELEVANT MEDICAL HISTORY

Name of condition, including dates where relevant:

Page ☐ **of** ☐ **Relevant Medical History Supplemental Page**

Completed by | Date Day Month Year

Please fax RUSAE reports to the SMART Research Fellows.
The SMART Research Fellows will notify the main REC and Sponsor, as appropriate.

For office use only	Computerised: Date / Initials	Verified/Checked: Date / Initials	SAE code

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Form 10
Page 1 of 2

Related and Unexpected Serious Adverse Events (RUSAE) Report

Date of Birth (Day / Month / Year) | Patient Study Number

Complete this form for RUSAEs occurring within the SMART trial. Fax immediately to the SMART Research Fellows

Report type: ☐ Initial ☐ Follow-up

a) Serious Adverse Event Information

a1) Date of SAE (Day / Month / Year)

a2) Date study team first aware of SAE (Day / Month / Year)

b3) **Main diagnosis/symptom**

b4) **Associated symptoms** that caused the main event to become serious *(if applicable)*

b5) **Brief description** of the SAE *(Including signs/symptoms and any other relevant information)*

a6) Place where SAE started ☐ Hospital ☐ Outpatient clinic ☐ Home ☐ Other *(specify)*

b) Seriousness criteria *(tick all that apply)*

- ☐ c1) Participant died
- ☐ c2) Life threatening
- ☐ c3) Required/prolonged hospitalisation
- ☐ c4) Persistent or significant disability/incapacity
- ☐ c5) Congenital anomaly/birth defect
- ☐ c6) Other important medical event

c) Outcome *(at the time of this report)*

- ☐ d1) Recovered → Date of recovery (Day / Month / Year)
- ☐ d2) Recovered with sequelae
- ☐ d3) Condition improving
- ☐ d4) Condition still present and unchanged
- ☐ d5) Condition deteriorated
- ☐ d6) Ongoing at time of death
- ☐ d7) Death *(only applicable if participant died due to the SAE)*

Date of death (Day / Month / Year)

Post-mortem undertaken? ☐ Yes ☐ No

***If yes**, please send in an anonymised copy of the report*

d) Participant's relevant medical history

d1) Does the participant have any other relevant medical conditions? *(Such as diseases, allergies or similar experiences)* ☐ Yes *(please give details)* ☐ Unknown ☐ No *(go to Section f)*

Name of condition, including dates where relevant:

Additional medical history may be provided on the RELEVANT MEDICAL HISTORY SUPPLEMENTAL PAGE ☐ *Tick if using*

Completed by | Date (Day / Month / Year) | *Form continues on next page ►►*

Please fax RUSAE reports to the SMART Research Fellows.
The SMART Research Fellows will notify the main REC and Sponsor, as appropriate.

For office use only | Computerised: Date / Initials | Verified/Checked: Date / Initials | SAE code

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Form 10
Page 2 of 2

Related and Unexpected Serious Adverse Events (RUSAE) Report

Date of Birth (Day Month Year)	Patient Study Number

e) Study Procedures, Treatment and Action

e1) Was the participant undergoing any study procedures at the time of the SAE? ☐ Yes *(Please give details)* ☐ No

Trial procedure	Was any action taken/ treatment given? Yes*	No	*If yes, provide details
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	
	☐	☐	

f) Relatedness and Expectedness

f1) Is the SAE suspected to be related to the study procedures? ☐ Yes → Please specify ☐ No

Expectedness ☐ Expected *(If this is ticked then this is not an RU SAE)*
☐ Unexpected *(= RU SAE)*

THE SAE MUST BE REVIEWED AND THIS SECTION COMPLETED BY THE INVESTIGATOR OR AN AUTHORISED DELEGATE.

Reviewer name _____ Reviewer position _____

Reviewer signature _____ Date (Day Month Year)

g) Is there any additional information not reported above? ☐ Yes ☐ No

Completed by _____ Date (Day Month Year) *Last Page* ■

Please fax RUSAE reports to the SMART Research Fellows.
The SMART Research Fellows will notify the main REC and Sponsor, as appropriate.

h) Report Handling (CTRU USE ONLY)

Is this event a RU SAE? ☐ Yes ☐ No

Date of initial report (Day Month Year)

SAE code *(Please also add to footer of previous and supplemental pages)*

Date this report received (Day Month Year)

Date reported to main REC (Day Month Year)

For office use only	Computerised Date	Initials	Verified/Checked Date	Initials

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Appendix 18 Nurse self-management conversation prompts

Supportive self-management in palliative care

> *. . . assessing, planning and implementing appropriate care to enable the patient to live until they die and supporting the patient to be given the means to master or deal with their illness themselves.*
>
> *Johnston* et al.[51]

Conversational process

Phase of self-management conversation	Approach/role (Johnston *et al.*[51])	Skills	Example
Orientation to self-management	• Person centred • Problem centred • Moment centred • Meaning centred	Emotion work: take account of what is important to the person, their identity, to their previous experience and how they are making sense of the current situation[66]	
		Focus on maintaining normality (Johnston *et al.*[51])	
		Suspend concerns about time the conversation will take	
Assess: purpose to identify • how a person is managing their pain and their pain medications (the behaviours associated with taking medicines for pain) • what beliefs are influencing their pain medicine management • their knowledge of their pain medicines	• Facilitator	Start with open question focused on intention of conversation	*Can you tell me how you have been getting on with managing your pain medicines?*
		Recognise and validate the feeling expressed by the patient	*It sounds as though this has been really tough*
			It sounds as though you have been working hard to try and get on top of your pain
		Use probing questions to find out in more detail about how the person is managing their pain medicines – what they are doing, how they are understanding analgesics and the beliefs influencing this understanding	*So one of the challenges you are facing is . . . can you tell me a little more about . . .*
			Are there other concerns that are influencing how you are managing your medications?
		Check for other concerns and repeat process of gathering and reframing	
		If not already mentioned, check whether or not person has any concerns raised by	*Can I just check whether you have any concerns about taking medications for your pain; for example, many people worry that they will get addicted to*

Phase of self-management conversation	Approach/role (Johnston *et al.*[51])	Skills	Example
		beliefs about pain medications (e.g. typical fears about opioids such as dependence and tolerance, meaning of being on opioids, etc.) and previous experience of pain medications (such as family members who have taken opioids)	*the medicines or that if they take them now they will not work so well if the pain gets worse, or some people have worries that relate to their own or a family member's experiences of taking pain medicines in the past*
		Ask patient to identify most pressing concern(s)	*So to summarise, the key things influencing your ability to manage your pain are (list a, b, c, etc.)*
			Which of these is most important for us to address today?
		Agree a plan for what to discuss today – negotiate to add a topic to the patient's list if you feel is it significant to improving their pain medicine management	*OK let's talk about that a bit more X*
			If you need to add a topic: 'Once we've done that I would like to talk a bit more about Y because I think this will also help. Would that be OK?'
Inform: purpose • to tailor information, specific to the identified concerns • to provide information that will positively alter behaviour and address beliefs to improve pain medicine management and pain relief	• Communicator • Educator • Problem-solver	Restate the issue to be discussed	*So the issue you have identified as being most challenging is . . .*
		Normalise the issue	*This is something that many people have concerns about*
		Introduce the educational resource relevant to this issue	*I think this resource will be helpful, let me go through it with you/tell you about it . . .*
		Reinforce the information: key points	*This factsheet/podcast explains that it is important to a, b, c*
		Check understanding/ response	*How does this sound to you? Does this information help your concerns?*
		Address any remaining concerns (may need to reassess concerns and provide other information)	
		If appropriate suggest ways of monitoring pain (pain diary and pain medication chart)	

Phase of self-management conversation	Approach/role (Johnston *et al.*[51])	Skills	Example
Setting self-management goals: purpose • to draw up, together, a plan that responds to the concern(s) and that has the potential to improve their pain management	• Goal-setter • Reporter	Begin to explore some possibilities for positively influencing pain management	*Having gone through this information, do you think there are some things that you can try which will help you to manage your medicines/ pain differently?*
		Check out the things suggested	*Which of these ideas will be realistic to try this week?*
			Are there things that will make this difficult for you to do?
		Refine the suggested plan	*So just to recap, you are going to (state what the patient is going to do), because this will help your pain by (state how this behaviour is going to help manage medicines or control pain). If you do this you are hoping that (state expectation of action) by (state time frame)*
		Record suggested plan	*Let's just make a note of what you are hoping to achieve in the next week, so that we can review how things have gone when we next meet*
Agreeing self-management goals	• Advocate	Remind patient of resources available to support agreed plan	*Don't forget that there are some other things available to support you with your plan. I'm going to leave the fact sheet with you so that you and your family can read and refer to it, in your own time. There are other sources of reliable information available on the internet so I'll leave you a list of where to look. Also, if for any reason the plan we have discussed is not possible or your pain increases then we would want to know. (Then go through who to telephone/ contact etc.)*
Regular review	• Monitor	Make a plan to review	*So the last thing is to make a date and time for us to review the plan that you have made and your pain management . . .*

Appendix 19 Making action plans

Making action plans with individuals

One of the most important self-management skills is goal-setting. Goals often need to be broken into smaller, more achievable steps or tasks. Once a goal has been set, it needs to be decided how exactly it can be achieved, by making an action plan.

An action plan should be time limited (i.e. 1 or 2 weeks) and be related to a goal that the individual really wants to achieve. The individual should be able to achieve the action plan and the plan should be very specific, specifying what, how much, when and how often.

Parts of a personal action plan

1. Something the individual wants to do.
2. Reasonable/achievable (something that the individual could expect to be able to achieve within the week).
3. Action/behaviour specific.
4. Answer the questions: what, how much, when, how often.

Consider

- The specific steps needed to achieve the goal (include what, when, how, where and how often).
- The things that could make it difficult to achieve the goal.
- The plan for overcoming these challenges.
- Supports and resources needed to achieve the goal.

Appendix 20 Aide memoire for researchers to use with study nurses

Researcher aide memoire

Supporting the nurses in their use of the four-step educational approach:

Needs assessment

- What is your experience of asking patients how they are managing their pain medicines?
- How are you finding using the four-step conversational process?

Information provision

- Thinking about your experience of providing the intervention, are there parts of it that feel easier/more appropriate to do than others?
- Could we do anything additional to support you in delivering the process? Are there any extra resources/materials that might be of help to you?

Goal-setting

- Thinking about the process of goal-setting with study patients, what are the kinds of things patients are prioritising? Do you feel that this prioritisation process is helpful in supporting self-management?
- Are you managing to use the goal-setting sheet at each visit? How are you finding this? What sort of action plans are you developing with the patients (are they practical steps, action orientated, time specified, barrier focused with strategies for overcoming these, etc.)?

Review and coaching

- I'll be here next week; can we talk over these issues again to see if there are any changes or additional things that would help you?

Appendix 21 Framework for researcher field notes

Ongoing supportive visits

Visits with CNSs – reinforcing the workshop session.

Needs assessment

- Response to how she/he is finding asking patients about their needs (beliefs, behaviours and knowledge), resulting discussion, any researcher recommendations.

Information provision

- Response to how she/he is finding providing information, issues raised and researcher's response, when appropriate.

Goal-setting

- Response to how she/he is finding using the goal-setting sheet, resulting discussion and recommendations.

Coaching

- Response to how she is finding the reviewing with the study patient(s), resulting discussion and coaching of CNS by researcher.

Delivery and discussion of further training resources:

- For example, Johnston *et al.*'s[51] self-management definition, self-management conversational prompts, audio file of modelled self-management conversation, action-planning sheet.

Response of the CNS to the above process and trial delivery.

Any confounding factors?

- Lack of CNS availability/time?
- Lack of receptiveness? Is there an apparent reason for this?

Researcher reflexivity

- Should I have handled anything differently?
- What lessons can be learnt for the other CNSs or other patients in terms of delivery of the intervention by the respective CNS?

Appendix 22 Feasibility study interview guide

Phase 3 Interview Guides

Patients/Carers

Introduction

- Confirm consent to participate (patient written informed consent on recruitment)
- Interview up to 45 mins. In this interview, I am interested in two main things: what it's like for you to be involved with managing your pain medicines, and what it's been like to take part in the research
- Confirm consent to audio record and switch on audio recorder

I have 2 main groups of questions. Firstly, those that focus around the context for you of taking part in the study and managing your medicines

- What was your motivation for taking part in the study? What has it been like taking part in the research?
- What have you been doing to manage your pain medicines and those for constipation, drowsiness and sickness? Have any been adjusted or changed since you've been involved in the study?
- Could you explain to me a bit more about how you've managed these medicines? How confident have you felt about managing your medicines? Have there been any barriers or problems to you managing your medicines?
- Can you tell me who you have worked with to manage these medicines? Who else is involved?
- What do you see as your role in managing these medicines? What does doing these things mean to you?
- Thinking about all of the things you are doing with the medicines, how are you finding it?

The second group of questions is around your experience of the intervention – both the educational process used by the specialists nurse and the toolkit itself.

Acceptability of the educational process

- Tell me about your experience of the nurse talking with you about the pain medicines and any medicines for the related side effects?
- How have you found the information giving process used by your specialist nurse?
    - What has worked for you? Tell me about why that was helpful.
    - What hasn't been so useful? Tell me about why it wasn't helpful.
    - Has anything been missing?
    - Have there been any barriers or problems?
- Tell me about your experience of you and the nurse setting goals for your pain / pain medicines / constipation, nausea / drowsiness?
    - Was this a useful process?
    - Were your goals achieved? Why? Why not?
- Overall, did talking with the nurse have any impact on your confidence in managing your medicines and / or you taking your medicines to control your pain more effectively?

Uptake and acceptability of the toolkit

- Has the nurse given you any factsheets/charts to help with managing the pain medicines? What did you use from the toolkit?
- Which factsheets? Were any factsheets discussed with you? How was this done? Taking each in turn, what are your views of them? What impact, if any, did they have on you managing your pain / pain medicines / constipation / nausea / drowsiness?

- Have you accessed the podcasts? What are your views of them? What impact, if any, did they have on you managing your pain / pain medicines / constipation / nausea / drowsiness?
- Did you use the pain diary or medicines chart? What impact, if any, did they have on you managing your pain / pain medicines / constipation / nausea / drowsiness?

If you consider the outcomes for you of both the information giving process by your specialist nurse and your use of the toolkit resources.

- Have you felt confident in managing your medicines?
- What has it led you to do differently to how you were managing your medicines prior to taking part in the study?

And finally

How have you found completing the questionnaires with the research team so far? Have the questionnaires captured what's been important to you?

Ending

- Is there anything else you would like to tell me today?
- Turn off recorder
- Thank you

Appendix 23 Non-study clinical nurse specialist survey

Survey of palliative care nurses at SMART study recruitment sites

0% complete

Page 1

1. Name

2. Place of Work

Please select

3. Sex

- Female
- Male

4. Age

5. Length of time working in specialist palliative care services

6. Are you an independent prescriber?

- Yes
- No

7. Current Grade/band

8. Have you been aware that some of your colleagues have been taking part in the SMART study?

- O Yes
- O No

9. Are you aware of what the SMART study is about?

- O Yes
- O No

a. Could you briefly describe it?

10. Did your colleagues taking part in the study discuss with you the self-management support process or the educational materials?

- O Yes
- O No

11. Has their involvement in the SMART study had influence on your practice?

- O Yes
- O No

a. If so, how?

12. Have you seen any of the patients who have taken part in the study?

- O Yes
- O No

a. If so, when and how?

Finish ✔

Appendix 24 Analyses of the feasibility study qualitative findings

Thirteen patients and seven carers participated in 13 interviews at the end of their involvement in the feasibility trial (*Table 37*). They were asked about their last main occupation and their highest educational achievements (*Table 38*).

TABLE 37 Qualitative data sources obtained during the feasibility trial and the purpose for which they were used in the process evaluation

Research design and processes	The intervention
Deliverability, acceptability, perceived benefits and disadvantages of: • eligibility criteria • screening process • recruitment Data sources: CNS interviews and researcher field notes	Deliverability of four-step approach Data sources: CNS interviews and researcher field notes
Deliverability, acceptability, perceived benefits and disadvantages of: • study period: 6 weeks Data source: patient/carer interviews	Deliverability of SMST Data sources: CNS interviews and researcher field notes
Deliverability, acceptability, perceived benefits and disadvantages of: • PROMs at four researcher visits Data sources: patient/carer interviews and researcher field notes	
Deliverability of: • initial CNS SMART visit within 1 week of baseline visit by researcher Data source: study mapping Excel spreadsheets	Acceptability of four-step approach Data sources: CNS interviews and researcher field notes
Deliverability of: • CNS visits – as normal care but minimum of three face-to-face visits over 6-week study period Data source: study mapping Excel spreadsheets	
Deliverability, acceptability, perceived benefits and disadvantages of: • training to deliver the intervention ○ initial session and ongoing Data sources: CNS interviews and researcher field notes	Acceptability of SMST Data source: CNS interviews
	Perceived benefits of four-step approach Data source: CNS interviews
	Perceived benefits of SMST Data sources: CNS interviews and patient/carer interviews

continued

TABLE 37 Qualitative data sources obtained during the feasibility trial and the purpose for which they were used in the process evaluation (*continued*)

Research design and processes	The intervention
	Perceived disadvantages of four-step approach Data source: CNS interviews Perceived disadvantages of SMST Data source: CNS interviews and patient/carer interviews

PROM, patient-reported outcomes measure.

TABLE 38 Phase III qualitative data sample: patient and carer interviews

Demographic data: patient and carer Phase III interview sample			
Number of interviews	$n = 13$ Thirteen patients, seven carers participated in dyad interviews with patient Remaining six patients recruited to feasibility study – one admitted to hospice post trial, other five withdrawal or loss to follow-up of the patient during course of trial		
Last main (or current) occupation			
Patients	Car mechanic, care worker, coach trip business, education welfare officer, electrical engineer, fitters mate, nurse, professor, publisher, secretary, senior lecturer, shop manager, vehicle inspector		
Carers	Anglican minster, architect, brick layer, care worker, nursery school worker, secretary, security worker		
	Number of qualifications	***Professional, vocational or other work-related qualifications below degree level***	***Professional, vocational or other work-related qualifications at degree level or higher***
Patients	4	6	3
Carers	1	5	1

All but one ($n = 11$) of the 12 study nurses participated in an interview at the end of the feasibility trial (*Table 39*).

The Phase III qualitative data results have been presented in tabular form for clarity and brevity, within an analysis framework designed for the study. The initial focus was on the findings regarding deliverability, acceptability, perceived benefits and possible disadvantages of both the research design and the intervention itself.[99] In line with the recommendations of Moore *et al.*[76] regarding process evaluation of complex interventions, the final column of the analysis framework, and the ultimate higher level of analysis, focuses on the mechanisms of action – the participant responses to the research design or intervention, the mediating factors and the consequences (*Tables 40* and *41*).

TABLE 39 Phase III qualitative data sample: CNS interviews

Demographic data: CNS Phase III interview sample	
Number of interviews	$n = 11$
Location	$n = 5$ Yorkshire based (out of 6 study nurses); $n = 6$ Hampshire based (out of 6 study nurses)

TABLE 40 The process evaluation of qualitative outcomes regarding the feasibility trial research design

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences
• Eligibility criteria	• The eligibility criteria were initially seen by nurses as being acceptable by being open and wide. However, in terms of delivery, the CNSs were surprised by the relative lack of individuals who met the eligibility criteria. Then, of those who did meet the eligibility criteria they were often those with complex end-of-life needs where the individuals would have been 'on their reserves to do it (take part)' (H2CNS002)	• CNS responses: *It's interesting that . . . there's quite a lot of patients that aren't even on opioids* *H1CNS002* *Maybe 50% weren't on opioids . . . I thought that would be really easy actually! I was very shocked that it wasn't* *H2CNS002* *I was surprised in a way that I didn't have any patients that would be applicable for the study . . . maybe, that shows how complex the patients are that come to us, and how quickly people who may possibly have been suitable deteriorated* *H1CNS004* • Mediating factors: late referrals to specialist palliative care services, resulting in many on their caseloads being close to imminent end of life (< 6 weeks) and complex needs of others • Consequences: o Smaller numbers of theoretically eligible patients than expected, and of those who were 'eligible' they often had very complex needs o Therefore, overall consequence was lower than expected recruitment

continued

TABLE 40 The process evaluation of qualitative outcomes regarding the feasibility trial research design (*continued*)

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences

• Screening process	• Deliverability and acceptability of screening process with CTA/CTP generally seen as acceptable by the CNSs, but they were very aware that they (and sometimes the CTA/CTP) were often not available when they had said they would be for screening appointments	• CNS responses:
		
		It was only tricky because of time
		H1CNS002
		
		• Mediating factors: the existing pressures on their role (CNS but also CTA/CTP role) and the often high caseloads of the CNSs
		• Consequences:
		  ○ Screening appointments frequently needed to be rearranged/reattempted, meaning screening was missed on some weeks
		  ○ One CNS stated that she found the screening onerous and two CNSs said they would have preferred to screen with the researcher (rather than having to deal with two people regarding the study – CTA/CTP and researcher)
		  ○ Therefore, overall consequence was that screening was regularly undertaken but not always on a weekly basis

• Initial approach of eligible patients	• Deliverability of approaching 'eligible' patients often challenging [e.g. patients already approached regarding drug trials, patients admitted to alternative care settings (hospital, hospice and nursing homes)]	• CNS responses: approaching patients to introduce the study, although challenging, was not an issue in itself for most • Mediating factors: it was the circumstances around end of life that were challenging [e.g. frequent admissions, complex physical (often infections and sepsis) symptoms, psychological and social issues] • Consequences: the complex social/psychological issues at end of life meant that the CNSs felt, for some patients, that they 'couldn't burden them with something else at that time' (H1CNS002). Nonetheless, this was not inappropriate gate-keeping, but rather challenging circumstances such as patients caring for others

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences
• Study period: 6 weeks	• The study period was universally seen as 'about right' or 'just right' by the patients and their carers • The CNSs also appeared to agree on the acceptability and deliverability of a 6-week study period	• Patient responses: *I think it's just about right actually, you probably need that length of time to get any results* H2Pt019 *It seems to have gone quick* H1Pt001-C • Mediating factors: the end-of-life context and many study patients experienced uncontrolled symptoms (not just pain) and infections during the course of the study • Consequences: despite this, relatively few patients were lost to follow-up during the 6 weeks

• PROMs at four time points	• The patients, in interviews, all stated that it was acceptable completing the PROMs battery at 2-week intervals over the 6 weeks (at four time points). Some emphasised the importance of completing them face to face with a researcher, 'you gave us the comfort and support to go through them' (H1Pt001). A small number of patients criticised the 'duplicity' (H4Pt001) of some questions given the combination of five different measures, or said that they were 'long'
	• Nevertheless, the researcher field notes captured some difficulties for patients with the PROMs in the end-of-life context during the process of data collection:
	  ○ BPI:
	  ○ % of relief from medicines – patients were frequently uncertain how to answer this as they often stated that they were not going to come off their medicines to find out the answer to this. It was also difficult to answer in the context of complex neuropathic pain with intermittent severe pain episodes such as from trigeminal neuralgia
	  ○ 'normal work' and 'enjoyment of life' were seen as inappropriate wording for end-of-life context
		• Patient/carer responses:
		'I've learnt stuff' by completing them H4Pt013
		I found them really useful . . . it put things more into perspective H3Pt041
		It's the sort of questions you expect in something like this H1Pt009
		It's made you focus on how you feel H2Pt007-C
		• vs.
		Hang on a minute I've just answered that one
		Some of the questions were a bit hard to answer H2Pt019

continued

TABLE 40 The process evaluation of qualitative outcomes regarding the feasibility trial research design (*continued*)

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences
	○ ESAS: ○ anxiety and depression questions were sometimes sensitive areas given high rates of clinical depression and use of antidepressants ○ 'well-being' question often disliked given end-of-life context ○ EQ-5D-5L: ○ general lack of acceptability of question regarding how good/bad health is today on scale of 1–100 'it's a stupid question to ask people in palliative care' (H1Pt011-C) ○ SIMS: ○ general difficulty remembering what specific information about medicines had been received over the last 2 weeks	*'The only one that confused you was the last one with the 1–100' (how good or bad your health is today on the EQ-5D-5L)* H1Pt015-C • Mediating factors: the study PROMs, although utilised in palliative care studies, are not specifically worded for the end-of-life context. The patients and carers were more positive about PROMs completion in the interviews at the end of the study than during the study, when completing them with the researchers • Consequences: ○ Dichotomy between the value of the PROMs completion process in itself for some patients (evaluating the impact of pain and medications) vs. the inappropriate wording of some questions, resulting in questions not being completed ○ Therefore, overall consequence was that patients' experience of PROMS completion was acceptable, but there were some limitations related to the wording of questions for the end-of-life context
• Four researcher visits	• The patients and carers all stated that the frequency of researcher visits (fortnightly) was acceptable and some really looked forward to these visits	• Patient responses: *It's been very nice you coming in* H2Pt019 *It's been lovely. I enjoy you coming . . . you're so easy to talk to, you ask the right questions* H1Pt009 • Mediating factor: the value of taking part in a research study, seeing a researcher external to their care team and developing a relationship over 6 weeks

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences
• Initial CNS SMART visit within 1 week of baseline visit by researcher • CNS visits – as normal care but minimum of three face-to-face visits over 6-week study period	• In Hampshire, all study patients were seen within 6 days of recruitment by their CNS for first study visit • In Yorkshire, 8 out of 10 patients were seen within 7 days of recruitment by their CNS for first study visit • All study patients (who were not lost to follow-up) received three face-to-face visits as a minimum over the 6 weeks (maximum number of face-to-face visits by a CNS was five)	• Consequences: the SMART CNS visits followed their normal pattern of care, enabling the minimum dose of the intervention (three face-to-face visits over the study period) to be successfully delivered to all study patients

• SMART CNS visits	• The study nurses successfully delivered their visits and they were acceptable as they matched their normal visiting pattern
	• However, in relation to the acceptability of the extended length of the visits, the nurses were very conscious of the extra time required for study visits – approximately 30 minutes for first visit and 15 minutes for each further visit, and the impact on their workload
		• CNS responses:
		
		We (one study CNS and another) talked about timekeeping a lot, because in my first couple of SMART study appointments they were really long, partly because the lady I had, it was quite difficult to keep to time with them anyway
		
		H2CNS001
		
		• Mediating factors: the time-pressured nature of CNS role; this was partially offset by the CNSs in the Wessex region being reimbursed for their excess treatment costs (the extension of their visits)
		• Consequences:
		  ○ The nurses managed to successfully accommodate this additional workload (which had been made clear from the start of the study), without changes to their care patterns, except for one (part time) study nurse who asked a colleague to follow-up some patients on her caseload by telephone on a single day because of a study visit
		  ○ The extra time required for visits led the study nurses at the individual sites to discuss this impact with one another

continued

TABLE 40 The process evaluation of qualitative outcomes regarding the feasibility trial research design (*continued*)

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences

• Training to deliver the intervention	• A bespoke training workshop was successfully delivered via two sessions to all the study nurses by a skilled nurse educator
	• Approximately half of the study nurses found the workshop session acceptable. The response to the session was widely variable from the overtly positive:
	
	I wasn't really sure what to expect really. I think it sort of got you into thinking . . . about these four steps as a way of sort of addressing each problem that you would have with the patient, and then . . . alongside that introducing the individual appropriate tools. So I think for me it was a good afternoon . . . Because I'm more of a reflective person . . . I'm not the sort of person who likes to rush in, grab everything and rush out . . . So for me, 'just sort of go with the flow, and see how the afternoon unfolded', that was comfortable for me . . . whereas I think some of the other members of the group there, I think they wanted the end at the beginning . . . I was quite happy to go through that process. And I think having gone through the process, I came away thinking 'Right, I know what I'm doing'
	H4CNS003
	
	I thought it was very good, very informative, gave us a good baseline to work from and to understand the study
	H4CNS001
	
	Personally I found it really helpful. I would in a visual[a] way. I work with imagery and I'm naturally predisposed to responding with emotion and . . . other people don't, so I know other people didn't find that day particularly helpful or aspects of it
	H3CNS002
	
	• To the less positive:
	
	It was OK . . . it was relevant and it put it (the intervention) in a bit more perspective
	H4CNS002
		• CNS responses:
		  ○ The general response was that the workshop covered everything required for their study involvement
		  ○ However, some nurses felt that the session made the four-step educational approach seem more complicated that it actually was, rather than a normal part of everyday specialist practice (which they all recognised once using it)
		  ○ Some CNSs perceived that the description of the four-step educational approach and the stages of the therapeutic conversational process, did not completely match and overlay one another, causing them a degree of confusion
		• Mediating factors:
		  ○ The workshop raised some anxieties 'just give me the facts I'm too busy for all this' (H3CNS001) and 'it made me think – oh my goodness this is going to be quite intense and hard' (H1CNS002)
		  ○ Responses to the workshop varied with some liking the thought-provoking/reflective nature of the session and others desiring alternative approaches
		• Consequences:
		  ○ The researchers clarified, where necessary, the four-step educational process to the nurses via ongoing support
		  ○ The subsequent need to provide a modelled self-management-focused professional conversation to the study nurses was also apparent. This was audio-recorded and provided to the CNSs, but only a few listened to it
		  ○ The overall consequence of the workshop was, however, successful delivery and introduction of the nurses to the research processes and the four-step educational process, delivered by a conversational process

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences
	It was good and covered everything . . . it (the four step educational approach) just needed to be clearer *H1CNS002* • And the more explicitly negative: *I found it quite frustrating, because I thought it's not really my style . . . like putting the cards out on the floor and all that . . . I would have been happy for you just to tell us (about the four step educational approach) . . . it's not a process that we're not familiar with* *H3CNS001* *I remember being a bit confused . . . the four things (four steps of the educational process) weren't quite the same as the other four things exactly (in the conversational process)* *H1CNS001* *I felt the training we went on could have been shorter or it could have been more in-depth about the key things we really needed to focus on, which was about the goalsetting and things. I was a bit worried at the beginning – for me! And I thought 'is this really what we need . . . we are all experienced CNSs, can't we just focus on what . . . kind of questions can be used?' (in each step of the conversational process)* *H2CNS002* *That afternoon training where the lady was talking with pieces of paper on the floor, was a bit of a wasted opportunity . . . 15 minutes into her conversation I didn't really know what she was talking about . . . she was trying to get us to talk through our normal assessment, and then apply that to self-management per patient. But for me . . . it wasn't clear enough what we were talking about until the end. So then you're kind of sat there wasting time where you're making memories, wondering what on earth is going on, rather than 'I know exactly what we are going to be talking about, and now I'm making memories, we are enforcing the goals of this.' . . . It was quite stressful really* *H2CNS001*	

continued

TABLE 40 The process evaluation of qualitative outcomes regarding the feasibility trial research design (*continued*)

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences
	I must admit, at first when I did the picture cards I sort of got lost with 'where is this going, what's this about?' And I think that bit was quite time consuming as well if I remember rightly *H1CNS003* *I got confused with the training . . . I found it quite a lot of information taking . . . the four steps weren't the same (as the conversational process)* *H1CNS004* • Some CNSs readily understood the self-management ethos, others were more challenged by it. For those that understood the ethos there was a perceived benefit of refocusing the professional conversation on self-management of analgesia and related treatments which was gained from the workshop and further support	• CNS responses: the self-management ethos required a shift in thinking and emphasis by the nurses 'I just had to remember not to do my usual line of questioning around pain, around background pain, breakthrough pain, focusing on descriptions of pain, but more on their experience of the pain and their experience of managing the pain' (H2CNS001). 'My practice needs to be a more defined process of allowing them (patients) to be independent in all ways, not just in goalsetting around their medication . . . it's a whole change of behaviour, I think, by me' (H3CNS002) • Mediating factor: this refocusing challenged the professional identity of these specialist palliative care nurses, where their therapeutic role is measured by their effectiveness at removing pain • Consequences: it was harder for some nurses to adapt their practice from 'imposing views' telling patients how to use their opioids, to collaborative discussion focused on patients using and developing their own self-management strategies as result of information provision from the CNS

Feasibility of research design and processes	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to the research design and processes, mediating factors, consequences

	• The researcher field notes captured inherent difficulties in providing ongoing support to the CNSs during the course of the trial:
	  ○ Difficulty making appointments to meet with CNSs, usually had to be first thing at the start of their working day
	  ○ The CNSs were not always available when they said they would be (due to extended/unexpected patient visits, over-running meetings, their own illness, etc.)
	  ○ However, when they were available they were usually open in their discussion of their study experiences and willing to be supported via discussion and further training resources (yet this time was always pressured or limited)
		• Mediating factors:
		  ○ Nurses were time pressured, some were difficult to make appointments with because of workloads
		  ○ Not all of CNSs visited their office before going out to visit patients and none wished to make appointments at the end of the day
		  ○ Visits to CNSs were also complicated by CNSs covering weekend working and, therefore, having days off in the week
		• Consequences:
		  ○ The CNSs responded openly to being asked questions about study experiences of needs assessment, information provision, goal-setting and coaching. However, the limiting factor was the lack of CNS availability and time. Over the course of trial the CNSs were visited usually once a fortnight depending on their availability. The original intention had been weekly visits
		  ○ Therefore, the overall consequence was that the delivery of follow-up support to the nurses was less than originally intended

CTA, clinical trials assistant; CTP, clinical trials practitioner; PROM, patient-reported outcome measure.
a The nurses were asked to select pictures that represented elements of supportive self-management to them.

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences
The four-step educational approach: • needs assessment • information provision • goal-setting • review and coaching	• Deliverability of the educational approach to focus on supported self-management required practice: ○ perceived challenge of delivery of the four steps in a therapeutic conversation, so that it flowed naturally and covered all areas • The educational approach itself was seen as acceptable as the steps were noted to be inherently part of what specialist CNS practice looks like	• CNS responses: *I think I needed to adjust my meetings with the patients, because I was very much solving the problem. A couple of patients I was suggesting things, rather than letting them tell me what their goals were, so I think that changed . . . it took two or three interventions (visits) to realise that* *H2CNS002* *It's not so much what we did but maybe how we did things, you know, focusing differently . . . it made you focus on that subject (self-management of analgesia) each time you saw them . . . It's made me think more about following that structure, which is good and seeing how people respond* *H1CNS002* *It's just re-learning a conversation* *H2CNS001* *The four-step process sort of reflects the nursing process really doesn't it? You know that's what you do, or what you should be doing. But I think having it in your head more concretely and having things that you do at each of those steps just makes it more real* *H4CNS003* *I followed this process . . . I found that kind of reflected pretty much what we do with that sort of pain assessment and their usage of medication assessment that followed quite well anyway. The bit here about the needs assessment and assessing their beliefs and knowledge, I kind of do that anyway, but you thought about it more, because you were doing it as part of this process; because obviously you need to understand from their point of view, why they were taking the medication, because it might be that you are going to tip it on its head when you were reviewing what they'd done – when you went back to review your goal-setting* *H4CNS001* *I just think it has more meat on the bones . . . it's a much more focused way of practising* *H4CNS001*

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

		• Mediating factors:
		  ○ Fully embedding the concept of supported self-management in end of life took time and practice, and challenged the desire of nurses to go in and immediately 'come up with solutions' (H2CNS002)
		  ○ The structure of the four-step approach also challenged the CNSs who were all experienced and therefore had their 'own little style' or 'our sort of patter' that they had already 'evolved into' (H2CNS002; H1CNS002)
		  ○ The nurses often wished to have delivered the four-step approach more during the course of the study to have further practised their delivery of it, for example to 'five patients or something to sort of get into it' (H1CNS002)
		  ○ For some CNSs the ethos of supported self-management was easier to adopt that for others. For some relinquishing control was easy 'I don't think we should have control'(H2CNS001) and it was all about empowering patients
		  ○ In normal practice the nurses may not have discussed medicines management at each visit 'with a lot of the patients that we see, it's amazing that one week medication will be such a problem, it will just be overtaking them. And then, with a few changes, then it won't be the big focus on their mind . . . I suppose if it wasn't for the study . . . you might have done it every second or third visit' (H1CNS002)
		• Consequences:
		  ○ The shift in thinking required for delivery of the self-management ethos within the educational approach was accommodated more successfully by some of the study nurses than others. For example, 'I need to just take a little step back and let the patient tell me what they want to do a little bit more' (H2CNS002)
		  ○ All the nurses managed to deliver the educational approach via a conversational process, as per normal therapeutic practice

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

The SMST: all the factsheets	• Deliverability and acceptability of the factsheets:
	  ○ staged and individualised provision of the factsheets worked well for most CNSs, preventing the patients from becoming 'overwhelmed'
	  ○ for a minority (two study nurses) they delivered all the factsheet resources at their first visit (despite training), 'I just handed everything over' (H4CNS001), perhaps highlighting areas that they felt were relevant. This type of delivery negatively influenced the acceptability of the factsheets to the patients
	  – the argument made by the nurses for doing so was 'when somebody's newly started on an opioid or indeed if you're very fresh to the patient, you can't kind of pre-guess what they're going to need. And to me the whole point of it is that you are giving them the tools to be able to self-manage, but because you can't guess which one they're going to need really, they should have all of them at the beginning so that they've got the information there' (H4CNS001)
	
	• Perceived benefit of the factsheets:
	  ○ stimulated patients to ask further questions
		• Patient/carer responses:
		  ○ Easy to read/look at, clear and not too long
		
		Keep it like that, pamphlet form, I think more people will be able to read it because it's not too long
		H1Pt015
		
		The side effects one was interesting . . . it was mostly information I know, but it's good to sit and just read it through
		H1Pt015-C
		
		• CNS responses:
		
		It's good having them broken down (into sections), you can select what you need out of them
		H2CNS002
		
		'It's nice to have the written back up' to verbal information giving
		H1CNS002
		
		  ○ They were universally perceived as easy to read – pitched at the right level, spanning the spectrum of those with no medical knowledge and those that did
		
		I enjoyed using the factsheets
		H2CNS001
		
		  ○ They were viewed as something new and beneficial that was not available to them in their everyday practice
		
		It's good to go through the basics of the factsheets with them, depending on time restraints, so that you're pointing out the bits that maybe relevant and show them, and talk around the bits on the factsheet as well, with examples
		H1CNS002

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences
		The way that the documentation was presented, it was very professional looking, which sort of enabled the patient to take it more seriously *H4CNS003* ○ That is, buy into it *She's a very independent lady, so if she could manage to solve a problem without contacting somebody, she wanted to do that, and obviously the advice sort of gave her the ability to do that . . . she knew . . . that the information was there* *H4CNS001* *When I did my next review she actually had half a dozen questions from the factsheets . . . it was all relevant . . . it just took extra time* *H1CNS001* • Mediating factors: ○ Value of having written information to reinforce or act as a reminder to verbal information provision ○ Not all patients/carers value written information – 'it's really helpful for the people who are going to read it' (H3CNS001) ○ Not always delivered appropriately. This was not just handing over all the factsheets at once, for other CNSs the factsheets were not always discussed with the individual or they were posted to the individual (when the CNS forgot her master file of factsheets). One patient received no factsheets during the course of the trial • Consequences: ○ Only one patient, on his request, received no factsheets during the course of the study ○ All other study patients received factsheets and, for those that read them (the majority), they perceived a benefit from them (backing up information that had been provided verbally and stimulating them to ask further questions) ○ For the few patients who received factsheets and did not read them or just scanned them, the resources were usually read by their carer and were perceived to be of benefit to them

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences
		○ For a minority of patients for whom the delivery was poor (e.g. not discussed with the patient, all given at once, posted to the patient), this negatively influenced the benefit of the resources. For some, they were not utilised or read as a result
• Common concerns factsheet	• Perceived benefit of the 'common concerns when taking opioid medicines' factsheet	• Patient/carer responses: *I'm not so scared of it (morphine) now, because I know that I'm in charge now. I know what happens if I do take too much, and I can look for those signs within myself, and know where the limit is versus pain . . . it's opened my eyes a lot to it* *H4Pt023* • CNS responses: *I think that perhaps all patients should have that information as a standard* *H1CNS001* ○ Felt that it helped to normalise patient and carer concerns • Consequences: ○ The perceived benefit of this factsheet was seen as great by the nurses, patients and carers alike ○ The nurses felt that it helped them to focus to a greater extent on patients' fears regarding opioids and to 'unpick things more' (H4CNS003)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

• Contact factsheet	• Deliverability and acceptability of the contact factsheet:
	  ○ Often poor delivery of the factsheet (non-completion by the nurses)
	  ○ However, the acceptability of the factsheet was seen as high by patients
	
	• Perceived benefit of the contact factsheet to be limited due to frequent non-completion
		• Patient/carer responses:
		
		All the numbers you need are there, it's a brilliant idea *H1Pt015-C*
		
		It's just reassurance you know, an easy reference, just in case, I've got those contact details there in a handy sort of leaflet *H2Pt007*
		
		• CNS responses:
		
		I like the idea of it to help get all those numbers together, because it's really confusing for them *H2CNS001*
		
		• Mediating factors:
		  ○ Such as the goal-setting sheets, this was the only other core component of the SMST that the study nurses were asked to ensure that all the study patients had and completed (on their first study visit). Despite this, although the patients often had this factsheet in their folder, it was commonly uncompleted by the nurses
		
		• Consequences:
		  ○ As a result of the often non-completion of this factsheet by the nurses, it was often not used by patients
		  ○ Nonetheless, all patients and carers liked the idea of it
		  ○ There is a potential need for further development of the factsheet to outline 'a next step of the decision tree' (H2CNS001), i.e. a flow chart of who the best contacts are in specific circumstances/ situations to help patients make these often complex decisions

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

• Medication chart	• Deliverability and acceptability of the medication chart:
	  ○ The deliverability of the medication chart was limited by the frequent non-completion of the chart by the nurses
	  ○ However, the delivery of the study chart was designed to allow flexibility to meet individual patient/carer needs
	  ○ Therefore, some nurses provided and completed an alternative for patients, which suited the individual better (e.g. a simpler one-page chart)
	  ○ Some patients produced their own charts – completing the study version themselves or producing their own versions, often based on a hospice discharge chart or using Excel spreadsheets
	  ○ Patients, or their carer, all saw having a current up-to-date version of a medication chart in their home as acceptable and of value
	
	• Perceived benefit of the study medication chart limited due to frequent non-completion:
	  ○ Nonetheless, it often stimulated the use of alternatives
		• Patient/carer responses:
		
		From a carer's point of view it's a good thing to have it in the house . . . if there came a point when I couldn't do it myself, then it would be very useful for (carer's name)
		H2Pt019
		
		It's handy, you can see straight away . . . what they're all for
		H1Pt001
		
		It made me more organised. (Carer's name) found it useful, because if I'm drowsy or unwell, he's known what time I take it, when I take it, and what it's used for
		H3Pt002
		
		  ○ The charts helped some plan activities away from the home and what medications to take with them
		
		• CNS responses:
		
		It would have been another job for me to do . . . it didn't occur to me to actually fill it out because I was thinking it was for them to do
		H1CNS001
		
		• Mediating factors:
		  ○ One patient filled it out himself as a distraction from his depression
		  ○ Despite frequent poor delivery, it facilitated carer involvement and allowed for pre-emptive planning for deterioration of the patient (i.e. the respective carers knew there was a medication chart if they needed to administer them)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

		• Consequences:
		  ○ The medication chart was often not completed by the nurses, there appeared to be an assumption (despite training) that patients could complete the study chart themselves
		  ○ Nonetheless, its supply often stimulated adaptations or the use of alternatives, for example a one-page chart by the CNS that could be viewed simply at a glance, the use of Excel spreadsheets by patients, patient adaptation of a chart that had been supplied on discharge from the hospice
		  ○ When a version existed, it was valued as a reference for carers
		  ○ It was also viewed as particularly valuable in the context of opioid induced drowsiness where patients could not remember details of the medications and if they had already taken them (so the ability to cross off doses on the study chart was valued for this reason)
		  ○ There was an additional perceived benefit if a patient had an unexpected hospital admission. For example, 'Everyone I showed them to [at the hospital], they said 'oh what a great idea . . . that's saved us so much work' (H3Pt022)

• Pain diary	• Deliverability and acceptability of the pain diary:
	  ○ Successfully delivered to 15/19 participants
	  ○ For those that received the diary they viewed it as acceptable and used it
	
	• Perceived benefit of the pain diary as a decision-making aid for nurses and patients:
	  ○ For patients, it helped justify/stimulate the use of breakthrough analgesia where pain scores increased
	  ○ For nurses, it helped facilitate adjustment of doses
		• Patient/carer responses:
		  ○ Formalised and recorded information more comprehensibly
		  ○ It also helped with decision-making (e.g. if the pain rating increased then it helped to encourage the use of breakthrough analgesia)
		
		That pain diary is helpful, because for me I can look back and see how the day . . ., because you forget from day to day
		H2Pt019
		
		And (CNS name) found it useful too when I was able to say what I'd taken, what pain relief, what pain I was in, how long did it take for me to make the pain manageable
		H3Pt003
		
		I don't know if I would have been able to create my own form to suit my needs. It's great to have something like that available
		H2Pt007

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences
		○ Stimulated some patients/carers if not using the diary to note down breakthrough doses of opioids ○ Motivated other patients to use alternative versions of a pain diary (e.g. Macmillan) or develop their own (i.e. to engage in their own self-management activities as a result) • CNS responses: ○ Universally seen as helpful by the CNSs as allowed them to evaluate the effectiveness of the medications more easily ○ Enabled patients to formally record their experiences and what was happening to them • Consequences: ○ It helped patients keep track of the effectiveness of their medicines ○ It relieved the pressure on patients to remember these details (when breakthrough doses had been taken and responses to the medication) ○ It made patients, carers and CNSs observant of the patterns of pain throughout the day and stimulated thinking regarding what could and should be adjusted in the medication regime
• Podcast films	• Deliverability and acceptability of the podcast films: ○ The films were offered to eight participants to watch – five patients watched them during the follow-up period • Perceived benefit of the podcast films: ○ Those that did receive them watched them (with the exception of one patient) ○ These patients found them to be acceptable and have benefit	• Patient/carer responses: *Reassuring . . . I think the information was very useful, because it did home in on the fact that you're in control . . . that came across very clear* *H2Pt019* *I think that would be useful if I was at the start of the process, but now, with all the things that were said in the DVD, I kind of already knew, especially the chap who was managing his prostate cancer, I've been through the same process myself* *H3Pt002*

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences
		○ The patient in the podcast discussing how he managed the supply issues related to his medicines was seen as particularly beneficial. It stimulated one study patient to use exactly the same system to keep track of his medicines and their supply, 'it's how he does it, it just makes so much sense . . . in fact, it was very short and was a big disappointment wasn't it when it finished!' (H4Pt023) ○ The information reaffirmed what was already known from the factsheets, but it was more easily absorbed in the form of the short podcasts • CNS responses: *I do think that the videos were very good* *H1CNS002* *You need an alternative to paper . . . you shouldn't exclude anyone* *H4CNS002* • Mediating factors: ○ Predominantly not offered by the CNSs, but often the patients said that they would have watched them had they been offered ○ This may have been an issue of practicalities – either that the nurses forgot about them and therefore did not offer them or forgot to carry them with them in their master files ○ Authentic value of patients sharing their own experiences and self-management strategies, seen as something that specifically related to the viewers. For example, 'He's just an ordinary guy, he's gone through this, this is what he's doing in his words and how he's dealing with it, and you can make that relate then to yourself' (H4Pt023-C) ○ Only one patient who received them had not watched them but this was in the context of untreated depression • Consequences: ○ They were seen as beneficial by the few that were offered them ○ The patient podcast, because of its authenticity and the value of hearing the experiences and strategies of others in a similar situation, was particularly valued

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

• Goal-setting sheets	• Deliverability and acceptability of the goal-setting process and sheets:
	  ○ Universally delivered and completed for all study patients
	  ○ The completion of the sheets at each CNS visit illustrates the acceptability of the sheets to the nurses
	  ○ In the majority of cases the sheets were delivered and completed well, with appropriate-patient focused goals set and action plans to achieve the goals
	
	• Perceived benefit of the goal-setting process and sheets when delivered well (focused on the patient's goals):
	  ○ Value to CNSs
	  – formalising and evidencing specialist practice, 'I could actually say to you now, with the patients, I'm actually at this point with them . . . we've set these goals and I'm off today to reflect on those and identify any other issue' (H4CNS003)
	  – Also facilitated review and coaching, as the previous goals were there to 'reflect back on' (H4CNS003)
	
	  ○ Value to patients – It's 'looking at it from a different angle, what they (patients) want to achieve' (H1CNS001)
	  ○ Perceived potential disadvantage/harm of goal-setting if not patient generated – 'sometimes your perception of what they are going to write is just completely different to what they come out with' (H2CNS001)
	  ○ Two patients appeared to find the goal-setting documentation (as opposed to the discussion of it with the CNS) wearisome, but this was in the context of depression
		• Patient/carer responses:
		
		That's been helpful . . . I think it has made me a bit more explicit about setting goals and saying to (CNS name) 'I'd like to do this, can you help me do this?
		H3Pt002
		
		I've found it quite manageable to think, look at that, and then think about what I've achieved
		H2Pt019
		
		I think it's a really good idea to try and make yourself do things
		H1Pt001
		
		Setting a goal . . . I think is a must
		H4Pt013
		
		  ○ The goal-setting was beneficial as is stimulated thinking such as 'right this is what we've got to do now, and get this sorted . . . it's made us more aware to help things along' (H1Pt015) (e.g. constipation related to opioid usage)
		  ○ They were often something that study patients wished to continue with after the study
		
		• CNS responses:
		
		That was actually very useful, and I think that's one thing I would take away and carry on with, just from the focus of actually what you would like to achieve this next week or two weeks. That is quite a useful angle to look at things from . . . It was actually quite good getting them (patients) to think about what they could do to help themselves
		H1CNS001
		
		To write those weekly goals is a completely new change in practice for me. But I liked it. I think it was really useful, and you know, they liked it as well, the patients and carers
		H2CNS001

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

		• Mediating factors:
		  ○ The goal-setting sheets, along with the contacts factsheet were the core components of the SMST, to be completed at every visit. However, unlike the contacts factsheet they were universally completed by the nurses
		  ○ Some patients struggled to think what their goals would be in the context of clinical depression or a degree of memory loss
		  ○ Even where the goal was not achieved there was a recognition that the process of setting goals was useful in itself (perhaps because it focused on defining small practical and achievable steps towards the overall goals), 'If you set a goal, even if you don't reach it. I still think it's a good thing to do' (H4Pt013)
		
		• Consequences:
		  ○ Goal-setting often became the mechanism by which patients were helped to focus on doing things for themselves (i.e. to implement self-management strategies)
		
		Because you make a realistic goal, and then you make a change, because they're aiming for a realistic goal I think the patient adhered to the change a little bit better. And then you see some progress, so even if some things, we did . . . roll on a goal (over the weeks) . . . we would see some improvement that gives people some positivity that they've made a change, they can look on paper what their goal was . . . it keeps patients real because they forget how things were a week ago and actually you've made a change and it's better
		H2CNS001

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

• The SMST in its entirety	• Deliverability and acceptability of the SMST as a whole:
	  ○ This was a complex picture given the end-of-life context so not all patients fully engaged with the SMST, additionally complicated by the fact that the resources were frequently not delivered as ideally desired
	
	• The perceived benefit of the SMST as a whole:
	  ○ There was always some benefit, just that the level of benefit was widely variable, of the SMST to the patient and carer (but also additionally to the CNS):
	  – The goal-setting was the most frequently valued element
	  – There were often other elements that were also liked (e.g. the pain diary)
	  – The factsheets often reinforced information provided by the CNSs or that the patients already knew
	  – If the factsheets were not read by the patient they were often valued by their carer
	  – The CNSs particularly valued the common concerns factsheet
	  – The podcast films were valued by those who had been provided with them
		• Patient/carer responses:
		  ○ Range of responses from 'we'll treasure that' (H1Pt001) and 'it has helped me, definitely' (H3Pt041) to a minority of patients who did not fully engage with it
		  ○ All patients used the goal-setting, but it was a core component of the SMST
		  ○ The SMST appeared to become onerous, and therefore not fully used, in the context of clinical depression
		  ○ For two patients, the resources were seen as 'a bit too nice and tidy actually. I thought 'I will just scrawl all over them and make a mess of them'. That's probably why I've not used them to be honest, because of my scatty writing' (H3Pt002). For the other patient, she ended up transcribing notes she had already written neatly into her pain diary
		
		• CNS responses:
		
		It's just a solid piece of evidence, rather than us just trying to explain things to patients and sort of jot things down for them, they've actually got information that we can leave with them that they can use . . . I'd like to be able to use these tools with other people that come onto my caseload. I think they are very useful
		H4CNS003
		
		To have all of this to give them, kind of backs up what we say, rather than it's just you talking to the patient, and then the minute you've left the house they've got nothing then to hold on to
		H4CNS001
		
		I'd seen him once or twice and his wife became quite poorly, and so then actually kind of utilising their folder was, they didn't do it really. And not because they didn't want to . . . they hadn't had the time . . . when they'd wanted to
		H4CNS001

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

		Unfortunately things have gone from bad to worse with him (study patient) deteriorating and X (carer) not being very well, I think it was just perhaps a bit too much
		H1CNS001
		
		• Mediating factors:
		  ○ The complexity and illness of end-of-life patients meant that not all patients benefited from the SMST themselves; however, the resources were viewed as of value to others within the respective families/households
		  ○ Frequently less than ideal delivery of the resources by the CNSs. This had a major impact on the acceptability and benefit of the resources as a result – particularly when they were not discussed or talked through, and when all the factsheets were given all together as a large file
		  ○ Difficulty given the unpredictability of end of life in providing the intervention at the perfect time for patients (i.e. while they are well enough to engage in it)
		
		• Consequences:
		  ○ Overall, the SMST helped to provide suggestions for self-management strategies and then evidence for patients, carers and CNSs as to which strategies worked for the individual
		  ○ The SMST also stimulated appropriate questioning by the patient/carer to the CNS. For example, 'it's been easy to ask questions' (H1Pt001)
		  ○ Patients who were already effective self-managers prior to the trial felt that they would have used the materials more if they had received them earlier (at their first contact with their CNS). For example, 'I've been doing this for over a year. And a lot of the things in here I knew. And frankly, I'm a very organised person, so I've got all the diaries, and I've got all the prescriptions, and they're all online. Whereas it takes a while to get to that stage, to figure out what you're meant to be doing, how you're meant to be doing it' (H3Pt002)

continued

TABLE 41 The process evaluation qualitative outcomes regarding the SMART intervention (*continued*)

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences
• The four-step educational approach and the SMST (i.e. the intervention in its entirety)	• The deliverability of the intervention was seen as acceptable to the CNSs who did not perceive that they needed any additional skills to deliver it (i.e. it was viewed as a normal part of the specialist role): *Not different from my normal job . . . I think it would be different for a general nurse to do it, definitely* *H1CNS001* ◦ Yet 'you learn from it and it just makes you do your things a little better' (H2CNS002) and 'it just makes you think about things more' (H1CNS002) • Perceived benefit of the intervention: ◦ Delivered within the complexity of delivery at end of life with frequent deterioration of condition and depression	• Patient/carer responses: *I think it's made us more aware that you must take your tablets, you must take the Movicol [magrogol; Movicol®, Norgine Ltd, UK] and your medication regular, and you know, keep everything under control . . . I just issue them [the medicines], you know give them to [patient's name] as and when. I'm quite happy and confident to do it* *H1Pt015-C* *It's felt easier for me to manage the medications, to try and understand and ask questions* *H4Pt023* ◦ For those that were already effective self-managers of their analgesia prior to the study and had been seeing their CNS for a matter of months – 'I've got the same level of understanding and nothing's changed there' (H2Pt007), but the intervention stimulated more questioning regarding the side effects of the medications • CNS responses: *The study allowed them (the patient and carer) to think more broadly about how they manage pain* *H4CNS001* *It was almost as if I was handing her responsibility for her regime, if you like. So I was allowing her to have, she was making a much more informed choice about what she took, when she was to take it, why she was taking it. And also leverage in terms of parameters of medications, so it wasn't just 'right take this at 6 o'clock' it was 'well actually you could maybe try doing this, or you could try doing that' and allowing her to make those choices based on the literature* *H3CNS002*

Feasibility of intervention delivery	Findings from the data: deliverability, acceptability, perceived benefits, disadvantages	Mechanism of action: participant responses to and interactions with the intervention, mediating factors, consequences

		• Mediating factors:
		  ○ Many patients already had pre-existing relationships with their CNSs and had great confidence and trust in them and their abilities
		  ○ The confidence derived by patients and carers was in the face of often complex medication regimes and decision-making processes
		  ○ Not all patients appeared to really benefit from the intervention – for these the issue appeared to be one of timing, 'I think it kind of came too late' (H3CNS001)
		  ○ For others suffering with depression the value of the intervention was lessened as a result
		• Consequences:
		  ○ All patients stated that they derived a benefit from the intervention via face-to-face contact with their CNS (in the form of the four-step educational process, although it varied as to how much the patients knew about and acknowledged this process)
		  ○ The acceptability of the delivery of the intervention and resulting benefit was increased for the patients and carers because of the almost universal value that they placed in contact with their CNS (particularly when face to face and in their own homes); for example, 'She's very efficient when she comes, she's probably here an hour and we don't stop talking, mainly about the meds and why I'm doing all that. So that's absolutely brilliant' (H2Pt007)
		  ○ A minority of patients did not really engage with the SMST, but for these patients their carer often did and they received a benefit from the SMST
		  ○ Overall, the intervention was stated to generate confidence in the patients, and carers, in their ability to manage their medicines, 'My understanding has increased a lot . . . I feel . . . happier with the medication I'm on and how it works . . . I don't think I'm on my own being scared of taking a lot of medication . . . it's put me at ease' (H4Pt023); 'And the confidence. You know now if I go to the doctors, I would ask questions about medications and things' (H4Pt023)
		  ○ The intervention facilitated patients appropriately adjusting doses of medications, especially laxatives, and administering analgesia within prescribed ranges (e.g. prophylactic use of breakthrough analgesia prior to activities at the lower end of the range, compared with use of breakthrough analgesia when in pain at the higher end of the range)

Appendix 25 Definition of self-management and professional roles

Johnston *et al.*'s definition of supported self-management in palliative care:[51]

> *Assessing, planning, and implementing appropriate care to support the patient to be given the means to master or deal with their illness or its effects. Supported self-management in advanced disease, by nurses, can, empower people to acknowledge the impact of their condition on their life, and enable them, where possible, to face the range of challenges they may have, and identify areas where they need further support, help or care. Therefore, for individuals it's about being provided with the means to master or deal with problems rather than relinquish them to others.*
>
> *Johnston* et al.[51]

Johnston *et al.*'s related professional roles:[51]

> *Self-Management Support: Professional Roles*
>
> 1. *Advocate – To support self-management and the right of palliative patients to receive appropriate medicines to meet their symptom control needs*
> 2. *Educator – To provide instruction regarding medicines to allow patients to self-manage*
> 3. *Facilitator – To promote relationships between healthcare professionals and patient/carer to enable effective access to and use of medicines*
> 4. *Problem Solver – To use expertise (underpinned by robust needs assessment) to work out whether current medicines and dosages are appropriate, or whether they should be altered*
> 5. *Communicator – To facilitate communication between individuals e.g. encouraging a patient to discuss their pain with their carer*
> 6. *Goal Setter – To identify specific goals that the patient wishes to achieve, and the methods to achieve the goals. This is motivational and enhances self-management performance*
> 7. *Monitor – To observe and constantly re-assess self-management of medicines over time. This requires evaluation of an individual's capacity to self-manage vs. their willingness to engage and compliance*
> 8. *Reporter – To gather information and report it e.g. at multidisciplinary team meetings*
>
> *Johnston* et al.[51]

Appendix 26 The SMART intervention costs

TABLE 42 The SMART toolkit content unit costs

SMART toolkit contents: unit title	Quantity	Pages	Cost (£)	Unit cost (£)
Goals folder	50	4	164.79	3.30
NCR sets	300	4	120.26	0.40
Folder (with insert and spine)	50	1	435.70	8.71
Checking opioid medicines are managing pain	50	4	116.64	2.33
Pain diary	50	4	116.64	2.33
Common concerns	50	4	116.64	2.33
Contacts and further information	50	4	116.64	2.33
Keeping on top of side effects	50	4	116.64	2.33
Organising opioid medicines	50	4	116.64	2.33
Fitting pain control into my daily routine	50	8	218.24	4.36
Getting prescriptions and obtaining medicines	50	8	218.24	4.36
Managing pain with opioid medicines	50	8	218.24	4.36
Medicine chart	50	8	218.24	4.36
Total SMART folders			2293.55	43.83

NCR, no carbon required.

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