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

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Scientific summary

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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.

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