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original report abstract

Multidisciplinary Software Design for the Routine Monitoring and Assessment of Pain in Palliative Care Services: The Development of PainCheck

Matthew J. Allsop, PhD[1]; Owen Johnson, MSc[1,2]; Sally Taylor, PhD[1]; Julia Hackett, PhD[1]; Peter Allen[1]†; Michael I. Bennett, MD[1]; and Bridgette M. Bewick, PhD[1]

PURPOSE The use of health information technology (HIT) to support patient and health professional communication is emerging as a core component of modern cancer care. Approaches to HIT development for cancer care are often underreported, despite their implementation in complex, multidisciplinary environments, typically supporting patients with multifaceted needs. We describe the development and evaluation of an e-health tool for pain management in patients with advanced cancer, arising from collaboration between health researchers and a commercial software development company.

METHODS We adopted a research-led development process, involving patients with advanced cancer and their health professionals, focusing on use within real clinical settings. A software development approach (disciplined agile delivery) was combined with health science research methods (ie, diary studies, face-to-face interviews, questionnaires, prototyping, think aloud, process reviews, and pilots). Three software iterations were managed through three disciplined agile delivery phases to develop PainCheck and prepare it for use in a clinical trial.

RESULTS Findings from development phases (inception, elaboration, and construction) informed the design and implementation of PainCheck. During the transition phase, where PainCheck was evaluated in a randomized clinical trial, there was variation in the extent of engagement by patients and health professionals. Prior personal experience and confidence with HIT led to a gatekeeping effect among health professionals, who were reluctant to introduce PainCheck to patients. Patients who did use PainCheck seemed to benefit, and no usability issues were reported.

CONCLUSION Health science research methods seemed to help in the development of PainCheck, although a more rigorous application of implementation science methodologies might help to elucidate further the barriers and facilitators to adoption and inform an evidence-based plan for future implementation.

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INTRODUCTION

For patients with cancer, research shows that pain is frequent, burdensome, and undertreated.[1-4] More than two thirds of patients with cancer will experience pain during the advanced, metastatic, or terminal stage of their cancer.[4] Pain is a major source of suffering for these patients, having adverse effects on their quality of life, leading to unplanned hospital admissions with uncontrolled symptoms,[5] and negatively affecting caregivers.[6] Although a number of evidence-based clinical practice guidelines are available, pain continues to be undertreated.[7,8] Barriers to effective pain management have been identified at the patient (eg, reluctance to complain about symptoms, fear of pain), health professional (eg, inadequate assessment of pain, reluctance to prescribe or monitor analgesics), and health care system levels (eg, ineffective communication about data on pain, preventing patient access to timely analgesia).[9]

Information and communication technology, and specifically health information technology (HIT), can support patient and health professional communication as part of cancer care[10] and facilitate approaches that target known barriers to pain management. Examples include HIT use to capture patient-reported outcomes,[11-13] self-reported symptom information,[14] and delivery of educational interventions.[15] Well-validated patient-reported outcomes have been developed specifically for the oncology setting (eg, the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events[16]). Efforts to leverage HIT to capture and use such patient-reported outcomes have been reported.[17,18] When HIT is used in such ways, it can have a positive impact on care, reducing symptom distress,[15] improving quality of care,[12] and enabling real-time reporting to support earlier clinical decision making.[19] For the management of cancer pain, technology can be used as an

ASSOCIATED CONTENT

Data Supplement

Author affiliations and support information (if applicable) appear at the end of this article.

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CONTEXT

Key Objective

How can information and communication technology (ICT) systems be developed and implemented rigorously in the context of cancer and palliative care services?

Knowledge Generated

Multidisciplinary teams are able to work and communicate effectively to undertake user involvement and generate valuable and rich data that can meaningfully inform software design decisions for cancer and palliative care services. Subsequent implementation of ICT systems in palliative care must ensure that health professionals are well trained, are supported in ICT use, and perceive benefits for patients; otherwise, uptake and engagement could be adversely affected.

Relevance

Our approach, detailing methods for engaging patients receiving palliative care and their health professionals from conception to implementation, provides a framework to guide rigorous development of future e-health systems intended for use in cancer and palliative care services.

intermediary for patients to report their pain,[20] addressing known barriers to good pain management. HIT, used in this way, has both patients and providers as end users, augmenting communication beyond face-to-face consultation. However, HIT systems for use in advanced cancer are at an early stage of adoption, with little information on how HIT tools are being designed and developed, leading to a lack of clarity on the best methods for development.[21]

HIT systems are typically complex interventions. When developed in the context of care for patients with advanced cancer, system implementation often occurs within challenging, complex, multidisciplinary environments. Patients with advanced cancer are often supported by palliative care services in acute, community, and hospice settings.[22] Palliative care services support people with progressive, life-threatening diseases with no possibility of obtaining remission or stabilization or modifying the course of the illness, often with accompanying symptoms that may require pain management.[23] The complexity of palliative care delivery models for patients with often complex needs highlights the importance of developing HIT systems that are informed by and aligned with the needs of end users.[24]

Approaches to software development have a long history of gathering the needs of users through developing a list of their requirements based on needs and preferences.[25] Modern software development teams are typically organized into small groups that work flexibly and collaboratively with a range of stakeholders to inform the development of an HIT system or product. The identification of user requirements as part of this process can lead to the development of HIT systems that are more successful in supporting patients with complex needs and symptoms.[26-28] Currently there is a lack of literature to guide method selection to support HIT systems for pain management in cancer care.[21] This report describes our experience of combining modern software development with health science research methods to create PainCheck, an HIT system designed to overcome known barriers to effective pain management for patients with advanced cancer. PainCheck was specifically developed to be suitable for a clinical trial as part of a complex intervention. It has now been implemented in palliative care settings.[29] We document the methodology adopted for undertaking research and working with system developers, alongside reporting the experience of patient and health professional users of PainCheck in the context of routine care as part of a clinical trial. Our aim is to share our methodology to provide a template to support research-led development of HIT systems for palliative care.

METHODS

Context of HIT System Development

PainCheck stemmed from a large research program (IMPACCT [Improving the Management of Pain From Advanced Cancer in the Community; ISRCTN registry No. 18281271]) in the United Kingdom,[29] with a specific work stream dedicated to routine assessment and monitoring of pain in patients with advanced cancer. Complementary parallel work streams explored pathways of care for patients with advanced cancer, the role of educational interventions to support self-management of pain, opioid-prescribing practices, and the cost effectiveness of reducing pain and related distress. A multidisciplinary team was formed to develop PainCheck. The team was led by a psychologist and included social scientists, palliative care professionals, public and patient involvement representatives, and a private software company (X-Lab, Leeds, United Kingdom). X-Lab was contracted a set amount of funding to perform the development work. X-Lab had previously developed QTool, an electronic online questionnaire management software suite. QTool is used by health care practitioners and researchers to build and schedule complex questionnaires that can be completed by patients and clinical staff. Examples of its use include patient-reported outcomes in cancer survivors[30] and self-report and

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management of adverse events during cancer treatment.[31] QTool was selected as a starting point for the development of PainCheck.

Overview of Approach to HIT System Development

The software development team consisted of three developers and a business analyst, all trained in agile methods.[25] Development followed the disciplined agile delivery (DAD) methodology, which is a formal structure used by software developers to guide HIT system development from the initiation of ideas through implementation and eventual retirement.[32] The DAD methodology shares principles of approaches often used to develop interventions in health research, such as user-centered design[33] and participatory design,[34] where the stakeholder, or end user of a technology or product, is central to its design and development. Working within the DAD framework provided a clear development process for the system developers. It also provided clear time points for the research team, highlighting when findings from research activities were required by system developers to inform the next stage of development. The research team adopted a mixed-methods approach, combining surveys with qualitative interview studies and usability testing.

The DAD framework plans system development over four phases: inception, elaboration, construction, and transition. The inception phase of the project began with the team generating a working technical specification document, which outlined the planned components and functions that were initially deemed necessary for an HIT system for pain management (eg, ability for reporting of pain scores, communication between patient and health professional). During the inception phase and subsequent elaboration and construction phases, we conducted a range of research activities with patients, their caregivers, and health professionals to guide the subsequent development of the HIT system. Throughout each phase of development, the following process was followed:

1. The research team synthesized findings from its research activities for the software development team;
2. The research findings were used by software developers to update and modify the technical specification document for the HIT system; and
3. The revised technical specification document was used to update the HIT system and provide a prototype matching the revised technical specification document.

The research team used the most recent prototype during research activities with patients, caregivers, and health professionals.

Procedure for HIT System Development

Before involvement of patients with advanced cancer, caregivers, and health professionals, two preliminary activities were undertaken as part of the inception stage:

1. Assessing the quality and completeness of data captured by the QTool infrastructure; and
2. Engaging with a member of our patient and public involvement group to undertake preliminary exploration of the context and experience of patients with advanced cancer and their caregivers, alongside reviewing study documentation (Data Supplement provides details and examples of involvement).

The quality and completeness of data captured through QTool were tested using a population of people with chronic pain,[35] assessing the quality of data collected and stored by QTool.

After these preliminary activities, user engagement was structured within the four phases of DAD methodology: inception, elaboration, construction, and transition. Figure 1 outlines the different stages of development; methods applied at each stage, including participant numbers; and citations for research activities across the inception, elaboration, and construction phases that have been published previously.[21,35-38] At the end of each phase, research activities were summarized by the health researchers and outlined in a spreadsheet, with actions for the research team and proposed software development changes that aligned with the needs and preferences of patients, caregivers, and health professionals. Software requirements were documented and discussed with the software developers to determine how these translated into appropriate adaptations to QTool. Software developers then used a final list of requirements to develop another iteration of the HIT system using QTool.

The final system, called PainCheck, was evaluated as part of a pragmatic multicenter randomized controlled trial. A full protocol for the trial has been published.[29] Patients were recruited from six of the eight participating oncology clinics across the United Kingdom who met the eligibility criteria (outlined in the transition section of Table 1). A process evaluation was undertaken during this stage as part of the trial. This involved semistructured interviews being conducted at 6 or 12 weeks postrandomization with patients with advanced cancer and community palliative care (CPC) nurses (sampling approaches are outlined in the Data Supplement). Interviews sought to gather perspectives on the implementation of PainCheck to support pain management for patients with advanced cancer in the context of routine palliative care. Data collection and analysis were undertaken by the research team. Additional details of the approach to analysis are outlined in the published trial protocol.[29]

Human Investigations

The investigators performed the human investigations after approval by a local human investigations committee (National Research Ethics Service Committee Yorkshire and the Humber–South Yorkshire; 13/YH/0054). They obtained informed consent from each participant. The name of the

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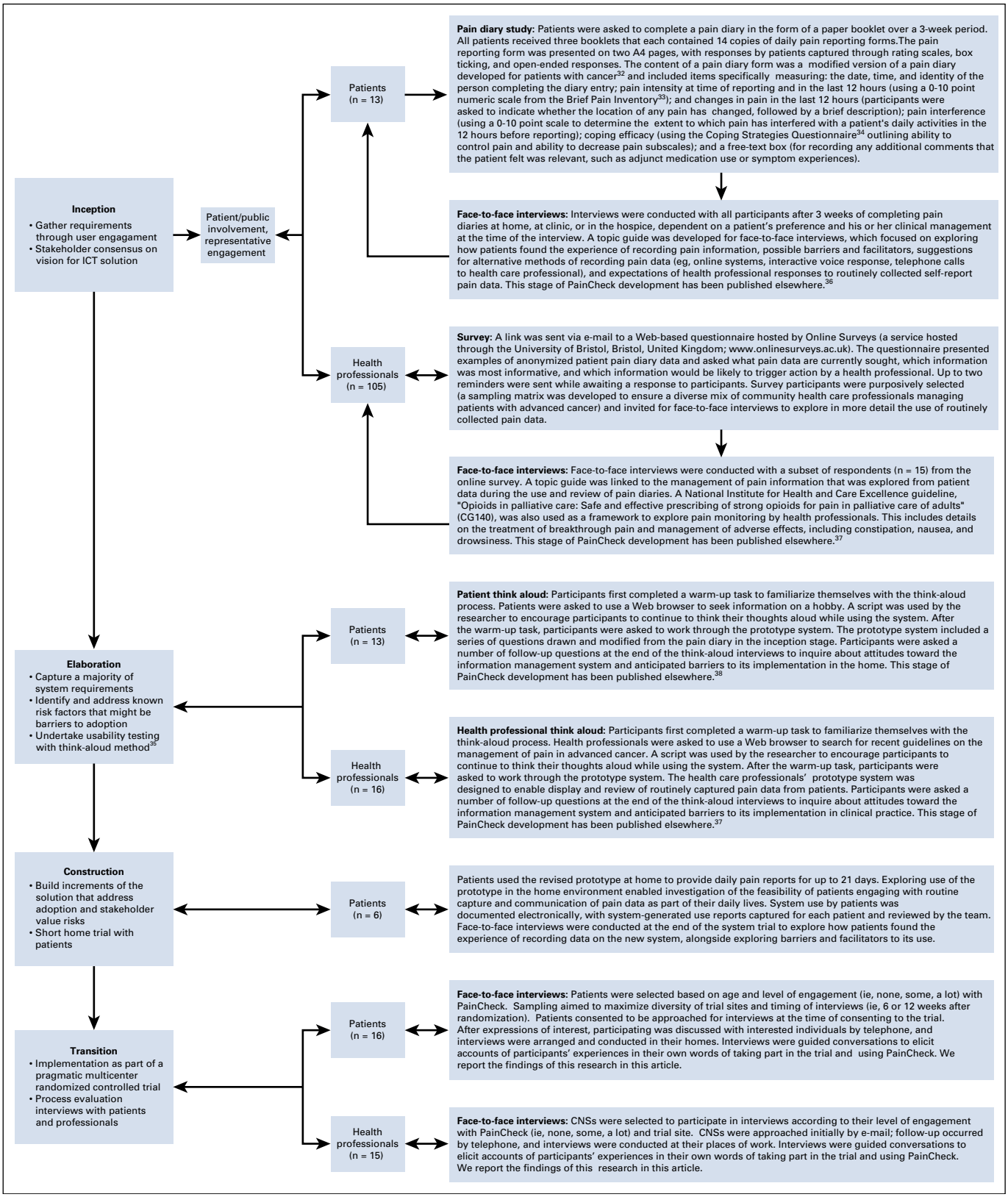

FIG 1. Overview of the methods used during the inception, elaboration, construction, and transition phases of PainCheck development. CNS, clinical nurse specialist; ICT, information and communication technology.

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TABLE 1. Definition and Details of Study Population Involved in Development of PainCheck and During Implementation Trial

Development Stage and Population	Definition
Inception, elaboration, and construction	
Patients	
Patients who were receiving palliative care, were using regular analgesics, and reported being in pain and/or suffering from pain and satisfying the inclusion criteria:	Age ≥ 18 years
	Advanced cancer and pain
	Good level of spoken and written English
	Able to provide informed consent to participate
	Patients with advanced cancer were defined as those with metastatic cancer (histologic, cytologic, or radiologic evidence) and/or those receiving anticancer therapy with palliative intent. Patients with pain were defined as those receiving analgesic treatment of cancer symptom–related pain and/or those receiving analgesics for treatment of cancer therapy–related pain.
	Participants who met inclusion criteria were identified by research nurses based in the research team who reviewed lists of patients attending an oncology outpatient department and two hospices in Leeds, UK. Patients meeting the inclusion criteria were given a recruitment letter by an oncologist or clinic/hospice day center nurse. The options to express interest in participation included telephone, e-mail, or letter. After initial recruitment, patients had the option to participate in each stage of the research, with additional recruitment taking place in response to attrition. A research nurse was consulted before recontacting patients between different phases of the study to check the health status of the patient.
Patients were excluded from the study if they:	Were unconscious or confused
	Were, in clinician's opinion, unable to understand or participate (eg, because of cognitive impairment)
	Were unable to provide informed consent
Health professionals	
Health professionals involved in different phases of the system development were community-based palliative care health professionals.	Existing e-mail lists linked to regional palliative care research and education meetings were used to invite health professionals during the different phases, although members of an initial cohort recruited in the initial phases remained involved in subsequent phases. Clinical nurse specialists were involved in a final, qualitative evaluation of PainCheck, as because they were key facilitators of its introduction and use by patients. The recruitment of clinical nurse specialists was determined by their location and the extent of PainCheck use by their patients.
Four health professional groups were included in the system development:	Clinical nurse specialists based in hospices
	Palliative care physicians
	District nurses
	General practitioners
Transition (clinical trial)	
Patients	
Inclusion criteria:	1. Male or female patient age ≥ 16 years
	2. Diagnosis of advanced incurable cancer (locally advanced or metastatic); experiencing cancer-related pain (tumor or treatment related) with a pain score of ≥ 4 on the "average pain" item of the Brief Pain Inventory
	3. Has the potential to benefit from pain management
	4. Expected prognosis of ≥ 12 weeks
	5. Living at home
	6. The patient is living in the local catchment area for a participating hospice
	7. The patient is able and willing to provide written informed consent

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TABLE 1. Definition and Details of Study Population Involved in Development of PainCheck and During Implementation Trial (Continued)

Development Stage and Population	Definition
Exclusion criteria:	1. Patients who are currently receiving or have previously received community palliative care support
	2. The patient has insufficient literacy, or proficiency in English to contribute to the data collection required for the research
	3. Patients will be excluded if they lack capacity to provide informed consent to this trial
	4. Patients with dominant chronic pain that is not cancer related (tumor or treatment)
Health professionals	Community palliative care nurses in a local hospice-based palliative care team

woman with cancer outlined in the Data Supplement, Barbara, was not changed, because Barbara was aware of the potential wider use of the data generated by Peter Allen, the husband and caregiver of Barbara and coauthor of this report, who agreed to its publication. This position was discussed and agreed with the local institutional ethics board of the Faculty of Medicine and Health at the University of Leeds (Leeds, United Kingdom).

RESULTS

Findings From the Inception, Elaboration, and Construction Phases

We present the findings from the inception, elaboration, and construction phases in Table 2. These outline the user requirements that were extracted from research activities undertaken at each stage of development. Although the research methods and findings have been published elsewhere, the user requirements extracted from this work have not been reported previously. For each phase, Table 2 lists the evidence generated and subsequent action by the research team and software developers.

Findings From the Transition Phase

The design and content of PainCheck were finalized before its inclusion in a pragmatic multicenter randomized controlled trial. The way in which PainCheck was introduced and used in the context of the trial is outlined in Figure 2, alongside examples of system content provided for both patients and health professionals. Full details of the intervention content have been published.[29]

In total, 47 of the 80 intervention participants were introduced to PainCheck. The key findings from the process evaluation interviews undertaken as part of the clinical trial are listed in Table 3. As shown in Figure 3, not having a computer was the most common reason for patients not to use PainCheck. Patient access to PainCheck was also influenced by health professionals, and CPC nurses had the role of facilitating and monitoring patient interaction with PainCheck. Some patients were not introduced to PainCheck to avoid what CPC nurses perceived as an unnecessary additional burden for them. For patients, a lack of familiarity with HIT or not having an Internet connection at home also influenced the perceived value and uptake of PainCheck.

A more detailed overview of the number of patients recruited to the trial, alongside the numbers of patients who engaged with the PainCheck intervention, is provided in Figure 3. Of those introduced, varying levels of engagement were identified. Across patient participants, there were those who completed no reports during the trial (n = 15), alongside those completing reports one to two times (n = 9), three to four times (n = 6), five to nine times (n = 7), 10 to 19 times (n = 5), and more than 20 times (n = 5). For those patients who completed reports, a large proportion (n = 27; 84%) used the diary function, opting to send free-text reports to their health professionals. Where patients and CPC nurses did interact through PainCheck, a range of approaches was identified. There was a mix of proactive and reactive styles of interaction by CPC nurses, accompanied by varied frequencies in the timing and extent of PainCheck use by patients. Proactive use of PainCheck involved CPC nurses reviewing patient reports to plan and manage their workload, alongside sending messages directly to patients. Reactive styles involved CPC nurses being prompted to review and interact with PainCheck when alerted by submission of reports suggesting high levels of pain were being experienced by a patient. Despite variation in use, both patients and CPC nurses who engaged with PainCheck reported benefits to overall pain management. CPC nurses saw systems like PainCheck as having a place in current practice, but they were clear that the role of PainCheck should be to enhance existing care delivery rather than replace it.

DISCUSSION

This article reports the development of an HIT system for palliative cancer care across all stages of development; to our knowledge, this has not previously been reported in systems supporting patients with advanced cancer.[21] The HIT system, PainCheck, was developed collaboratively by researchers and software developers across four phases of development. This approach combined modern system development with methodic approaches by health researchers, enabling a feasible and reproducible approach to HIT development. Involvement of patients and health professionals during each phase ensured that a focus on user needs and preferences informed the design process and that numerous problematic aspects of the system were identified and rectified. This was achieved in the context of

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TABLE 2. Overview of Key Findings From Inception, Elaboration, and Construction Phases

User Group	Evidence Generated	Actions by Research Team	Actions by Software Developers
Inception			
Patients: those with advanced cancer (n = 13) completed pain diaries for 3 weeks and participated in face-to-face interviews	1. Determined patient willingness to routinely report pain	1. Refined and developed initial requirements for system, including modes required for accessing system (Internet-based devices through Web browser and via SMS text messaging)	1. Tailored version of site developed for mobile phone display
	2. Ability to share free-text information viewed as important to patients, enabling more contextual and detailed information to be shared	2. Communicate need for free-text information to be shared by patients through system	2. Diary function developed for system, enabling patients to store daily diary notes, with option to share content with their health professional
	3. Verified pain diary items were understandable and relevant to patients; identified patient preferences for reporting pain (eg, pain descriptors preferred to pain scales alone)	3. Adapted pain diary for presentation and use in electronic format, including development of items for use in pain questionnaire	3. Built patient pain questionnaire based on research team user engagement and questionnaire development
	4. Identified patient expectations of health professionals in responding to reports of pain	4. Development of algorithms to trigger alerts for health professional when patients report high pain or low control	4. Developed health professional e-mail alert system using algorithms developed by research team
	5. Identified approaches adopted by patients when managing pain (eg, medication use and self-management approaches)	5. Developed list of evidence-based self-management approaches to describe in patient system and generated dependencies to determine which self-management approaches are displayed based on patient responses	5. Built dependencies for patient feedback relating to pain self-management approaches into system, including presentation of self-management feedback on system to be viewed by patients
	Additional: Identified variation in technology use by patients and willingness to explore its use for pain reporting Understood existing ways that technology is embedded in lives of patients Insight gained into patient experience of pain and efforts to control it		Additional: Functionality developed for SMS as route for interacting with system, providing options for mode of delivery of intervention in future testing Confirmation of technical architecture Clarified requirements on format of data when exported from system for analysis Development of vision and storyboards

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TABLE 2. Overview of Key Findings From Inception, Elaboration, and Construction Phases (Continued)

User Group	Evidence Generated	Actions by Research Team	Actions by Software Developers
Health professionals: (n = 105); included general practitioners (n = 21), cancer or palliative care specialist nurses (n = 21), district/community nurses (n = 45), and palliative care physicians (n = 23) completed online survey; a subset (n = 15) included general practitioners (n = 4), cancer or palliative care specialist nurses (n = 4), district/community nurses (n = 3), and palliative care physicians (n = 4) participated in face-to-face interviews	6. Determined how health professionals interpret and respond to routinely collected pain data	6. Developed health professional system content, including information relevant to assessment of pain, aligned with current practice and preferences	6. Built health professional user interface, work dashboard, and alerting systems to indicate when new patient reports have been submitted
	7. Identified preferences of health professionals for electronic pain monitoring system to support patients with advanced cancer	7. Developed designs of graphical displays of longitudinal pain scores as reported by patients	7. Aligned user interface presentation with existing electronic clinical record systems to align with any existing health information technology use
Elaboration			
Patients (n = 14) with advanced cancer from inception stage (n = 1), and newly recruited (n = 13)	8. Gathered feedback on system content: Confusion over terms "rescue" or "breakthrough" medication Uncertainty whether "over-the-counter medication" referred to prescription or nonprescription medicines Relevance of self-management recommendations queried, such as suggestion of having bath to support pain management where patient only has shower	8. Evaluated feedback on system content and generated recommendations for changes to system content; review of feedback sought to ensure clarity and ease of use for users; analysis of usability issues also undertaken to identify solutions to improve usability of interface	8. Refinement of content (eg, into user-friendly language) and user interface based on usability issues highlighted by patient (eg, uncertainty about how to share entries placed in diary section of system). Modified layout and content of graphs and feedback screens and limited issues reported with accessing the system
Health professionals (n = 16) comprising multiple roles (cancer or palliative care specialist nurses [n = 4], district/community nurses [n = 3], general practitioners [n = 4], and palliative care physicians [n = 5])	9. Concerns over workload pressures influencing ability to engage with system and need for a system that could be accessed by multiple health professionals from the same team	9. Review of workflow design and considerations for future implementation	9. Implementation of new workflow design to fit needs of health professionals working as teams to support multiple patients
	10. More information desired regarding specific clinical information, details about medications, contact with health professionals, and how pain had changed over time	10. Developed additional types of content that could be included and modified in health professional system	10. Additional graphing features for reviewing pain over time added Additional: Review of options for integration with medical records Full working prototypes produced for construction phase evaluation

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TABLE 2. Overview of Key Findings From Inception, Elaboration, and Construction Phases (Continued)

User Group	Evidence Generated	Actions by Research Team	Actions by Software Developers
Construction			
Patients: (n = 4) involved in home trial	11. Confirmed ease of access and use as reported by patients: Minor usability issues identified (eg, minor spelling errors in content; need to make elements of text bold to enhance readability; and reduction of two self-management feedback screens to one screen)	11. Documentation of identified usability issues and discussion with developers	11. Solution viability confirmed alongside final adjustments to content of system based on patient feedback; patient usability further refined
Clinical trials unit staff	12. Preparatory work for trial of system, including training sessions at trial sites	12. Training conducted at 11 sites, including demonstration of patient and health professional system interaction; identification of e-mail addresses and administration at each site for registration on system	12. Build of PainCheck for number of sites recruited to trial
	Additional: Identified need for additional materials to support implementation of PainCheck system	Additional: Generated instructions for patients and health professionals	Additional: Integration/migration of prototype to servers End-to-end tests of system focused on workflow management Preparations for transition

Abbreviation: SMS, short message service.

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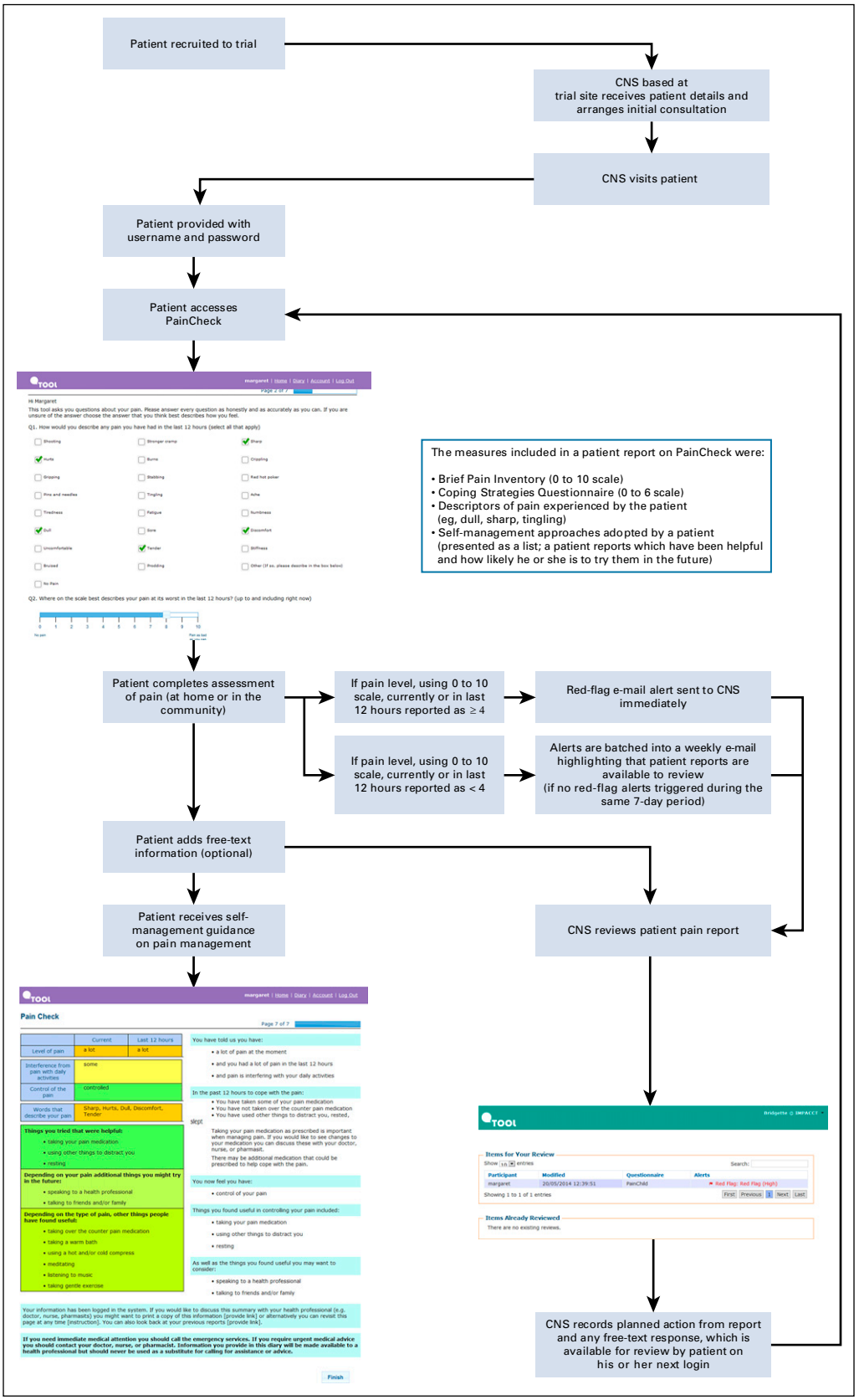

FIG 2. Schematic of PainCheck system implementation in the context of a clinical trial, with screenshots. CNS, clinical nurse specialist.

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TABLE 3. Findings From Process Evaluation Interviews

Topic	Summary	Supporting Quotes
Acceptability and access to PainCheck	Professionals were gatekeepers to patient access to PainCheck. Many professionals lacked knowledge, understanding, familiarity, and perceived expertise with system. This affected the degree to which they encouraged and facilitated patient use.	"I haven't looked at any of the electronic stuff. I could have made better use of the materials, and then if I had, I would have been more likely to encourage my patients to make better use of them." (health professional; no interaction with PainCheck during trial)
		"She was giving me some wrong information about the website; I thought it was a waste of time 'coz she didn't know what we were talking about. If she'd been up to spec on what she was supposed to be saying about it, I might have done it." (patient; prostate cancer; age group, > 61 years)
	Where professionals introduced and went through the PainCheck system during an initial appointment, patients were more likely to continue to use the system.	"When people are referred to the team when they're too poorly, this [PainCheck] can be a bit of an overload with things and it's yet another thing that you're expecting the patients to take on board, so it's just judging who can." (health professional; no interaction with PainCheck during trial)
	Professionals made judgments on the appropriateness of introducing PainCheck to some patients and sometimes did not introduce them to the system, despite patients giving consent to take part in the study; judgments were based on key factors, such as usual coping strategies, level of disease burden, and personality characteristics.	

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TABLE 3. Findings From Process Evaluation Interviews (Continued)

Topic	Summary	Supporting Quotes
Engagement with PainCheck	Professionals reported engaging with PainCheck in different ways; some used it proactively to communicate bidirectionally with patients, whereas some used it reactively as an alert system, triggering a telephone call to patient.	"We commented backwards and forwards quite a few times. If I was at my desk when an alert came, and I'd time, I'd look at it there and then, if not I just made time at the end of the day to look, but I would do that generally, I always check everything before I go home like emails and if there's anything different come in or any tasks on SystmOne you know from GPs, so it's just my way of working really." (health professional; regular user of PainCheck, interacting > 5 times)
	Some health professionals used PainCheck to provide context before they contacted a patient by telephone for an overview of how the patient had been.	"If I was going to visit a patient I'd look on the system prior to going and visiting them. I would look just before I made that phone call so I'd got an overview of what had been going on but I wouldn't check in between that." (health professional; regular user of PainCheck, interacting > 5 times)
	Patients also engaged with PainCheck in a number of different ways and frequencies, ranging from never, once or twice, weekly, or fortnightly to every day; those who completed it every day cited reasons, such as it had become part of their daily routine, or wanting to provide as much information for researchers as possible; those who completed it frequently, but not every day, cited reasons, such as they did not feel any need to complete it if they had no pain, or their pain was well controlled.	"I know I haven't done them every single day but obviously if there's something happening I do, I do go online and I do highlight it that there is for whatever reason, you know my medication's not doing what it's meant to be doing." (patient; breast cancer; age group, 41-60 years)
	Patients described the system as straightforward, easy to use, quick, user friendly, and unobtrusive and considered the system to be a simple tool to aid with monitoring their symptoms and communicating with professionals.	"It's not in any way obtrusive. It doesn't interfere with work or being at home on the evening. I liked it because it's simple, it's quick, it's easy. It's not too long, it doesn't feel too short. A simple tool is the best tool." (patient; rectal cancer; age group, 41-60 years)
	Subsequently, this improved access to pain medications, resulting in improved overall pain management; patients felt that PainCheck had increased their levels of care and provided them with a support system; patients no longer felt isolated; instead, they felt connected to and embedded within services; subsequently, they felt reassured that help was there when needed.	"I think it's that thing of being connected up and not feeling as isolated. Because it's all one big team and everybody's joined up, there seems to be a complete sort of a treatment whether it be medical or just somebody to talk to, so that's been a big help." (patient; thymus cancer; age group, 41-60 years)
	Those who had limited engagement with PainCheck were not regular users of technology or computers and often did not have or were unable to use Internet connections; they found engaging with it stressful and subsequently were not interested in integrating it into their daily lives	"Personally I couldn't do it because I'm not au fait with computers so it would have been better if you fill in a paper questionnaire. I don't even know how to turn the page. Same with mobile phones I don't have one of them either." (patient; prostate cancer; age group, > 61 years)
		"All three declined to use it, they all said to me that although they have the internet they don't use it that often, they're not that confident with it." (health professional; no interaction with PainCheck during trial)

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TABLE 3. Findings From Process Evaluation Interviews (Continued)

Topic	Summary	Supporting Quotes
Feasibility in practice	Professionals felt that there was a place for PainCheck within current practice if its usage was streamlined; some felt that it easily supported their current way of working by adding in another layer of detail, which they could use to monitor patients' pain; others felt that it enhanced care they provided because it enabled them to think about other aspects of pain management.	"I do like the attention to detail in terms of what you're asking the patient because I don't think we are that great at looking at pain from a very psychosocial way, there is a tendency to look at drugs a bit too much and not to attend to other factors, like the impact on social things, daily activities, and relationships. It brought me up short and made me think actually we really could sharpen up the way that we assess patients and their pain." (health professional; regular user of PainCheck, interacting > 5 times)
	Although digital technologies were viewed as becoming more pervasive within health care, professionals believed they would not replace their current way of working.	"I think a lot of things are going more into technology in health care… but we've not moved to the point where we would be using it as a clinical gauge and acting on it every time." (health professional; no interaction with PainCheck during trial)
Recommendations	During interviews with health professionals, a number of additional recommendations for improving PainCheck implementation were gathered from a mix of PainCheck users and those who did not interact with the system.	"Having the patient practice using it in the clinic first, give them a trial run of it, so they would know what the questions look like or know how to log in and have a practice using it 'cos most of these people were quite under confident." (health professional; no interaction with PainCheck during trial)
		"It may be helpful if relatives could have some facility to input information as well to see whether what they thought matched up with what the patient thought 'cos I suppose that's something that we kind of do informally anyway." (health professional; user of PainCheck, interacting 1-4 times during trial)
		"Some kind of supportive technology that would be quick and lightweight so that you could take round like an iPad or something would be much more usable than having to set up a laptop." (health professional; no interaction with PainCheck during trial)
		"When you can show evidence that it has worked in other areas encourages you to try it yourself. So for patients trying to show them the potential benefits of it, trying to explain how it might benefit them, or might work round their lifestyle better than getting phone calls and things." (health professional; no interaction with PainCheck during trial)
		"I think some of the wording, things like interfering with sleep and interfering with activity, is quite useful because I think that's something patients can relate to rather than just a score." (health professional; regular user of PainCheck, interacting > 5 times)
		"I don't know whether it gives like a false sense of because they're logging into it that somebody's actually monitoring it all the time." (health professional; regular user of PainCheck, interacting > 5 times)

Abbreviation: GP, general practitioner.

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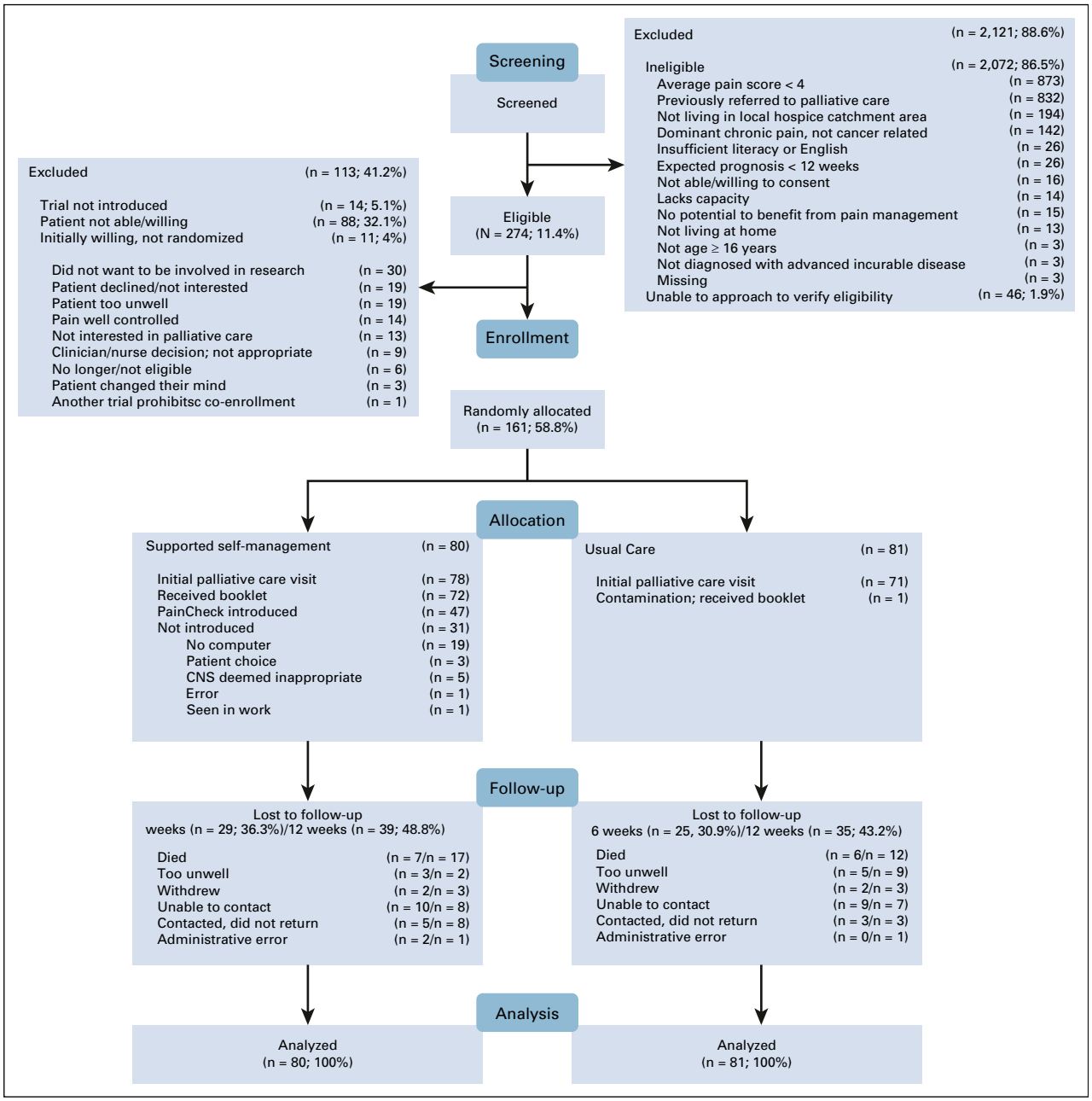

FIG 3. CONSORT diagram of participant progress through the phases of the trial and numbers of patients who engaged with the PainCheck intervention. CNS, clinical nurse specialist.

palliative care delivery, which involved multiprofessional teams and patients with advanced disease, some of whom were close to death. The documentation of our approach and the experience of PainCheck users are intended to inform future research-led development of HIT systems for palliative care. The absence of usability issues identified with PainCheck may have arisen through continuous user involvement during HIT system development.[40]

In the context of the trial, barriers to uptake of PainCheck were identified. For patients, their own familiarity with technology, alongside access to a computer and the Internet, was a barrier. For health professionals supporting the introduction and use of PainCheck in the community, barriers included a lack of confidence and familiarity with PainCheck, and HIT generally, which influenced decision making around whether they introduced the system to patients. This may have been combined with a common focus by health professionals on the vulnerability of patients, coupled with an emphasis on the duty to protect patients, when considering suitability for research.[41] Reluctance to introduce PainCheck may have also been influenced by the protocol for delivery of health professional

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training on using the system. Training occurred during site setup for the trial, often occurring months before recruitment of the first trial participant. This may have led to health professionals being less confident in the use of PainCheck. Enhancing delivery of training to ensure it occurs close to planned system use may reduce the likelihood of such gatekeeping during future implementation of PainCheck. It may also be important to emphasize the intended value and benefits of an HIT system for patients to address health professional uncertainty and concerns around its impact on patients.

Patients who engaged with PainCheck did report benefits (eg, feeling more connected with their care team, perceived improvements in pain management), but there was wide variation of interaction with the system. This highlighted the need to consider both the technology and behavioral aspects surrounding PainCheck. Use alone does not provide a valid indicator of engagement.[42] Future development will need to consider the wider context and mechanisms of action surrounding PainCheck to understand how best to measure and target improvements in engagement. This will require consideration of the complexity of the pain experience and its meaning for patients with advanced cancer.[37] Another consideration is the need to explore ways of augmenting PainCheck for patients who do not use a computer or are not familiar with HIT (ie, one quarter of trial participants in the intervention arm of the trial involving PainCheck). The rationale for developing PainCheck was to increase routine monitoring and assessment of pain using an HIT system. Future iterations of PainCheck could also explore approaches such as voice response technology to gather data by telephone, an approach that has been implemented previously for symptom management in palliative care populations.[43]

The development of PainCheck highlighted a tension between the continuous, iterative development of HIT systems by software developers and the controlled processes of formal evaluation in research. Approaches to evaluation that incorporate, for example, randomized controlled trials are only recommended when the intervention and its delivery package are stable. These can be implemented with high fidelity, and there is a reasonable likelihood that the overall benefits will be clinically meaningful (ie, improved outcomes or equivalent outcomes at less cost).[44] Within current clinical trial design, there is not sufficient scope for ongoing, iterative development of HIT-based interventions. This issue requires attention to ensure that the development and evaluation of e-health tools for cancer care keep pace with efforts to increase the use of ever-evolving HIT systems. Rightly, in this context, the demands for rigorous evidence underpinning HIT are increasing. For example, the UK Medicines and Healthcare Products Regulatory Agency classifies some software as a medical device,[45] requiring high standards of quality certification and evaluation, extending from CE marking to more formal regulation. However, although prospective exploration of user perspectives and forecasting of issues are essential during system development, these activities may identify the need for a system to be modified. The development of more nuanced experimental approaches that enable evaluation alongside ongoing and continuous adaptation of systems could facilitate simultaneous development and rigorous evaluation of HIT systems. This challenge echoes literature on the development of quality improvement interventions, with the need to reconcile pragmatism (eg, the generation of HIT systems by software developers) and research rigor (eg, understanding the underlying mechanisms of HIT interventions and the influence of contextual factors).[46] Solutions may arise in the development of trial methodology aimed at minimizing the risks of in-trial changes to intervention technologies and maximizing the potential for knowledge acquisition.[47]

This research has limitations. It was undertaken in the context of a research program with a preplanned schedule for system development. This reflects a common approach required for academic research, where methodology is often determined and fixed before obtaining funding. In this study, we had specific points for liaising with developers, and these were constrained by a predetermined budget, limiting the extent to which desired system features might be included. Furthermore, the design of the trial in which PainCheck was implemented may have inadvertently reduced uptake of the system by patients through, for example, the timing of health professional training. The resultant low uptake by patients limited our ability to fully understand factors that influenced interaction and use of PainCheck. Future evaluation of PainCheck could benefit from an alternative trial design, such as a stepped-wedge cluster design,[48] where sequential introduction of an intervention across sites may avoid long delays between site recruitment and introduction of PainCheck to trial participants.

In conclusion, the use of HIT systems to support patients with advanced cancer is a key area for improving health care and is at an early stage of development. Developing reliable, scalable HIT systems, sharing best practices, and ensuring transparency throughout system development are crucial. Although HIT and care coordination for individuals with complex needs are high priorities for quality improvement in health care, empirical guidance on its development and implementation is lacking.[49] The use of an overarching framework, borrowed from software development methodology, provided a reproducible structure to interaction and information sharing across our team. The multidisciplinary approach adopted in this research enabled cooperation between health researchers and software engineers, a crucial component in e-health design,[50] creating an intervention for a palliative cancer care clinical trial.

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AFFILIATIONS

[1]University of Leeds, Leeds, United Kingdom
[2]X-Lab, Leeds, United Kingdom

†Deceased.

CORRESPONDING AUTHOR

Matthew J. Allsop, PhD, St Gemma's Academic Unit of Palliative Care, Leeds Institute of Health Sciences, University of Leeds, Leeds, UK, LS2 9LJ; Twitter: @matthewallsop, @UniversityLeeds; e-mail: m.j.allsop@leeds.ac.uk.
†Deceased.

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AUTHOR CONTRIBUTIONS

Conception and design: Matthew J. Allsop, Owen Johnson, Sally Taylor, Michael I. Bennett, Bridgette M. Bewick
Administrative support: Michael I. Bennett
Provision of study material or patients: Peter Allen
Collection and assembly of data: Matthew J. Allsop, Sally Taylor, Peter Allen, Bridgette M. Bewick
Data analysis and interpretation: Matthew J. Allsop, Owen Johnson, Sally Taylor, Julia Hackett, Peter Allen, Michael I. Bennett, Bridgette M. Bewick
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Owen Johnson
Leadership: X-Lab
Stock and Other Ownership Interests: X-Lab
Consulting or Advisory Role: Advanced Digital Interaction Shipley
Travel, Accommodations, Expenses: X-Lab

Peter Allen
Consulting or Advisory Role: Sanofi
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Michael I. Bennett
Consulting or Advisory Role: Shionogi

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