Pain self-management interventions for community-based patients with advanced cancer: a research programme including the IMPACCT RCT

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Scientific summary

Pain self-management interventions for advanced cancer

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Scientific summary

Background

Each year in England and Wales, 150,000 people die from cancer, of whom 110,000 will suffer from cancer pain. Patients spend 65–80% of their last 6 months of life living at home (community-based patients). Research shows that, for these patients, pain remains common, severe and undertreated, and may lead to hospital admission.

Objectives

1. To model and test a cancer pain pathway for patients with advanced cancer that optimises support and advice, delivers brief educational interventions and can be delivered to promote self-management.
2. To develop systems for capturing and communicating clinical and patient-reported outcomes on pain assessment that can be integrated into the routine practice of community-based health professionals.
3. To determine whether or not key aspects of medicines management, such as prescribing practice and access to analgesia, can be modified to ensure that patients with cancer pain benefit from timely intervention.
4. To implement and evaluate the clinical effectiveness and cost-effectiveness of a cancer pain pathway (based on objectives 1–3) in reducing pain and related distress, and in reducing pain-related hospital admissions.

Methods

Our work comprised four workstreams: three intervention development workstreams and one evaluation workstream.

1. People: an integrated system of support

We conducted longitudinal qualitative interviews with patients and caregivers from oncology and palliative care, exploring their experiences of pain and pain management. We analysed local data and obtained data from 64 hospices nationally. We calculated the interval between time from referral to palliative care services and death for each patient, and then calculated the median value of this variable for the whole sample. We identified which factors influenced this interval.

We explored oncology health professionals' perceptions of the advanced cancer trajectory, their work relating to it and their engagement with palliative care over its course, and examined variations in primary care practice. We then reviewed existing literature on patient support materials and surveyed regional oncology units to assess information provision for patients with advanced cancer regarding palliative care support.

We took the results from four existing systematic reviews of educational interventions and integrated these with the findings of three systematic reviews of qualitative research exploring patient and carer experiences of specific cancer pain management advice to inform the development of an educational intervention for patients and carers. We undertook focus groups to ascertain specialist palliative care health professionals' views on patient self-management of cancer pain. This work informed the development and feasibility testing of our educational intervention, *Tackling Cancer Pain*.

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2. Data: routine assessment and monitoring of pain

We conducted face-to-face interviews with both patients with advanced cancer receiving palliative care and health professionals providing community palliative care to understand user needs and concerns.

We began by identifying existing approaches to information and communication technology use in pain management in palliative care services through a systematic review. Requirements identified from user engagement activities informed the architecture and content of an information and communication technology system. We tested the underlying infrastructure of the system to ensure its integrity for data collection. We conducted this work with participants with chronic pain before carrying out usability testing of a prototype system with patients with advanced cancer and health professionals, which led to the inclusion of the information and communication technology system in the main feasibility study.

3. Medicines: good management of analgesic drugs

Using an innovative cross-organisation data linkage process, we linked data from patients who died from cancer and analysed prescribing data in the year before death to determine access to opioids and factors that influenced this access. We conducted a systematic review of studies that examined the association between regular systemic opioid analgesia and survival in adult patients with cancer to determine whether or not opioid analgesia was associated with a shorter survival period. We examined the extent and impact of non-medical prescribing within palliative care through regional and national surveys of nurse and pharmacist prescribers. We developed a novel methodology to establish the level of non-medical prescribers' activity in palliative care across England between April 2011 and April 2015 using specific palliative care drugs prescribed by these health professionals. We used data extracted by NHS Digital from the electronic Prescribing Analysis Cost Tool (ePACT) system.

Using a structured online survey, we explored the knowledge, experience and opinions of health professionals about the role that community pharmacists could play in the management of patients with cancer pain. We conducted a qualitative study to explore how patients with pain from advanced cancer used community pharmacies and their attitudes towards medicine consultations with pharmacists. We triangulated these findings to establish pathways to identify and refer patients to a community pharmacy for a Medicines Use Review intervention.

We modelled a Medicines Use Review for patients with cancer pain and their carers. We first conducted a systematic review and meta-analysis of pharmacist educational interventions for cancer pain management. Following this, we held a multistakeholder workshop and used these, together with our patient interview findings, to inform our Medicines Use Review intervention prior to evaluating its feasibility and acceptability.

We invited patients with advanced cancer living in the community to a consultation with a pharmacist in the pharmacy or remotely by telephone outreach. We provided an interactive learning event for the pharmacists to address consultation and palliative care team networking skills. After the consultations, we assessed medicines-related problems and actions by the pharmacists, including referral of patients to other team members, and conducted a survey of patients' experiences.

4. Evaluation: cost-effectiveness and feasibility

We developed two approaches to estimate the cost-effectiveness of a supported self-management intervention: a model-based economic evaluation and a trial-based economic evaluation. For the model-based economic evaluation, we conducted a discrete choice experiment with patients with cancer pain to understand their preferences for pain management services and to inform service development. Focus groups were used to develop the attributes and levels of the discrete choice experiment. We explored how a questionnaire survey could capture quality of life (utility) and resource use to inform the model-based economic evaluation.

In the trial-based economic evaluation, we estimated costs and health-related quality-of-life outcomes using seemingly unrelated regression. We calculated incremental cost-effectiveness ratios per quality-adjusted life-year for the trial period.

We conducted a pragmatic, multicentre, randomised controlled trial to assess the feasibility, acceptability, clinical effectiveness and cost-effectiveness of a multicomponent intervention for pain management in patients with advanced cancer (the trial was registered as ISRCTN18281271). The intervention comprised our *Tackling Cancer Pain* patient support book (developed in work package 1) and the PainCheck online symptom monitoring system (developed in work package 2). We recruited 160 patients with solid tumours (locally progressive or metastatic), rather than those with haematological cancers, and randomised them to receive either enhanced supportive care alongside standard community palliative care support (intervention) or standard palliative care support alone. Evaluation measures were conducted at baseline, week 6 and week 12 (end of study).

Results

1. People: an integrated system of support

We found that pain in advanced cancer is complex, multidimensional and dynamic. This presented a major challenge for patients in managing it and in securing 'good enough' relief, consistent with balancing medication side effects and sustaining what they valued in their lives. For patients and caregivers, neither pain relief nor the expertise in managing it was secured once and for all.

Nationally, the median time between referral to palliative care services and death for 42,758 patients is 48 days. Significant differences in referral to death days are found between those with cancer (53 days) and those without cancer (27 days). As age increases, the median number of days from referral to death decreases.

Oncology health professionals said that although the term 'advanced cancer' is commonly understood as 'active', non-curable cancer, it conceals considerable variability in the advanced cancer trajectory. The varied pattern of survival across cancer types reinforces the need for supportive care alongside treatment in advanced cancer.

Within primary care, we identified distinct differences in the drivers of and barriers to community advanced cancer care co-ordination. These included proactive identification processes, time and resource pressures, unclear roles and responsibilities, poor multidisciplinary working, and inflexible models of referral and prescribing.

Our literature review identified patient-related barriers to earlier integration of palliative care, including misconceptions about what palliative care is and a limited understanding of the role and breadth of services available. Our regional survey found that patient information relating to palliative care was rarely available.

Four systematic reviews of effectiveness were identified and integrated with three qualitative evidence syntheses. Key components for self-management included individualised approaches to care; the importance of addressing patients' knowledge, skills and attitudes towards pain management; and the significance of interdisciplinary working in the management of pain. We developed and tested our *Tackling Cancer Pain* resource for acceptability.

2. Data: routine assessment and monitoring of pain

Patients with advanced cancer told us that an electronic system needs to take account of the complexity of pain experiences and existing relationships with health professionals. Health professionals could envisage the potential benefits of an electronic patient-reported pain monitoring system but had reservations about how PainCheck would be implemented.

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The majority of the literature identified for our systematic review of the information and communication technology system development in palliative care employed non-experimental research designs, and no systems had been successfully implemented in routine care. Most information and communication technology systems measured pain as part of quality-of-life measurements, although approaches to assessing pain varied widely.

We developed and tested a prototype PainCheck system, which users were generally positive about and found easy to understand, although they had some concerns about how it might work in clinical practice.

3. Medicines: good management of analgesic drugs

Strong opioids were prescribed for 48% of patients in the last year of life at a median of 9 weeks before death. Prescribing was not influenced by cancer type, duration of illness or sex, but it was strongly associated with patient age; older patients were much less likely to be prescribed a strong opioid than younger patients. Our systematic review suggested that opioids were associated with a shorter survival period, but no definitive conclusions could be made because of methodological weaknesses.

Non-medical prescribers prescribed a wide range of drugs for cancer pain, but we identified scope to maximise economic and clinical benefit by improving the transition from qualified to active non-medical prescriber. Nationally, the number of prescriptions issued by non-medical prescribers rose by 28% every year between 2012 and 2015; this growth was almost entirely attributable to an increase in opioid prescriptions. However, the contribution of non-medical prescribing to overall palliative care prescribing was very small.

Patients largely agreed that community pharmacists should become part of the palliative care team but said that additional training about cancer pain management and consultation skills were needed. Patients had low expectations of what community pharmacists and their teams might provide, but most accepted the idea of a community pharmacy medicines consultation. We found a need for pain medicines support among patients with advanced cancer, particularly among those who were not receiving specialist palliative care.

Our systematic review and meta-analysis found improvements in pain intensity following a pharmacist-based medicines review. In our Medicines Use Review feasibility study, we delivered consultations to patients in which many medicines-related problems were identified. Most patients would recommend the consultations to others, and a small number of patients reported that their knowledge about their pain medicines had improved.

4. Evaluation: cost-effectiveness and feasibility

We found both interventions to be cost saving. The model-based economic evaluation demonstrated that the most important driver of cost-effectiveness was the level of pain reduction, and, using a cost-effectiveness threshold of £20,000 per quality-adjusted life-year, there was a 67% chance that our interventions were optimal. The model-based evaluation was not used to extrapolate the outcomes of the trial over a longer time horizon because the statistical analysis of the trial data found no difference between the trial arms in terms of the primary outcome measure (pain severity). The trial-based economic evaluation indicated that our interventions reduced health-care costs by £587 per patient. The difference in quality-adjusted life-years between the trial arms was negligible and this was not in line with the decision model that had been developed.

Between October 2015 and January 2018, 161 patients were randomised [80 in intervention (supported self-management), 81 in control (usual care)]. Three-quarters of randomised participants had Brief Pain Inventory score of 4–6, representing mild to moderate levels of pain, whereas one-quarter had a score of 7–10, representing severe levels of pain.

In the intervention arm, 72 patients (90%) received *Tacking Cancer Pain* and 47 (58.8%) were introduced to the PainCheck online monitoring system. A total of 115 (71.4%) patients completed at least one successful follow-up, with questionnaires completed at 6 or 12 weeks post randomisation. Median survival from randomisation was 53 weeks. Primary and sensitivity analyses found no significant treatment differences for the primary outcome or for other secondary outcomes of pain severity items on the Brief Pain Inventory. The trial did not demonstrate that the intervention significantly affected health-related quality of life or cancer-specific quality of life. The supported self-management arm appeared to incur higher hospice use costs than usual care, but the latter arm incurred higher hospital use cost.

Our process evaluation revealed that half of patients and one-third of oncology professionals described the association of palliative care with closeness to death as a barrier to accessing supportive care for pain. Patients felt that taking part in the trial had enhanced their care and provided them with a support system. Patients and health professionals asserted that both *Tackling Cancer Pain* and PainCheck improved patients' self-management of pain. However, many health professionals reported a lack of knowledge about, understanding of and familiarity with PainCheck, which, in turn, undermined their support and enthusiasm when introducing it to patients.

Limitations

In the randomised controlled trial, the low fidelity of the interventions (in particular the low engagement of patients and professionals with PainCheck) and the challenge of the study design that forced the usual care arm to have earlier access to palliative care services might explain the lack of observed benefit. Overall, 71% of participants returned outcome data at 6 or 12 weeks and so we used administrative data to estimate costs. Our decision model did not include the negative trial results from our randomised controlled trial and, therefore, may overestimate the likelihood of cost-effectiveness.

Conclusions

Our programme of research has revealed new insights into how patients with advanced cancer manage their pain and the challenges faced by health professionals in identifying those patients who need more help. This was also evidenced by late referrals to palliative care nationally and the lack of information available to patients regarding this type of care. We found that access to opioid analgesia occurs relatively shortly before death. Initiatives such as non-medical prescribing have the potential to improve this situation, but their current impact is limited. There is a clear opportunity to provide better support for medicines management by engaging pharmacists more closely in cancer pain management, and we have demonstrated a means of delivering this, which still requires further evaluation.

Patients and health professionals recognised the value in providing materials to support self-management and in using electronic symptom monitoring systems. Patients and health professionals had reservations about how these might be implemented in practice. Nevertheless, we co-designed these interventions with patients and health professionals using a theoretical basis and user testing to optimise acceptability. We do regard the low engagement not as a failure of the research study but as a finding; engagement with digital technology in routine palliative care was low.

We identified aspects of pain management of greatest value to patients and used these to develop a health economic model. Our clinical trial showed that enhancing existing community palliative care support with patient educational materials and electronic symptom monitoring did not result in additional benefit. Both the decision model and the economic evaluation of the trial indicated that supported self-management could be cost-effective. The trial clearly demonstrated that patients

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experience high levels of pain around 1 year before they die, and that earlier integration of palliative care (involvement in the trial a median of 53 weeks before death compared with undergoing routine care a median of 7 weeks before death) resulted in significant reductions in pain among participants in both trial arms.

Trial registration

This trial is registered as ISRCTN18281271.

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