Development of a mobile application-based system for recording pain and supporting pain management in patients with cancer

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The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

Chapter 2 reports a systematic review that has been published in a jointly authored journal paper with the following publication details:

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I conducted and led all the stages required for this work. My supervisor, Lucy Ziegler, co-participated in selecting the studies and reviewed the work conducted in other stages. The contribution of the other authors was advisory. I wrote the first draft of the manuscript and all authors contributed to and approved the final draft.

Chapter 4 reports the design of the pain recording system and includes work that has been published as a jointly authored conference paper with the following publication details:

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I conducted and led all the work reported in the paper. A supervisor, David Wong, helped review the tasks I wrote for the usability study. The contribution of the other authors was advisory. I wrote the first draft of the manuscript and all authors contributed to and approved the final draft.

Dedication

To my nuclear family, who made the journey of completing this thesis possible. Special thanks go to my husband, Mohammad, whose continued support, patience and words of encouragement have motivated me to achieve many of my goals, including this PhD. Thank you, my darling, for always believing in me.

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Abstract

Pain is one of the most common symptoms experienced by patients with cancer at all stages of the disease. It is estimated that 32% of patients who experience pain do not receive effective treatment. Many cancer patients with increasing survival rates, most of them living in the community with inadequate support, continue to experience an accumulating symptoms burden and deterioration of function. Poor cancer pain management is a multifactorial issue attributed to numerous contributing factors including insufficient pain assessment and patient-related cognitive and communication barriers. The complex and dynamic nature of cancer pain adds unique challenges to pain classification and management, presenting a pressing need for high-quality descriptive research to define optimal management approaches. Collecting pain data, however, is challenging.

The widespread use of mobile phones, along with people's attachment to their phones, has made mobile health (mHealth) approaches an innovative and timely method for remotely delivering health interventions and collecting health data. Evidence shows that mHealth applications (apps) development is an emerging area of research. mHealth interventions have been increasingly explored in the context of various chronic health conditions, showing acceptability and encouraging results, but very little attention has been given to investigating these approaches in the field of pain management in cancer patients.

As an attempt to fill this gap, this thesis presents the design, development, and early testing of a complex mHealth based intervention, the Pain Recording System, to support better pain management for UK-based adult cancer patients living in the community. The system sought to both support pain self-management and facilitate routine reporting of pain data to healthcare professionals (HCPs) and researchers. The thesis adopted the United Kingdom Medical Research Council (UK MRC) guidelines with the integration of the User-Centred Design (UCD) framework. The integrated approach enabled a systematic and iterative development and built the system to be underpinned by

evidence and theory and informed by potential users, who are patients, HCPs, and researchers. Early testing showed that the developed system is feasible and acceptable and that potential users can see the benefits they may reap from it in relation to both practice of and research into pain management in patients with cancer. Importantly, the thesis concluded that there is a potential for mHealth interventions to be effective in optimising pain management for cancer patients. Further exploration, however, is necessary to provide conclusive evidence in relation to the system's usability and acceptability, as well as to establish suitable approaches to implementation in the context of home-based palliative care.

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List of Abbreviations

APEASE	Affordability, Practicability, Effectiveness/cost-effectiveness, Acceptability, Side effects/safety, Equity
API	Application Program Interface
Apps	Mobile Applications
BCTs	Behaviour Change Techniques
BCTTv1	BCT Taxonomy Version 1
BCW	Behaviour Change Wheel
BPI	Brief Pain Inventory
BPI-SF	Brief Pain Inventory-Short Form
CFA	Confirmatory Factor Analysis
CI	Confidence Interval
CLI	Command Line Interface
COM-B	Capability Opportunity Motivation –Behaviour
COSMIN	COnsensus-based Standards for the selection of health Measurement Instruments
CPI	Cancer Pain Inventory
CRUK	Cancer Research UK
CSS	Cascading Style Sheets
DBCIs	Digital Behaviour Change Interventions
ER	Entity Relationship
GDPR	General Data Protection Regulation
GP	General Practice
HCPs	Healthcare Professionals
HI	Health Informatics
HTML	HyperText Markup Language
HTTP	Hypertext Transfer Protocol
ID	Identification Number
IDE	Integrated Development Environment
L-BASIC	Location-Based Assessment of Sensory Symptoms in Cancer
M	Mean
MARS	Mobile App Rating Scale
MAUQ	mHealth App Usability Questionnaire

mHealth	Mobile Health
MPQ	McGill Pain Questionnaire
MPQ-SF	MPQ-Short Form
MRC	Medical Research Council
MVC	Model View Controller
NCCN	National Comprehensive Cancer Network
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NRS	Numerical Rating Scales
ORM	Object-Relational Mapping
PDAs	personal digital assistants
PHP	Hypertext Preprocessor
PRISMA	The Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROMs	Patient-Reported Outcome Measures
Props	Properties
QoL	Quality-of-Life
RCTs	Randomized Controlled Trials
RN	React Native
SD	Standard Deviation
SEQ	Single Ease Question
SQL	Structured Query Language
SUS	System Usability Scale
UCD	User-Centred Design
UDID	Unique Device ID
UI	User Interface
uMARS	User Mobile App Rating Scale
UX	User Experience
VAS	Visual Analogue Scale
VRS	Verbal Rating Scales
WHO	World Health Organisation
YCCO	Yorkshire Cancer Community Organisation

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Dissemination

Multiple parts of the work presented in this thesis were disseminated and shared by the researcher in the following forms:

- Journal paper (jointly authored): 2019. PROMs for Pain in Adult Cancer Patients: A Systematic Review of Measurement Properties. Pain Practice. 19(1), pp.93-117.
- Conference poster: 2019. Development of evidence and theory-based pain self-management app for cancer patients. In: the 5th Centre for Behaviour Change (CBC) Digital Health Conference “Behaviour Change for Health: Digital and other Innovative Methods”, 9-10 April. 2019, London, UK.
- Conference poster: 2019. Development of evidence and theory-based pain self-management app for cancer patients. In: The Faculty of Medicine & Health Postgraduate Research (PGR) Conference, 17 June. 2019, Leeds, UK.
- Conference oral presentation and published paper (jointly authored): 2020. A pain recording system based on mobile health technology for cancer patients in a home setting: A user-centred design. In: 2020 IEEE International Conference on Healthcare Informatics (ICHI), 30 Nov.-3 Dec. 2020, Oldenburg, Germany. IEEE, pp.1-10.
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Chapter 1
Introduction

1.1 Chapter overview

The aim of this chapter is to present both: (1) the thesis overview, including its aim, objectives, scope, rationale and structure; and (2) the thesis background, covering the present state of key areas of literature relevant to the wider context of the thesis.

1.2 Overview of the thesis

1.2.1 Aim, objectives and scope

The overall aim of the thesis was **to systematically design and develop an evidence and theory driven, user-centred mHealth-based intervention, the Pain Recording System, to support better pain management for adult community-based cancer patients**.

In particular, the system sought to both support pain self-management and facilitate routine reporting of pain data to healthcare professionals (HCPs) and researchers.

To achieve the overall aim of the thesis, research activities were aligned to the United Kingdom Medical Research Council (UK MRC) guidelines for developing and evaluating complex interventions (Craig et al., 2013), informing the underlying objectives of the thesis. The UK MRC is a well-established framework for developing and evaluating complex interventions. It has been increasingly followed in guiding recent development of digital health and behaviour change interventions which are typically regarded as complex interventions (Walsh et al., 2018; Ross et al., 2018; Cai et al., 2017; Barker et al., 2016; Jibb et al., 2014). A complex intervention mainly involves a number of interacting components but it has other features, including a number of: (1) groups or organisational levels targeted by the intervention, (2) variable

outcomes, (3) behaviours that are targeted for change, and (4) tailored characteristics based on characteristics of those receiving the interventions (Craig et al., 2013). The MRC guidelines suggest a four-stage process that may not be a linear or even a cyclical sequence in practice: 'Development', 'Feasibility/piloting', 'Evaluation' and 'Implementation', as indicated in Figure 1 (Craig et al., 2013). The guidance highlights the importance of developing an intervention systematically. This is done by developing a theoretical underpinning through generating new, or drawing on the best existing evidence and appropriate theory and conducting a sequence of pilot studies targeted at each of the main uncertainties in the design before moving on to an exploratory and then a definitive evaluation (Craig et al., 2013). The thesis identifies and forms the first (Development) and partially the second (Feasibility/piloting) phases of the framework as shown in Figure 2. This necessitated the achievement of six research objectives, encapsulated in four main research phases, that eventually formed the thesis outcomes (see Figure 2):

Phase 1: aimed to identify the evidence and theoretical-based core contents and features of the system by accomplishing the following two objectives:

1. To identify a validated pain measure.
2. To establish the theoretical foundation of the system.

Phase 2: aimed to identify and refine the system design based on potential user needs and preferences through achieving the two objectives below:

3. To model the system functionalities.
4. To conduct usability testing.

Phase 3: aimed to develop the system through accomplishing one objective:

5. To build the system.

Phase 4: aimed to evaluate the system acceptability and feasibility through achieving one objective:

6. To test the system feasibility.

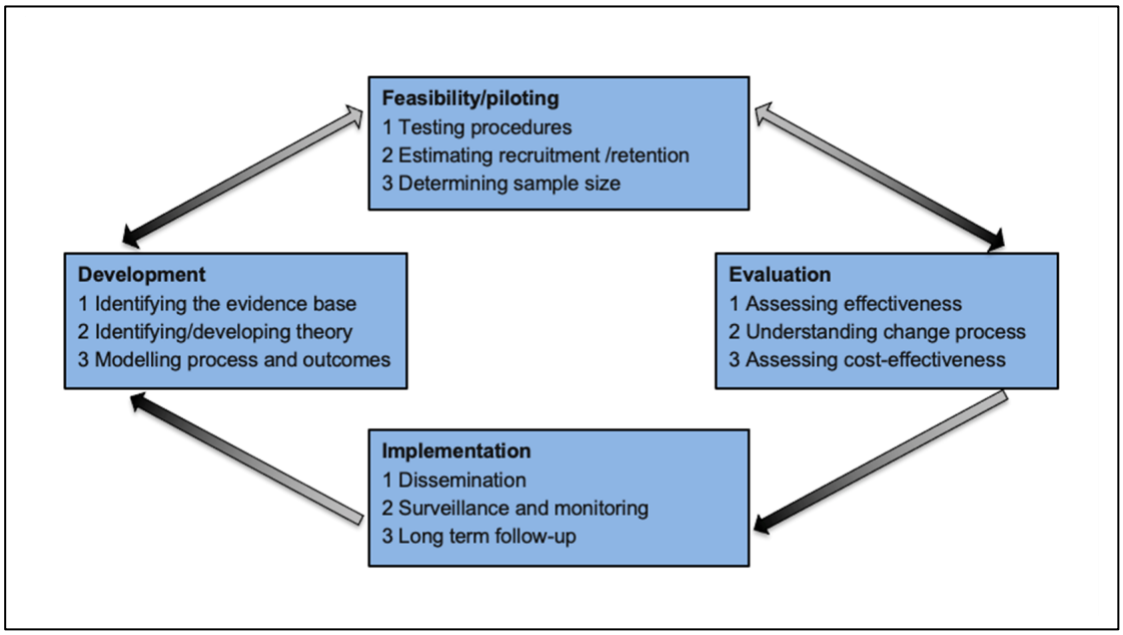

Figure 1: Key elements of the development and evaluation process of complex interventions, adapted from Craig et al. (2013, p. 589).

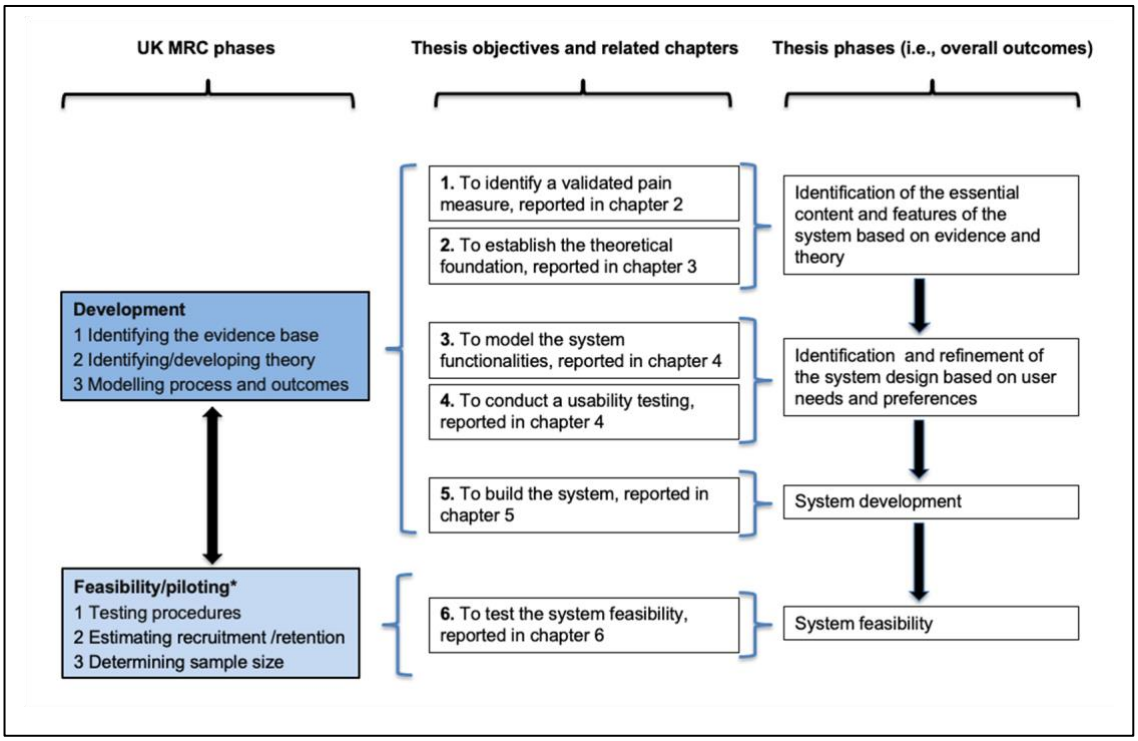

Figure 2: Research phases and the mapping thesis objectives, informed by the UK MRC framework.

*** Thesis covered the early stage of this phase.**

1.2.2 Research rationale

Pain is one of the most common symptoms experienced by patients with cancer at all stages of the disease (van den Beuken-van Everdingen et al., 2016), many of whom experience poor pain control (Bennett et al., 2019). At an international level, while there is evidence of progressive improvements in pain management from 1994 to 2013, there is also evidence that one-third of cancer patients who experience pain are undertreated (Greco et al., 2014; Deandrea et al., 2008). Poor pain assessment is considered a significant barrier to achieving effective and sufficient pain management (Kwon, 2014; Shute, 2013); therefore, routine and systematic pain assessment, including detailed documentation of pain history and medication efficacy, is emphasised by international and national pain management guidelines (Chapman et al., 2020; NCCN, 2017; Shute, 2013). Evidence suggests that measuring and documenting pain on a regular basis for inpatients improved both pain assessment and pain management (Erdek and Pronovost, 2004). In terms of the inpatient setting, hospital admissions for patients with cancer vary at different stages of the disease, from diagnosis to palliative and end of life care (Bardsley et al., 2019; Maddams et al., 2011). Routine monitoring of pain in patients with cancer is more challenging when patients are in community settings, such as their home where access to advice from cancer specialists is limited to follow-up hospital appointments. The community setting presents an opportunity for exploring the role of routine, remote monitoring of pain in patients with cancer.

Pain has a complex and dynamic nature (Hackett et al., 2016) and can originate for different reasons in patients with cancer (Pergolizzi et al., 2015). There is a need for high-quality descriptive research using prospective and longitudinal study designs to provide better insight into pain transitions and states across the cancer trajectory (Hackett et al., 2016). Collecting pain data, however, is challenging, especially in a community setting. The majority of published works present pain measurement during end-of-life or during active treatment (van den Beuken-van Everdingen et al., 2016). During these stages, patients are usually in hospital or have frequent clinical contact, facilitating pain data collection. Achieving consistent and frequent recording of pain scores is a well-known challenge within pain trials in at-home settings, due to low compliance

with the completion of pain measures and pain diaries on paper (Stone et al., 2003; Jamison et al., 2001).

An emerging evidence base for management of pain in patients with cancer relates to self-management approaches. Research evidence has shown that pain self-management interventions for cancer patients are effective for better overall pain management (Chapman et al., 2020; Howell et al., 2017; Koller et al., 2012; Bennett et al., 2009). One meta-analysis that quantified the benefit of educational interventions for patients showed a decrease in average pain intensity by 1 point on a 0–10 rating scale (Bennett et al., 2009). Mobile applications (apps) are a rapidly emerging mode for delivering health behaviour change and self-management interventions for a variety of conditions (Vollmer Dahlke et al., 2015); however, many apps lack theoretical and evidential foundations and involvement of patients and health professionals in the development stages (Vollmer Dahlke et al., 2015; Lalloo et al., 2015; Wallace and Dhingra, 2014).

In an attempt to address the mentioned issues at three levels: (i) routine assessment and monitoring of pain in community settings at the level of healthcare professional (HCP), (ii) collecting pain data at the level of researcher, and (iii) supporting pain self-management using a scholarly mobile app at the level of patient, this thesis aimed to design and develop a pain recording system utilising mHealth technology. The latter is considered an innovative and timely method for monitoring and optimising cancer pain management in the home setting (Adam and Murchie, 2014; World Health Organisation, 2011). Notably, it has shown its acceptability in various chronic health conditions (Kosse et al., 2017; Whitehead and Seaton, 2016; Irvine et al., 2015; Lakshminarayana et al., 2014), but few mHealth interventions in the field of pain management in cancer patients have been attempted with different settings (Adam et al., 2021; Jibb et al., 2017; Fortier et al., 2016). Development of this approach is still at a very early stage and the needs and preferences of users are not well understood. It warrants, therefore, further exploration of user needs and optimisation of the process of design and development which have been sought to accomplish by this thesis.

1.2.3 Thesis structure

The thesis is composed of seven chapters, including this chapter, which presents a general introduction including an overview of related literature.

Chapter 2 (phase 1) reports the systematic review of measurement properties of patient-reported outcome measures (PROMs) used to measure cancer pain. The chapter describes the rationale for conducting the review and how the latter fulfilled the first objective of the thesis. It introduces the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) framework adopted to guide the study, with a justification of its selection. Then, the results are presented and discussed including the strengths and limitations of the review.

Chapter 3 (continuing phase 1) describes the application of the Behaviour Change Wheel (BCW) framework to establish the theoretical foundation of the app which is the patient-facing components of the system. The system includes multiple components including the app and capture/sharing of data. These definitions for the app and the system are used throughout the thesis. The chapter starts by introducing the rationale for adopting the BCW framework to inform the app development. Next, it outlines the methods conducted according to the BCW guide. This is followed by analysis and discussion of the results, including a list of the behaviour change techniques (BCTs) that needed to be incorporated in the app design.

Chapter 4 (phase 2) reports the integration of the User-Centred Design (UCD) framework with the MRC guidelines to guide an iterative design and development of the system. It covers the first cycle of the framework that was intended to design the system. The chapter describes different techniques adopted to provide more insight into the system requirements and design. This included conducting a small scoping review on available pain apps, developing user personas, and modelling the system. The chapter provides a provisional design of the system based on synthesising and integrating the results from these techniques in addition to findings from studies reported in chapters 3 and 4. This is followed by a report of usability testing of system prototypes.

Chapter 5 (phase 3) describes the development of the working system prototypes establishing the second cycle of the UCD that was focused on developing the system. It explains the technical choices and the implementation process for each of the system components. The challenges encountered throughout the implementation process and how they were overcome are also discussed.

Chapter 6 (phase 4) reports on the feasibility study for the developed system prototypes as part of the second cycle of the UCD. It outlines the aim and scope of the study and the adopted methods, findings, and discussion.

Chapter 7, the final chapter, presents a general discussion of the thesis outcomes and their implications. This chapter highlights the contribution of the thesis, considering the limitations and strengths of the methods used. It then concludes with plans and recommendations for future research.

1.3 Background

1.3.1 Cancer pain

In the UK, there are around 367,000 new cancer cases every year, or around 1,000 every day, based on data collected between 2015 and 2017 (Cancer Research UK, 2021). Cancer patients are increasingly living longer, mainly due to advancements in both medical treatments and early cancer detection methods (Kamal et al., 2011; Brannon-Peppas and Blanchette, 2004). The number of patients who have survived the disease for five or more years from diagnosis has increased by over 21% in the years between 2010 and 2015 (Macmillan Cancer Support, 2019).

In patients with cancer, pain is the most common symptom at presentation that leads patients to seek medical advice and diagnosis (Schmidt, 2015). It is one of the most devastating symptoms for patients throughout the cancer stages, during which it increases in prevalence throughout and beyond cancer treatment (Besse et al., 2016; van den Beuken-van Everdingen et al., 2016).

Pain affects up to 40% of cancer survivors, whose curative treatment was completed, 55% of patients during anticancer treatment, and at least 66% of patients with advanced progressive disease (Bennett et al., 2019; van den Beuken-van Everdingen et al., 2016).

In addition, the prevalence of pain in cancer patients varies depending on the type of disease. Pain is most frequently observed in head/neck, gynaecological, gastrointestinal, lung/bronchus, breast, and urogenital cancers with a prevalence rate of 70%, 60%, 59%, 55%, 54%, 52% respectively (van den Beuken-van Everdingen et al., 2007). Meta-regression analyses found that pain prevalence in prostate cancer patients was significantly lower than in head and neck, lung, and breast cancer patients (van den Beuken-van Everdingen et al., 2016).

Symptoms of pain in cancer patients can be caused directly by a cancerous tumour (Pergolizzi et al., 2015), or by the spread of cancer, as with metastatic bone pain (Smith and Mohsin, 2013). Pain may also be caused by side effects of cancer treatments, including chemotherapy, radiotherapy, and surgery (Pergolizzi et al., 2015). Evidence shows that breast and lung cancer patients are more likely to suffer from surgery-related chronic pain (Sun et al., 2008), and chemotherapy-treated patients to suffer from chemotherapy-induced peripheral neuropathy (Pergolizzi et al., 2015). Irrespective of how pain originates, there are seven common types of pain observed in patients with cancer, as outlined in Table 1 (Pergolizzi et al., 2015).

Table 1: Common types of pains observed in patients with cancer, adapted from Pergolizzi et al. (2015, p. 779)

Type of pain	Description and associations
Acute	Pain is of short duration and may be associated with a course of treatment, surgery, or changes in the disease.
Analgesic gap	Pain occurs at the end of a dose of pain medication and may be perceived by the patient as severe sudden-onset pain.
Breakthrough	Refers to any type of severe to very severe episode of pain against an ambient background of persistent and treated pain; may occur

	spontaneously or be incident pain. Typical episodes last about 30 minutes, but breakthrough pain can last for hours.
Chronic	Persistent pain, often diffuse, secondary to the disease and/or its treatment.
Incident	Mostly movement-related pain related to a specific activity such as rolling over in bed or standing up. It is a severe, sudden exacerbation of pain against a background of lower-level ambient pain and is a common type of breakthrough pain.
Neuropathic	Sharp, shooting, burning pain, often described as “shocks” or bee stings or “pins and needles”. Often associated with numbness or tingling of the affected area. Peripheral neuropathy is a progressive condition, associated with many types of chemotherapy.
Nociceptive	Also called inflammatory pain. If it is somatic, it is described as a dull, aching pain and can be localised by the patient. If it is visceral, it is more difficult for the patient to localise and may be referred to distant sites from the source.

1.3.2 Cancer pain: nature and experience

Pain is defined as “*an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage*” (IASP, 2018). It is always a subjective experience that is influenced to variable degrees by biological, psychological, and social factors (IASP, 2018). In other words, pain perception is affected by those factors which show large inter-individual differences (Haefeli and Elfering, 2006). Evidence identified an association between cancer pain and psychological distress as well as social support (Zaza and Baine, 2002). Cancer pain has a complex nature defined by different aspects including intensity, related disability and duration (Cluxton, 2019; Haefeli and Elfering, 2006).

Cancer pain is not a static symptom and fluctuations are very common (Zhao et al., 2019; Adam and Murchie, 2014). People tend not to remember accurately at what level their pain was, as research evidence confirmed that pain intensity is poorly recalled (Linton, 1991; Linton and Melin, 1982). In addition, it has been found that the present pain experience affects and disrupts the recall of previous experiences (Haefeli and Elfering, 2006; Haas et al., 2002). Some studies revealed that prior pain level is usually overestimated when current pain is higher and underestimated when it is lower (Haefeli and Elfering, 2006;

Linton, 1991; Eich et al., 1985). Other studies reported that, in general, remembered pain intensity is overestimated (Daoust et al., 2017; Lewandowski et al., 2009; Linton and Melin, 1982). Importantly, these studies collectively suggest that retrospective pain assessment is unreliable.

1.3.3 Current state of cancer pain management

The World Health Organisation's analgesic three-step ladder is the definitive clinical principle for cancer pain management (Raphael et al., 2010). It has been used since 1986, and involves a stepwise approach to analgesic prescriptions for cancer pain, with non-opioid analgesics for mild pain, weak opioids for moderate pain, and strong opioids for severe pain (Gao et al., 2014; WHO, 1986). Despite improvements in pain management with the application of these guidelines (Azevedo Sao Leao Ferreira et al., 2006; Ventafridda et al., 1987) alongside other European guidelines, evidence shows that pain is still uncontrolled in this population (Bennett et al., 2019; Pergolizzi et al., 2015). At least 38% of cancer patients suffering from pain reported moderate to severe pain (van den Beuken-van Everdingen et al., 2016). Greco et al. (2014) updated a systematic review initially conducted by Deandrea et al. (2008) to assess the quality of pain management in adult cancer patients and revealed modest improvements in pain management, but confirmed that around one third (31.8%) of patients who experience pain do not receive pain medication proportional to their pain intensity. A more recent study even found a slightly higher rate of undertreatment, 33% (Vuong et al., 2016), but that could be attributed to the practice setting. The study utilised data collected in an outpatient palliative radiotherapy clinic where many referred patients are symptomatic and seeking pain relief.

Failure to sufficiently manage cancer pain has important consequences for both patients and healthcare systems. Presence of pain may have unfavourable effects on function and social and psychological well-being (IASP, 2018). Uncontrolled pain has a significant disabling effect on a cancer patient's daily activities and emotions, reducing quality of life (Te Boveldt et al., 2013; Kuzeyli Yildirim et al., 2005). If cancer pain is not managed promptly or adequately, it may progress to pain crisis requiring immediate intervention. Pain crisis is

known as an episode of severe and uncontrolled pain that causes significant distress to the patient and family members (Agboola et al., 2014; Moryl et al., 2008). Uncontrolled pain is the most frequent cause (33%) of community-based cancer patients requesting urgent medical help from out-of-hours primary care services in the UK (Bennett et al., 2017; Adam et al., 2014) and is one of the leading causes of their hospitalisation (Numico et al., 2015). Unscheduled hospital admissions are associated with greater healthcare costs. The total estimated annual cost for cancer patients in the United States is $12,000 per patient with breakthrough pain and $2,400 per patient with other types of pain, 90% and 88% of which respectively accounted for pain-related hospitalisation (Fortner et al., 2002).

1.3.4 Barriers to and facilitators of adequate cancer pain management

Inadequate cancer pain management is a multifactorial issue (Adam and Murchie, 2014). There is an extensive body of literature that discusses barriers to and facilitators of better pain management in patients with cancer. A combination of contributing factors and behaviours at the level of patients, HCPs and the healthcare system have been identified for cancer pain management (Kwon, 2014; Jacobsen et al., 2009a).

1.3.4.1 Patient factors

Evidence suggests that patient-related barriers form a large portion of the factors hindering effective pain management (Jahn et al., 2014; Koller et al., 2012). One of them is patient attitudes and beliefs about pain and pain treatment, known as patient-related cognitive barriers. Examples of these include misconceptions and worries about harmful and physical effects of pain medication, fatalism, and belief that the pain is untreatable (Jahn et al., 2014; Kwon, 2014). In addition, communication-related barriers with HCPs, including reluctance to report and discuss pain, are well-recognised aspects of failure to receive optimal care (Luckett et al., 2013; Potter et al., 2003).

Evidence suggests that empowering cancer patients and endorsing pain self-management have significant benefits in optimising pain management (Chapman et al., 2020; Howell et al., 2017; Koller et al., 2012). Patients need to monitor pain, obtain and take the prescribed pain medication, use non-pharmacologic pain management strategies, and finally evaluate the effectiveness of these strategies and consider adaptations if needed, by effectively communicating with their HCPs (Luckett et al., 2013; Koller et al., 2012). Research evidence has shown that the activation of self-management behaviours can reduce disease symptoms, enhance health outcomes and considerably reduce both health service consumption and related healthcare costs (Howell et al., 2017). Improvement in both the sense of control and knowledge about pain and its medications is required for effective pain management (Luckett et al., 2013; Jacobsen et al., 2010). Educational interventions for cancer patients showed a decrease in average pain intensity by 1 point on a 0–10 rating scale, according to a meta-analysis that quantified the benefit of these interventions (Bennett et al., 2009).

As part of endorsing pain self-management, there has been an increase in attention to the use of complementary and non-pharmacologic approaches in pain management, such as acupuncture and massage therapy (Erol et al., 2018; Luckett et al., 2014; Luckett et al., 2013; Potter et al., 2003). Despite a limited evidence base, some pain management guidelines include recommendations for these approaches (Chapman et al., 2020; Luckett et al., 2014). A recent practice review of the evidence supporting the use of interventions in pain management has found limited evidence supporting the effectiveness of non-pharmacologic strategies such as music therapy, but no adverse effects have been reported. Consequently, a tentative suggestion to consider them as part of a holistic management plan has been made (Chapman et al., 2020).

1.3.4.2 HCP factors

Inadequate pain assessment is the leading physician-related barrier to effective and sufficient pain management among less frequently mentioned barriers, including reluctance to administer opioids and lack of knowledge (Kwon, 2014;

Luckett et al., 2014; Shute, 2013). Assessment of pain in cancer patients is primarily clinical and is based on pattern recognition (Hearn and Higginson, 2003). International and national pain management guidelines emphasise routine and systematic pain assessment including detailed documentation of pain history and medication efficacy (Chapman et al., 2020; NCCN, 2017; Shute, 2013). Lack of longitudinal pain data frequently leads HCPs to under-prescribe or over-prescribe pain medicine, resulting in improper pain management or side-effects along with abuse/misuse of the medications respectively (Zhao et al., 2019). Screening of pain and regular review and evaluation of the outcomes of cancer pain treatment are effective in improving pain management, as shown by research evidence (Chapman et al., 2020). A study found that measuring and documenting pain every 4 hours for inpatients, including oncologic surgery patients, for 5 weeks improved both pain assessment (from 42% to 71%) and pain management (from 59% to 97%) (Erdek and Pronovost, 2004). Monitoring and recording pain regularly may be appropriate given the complex nature and unique experience of pain discussed previously (see section 1.3.2).

Self-reporting is the most recommended approach in pain assessment (Matza et al., 2012). It is considered the ‘gold standard’ in assessing pain, as it reveals the inherently subjective nature of pain (Kwon, 2014; Dworkin et al., 2005). A variety of reliable Patient-Reported Outcome Measures (PROMs) are available and recommended for assessing and measuring cancer pain (Stewart, 2014). They vary in complexity and number of measured dimensions. Some are simple and quantify only one dimension of pain, typically pain intensity, such as verbal rating scales (VRS) and numerical rating scales (NRS) (Younger et al., 2009; Holdcroft and Jaggar, 2005). Other measures are considered multidimensional, allowing a more detailed assessment of pain, such as the McGill Pain Questionnaire (MPQ) and the Brief Pain Inventory (BPI) (Younger et al., 2009). Evidence suggests that routine use of multidimensional PROMs with feedback to patients and/or HCPs in cancer care generally leads to better control of symptoms, including cancer pain (Graupner et al., 2021; Adam et al., 2017). In practice, however, these measures are rarely used and simple pain intensity scales are more frequently used (Kwon, 2014). The amount of extra administrative effort experienced by HCPs in using multidimensional PROMs is

the most likely reason they are not routinely used (Graupner et al., 2021; van Egdom et al., 2019). A study conducted in the UK indicated that there are no formal guidelines for cancer pain assessment and the majority of HCPs did not use formal assessment tools, but tended to ask patients to verbally rate their current pain (Taylor et al., 2017a).

1.3.4.3 Healthcare system factors

A number of barriers to effective pain management were identified at the level of healthcare systems. Lack of timely access to services and pain medications including opioids, due to policies and restrictions in some countries, is one of the reported issues (Kwon, 2014; Luckett et al., 2014). Importantly, the lack of effective coordination and communication across multiple providers is generally seen as a factor strongly related to inadequate pain management in cancer patients (Hackett et al., 2018; Luckett et al., 2014; Lovell et al., 2013; Kwon, 2014). Indeed, multidimensional pain control requires collaboration with different specialists, implying ease in accessing data of pain between them (Kwon, 2014; Luckett et al., 2014). Integration of care between primary and secondary care, including specialists, means that cancer patients can be safely and effectively followed up in the community (Buckland, 2016). A study reported that poor coordination caused medications to be ignored either by accident or deliberately by providers who were hesitant to prescribe opioids (Lovell et al., 2013). Out-of-hours services do not always have access to palliative care services and patients contacting the former are rarely managed by an HCP who knows them (Adam and Murchie, 2014). Patients often seek psychosocial support from community-based organisations, but little communication occurs between these organisations and the medical system (Rutledge and Robinson, 2009). Healthcare, social care and third-sector services are not always linked, which hinders optimal cancer pain management in the community (Adam and Murchie, 2014).

1.3.5 Insight into pain studies

Several issues associated with pain studies obstruct better insight into pain and pain management. Despite the extensive pain literature, designs of pain studies

are often limited to healthcare settings which limits the generalisability of the findings. For example, pain prevalence estimates usually relate to patients referred to a specific healthcare service such as a pain clinic (Hearn and Higginson, 2003). Indeed, evidence of pain prevalence in cancer patients may need to be interpreted cautiously. Generalising the prevalence rate without specifying the type or stage of cancer may not be the most appropriate or informative approach. A meta-analysis study of prevalence of pain categorised studies into groups based on the included patients and their stages of cancer or treatment. The groups were (1) patients after curative treatment, (2) patients during anticancer treatment, (3) patients at end-of-life and (4) patients in all stages (van den Beuken-van Everdingen et al., 2016). Despite the exclusion of studies conducted at pain clinics, 86% of the studies were still conducted in an outpatient setting. Certainly, patients in the identified stages are often in hospital or have frequent clinical contact. The categories in the meta-analysis study, also, support the assumption that the prevalence rate of pain, in general, at advanced stages of cancer is well reported, while for other stages it is generalised and imprecise. Thus, little is known about cancer pain prevalence or nature for early and intermediate stages and for each specific cancer type. Understanding the pain pattern and trajectories of different types of cancer via longitudinal observations may contribute to better evidence-based practices and interventions in pain management. This may involve the development of preventive strategies through targeting the stages of cancer types more likely to involve pain.

Moreover, the complexity of cancer and pain experience, along with the latter being dynamic, adds unique challenges to pain classification and management (Hackett et al., 2016). This reinforces the need for high-quality descriptive research using prospective study designs and integrating consistent patient and clinician reports to define optimal management approaches (Hackett et al., 2016; Nekolaichuk et al., 2013; Laneader et al., 2007). Achieving consistent and frequent recording of pain data, however, is a well-known challenge within pain research in home settings due to difficulty in monitoring patients remotely and low compliance with the completion of pain measures and diaries on paper (Stone et al., 2003; Jamison et al., 2001). Importantly, challenges including recruitment, retention as well as ethical and methodological issues in

conducting studies with cancer patients, in general, were well documented within the literature (Adam et al., 2021; Reid et al., 2015; LeBlanc et al., 2013; O'Mara et al., 2009; Laneader et al., 2007). On the other hand, the presence of patients within healthcare settings may facilitate recruitment and pain data collection and could explain the focus of pain studies in these settings.

1.3.6 Community-based cancer patients

In the UK, the cancer journey for an individual experiencing symptoms which are suspected to be potentially cancer related, typically starts with a visit to their general practice (GP) where diagnostic tests can be arranged and conducted. If a patient is then suspected to have cancer, a referral to a hospital is usually arranged by the GP. In the hospital, specialists including a multidisciplinary team can confirm diagnosis and start a treatment plan based on the type and stage of cancer. During the treatment period, patients usually have regular visits and check-ups in the hospital. If it is determined that a cancer is unlikely to be cured, a patient might also be referred to a palliative care team, who could be based in the hospital, in a hospice or in the community, to help with managing symptoms such as pain (NHS, 2020a; Macmillan Cancer Support, 2020a; Macmillan Cancer Support, 2020b). For patients whose cancer is potentially curable, after the treatment plan ends, patients will usually have follow-up care at the hospital or their GP practice, or both, depending on their needs. Patients might have late effects of treatment (i.e., a condition that appears after the acute phase of an earlier, causal condition has run its course) which can become permanent (Macmillan Cancer Support, 2020d). The frequency of check-up appointments depends on different things, including: the type and stage of the cancer, the type of arrangement and treatment the patient had, and the patient’s individual needs. In general, check-ups are more frequent in the first year, and then reduced and afterwards might be stopped (Macmillan Cancer Support, 2020c).

In cases of advanced cancer, also referred to as metastatic or secondary cancer, in which the cancer has spread or returned after treatment, there is less chance of a cure. However, patients with advanced cancer might still receive treatment to try and slow the progression of the cancer and to relieve symptoms

associated with it. They may receive palliative care alongside or instead of cancer treatment. As patients with cancer approach the end of their lives, they may be cared for at home, in hospital, or in a hospice (Macmillan Cancer Support, 2020b).

Indeed, the cancer care pathway is not linear and although some aspects of it are standardised such as timescales from identifying a suspected cancer to seeing a specialist, much depends on the cancer diagnosis and stage and the patients' individual circumstances such as their age and any comorbidities they may have. Studies that explored current care provided to cancer patients in the community have recognised variations in practice, dynamic and complex interaction between level of services and professionals, and, more importantly, discontinuity of care (Hackett et al., 2018; Buckland, 2016; Mitchell et al., 2016).

Significantly, as patients with cancer are living longer, there is an associated increase in symptom burden and deterioration of function. Most patients are living in the community, that is, in their own homes or care homes (Kamal et al., 2011). A national survey in England on the quality of care provided to patients approaching end of life revealed that pain is significantly less controlled for patients at home compared to inpatients and those in hospice settings (Office for National Statistics, 2014). There is, therefore, a need to explore provision of support to community-based cancer patients. Interactive communication with HCPs, for example, is deemed fundamental to improvement in care outcomes and quality of life for a patient, and this need is unmet for this population (Allsop et al., 2019; Casey et al., 2014; Nilsson et al., 2006). Evidence suggests directing effort to home-based interventions for patients with serious and chronic diseases, including cancer, as 80% of patients with life-threatening diseases prefer to be cared for and to die at home. Importantly, such interventions have been found of benefit in reducing symptom burden (Gomes et al., 2013a; Gomes et al., 2013b).

1.3.7 The potential of mHealth in cancer pain management

The continuous and rapid development of information and communication technology (ICT) worldwide has been reflected in the growth of health

informatics (HI) applications (Blumenthal and Glaser, 2007). The field of health informatics or, as it is sometimes called, health information technology (HIT) or electronic health (eHealth), refers to the application of computers and technology in healthcare settings, implying the optimal use of information with the aid of technology to improve individual health, healthcare and health-related research (Hersh, 2009). Evidence suggests that digital health technologies have the potential to facilitate and enhance the quality of communication between patients with chronic diseases and HCPs, as well as increasing patient satisfaction with treatment services and promoting quality of life (Lanzola et al., 2017; Casey et al., 2014). The National Health Service (NHS), in the UK, has ongoing efforts and plans towards a digital healthcare system, believing that technology can effectively support patients and provide high-level and cost-effective healthcare services (Wachter, 2016).

Mobile health (mHealth) is a subcategory of HI which has been defined as the use of mobile devices, such as mobile phones and personal digital assistants (PDAs), to support medical and public health practice (World Health Organisation, 2011). Indeed, the increase in the use of mobile devices and smartphones has made mHealth an innovative and timely method for delivering health interventions (World Health Organisation, 2011). This increase has occurred in parallel with the rapid increase in the number of mobile applications (apps), the main component of mHealth, that has been experienced by the mobile phone applications industry (Bert et al., 2013). A mobile app is a software application developed exclusively for use on small mobile devices such as smartphones and tablets (Wigmore, 2013). In 2021, an annual report on digital and mobile usage has revealed that 66.6% of the total global population are mobile phone users, an increase of 1.8% compared to 2020. Importantly, 95.9% of the UK population own a smartphone device, 56.0% have a tablet device, 89.3% have internet access on their mobile devices, and 77.9% are social media users, who were fewer by 4.4% in the previous year (WeAreSocial, 2021). Throughout 2020, there were 2.41 billion apps downloaded in the UK, of which 35.2% were mHealth apps: mainly fitness and nutrition apps (WeAreSocial, 2021).

Besides the accessibility and widespread distribution of mobile phones, there are other positive attributes that maximise their potential for supporting health interventions. These include increasingly powerful technical capabilities as well as individuals' attachment to their phones and tendency to carry them everywhere, unlike other personal devices such as laptops (Curtis et al., 2015; Klasnja and Pratt, 2012). In addition, mobile phones offer benefits for researchers in relation to testing and implementation, such as low cost, ease of use and low participant burden, and in relation to real-time monitoring and data collection, offering less error and improved data quality (Curtis et al., 2015; World Health Organisation, 2011).

Indeed, there is a witnessed interest and a growing body of literature on mHealth-based interventions related to a range of health conditions, with a notable focus on chronic conditions (Fiordelli et al., 2013). A systematic review aimed at studying the use of mHealth interventions indicated that the majority of the interventions relied on use of basic mobile phone functionalities such as text messaging, while a few smartphone apps were also reported (Fiordelli et al., 2013). A newer systematic review revealed that mobile apps have been increasingly reported as delivering health behaviour change interventions, and showing promising results, although primarily at feasibility and piloting stages (Payne et al., 2015). Donker et al. (2013) systematically reviewed studies that examined the effect of mental health apps and concluded from the small number of studies looked at that the apps have the potential to be effective; however, more rigorous studies are needed to confirm this. The findings from these reviews suggest that mHealth app development is an emerging area of research that has not yet been well investigated. mHealth apps have been increasingly explored, for example, in supporting self-management and medication adherence for each of the following conditions: asthma (Kosse et al., 2017), Parkinson's disease (Lakshminarayana et al., 2014), lower back pain (Irvine et al., 2015), and chronic conditions (Whitehead and Seaton, 2016). In addition, mHealth apps have been investigated in the area of smoking cessation (Tombor et al., 2016) as well as health promotion and nutrition (Curtis et al., 2015). Significantly, evidence shows that self-management interventions for patients delivered via mobile apps were effective compared with self-management interventions delivered via traditional methods or along with usual

care in chronic conditions such as diabetes and cardiovascular diseases (Whitehead and Seaton, 2016).

In oncology, and specifically in pain management, there is a potential for the digital and mHealth technologies to address many of the multilevel barriers related to optimal pain management in the community. They could support cancer patients in monitoring, recording and communicating about pain (Adam and Murchie, 2014). Given that cancer patients are experiencing different needs in terms of medical care, psychological support and practical needs of daily life, mHealth apps could help by providing access to information and health behaviour interventions that are affordable and easy to access, with personalised features suited to their specific needs (Vollmer Dahlke et al., 2015). There is, however, a paucity of evidence exploring the use of mHealth apps for improving cancer patient care and particularly for supporting pain management. This was also observed by Boceta et al. (2018), who investigated the use of an app designed for clinical use to assist HCPs in the diagnosis and monitoring of pain in cancer patients. Evidence of digital technologies usage in cancer patient care has been mainly focused on collecting PROMs for general symptoms, well-being and quality of life via web-based forms (Absolom et al., 2021; Pompili et al., 2021; Kennedy et al., 2020; Adam et al., 2021; Ashley et al., 2013). Allsop et al. (2015) conducted a systematic review on HI systems designed for supporting the management of pain in patients with cancer. The review revealed that all the identified systems were still in design and development stages, and none were reported as being implemented in clinical practice. Importantly, it found only four web-based systems designed for remote use by patients, and identified no mobile app-based systems, which are the focus of this thesis. The study found that in most of the included systems pain was captured as part of quality-of-life measurement reported by patients, to be used by HCPs without providing feedback to the patient or engaging in active forms of communication.

Putranto and Rochmawati (2020) have recently reviewed the literature to explore cancer symptom management mobile apps designed for patient use at home. A total of eleven studies were included which are related to apps developed and tested in different countries, but none in the UK. Of these, five

apps have features for assessment and symptom reporting, only two of which were designed specifically for pain management, these being oriented to children with cancer. Indeed, a recent study by Adam et al. (2021) has reported the development and testing of a mobile app for optimising cancer pain management in the community. The app was designed to be used by adult patients to complete a weekly pain diary. A diary report is automatically emailed on a weekly basis to a prespecified address related to the patient's HCP. The reported app seems to be in an early stage of development, and the study lacked clarity in relation to the type and basis of the questions used to assess pain. The author, indeed, mentioned that embedding a validated pain measurement would be a next step in improving the app. In addition, emailing HCPs weekly with pain reports may create challenges to integration in routine care. Furthermore, the study participants felt that longitudinal pain data might be more meaningful to HCPs compared to assessment at a single point.

The above literature review emphasises that the development of a mobile app-based system to report pain and support pain management for UK-based adult cancer patients living in the community, the work presented in this thesis, is significant and innovative.

1.3.8 Appraisal of available pain self-management apps

A search of the app market for any health conditions would retrieve an endless list of commercial apps. There are indeed many pain self-management apps available for download, whether designed for specific health conditions or not specified, but most of them have been strongly criticised. A number of studies reviewed these apps and revealed that the majority of them: (1) lacked a theoretical foundation, (2) lacked evidence-based and reliable content, (3) lacked scientific evaluation and clarity with regard to effectiveness regarding pain-related health outcomes, (4) lacked the involvement of users (patients) and input from HCPs in their development, (5) lacked comprehensive pain self-management functions, and (6) lacked usability and engaging features (Zhao et al., 2019; Bhattarai et al., 2018; Lalloo et al., 2017; Machado et al., 2016; Portelli and Eldred, 2016; Lalloo et al., 2015; Reynoldson et al., 2014; Wallace and Dhingra, 2014; Rosser and Eccleston, 2011). These features are required

for a high-quality pain app with understood potential in relation to its effectiveness and, in parallel, to its long-term engagement (Portelli and Eldred, 2016; Rosser and Eccleston, 2011). Zhao et al. (2019) reported that no single pain management app available in the app stores could be recommended to patients. There is a substantial concern that available commercial low-quality pain apps might mislead individuals desperate for a solution to distressing pain conditions (Rosser and Eccleston, 2011).

1.3.9 Importance of user engagement with digital health technology

A mixed methods study identified engagement from both patients and HCPs as an essential factor in the success of digital health interventions intended for remote monitoring, including mHealth apps (Salisbury et al., 2015). Research evidence described long-term engagement as a proxy for the usability, feasibility, and acceptability of an intervention (Whitehead and Seaton, 2016). Achieving this, however, is considered challenging and many well-designed studies had struggled to engage participants where compliance tends to decrease over time, according to two review studies (Maeder et al., 2015; Paré et al., 2007). In addition, a national survey in the United States about the use of mHealth apps indicated that about half of the app users has stopped using them, mainly due to loss of interest and high data entry burden (Krebs and Duncan, 2015). Both Maeder et al. (2015) and Paré et al. (2007) highlighted in their reviews that decrease in adherence or discontinuity in using a digital health intervention is a critical issue that needs to be addressed, particularly for chronic diseases where long-term monitoring is required.

Similarly, it is vitally important to ensure that digital behaviour change interventions (DBCIs) are engaging and interesting to users. This is because the amount of a user's exposure to the intervention content is entirely mediated by engagement, which is required for the intervention to be effective (Wray et al., 2019; Perski et al., 2017). Indeed, engagement with DBCIs has been distinctively defined by an integrative systematic review as a multidimensional construct where (1) the extent of usage of an intervention, as behaviour implying frequency and duration, is underpinned by (2) the user's subjective experience (UX) in interacting with the intervention, implying attention and

enjoyment (Perski et al., 2017). Evidence revealed that a variety of engagement measurements were adopted by studies investigating DBCIs. Of these, module completions and logins were identified as the most commonly reported measures of engagement and, most importantly, they were generally found to be positively associated with outcomes of DBCIs (Donkin et al., 2011).

There are several aspects discussed in the literature that need to be considered when developing digital health interventions, including DBCIs, in which long-term engagement could be maintained. Evidence suggests that actively incorporating end-users in early stages of the design and throughout the development process, as well as understanding and considering their requirements and preferences, means that the resultant products are more likely to be engaging and used by them (Majeed-Ariss et al., 2015; Velardo et al., 2017; Jibb et al., 2014). Difficulty in using a digital intervention may limit the user retention rate, so a more significant emphasis should be put on usability, that is UX. In other words, it is important to consider: the age, health condition and technological literacy of target users; lowering the data entry barrier; and iterative usability evaluation (Alwashmi et al., 2019; Triantafyllidis et al., 2017; Zapata et al., 2015). Moreover, the clearly perceived usefulness of the intervention is equally important to the ease of use which contributes to a user's motivation to continue using the intervention (Mohr et al., 2014; Hilliard et al., 2014).

1.3.10 Electronic health data collection

The advances in accessible mobile technologies have led to an abundance of data and likewise facilitated collection of health data for clinical research purposes. This is apparent from an overview of the current state of mHealth interventions provided by Triantafyllidis et al. (2017). Triantafyllidis and colleagues identified three emerging areas of research: (1) mobile phone sensing with in-built or external sensors, (2) patient self-reporting for manually captured health information, such as symptoms and behaviours, and (3) social sharing of health information within the patient's community, using popular social media such as Facebook and Twitter.

Secure and electronic data collection of disease related symptoms is an established method for reliably and validly collecting daily data for research and clinical assessment (Cai et al., 2017; Bromberg et al., 2014; Connelly et al., 2012). Studies comparing electronic and conventional, mainly paper-based, data collection methods revealed that the former are highly preferable, faster, and often associated with more complete and accurate collected data, as people showed a much higher rate of compliance with using them (Dillon et al., 2014; Lewandowski et al., 2009; Lane et al., 2006; Jamison et al., 2001). Furthermore, evidence suggests that use of paper-based diaries, which does not ensure immediate and real-time feedback, may not truly reflect adherence to self-monitoring, as patients may falsify the time and frequency of self-monitoring. This is unlike use of electronic-based diaries in which the actual time of reporting can be stamped and tracked (Yu et al., 2015; Burke et al., 2008).

Given that mobile apps are ideal for self-reporting as they are reachable (Triantafyllidis et al., 2017) and pain is captured by self-reporting, there is scope to explore use of a mobile app as a means of routine and real-time collecting of pain-related data from cancer patients participating in a pain study. To the best of the researcher's knowledge, this has not been attempted before.

1.4 Chapter summary

This chapter provided an overview of the thesis and related literature. Pain is the most common symptom experienced by cancer patients. It has a complex and multidimensional nature, and its presence has devastating effects on function and well-being. Approximately one-third of patients with cancer who experience pain are undertreated. Inadequate cancer pain management is a multifactorial issue. Poor pain assessment and patient-related cognitive and communication barriers were identified as contributing factors. Community-based patients with cancer have limited support in pain management. mHealth interventions are considered an innovative and timely method for monitoring and supporting patients remotely. They have been increasingly explored in various chronic health conditions showing acceptability and encouraging results, but very little attention has been paid to investigate this approach in the

field of pain management in cancer patients. This thesis, therefore, aimed to design and develop a mHealth-based system which sought to both support pain self-management and facilitate routine reporting of pain data to HCPs and researchers. The chapter that follows considers the first objective of the thesis, “to identify a validated pain measure” and reports the systematic review of pain PROMs as a method used to address this.

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Chapter 2
PROMs for pain in adult cancer patients: a systematic review of measurement properties

2.1 Chapter overview

This chapter addresses the first objective of the thesis, which is 'to identify a validated pain measure'. It presents a published systematic review conducted to achieve this. The study informed the selection of a pain measure that was incorporated in a mobile app as part of the intended Pain Recording System as detailed in the forthcoming Chapters.

2.2 Introduction

Patient-Reported Outcome Measures (PROMs) are recommended for assessing cancer pain (Stewart, 2014). PROMs are frequently presented as questionnaires that are completed by patients to measure health-related constructs (Gilbert et al., 2015). Various PROMs are used for assessing pain in patients with cancer, including the Brief Pain Inventory (BPI) (Chow et al., 2016; Dalton et al., 2015; Montague and Green, 2009; Cleeland and Ryan, 1994), the McGill Pain Questionnaire (MPQ) (Gauthier et al., 2014; Shin et al., 2007; Melzack, 1975), the Numerical Rating Scale (NRS) (Besse et al., 2016; Bortolussi et al., 2016; Haefeli and Elfering, 2006; Hjermstad et al., 2011), and the Visual Analogue Scale (VAS) (Cong et al., 2015; Haefeli and Elfering, 2006). As the number of measurement instruments grows, it is increasingly challenging to identify which is the most appropriate one for use in a clinical or research setting. Systematic reviews of measurement properties are useful for critically appraising and comparing the content and measurement properties of all available tools measuring a specific construct to understand their strengths and limitations and make an informed choice (COSMIN, 2017; Mokkink et al., 2009).

The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) group is a committee that aims to improve the selection

of health-related measurement instruments by forming tools and guidelines, based on international experts' consensus, for conducting or assessing a systematic review of measurement properties (COSMIN, 2017; Mokkink et al., 2016; Mokkink et al., 2009). The need for such standards was identified in 2009 through reviewing systematic review studies of health status measurement instruments. The methods used to assess the quality of the studies and the quality of the results differed widely, and the methodological quality of such reviews should be improved (Mokkink et al., 2009). The COSMIN tools include a protocol for systematic reviews of measurement instruments, a checklist to assess the methodological quality of studies, and quality criteria for measurement properties (Mokkink et al., 2016; Terwee et al., 2012; Mokkink et al., 2010b; Terwee et al., 2007; Mokkink et al., 2006). Indeed, the quality of both validation studies and their results (measurement properties) is important to appraise instruments for a health construct. If the methodological quality of a study is inappropriate, the results cannot be trusted and the quality of the instrument remains unclear (Terwee et al., 2012; Higgins and Green, 2011). Since measurement properties are essential for evaluating an instrument (Englbrecht et al., 2012; Mokkink et al., 2009), and they are not clearly defined in the literature, the COSMIN group provides international definitions (Mokkink et al., 2016; Mokkink et al., 2010c).

A systematic review of the measurement properties of the established tools for measuring pain in cancer patients is crucial to compare them and identify the best validated pain measure for this population. Very few reviews of this type have been conducted previously. Jensen (2003) conducted a review of the validity and reliability of pain measures for adult cancer patients, but it has several limitations (Jensen, 2003). The review was not systematic and is now outdated. Publications were from a three-year period only, and their methodological quality was not clearly considered. There are systematic reviews of instruments related to the holistic symptoms of cancer (Kirkova et al., 2006) and Quality-of-Life (QoL) (Bonomi et al., 2000). In both these reviews there was no rigorous assessment or any consideration of the quality of the included studies and their results. These instruments are not specific for pain in cancer patients. Indeed, QoL instruments usually measure multiple constructs and general health perceptions; and are not designed to be a specific pain

measurement instrument, although they do contain symptom items (Kirkova et al., 2006; Mokkink et al., 2009). In addition, the WHO analgesic ladder is designed specifically for cancer patients (Gao et al., 2014; WHO, 1986). This implies that treatment of cancer pain requires an approach specific to cancer patients and that cancer patients are distinct from noncancer patients in the type of pain they experience. This relates largely to the meaning of the pain; cancer pain is often interpreted as an indicator of disease progression, and the association of pain with life-threatening disease is likely to account for why pain interference is ranked higher in cancer patients compared to noncancer patients, even when pain intensity is the same (Fordyce, 2001). As a consequence, it is logical to have a specific pain tool for cancer patients.

2.2.1 Aim of the study

The aim of the current study was to systematically review the measurement properties of PROMs for pain used in adult cancer patients following the COSMIN framework and recommendations. This was required to identify the best validated measure for adoption to the intended mobile app as part of the Pain Recording System. A secondary goal was to investigate the evidence of validated mHealth apps or mobile electronic tools used to measure pain in adult cancer patients.

2.3 Methods

The systematic review (registration number CRD42017065575[1] on PROSPERO, an international database of prospectively registered systematic reviews in health and other fields produced by Centre of Reviews and Dissemination at the University of York, U.K.) was conducted according to the guidelines from the Cochrane Handbook for Systematic Reviews (Higgins and Green, 2011), in combination with the protocol for systematic reviews of measurement properties recommended by the COSMIN panel (Mokkink et al., 2016; Terwee et al., 2011).

[1] Available from: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=65575

2.3.1 Search strategy

In accordance with the Cochrane guidelines, the population, intervention, comparison, and outcome (PICO) concepts were applied to the research question. Adult (≥ 18 years of age) cancer patients were considered as the population (P); the intervention (I) was PROMs used to measure pain; the comparison (C) concept was not applicable to the research question since this would require an unmeasured arm; while the measurement properties defined by COSMIN were considered the outcomes (O) for this systematic review. There are 9 measurement properties grouped within 3 domains: reliability (internal consistency, reliability, and measurement error), validity (content validity, construct validity [or hypotheses testing], structural validity, cross-cultural validity, and criterion validity), and responsiveness (Mokkink et al., 2010c) (see Appendix 1 for definitions of properties). The criterion validity was excluded for this review since no gold standards exist either for PROM instruments (Mokkink et al., 2010a) or for measurements of pain (Hearn and Higginson, 2003; McDowell and Newell, 1996).

Medline (Ovid from 1996), Embase (Ovid from 1996), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL; EBSCO from 1981) electronic databases were searched in January 2017. An updated search was run in March 2018, just prior to the start of the intended system design and development phase. This was important to consider any new evidence that could have emerged between the time of conducting the original review and developing the system. The results reported in this chapter represent the updated and published systematic review (Abahussin et al., 2019). A search strategy was designed and performed using search terms that had been carefully specified after several consultations with a librarian and an information specialist. In accordance with the Cochrane review guidelines, a combination of index terms, such as MeSH in Medline, and free-text terms for each identified PICO concept was searched combined by the conjunction “OR.” Then, the search results for all the concepts were combined by the conjunction “AND.” To focus the search to retrieve PROM tools, the Oxford filter for PROMs developed by the PROMs Group (COSMIN, 2017; University of Oxford, 2016) was used. The search was restricted to English language publications, with no time

limitation. The detailed search strategy applied on each database is illustrated in Appendix 2. Additional papers were identified by manually searching the reference lists of the included primary studies and key review studies, as well as searching forward referencing of these studies using the Web of Science database.

2.3.2 Eligibility criteria and selection of articles

Studies were selected based on the following criteria: a published primary validation study for a PROM used to specifically measure pain that reported one or more of its measurement properties, the instrument for which was administered on adult (≥ 18 years of age) patients with a definite cancer of any type. Studies that included patients with diseases other than cancer were excluded unless the results for the cancer patients were presented separately. PROMs that were specific to certain cancer types were excluded as the review aimed to select the best pain measurement tool for the wider cancer population. PROMs that were general (i.e., measured pain within other constructs) or were indirectly related to pain (such as QoL, disease symptoms, and treatment satisfaction instruments) were excluded. Furthermore, the review excluded studies that validated measures based on measures of our interest, randomized controlled trials (RCTs), or other longitudinal studies, as recommended by the COSMIN protocol. Such studies usually provide indirect evidence, and it is difficult to assess validity or responsiveness. No hypotheses regarding the validity or responsiveness of the instrument of interest are formulated and verified in these studies (Mokkink et al., 2016; Terwee et al., 2011).

The results from the searched databases were accumulated in reference manager software (EndNote X7), where any duplicate articles were removed. The studies' titles and abstracts were scanned against the specified inclusion and exclusion criteria before the articles were read as full texts and re-examined for eligibility. The selection of studies was conducted independently through the 2 stages by 2 reviewers (AA, the researcher and LZ, the academic supervisor), and any disagreements between them were resolved through discussion.

2.3.3 Quality assessment of the studies

The methodological quality of the included studies was evaluated and rated using the COSMIN checklist, which has a 4-point rating scale (Terwee et al., 2012; Mokkink et al., 2010b). The studies were rated by AA and reviewed by LZ. The checklist consists of 9 boxes representing the 9 measurement properties defined by the COSMIN panel. Each box has 5 to 18 items describing whether a study on a measurement property meets the standard for appropriate methodological quality. A score (poor, fair, good, excellent) was given to each item based on the level of adherence to a specific standard. The overall score for each measurement property was specified by considering the lowest score awarded to any item in the checklist box associated with the property. For example, if one item in the internal consistency box was graded as poor for a study, the overall methodological quality of this property was rated as poor. Each measurement property was rated separately.

2.3.4 Quality assessment of the instruments

The quality of the measurement properties of the instrument was assessed using the modified version of the quality criteria for good measurement properties published by the COSMIN panel (COSMIN, 2017; Terwee et al., 2007). The possible ratings specified by these criteria for a measurement property are “positive,” “indeterminate,” or “negative” (see Appendix 3). The measurement properties were assessed by AA and revised by LZ.

2.3.5 Best evidence synthesis

The strength of the evidence for the measurement properties for each tool was determined by considering the following: the number of studies, their methodological quality, and the consistency and quality of the results (Mokkink et al., 2016; Terwee et al., 2011). The evidence of a measurement property was considered strong (positive or negative) when consistent findings were derived from multiple studies (at least 2) of good methodological quality, or by 1 study of excellent methodological quality; moderate (positive or negative) when consistent findings were derived from multiple studies of fair methodological quality, or from 1 study of good methodological quality; limited (positive or

negative) when findings were derived from 1 study of fair methodological quality; conflicting when conflicting results were found in 2 or more studies; and unknown when findings were derived only from studies of poor methodological quality. AA and LZ attributed the level of evidence for the tools.

2.3.6 Data extraction

Two groups of data were extracted from each study and are reported in the tables. The first group, study characteristics, encompasses general information about the study and the evaluated instrument. This includes the authors (by reference number), year of publication, characteristics of the population among which the instrument was evaluated (disease, gender, mean age, settings, country, and language), and general features of the instrument as described by the study (name, construct, number of items, and version). The second data group, instruments' measurement properties, represents the results of the measurement properties of the tool reported by the study. All the necessary data were extracted by AA and checked by LZ.

2.4 Results

2.4.1 Study selection

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram (Moher et al., 2010) in Figure 3 shows the results from the literature search and the selection process. Sixteen validation studies of pain measurement instruments met the eligibility criteria. The review did not identify any studies that used a pain measurement instrument in a smartphone or tablet app oriented to adult cancer patients.

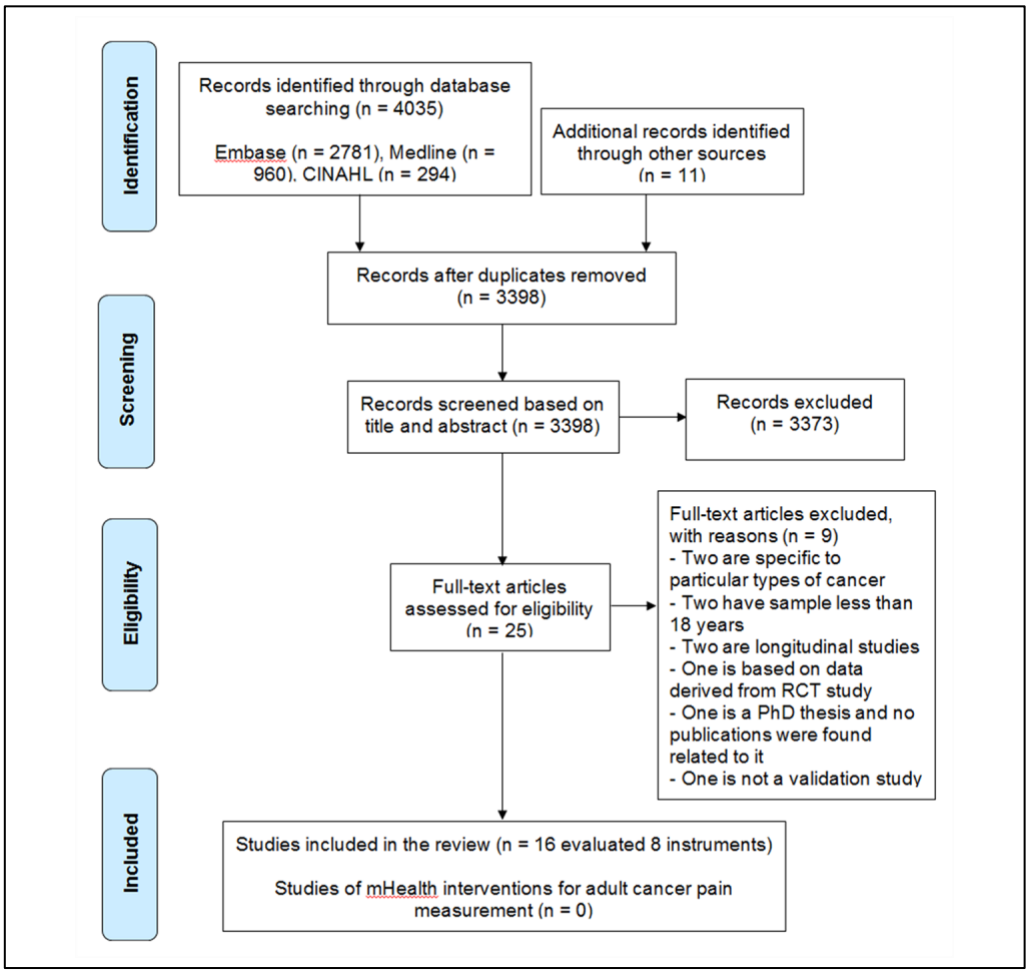

Figure 3: Preferred reporting items for systematic reviews and meta-analyses (PRISMA) diagram.

2.4.2 Study characteristics

Eight pain measurement instruments were evaluated by the included studies. The characteristics of the studies and instruments are illustrated in Table 2. Table 3 shows the results for measurement properties as reported by the studies.

Table 2: Characteristics of the identified studies

Article	Characteristics of the population						Characteristics of the tool			
	Disease	Sample size (% female)	Mean age (SD)	Settings	Country	Language	Name	Construct	Number of subscales and items	Version
(Ballout et al., 2011)	Mixed cancer diagnoses	75 adult oncology patients receiving pain treatment (44%)	Not provided 88% > 45 years	Inpatient and outpatient in departments of a major tertiary care centre in Beirut	Lebanon	Arabic	BPI	Pain	2 subscales with 15 items (severity and interference)	Arabic BPI
(Caraceni et al., 1996)	Mixed cancer diagnoses	104 cancer patients with pain (44.5%)	48.6 (not provided)	Inpatient and outpatient in the Pain Therapy and Palliative Care Division of the National Cancer Institute of Milan.	Italy	Italian	BPI	Pain	2 subscales with 15 items (severity and interference)	Italian (BQVD)

(Uki et al., 1998)	Mixed cancer diagnoses	121 patients experiencing pain (45%)	56 (not provided)	The Saitama Cancer Centre	Japan	Japanese	BPI	Pain	2 subscales with 15 items (severity and interference)	Japanese (BPI-J)
(Aisyaturridha et al., 2006)	Mixed cancer diagnoses	- 113 cancer patients with pain (37.2%) - 40 patients re-interviewed	45.7 years (±16.84)	Inpatients and outpatients at Hospital University Sains Malaysia (HUSM) and Hospital Kota Bharu (HKB), Kelantan	Malaysia	Malay	BPI	Pain	2 subscales with 15 items (severity and interference)	Malay (BPI-M)
(Ferreira et al., 2011)	Mixed cancer diagnoses	143 cancer patients with pain (61.54%)	57.3 years (±13.28)	Outpatients at Hospital das Clinicas, University of Sao Paulo	Brazil	Brazilian Portuguese	BPI	Pain	2 subscales with 15 items (severity and interference)	Brazilian (BPI-B)
(Mystakidou et al., 2001)	Mixed cancer diagnoses	220 cancer patients with pain (44%)	61.3 years (±14.84)	Patients at two Greek national cancer centres (Areteion Hospital and the Koropi Health Centre)	Greece	Greek	BPI	Pain	2 subscales with 15 items (severity and interference)	Greek (G-BPI)

(Saxena et al., 1999)	Mixed cancer diagnoses	300 cancer patients with pain (100 bilingual 40% female, 200 monolingual 55% female)	46 years (±13) for bilingual and 85 years (±12) for monolingual	Inpatients and outpatients at cancer referral centre in north India	India	Hindi	BPI	Pain	2 subscales with 15 items (severity and interference)	Hindi (BPI-H)
(Wang et al., 1996)	Mixed cancer diagnoses	147 cancer patients with pain (42%)	54 years (not provided) ranged from 18 to 86 years	Inpatients and outpatients at three cancer hospitals in Beijing.	China	Chinese	BPI	Pain	2 subscales with 15 items (severity and interference)	Chinese (BPI-C)
(Kalyadina et al., 2008)	Mixed cancer diagnoses	221cancer patients with pain (62%)	62 years (±14.1)	Inpatients and outpatients at four St. Petersburg hospitals: the City Oncological Centre (surgery, radiotherapy, and chemotherapy departments), the Russian Military	Russia	Russian	BPI-SF	Pain	2 subscales with 11 items (severity and interference)	Russian (BPI-R)

				Medical Academy (surgery, hematology, and clinical immunology departments), District Hospice No. 3, and the City Hospital No. 15, Kirovsky District (hematology unit)						
(Klepstad et al., 2002)	Mixed cancer diagnoses	235 cancer patients with pain (44.7%)	Mean and SD not provided (median = 63 years and range 29–89)	Inpatients at University Hospital of Trondheim	Norway	Norwegian	BPI-SF	Pain	2 subscales with 11 items (severity and interference)	Norwegian BPI
(Shin et al., 2007)	Mixed cancer diagnoses	119 Asian American cancer patients (82.4%)	52.2 years (±10.9)	Patients were recruited through both Internet (Web sites of the internet cancer	USA	English	MPQ-SF and BPI-SF	Pain	MPQ-SF: 2 subscales with 15 items (sensory and affective)	English MPQ-SF and BPI-SF

				support groups) and real clinical setting					BPI-SF: 2 subscales with 11 items (severity and interference)	
(Gauthier et al., 2014)	Mixed cancer diagnoses	269 advanced cancer patients with pain (%not provided)	Not provided – age ranged from 21 to ≥60	Outpatient clinics at a comprehensive cancer centre and those receiving home palliative care in Toronto, Ontario	Canada	English	MPQ-SF-2	Pain	4 subscales with 24 items (continuous, intermittent, neuropathic and affective)	English MPQ-SF-2
(Mystakidou et al., 2002)	Mixed cancer diagnoses	- 114 cancer patients with pain (49.1%) - 80 patients repeated the test	62.90 years (±10.38)	Inpatients and outpatients at the Pain Relief and Palliative Care Unit at the University of Athens	Greece	Greek	MPQ	Pain	4 subscales with 24 items (sensory, affective, evaluative, miscellaneous)	Greek (G-MPQ)
(Burkey and Kanetsky, 2009)	Mixed cancer diagnoses	- 97 Patients with pain or sensory complaints enrolled at clinic visits,	54.1 (not provided)	The Rena Rowan Breast Cancer Centre, the general oncology clinics and the	USA	English	L-BASIC	Location based sensory symptoms	4 items	English

		during a chemotherapy sessions or at presentation to the clinic. - 39 patients repeated the test.		Penn Pain Medicine Centre of the University of Pennsylvania						
(Deshields et al., 2010)	Mixed cancer diagnoses	262 patients with pain (62%)	52.1 years (±14.3)	Inpatient and outpatient from in an oncology clinic of an NCI-designated comprehensive cancer centre in a Midwestern metropolitan area	USA	English	CPI	Pain concerns	5 subscales with 19 items (Catastrophizing, Interference, Stoicism, Social Aspects, and Pain Medication)	English
(Maunsell et al., 2000)	Mixed cancer diagnoses	98 Ambulatory advanced cancer patients (50%)	56.7 years (±11.6)	Two hospital-based oncology clinics in Quebec City, Quebec	Canada	French	Brief 4-week pain diary	Pain	7 items in two sections: 1- Pain indicators: pain intensity and the number of opioid rescue doses, 2- Pain impact of	French

									quality of life indicator (5 items)	

SD = Stander Deviation, BPI = Brief Pain Inventory, L-BASIC = Location-Based Assessment of Sensory Symptoms in Cancer, CPI = Cancer Pain Inventory, MPQ= McGill Pain Questionnaire, MPQ-SF = McGill Pain Questionnaire-Short Form, BPI-SF = Brief Pain Inventory-Short Form, NCI = National Cancer Institute.

Table 3: Measurement properties of the identified tool

Tool (version)	Article	Internal consistency	Reliability	Construct validity	Structural validity	Cross-cultural validity
BPI (Arabic)	(Ballout et al., 2011)	Cronbach alpha for the two subscales: 0.82 (severity) and 0.92 (interference)		- Positive correlation between pain now item and VAS (r = 0.68, P<0.01). - Negative correlation between pain on average and the item about relief provided by pain treatment (r = - 0.19, P = 0.10) - Higher severity scores in patients with metastases compared with those	PCA with oblimin rotation: 2 factors (1-severity explaining 11.3% and 2-interference explaining 55.8%)	Forward and backward translation method

				without metastases (5.7±1.7 vs. 4.9±1.5, P=0.02) - Significant correlation between severity and interference items (r = 0.63, no p-value provided)		
BPI (Italian)	(Caraceni et al., 1996)	Cronbach alpha for both subscales: 0.78		- Positive strong correlation between the composite score for the interference subscale and the Therapy Impact Questionnaire (TIQ) composite based on activity and affect items (r = 0.66.) - Strong correlation between composite score for severity subscale and the pain item in the TIQ (r = 0.45). No P-value provided	PAF with direct oblimin rotation: 2-factor solution (1-interference explaining 31.4 % and 2- severity explaining 14.8%)	
BPI (Japanese)	(Uki et al., 1998)	Cronbach alpha for both subscales: 0.81			PAF with non-orthogonal (oblimin) rotation: 2-factor	Forward and backward

					solution (1- interference and 2- severity) % of variance explained by each factor is not provided	translation method
BPI (Malay)	(Aisyaturridha et al., 2006)	Cronbach alpha for the two subscales: 0.81 (intensity) and 0.88 (interference)	ICC for the two subscales: 0.61 (intensity) and 0.87 (interference)	High negative correlation with KPS (r ranged from -0.52 to -0.73, P<0.001)	PAF with direct oblimin rotation: 2 factors: 1- intensity (4 items), 2- interference (7 items); total variance explained 62.1%	Forward and backward translation method
BPI (Brazilian)	(Ferreira et al., 2011)	Cronbach alpha for the two subscales: 0.91 (severity) and 0.87 (interference)		- Positive and moderate to strong correlations with MPQ, and EORTC-QLQ30 pain scale (r ranged from 0.38 to 0.90, P<0.05) - Patients with poor performance status had greater pain than those with high performance status (scores ranged from 6.20 to 6.96, vs. 4.32 to 4.95, P=0.000 to 0.007)	CFA using structural equation modelling: a model with two dimensions (severity and interference) showed a good fit to data: GFI= 0.82, CFI=0.95, NFI=0.91, NNFI=0.94 and RMSEA= 0.11	Forward and backward translation method

				- Patients with metastatic disease had higher pain than patients with local or regional disease (scores ranged from 5.26 to 6.04 vs. 4.20 to 4.28, P=0.012 to 0.042)		
BPI (Greek)	(Mystakidou et al., 2001)	Cronbach alpha for the two subscales: 0.89 (severity) and 0.85 (interference)		Positive weak to moderate correlation with KPS scale (r ranged from 0.2 to 0.4; P<0.0005 to 0.003)	PAF with nonorthogonal (direct oblimin) rotation: 2 factors 1- interference (7 items) 2- severity (4 items) explained 44% and 19%, respectively of total variance	Forward and backward translation method
BPI (Hindi)	(Saxena et al., 1999)	Cronbach alpha for the two subscales: 0.89 and 0.88 (severity) and 0.91 and 0.78 (interference) for the bilingual and monolingual samples respectively			PAF with nonorthogonal rotation: 2 factors for the bilingual sample: 1- interference (7 items) 2- severity (4 items); 3 factors for the monolingual sample: 1- severity (4 items), 2- mood-related interference (3 items), 3- activity-	- Forward and backward translation method - Alternate-form reliabilities for the two subscales in the English

					related interference (3 items) % of variance explained by each factor is not provided	and Hindi version are 0.88 and 0.95 - The factor structure is similar across both versions
BPI (Chinese)	(Wang et al., 1996)	Cronbach alpha for the two subscales: 0.89 (severity) and 0.92 (interference)		- Positive moderate correlation with ECOG performance status (r 0.33, P<0.05) - Strong correlation between pain severity and greater pain interference (r 0.60, P<0.05)	PAF with oblimin rotation: 2 factors 1- interference (7 items) 2- severity (4 items) both explained 72% of total variance	Forward and backward translation method
BPI-SF (Russian)	(Kalyadina et al., 2008)	Cronbach alpha for the two subscales: 0.93 (severity) and 0.95 (interference)		- Patients with poor performance status had greater pain than patients with good performance status (scores ranged from 3.2 to 3.6 vs. 1.5 to 1.7, P<0.001)	PAF with direct oblimin rotation: 2 factors 1- interference (7 items) 2- severity (4 items) explained 73.5% and 6.5%, respectively of total variance	Forward and backward translation method

BPI-SF (Norwegian)	(Klepstad et al., 2002)	Cronbach alpha for the three subscales: 0.87 (severity), 0.92 (physical interference) and 0.91 (psychological interference)		Positive strong correlations with intensity and influence items in EORTC-QLQ30 (r ranged from 0.62 to 0.70; P<0.001)	PAF with oblimin rotation: 3-factor model:1- physical interference (3 items), 2- psychological interference (4 items), 3- pain severity (4 items) explained 82% of total variance	Forward and backward translation method
BPI-SF and MPQ-SF (English)	(Shin et al., 2007)	Cronbach alpha for total scale: 0.94 for the MPQ-SF, and 0.97 for the BPI-SF		- Positive moderate correlation between the total pain scores from the MPQ-SF and the BPI-SF and the usage of pain medications (r = 0.25 and 0.42 respectively, P<0.01) - Higher mean total pain scores in the pain medication group than the no pain medication group for the MPQ-SF (9.30, 3.86) and the BPI-SF (48.00, 20.56) - For MPQ-SF, the differences of the total scores and the sensory dimension scores	PCA with varimax rotations: - 2 factors for MPQ-SF: 1- sensory (11 items explaining 57.06 % of the variance), 2- affective (4 items explaining 8.66 of the variance) - 2 factors for BPI-SF:1- sensory (4 items explaining 71.96 % of the variance), 2- reactive (7 items explaining 10.35 % of the variance	

				between the two groups were not significant		
MPQ-SF-2 (English)	(Gauthier et al., 2014)	Cronbach alpha for total scale: 0.89 for younger group and 0.93 for older group		- For both groups, positive strong correlation with BPI average pain (r=0.67, 0.55, P≤0.01) - Moderate correlation with CES-D (r=0.27, 0.35), negative with Pain Relief (r=-0.34, -0.30) and with SF-36 physical health QOL (r=-0.23, -0.32) and with KPS (r=-0.25, -0.29) all at P≤0.01	CFA using SEM with maximum likelihood estimation: Model fit assessed with the SRMR =0.09, RMSEA =0.07, CFI=0.77, TLI=0.74 and AIC=927.39	
MPQ (Greek)	(Mystakidou et al., 2002)	Cronbach alpha for the descriptor scale 0.96	Positive weak to moderate correlation between pre and post treatment for PRI, PPI and NWC in the scale items (r ranged from 0.23 to 0.44; P 0.0005 to 0.045)	- Positive moderate to strong correlation between PRI, PPI and NWC in the scale items (r ranged from 0.42 to 0,92; P<0.0001) - Significant difference (P<0.005) between pre-treatment and post-treatment scores except for the PRI-evaluative item	PCA with varimax rotation: 2 factors: 1-sensory, affective and evaluative, 2-miscellaneous; explained 75% and 20.2% of total variance respectively	Forward and backward translation method

				- Significant difference (P<0.05) on the scale scores between patient with different performance status		
L-BASIC (English)	(Burkey and Kanetsky, 2009)	Cronbach alpha for total scale: 0.74	- Using Kappa statistic, good strict and relaxed agreement of location (k=0.76; 95% CI=0.66-0.86) and descriptor categories (k=0.80; 95% CI=0.70-0.89) used by a given patient without clinical change (n 32) at the two time points (interval median=14 days) - strong correlation between intensity values (r=0.72) and unpleasantness values (r=0.66) for 109 concordance body parts reported at test retest	- Significant correlation between the global body score and every item on the BPI pain (r range: 0.47-0.61) and functional interference subscales (r range: 0.22-0.49). - Significant correlations between worst body part score and every BPI item pain subscale item (r range: 0.54-0.60) and functional interference subscale item except pain-related interference with appetite (r range: 0.35-0.53) - Only a significant correlation between worst body part score and the pain item on the physical well-being		

			- Moderate correlations for the number of adjectival descriptors used per body part (r=0.48) and the mean adjectival descriptor severity weights (r=0.31) between test and retest. - Fair strict body part-to-body part agreement of adjectival descriptor categories used to score the 109 matched regions between the two time points (k=0.56; 95% CI=0.50-0.62)	subscale (r=0.33) of the FACT-G - Difference in the sensory qualities of the three distinct clinical constructs (head and neck cancer, breast cancer related upper extremity lymphedema, and chemotherapy related neuropathy) derived from difference in frequency of descriptor category among the three (X^2=223; P<0.001) - Significant correlation with the worst, least, average, and right now pain items on the BPI (r range: 0.59-0.67) for head (n=11) and neck (n=14) patients - No significant associations with items on the BPI or FACT-G for patients with upper extremity lymphedema		

				secondary to breast cancer treatment (n=27) as well as for patients with neuropathy (n=32); no r or P values provided.		
CPI (English)	(Deshields et al., 2010)	Cronbach alpha for total scale: 0.82, for the five subscales: 0.82 (Catastrophizing); 0.70 (Interference with Functioning); 0.62 (Stoicism); 0.51 (Social Aspects); and 0.63 (Pain Medication).		-Moderate correlations between the CPI subscales and each the measures of pain (BPI: r=0.38 for severity and r=0.45 for interference), pain disability (PDI: r=0.42), and depressed mood (CES-D: r=0.55) for all P<0.01. - Strong correlation between the CPI Interference subscale and each of the SOPA Disability subscale (r=0.6), the BPI Interference subscale (r=0.53), and the PDI Sum score (r=0.56) for all P<0.01. - Multiple positive correlations between	PCA with varimax rotation: 5 factors: 1-Catastrophizing (25.7% of variance), 2-Interference (10.4% of variance), 3-Stoicism (7.5% of variance), 4- Social Aspects (6.5% of variance), and Pain Medication (5.9% of variance)	

				Catastrophizing subscale and measures of disability and distress (r=0.45,0.48,0.40; P<0.01) and strongly negative correlation with expectations for a medical cure (r=-0.40; P<0.01) - Positive and moderate correlation between the Social Aspect subscale and the Depression measure (r=0.39) and negative with expectations for a medical cure (r=-0.18) P<0.01 -In general, low correlation between the Stoicism and Medication subscales and the other measures subscales (r ranged from 0.0 to 0.24) - A significant difference between inpatients (mean=2.08) and outpatients (mean=1.74) scores for the CPI		

				subscale measuring interference with functioning (P<0.05) - A significant difference between patients reporting higher pain (≥4 on BPI) (HP) from patients with lower levels of pain (LP) in scoring significantly higher on each of the CPI subscales: Catastrophizing (HP =2.24, LP=1.75, P<0.001), Interference (HP =2.35, LP=1.69, P<0.001), Stoicism (HP =2.26, LP=2.05, P<0.05), Social Aspects (HP =1.76, LP=1.50, P<0.001), Pain Medication (HP =2.15, LP=1.87, P<0.05)		
Brief 4-week pain diary (French)	(Maunsell et al., 2000)	Cronbach alpha for the pain quality of life impact indicator ranged from 0.87 to 0.92		- Positive strong correlations between pain intensity and both rescue doses and pain impact on quality of life indicators (r		

				ranged from 0.64 to 0.73 in Weeks 1–4, P <0.01) - Significant difference between patients' pain levels in relation to change in pain impact on quality of life indicators (p value ranged from 0.0004 to 0.05) - Positive correlation between each of: pain intensity, rescue doses, and pain impact on quality of life and the EORTC-QLQ30 symptom scales (r ranged from 0.30 to 0.73; P<0.01) (with the exception of appetite loss); and negatively correlated with the EORTC-QLQ30 functioning scales (r ranged from -0.26 to -0.62; P <0.05)		

The measurement error, content validity and responsiveness properties were deleted from the table because they were not evaluated by any study.
BPI = Brief Pain Inventory, PCA = Principal Component Analysis, CFA = Confirmatory Factor Analysis, L-BASIC = Location-Based Assessment of Sensory Symptoms in Cancer, FACT-G: Functional Assessment of Cancer Therapy-General, CPI = Cancer Pain Inventory, CES-D = Centre for Epidemiological Studies—

Depression scale, PDI = Pain Disability Index, SOPA = Survey of Pain Attitudes, MPQ-SF = McGill Pain Questionnaire-Short Form, SEM = Structural Equation Modelling, SRMR = Standardized Root Mean Square Residual, RMSEA = Root Mean Square Error of Approximation, CFI = Comparative Fit Index, TLI = Tucker-Lewis Index, AIC = Akaike Information Criterion, KPS = Karnofsky Performance Status, EORTC-QLQ30 = the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire, BPI-SF = Brief Pain Inventory-Short Form, PAF = Principal Axis Factor analysis, ICC = Intraclass Correlation Coefficient, MPQ = McGill Pain Questionnaire, GFI = Goodness- of-fit index, NFI = Normed Fit Index, NNFI = Non-normed fit index, CFI = Comparative fit index, RMSEA = Root-mean-square error of approximation, PPI = Present pain index, PRI = Pain rating index, NWC = Number of words chosen, ECOG = Eastern Cooperative Oncology Group, TIQ = Therapy Impact Questionnaire, VAS = Visual Analogue Scale, CI = Confidence Interval.

2.4.3 Study methodological quality and result quality

The ratings of the methodological quality of the studies and the quality of the results per measurement property and instrument are reported in Table 4. The strength of the evidence for each property per instrument is shown in Table 5. Summaries are provided in the ensuing subsections

Table 4: Methodological quality of the studies and quality of results reported per measurement property and tool.

Tool	Article	Internal consistency		Reliability		Construct validity		Structural validity		Cross-cultural validity	
		M	Q	M	Q	M	Q	M	Q	M	Q
BPI	(Ballout et al., 2011)	Poor	+			Poor	+	Poor	-	Poor	?
	(Caraceni et al., 1996)	Good	+			Poor	+	Fair	-		
	(Uki et al., 1998)	Good	+					Fair	?	Poor	?
	(Aisyaturridha et al., 2006)	Excellent	+	Poor	-	Fair	+	Excellent	?	Poor	?
	(Ferreira et al., 2011)	Fair	+			Fair	+	Fair	-	Poor	?
	(Mystakidou et al., 2001)	Fair	+			Poor	+	Fair	-	Poor	?
	(Saxena et al., 1999)	Fair	+					Fair	?	Poor	?
	(Wang et al., 1996)	Fair	+			Poor	+	Fair	?	Poor	?
BPI-SF	(Kalyadina et al., 2008)	Fair	+			Poor	+	Fair	+	Poor	?
	(Klepstad et al., 2002)	Good	+			Fair	+	Good	?	Poor	?
	(Shin et al., 2007)	Fair	?			Fair	+	Fair	+		
MPQ-SF	(Shin et al., 2007)	Fair	+			Fair	-	Fair	+		
MPQ-SF-2	(Gauthier et al., 2014)	Excellent	+			Fair	+	Excellent	-		

MPQ	(Mystakidou et al., 2002)	Poor	-	Fair	?	Poor	+	Poor	-	Poor	?
L-BASIC	(Burkey and Kanetsky, 2009)	Fair	+	Fair	+	Poor	+				
CPI	(Deshields et al., 2010)	Fair	+			Fair	+	Fair	-		
Brief 4-week pain diary	(Maunsell et al., 2000)	Poor	+			Fair	+				

The measurement error, content validity, and responsiveness properties were deleted from the table because they were not evaluated by any study.
M = Methodological quality of the study was rated as excellent, good, fair or poor; Q = Quality of the results were rated as + (positive rating), ? (indeterminate rating), or – (negative rating); BPI = Brief Pain Inventory, L-BASIC = Location-Based Assessment of Sensory Symptoms in Cancer; CPI = Cancer Pain Inventory; MPQ-SF = McGill Pain Questionnaire-Short Form; BPI-SF = Brief Pain Inventory-Short Form.

Table 5: Evidence synthesis of the measurement properties of the cancer pain measurement tools.

Tool	Internal consistency	Reliability	Construct validity	Structural validity	Cross-cultural validity
BPI	+++	?	++	--	?
BPI-SF	++	NA	++	++	?
MPQ-SF	+	NA	-	+	NA
MPQ-SF-2	+++	NA	+	---	NA
MPQ	?	?	?	?	?
L-BASIC	+	+	?	NA	NA
CPI	+	NA	+	-	NA
Brief 4-week pain diary	?	NA	+	NA	NA

+++/--- = strong positive/ negative evidence; ++/-- = moderate positive/negative evidence; +/- = limited positive/negative evidence; +/- = conflicting findings; ? = unknown evidence; NA = no information available.

Brief Pain Inventory (BPI): The BPI has 15 items and was evaluated in different languages in 8 studies (Ballout et al., 2011; Ferreira et al., 2011; Aisyaturridha et al., 2006; Mystakidou et al., 2001; Saxena et al., 1999; Uki et al., 1998; Caraceni et al., 1996; Wang et al., 1996), making it the most evaluated of all the instruments included in this review. The BPI was designed to measure the severity of pain and its impact on functioning of patients using an 11-point NRS. It also uses a drawing where patients mark the location of their pain, and asks about pain treatment and relief (Ballout et al., 2011). The majority of the studies identified 2 factors (severity and interference) for the BPI, using confirmatory factor analysis (CFA) to support structural validity. The quality of this result was rated negative because the ratio of the variance explained by the first to the second factors was < 4. This was consistent in multiple fair methodological studies (Ferreira et al., 2011; Mystakidou et al., 2001; Caraceni et al., 1996), leading to moderate negative evidence for structural validity. Indeed, the BPI structure validity was reported by an excellent

methodological study (Aisyaturridha et al., 2006), but the findings were rated as indeterminate, as the percentage of variance explained by each factor was not provided. Therefore, this result was ignored for evidence synthesis. The evidence for construct validity was moderately positive. Cross-cultural validity for the BPI was reported only by poor methodological studies (Ballout et al., 2011; Ferreira et al., 2011; Aisyaturridha et al., 2006; Mystakidou et al., 2001; Saxena et al., 1999; Uki et al., 1998; Wang et al., 1996), which had no multiple group CFA or differential item functioning. The quality of the findings was indeterminate in all the studies for the same reason. This resulted in unknown evidence for the BPI's cross-cultural validity. In terms of the BPI's reliability, only 1 study (poor methodological) (Aisyaturridha et al., 2006) reported test-retest reliability. This means there is unknown evidence for the BPI's reliability property. On the other hand, internal consistency was addressed in all 8 studies and showed strong positive evidence.

BPI-Short Form (BPI-SF): The BPI-SF has 11 items and was assessed in 3 studies (Kalyadina et al., 2008; Shin et al., 2007; Klepstad et al., 2002). It has the same 2 subscales as the BPI. This was confirmed by moderate positive evidence for structural validity. The latter was rated as positive (unlike the full version) because the first factor accounted for more than 20% of the variability, and the ratio of the variance explained by the 2 factors was > 4. Evidence for cross-cultural validity was unknown, as was the case with the original version. Assessment of construct validity and internal consistency properties showed moderate positive evidence.

McGill Pain Questionnaire (MPQ): One study (Mystakidou et al., 2002) assessed the MPQ and met the eligibility criteria of the review. The MPQ as described in the study has 4 subscales (sensory, affective, evaluative, and miscellaneous) with 24 items. The methodological quality for almost all the evaluated measurement properties was rated poor mainly because the sample size (N = 114) was inadequate (i.e., not > 7 times the number of items). This gave unknown evidence for these properties (see Table 5).

MPQ-Short Form (MPQ-SF): The MPQ-SF was validated in 1 study and has 2 subscales (sensory and affective) derived from the original MPQ, with 15 items

(Shin et al., 2007). It was unclear how missing items were handled through the analyses of this study, so the methodological quality for the evaluated measurement properties were rated as fair. There was limited positive evidence for internal consistency and structural validity and limited negative evidence for construct validity.

MPQ-SF-2: The MPQ-SF-2 is an update of the original version (MPQ-SF) that includes neuropathic qualities in addition to the sensory and affective qualities (Gauthier et al., 2014). It has 4 subscales (continuous, intermittent, neuropathic, and affective) with 24 items. It was assessed in 1 study, which showed excellent methodological quality for both internal consistency and structural validity. The findings for the latter were rated as negative, as a number of positive rating criteria were not met, including the Tucker-Lewis index, which was < 0.95. The methodological quality of the construct validity was rated as fair in this study because no hypotheses were formulated before testing, but it is possible to deduce what was expected. The evidence synthesis of the MPQ-SF-2 resulted in strong positive evidence for internal consistency, strong negative evidence for structural validity, and limited positive evidence for construct validity.

Location-Based Assessment of Sensory Symptoms in Cancer (L-BASIC): The L-BASIC includes 4 items and was evaluated in 1 study (Burkey and Kanetsky, 2009). The study tested 3 measurement properties, with fair methodological quality for internal consistency and reliability and poor methodological quality for construct validity. It was not clear how missing data were handled, and no information was given about the measurement properties of the comparator instruments. The evidence synthesis for the L-BASIC resulted in limited positive evidence for internal consistency and reliability, and unknown evidence for construct validity.

Cancer Pain Inventory (CPI): The CPI comprises 5 subscales (catastrophizing, interference, stoicism, social aspects, and pain medication) with 19 items. Three measurement properties for the instrument were tested in only 1 study (Deshields et al., 2010), which was rated with fair methodological quality. No explanation was given of how missing data were handled. The synthesis of evidence showed limited positive evidence for both internal

consistency and construct validity and limited negative evidence for structural validity, as the ratio of the variance explained by the first to the second factor was < 4.

Brief 4-Week Pain Diary: The brief 4-week pain diary has 7 items in 2 subscales (pain and pain impact on QoL). It was evaluated in 1 study (Maunsell et al., 2000), which tested internal consistency with poor methodological quality and tested construct validity with fair methodological quality. The study was rated thus because no factor analysis was performed, and there was no explanation of how missing items were handled. The synthesis of evidence resulted in unknown evidence for internal consistency and limited positive evidence for construct validity.

2.5 Discussion

In reviewing the literature, no recent systematic review was found on the measurement properties of the increasing tools for measuring pain in cancer patients. Such type of reviews was important to make an informed choice from these tools to use in a clinical or research setting (COSMIN, 2017; Mokkink et al., 2009). The current study mainly aimed to address this need and review the validated PROMs used to measure pain in cancer patients. This provides healthcare professionals and researchers with an evidence-based selected instrument.

The review found 3,398 studies from which 3,373 studies were excluded on the title and abstract screening stage to end with 25 studies. Nine further studies were excluded at the full text screening stage due to the reasons detailed in Figure 3. Sixteen studies that evaluated 8 pain measurement instruments were included in the review. These studies were conducted in various countries, so the languages of the instruments were also heterogeneous (see Table 2). The studies and their results for the measurement properties were systematically reviewed and appraised using the COSMIN checklist and good measurement properties criteria proposed by the COSMIN group, respectively (see Table 4). The strength of evidence was identified, based on the COSMIN best evidence

synthesis guidelines, for each of the evaluated measurement properties per instrument, as shown in Table 5.

Internal consistency was assessed in all the included instruments. Construct validity and structural validity were the second most frequently evaluated measurement properties. Cross-cultural validity was evaluated in 10 studies, 7 of which were about the BPI. Reliability was addressed in only 3 instruments. The remaining measurement properties, that is, measurement error, content validity, and responsiveness, were not tested in any instrument (see Table 3). Fifty-two of the sixty methodological qualities of the evaluated measurement properties ranged between poor and fair quality. The low ratings were generally due to insufficient sample sizes, vague or not previously formulated hypotheses, lack of information regarding the handling of missing items or regarding the constructs being measured by the comparator instruments or their measurement properties, internal consistency statistics not being calculated for each subscale individually, and multiple-group CFA not being performed for translated instruments.

The evidence synthesis presented in Table 5 shows that no instrument had strong positive evidence for all the evaluated measurement properties. Therefore, no strong recommendation can be derived from the available evidence in relation to identifying a fully validated pain measurement instrument for adult cancer patients. Based on the available evidence, the BPI-SF is the best evaluated instrument, as it shows moderate positive evidence in internal consistency, construct validity, and structural validity, whereas none of the other instruments showed comparable evidence. Indeed, the full BPI and MPQ-SF-2 showed stronger positive evidence for internal consistency compared to the BPI-SF. On the other hand, the BPI showed negative structural validity as reported by several fair methodological studies; this resulted in moderate negative evidence, while the BPI-SF had moderate positive evidence. The MPQ-SF-2 also showed negative structural validity in addition to inadequate evidence for the other measurement properties, indicating that the BPI-SF has greater validity.

The results of this review should be interpreted with caution. It should not be presumed that the instruments for which it was not possible to establish adequate validity are invalid. Typically, there was insufficient evidence to establish their validity; information was missing, and the quality of the available research was inadequate. Therefore, more validation studies of better quality are needed to address all the measurement properties of the identified instruments and to reveal more about their quality.

This review did not identify any studies that used pain measurement instruments in a smartphone or tablet app for adult cancer patients, which establishes the novelty of the thesis. Based on the review, the BPI-SF was selected as the most appropriate instrument to be incorporated in an app as part of the intended Pain Recording System. The review informed the design of the app and was cited in articles related to pain care (Wong et al., 2020) and the usage of mHealth tools in palliative care (Dickman Portz et al., 2020).

2.5.1 Strengths and limitations

This systematic review was informed by Cochrane guidelines and COSMIN protocol. This approach has added to the robustness of the study. Cochrane is particularly tailored to systematic reviews of RCTs, and this study was oriented to the analysis of measurement properties. As the former is well accredited and has more structured search strategy guidelines, it was used in line with the protocol to ensure advantages of both to achieve the aim of the review. COSMIN recommends building the search strategy in combination with a search filter for finding studies on measurement properties (COSMIN, 2017; Terwee et al., 2009). However, when this was piloted, it retrieved far fewer relevant studies compared to using Cochrane guidelines for constructing the search strategy and filtering the search using the Oxford filter. This may be because the COSMIN filter for measurement properties studies is designed and validated for PubMed (Terwee et al., 2009) and is not validated for the databases used in this review (COSMIN, 2017).

Using the Oxford filter is a probable explanation for not identifying any mHealth apps using PROMs for pain. While there may be mHealth apps for pain, the filter successfully excluded them because they did not use PROMs.

This study has some limitations. The assessment of the studies and measurement properties was limited in some instances by lack of information available in some papers. In these instances, no further information was sought from the original authors. In addition, the review was restricted to English language publications only; the researcher acknowledge that validation studies may have been published in other languages, which may provide further insight into these tools.

2.6 Conclusion

Sixteen studies were identified, but within these studies there was little evidence of thorough evaluation of pain tools. Given the extent of current published evidence, the BPI-SF is the most appropriate instrument to use in the development of the Pain Recording System. More validation studies of better quality are desired.

2.7 Chapter summary

In this chapter, a published systematic review, conducted to inform the selection of pain measure to integrate in the intended app, was reported. The review was used as a method for addressing the first objective of the thesis, ‘to identify a validated pain measure’. The following chapter presents the theoretical foundation established for the app.

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Chapter 3
Establishing the theoretical foundation of the app

3.1 Chapter overview

This chapter describes the theoretical basis used to underpin and inform the design and development of the central and patient-facing component of the Pain Recording System. It covers the second objective of the thesis which is 'to establish the theoretical foundation'.

3.2 Introduction

According to the United Kingdom Medical Research Council (MRC) guidelines for developing complex interventions, a good theoretical understanding of how an intervention causes change is needed to inform its development (Craig et al., 2013). Indeed, the use, in particular extensive use, of theory and multiple behaviour change techniques (BCTs) in internet- and mHealth-based interventions were associated with significant levels of effectiveness (Webb et al., 2010; Vollmer Dahlke et al., 2015). Contrary to this guidance however, evidence has shown that the use of theory was either not mentioned or not explicitly discussed regarding how it was applied to drive the design and development of mobile apps, particularly apps for people with cancer, such as the critical component of mHealth interventions (Vollmer Dahlke et al., 2015; Tomlinson et al., 2013). Many reviews on pain-related apps have confirmed that the reviewed apps lacked both theoretical rationale and evidence-based features and strategies (Wallace and Dhingra, 2014; Bhattarai et al., 2018; Lalloo et al., 2015) as discussed previously (see Chapter 1, section 1.3.8). The reviews concluded with highlighting the need to consider the theoretical and evidence-based foundation for designing and developing pain apps to better support patients' pain self-management. Although behaviour change interventions need to be theory- and evidence-based in order to be effective, other factors may affect the outcome, such as the intensity and duration of the intervention, having tailored components (Koller et al., 2012), and mode of delivery (Webb et al., 2010; Koller et al., 2012).

In relation to interventions for pain self-management for cancer patients, systematic reviews and meta-analyses have shown that such interventions are effective in supporting better pain management (Allard et al., 2001; Bennett et al., 2009; Devine, 2003; Koller et al., 2012; Howell et al., 2017). The studies however did not reveal which intervention component or combination of components is the most effective. Koller et al. (2012) and later Howell et al. (2017) reviewed the structure and content of interventions designed to improve patients' self-management of cancer pain, aiming to identify the efficacy of different components. Despite the detailed description of the interventions' components provided by the two reviews, the most efficacious component or group of components could not be determined. As discussed by the authors, this was related to the heterogeneity in the designs of the reviewed studies and the variability in the number of structure and content components of interventions. Therefore, there is a need for interventions to be designed and developed in light of a systematic approach that makes it possible to characterise interventions. Certainly, characterising interventions by standardised and well-defined BCTs, which are active components, is required to achieve two important aspects: (1) to enable tracking mechanisms subsidising effectiveness across interventions, and (2) to enable replication and development of effective interventions (Michie et al., 2011a; Michie et al., 2009; West et al., 2010; Michie et al., 2013). In addition, it seems that there is a variation in perceiving the term 'pain self-management'. This has led to heterogeneity in the focus and content of pain self-management support interventions for cancer patients. Indeed, Howell et al. (2017) emphasised the need for consensus when defining the essential components of cancer self-management to ensure consistent and effective delivery of such interventions.

3.2.1 Insight into pain self-management concept

A review of Cochrane reviews of self-management of chronic condition interventions stated that, in practice, the term 'self-management' has been used to describe both simple and complex interventions aimed to empower individuals to manage their own health. Such interventions focused on educating patients about their condition and/or providing them with basic skills

to manage their disease symptoms on a daily basis (Coster and Norman, 2009). The latter is required to build self-efficacy, which is deemed a key element attributed to behaviour change and health outcomes (Lorig and Holman, 2003). It refers to the belief in one's own abilities to establish and execute the courses of action required to achieve specified goals (Bandura, 1997).

Pain self-management interventions for cancer patients in particular have been described as complex interventions, as they need to incorporate several interacting components reflecting the complexity of cancer pain (Craig et al., 2013; Koller et al., 2018; Howell et al., 2017). A recent review has addressed the need for defining these components and detailed the concept of self-management of cancer pain (Yamanaka, 2018). The latter, consequently, has been defined as "*the process in which patients with cancer pain make the decision to manage their pain, enhance their self-efficacy by solving problems caused by the pain, and incorporate pain-relieving strategies into daily life, through interactions with health-care professionals*" (Yamanaka, 2018, p. 254). Thus, five attributes were identified for cancer pain self-management as follows: (1) interactions with HCPs, (2) decision-making for pain management, (3) pain-related problem solving, (4) self-efficacy, and (5) incorporating strategies for pain relief into daily life. These attributes were suggested to be used as modules of nursing practice promoting patient self-management of cancer pain (Yamanaka, 2018).

3.2.2 Behaviour change theories and models

There are many theories and models for behaviour change, such as the theory of reasoned action (Ajzen, 1980) and the theory of planned behaviour (Ajzen, 1991); but there has been a lack of guidance and rationale for selecting a specific model or theory for a particular context (Davies et al., 2010; Michie et al., 2011b). In addition, many of the models or theories share or have overlapping constructs making it difficult to know how to select and apply theories (Michie et al., 2005). Behaviour change intervention development frameworks, such as intervention mapping (Bartholomew et al., 1998) and Abraham's BCT taxonomy (Abraham et al., 2011), contribute to translating theory into practice (Michie et al., 2011b). Nineteen existing frameworks,

including the aforementioned, were identified in a systematic review study and evaluated in terms of usefulness, and were criticised in one or more of three aspects. These are as follows: not being linked to an overarching behaviour model, being conceptually incoherent, or being uncomprehensive in terms of offering designers the full range of options to change behaviour (Michie et al., 2011b). The Behaviour Change Wheel (BCW) framework was constructed to overcome these limitations by synthesising the common features of the frameworks. It provides a step-by-step method for systematic and theory-based design and development of behaviour change interventions that can be characterised by behaviour change techniques (BCTs) (Michie et al., 2011b; Michie et al., 2014).

The BCW, shown in Figure 4, is based on the COM-B behaviour model that suggests that interacting between three components, namely, capability (C), opportunity (O), and motivation (M), produces behaviour (B) that, in turn, influences them (see Figure 5) (Michie et al., 2011b; Michie et al., 2014). Thus, changing behaviour requires changing one or more of these components. Each component is subdivided into two types as follows: physical and psychological capability, social and physical opportunity, and reflective and automatic motivation (see Appendix 4, Table 20 for definitions). The BCW is designed to drive intervention designers into building behavioural analysis to understand the targeted behaviour using this model. The analysis helps identify what is missing and what needs to change for a desired behaviour to occur and contribute to solving a problem. Then, the BCW allows designers to identify which of nine possible intervention functions could best bring about change. Moreover, it supports the selection of the best policy category, if required, for delivering the intervention from seven specified categories (see Figure 4). It then suggests ‘stepping outside the wheel’ to specify the content of the intervention through selecting the appropriate BCTs that best serve the identified intervention functions. The BCTs or the ‘active ingredients of an intervention’, as described by the BCW, can be selected from the BCT taxonomy version 1 (BCTTv1). The latter is the international consensus taxonomy of 93 evidence-based BCTs clustered within 16 categories (Michie et al., 2013). The BCW framework also provides guidance in specifying the appropriate mode of delivery to implement

an intervention, if needed. Guidance on how all this can be achieved is provided through the BCW guide (Michie et al., 2014).

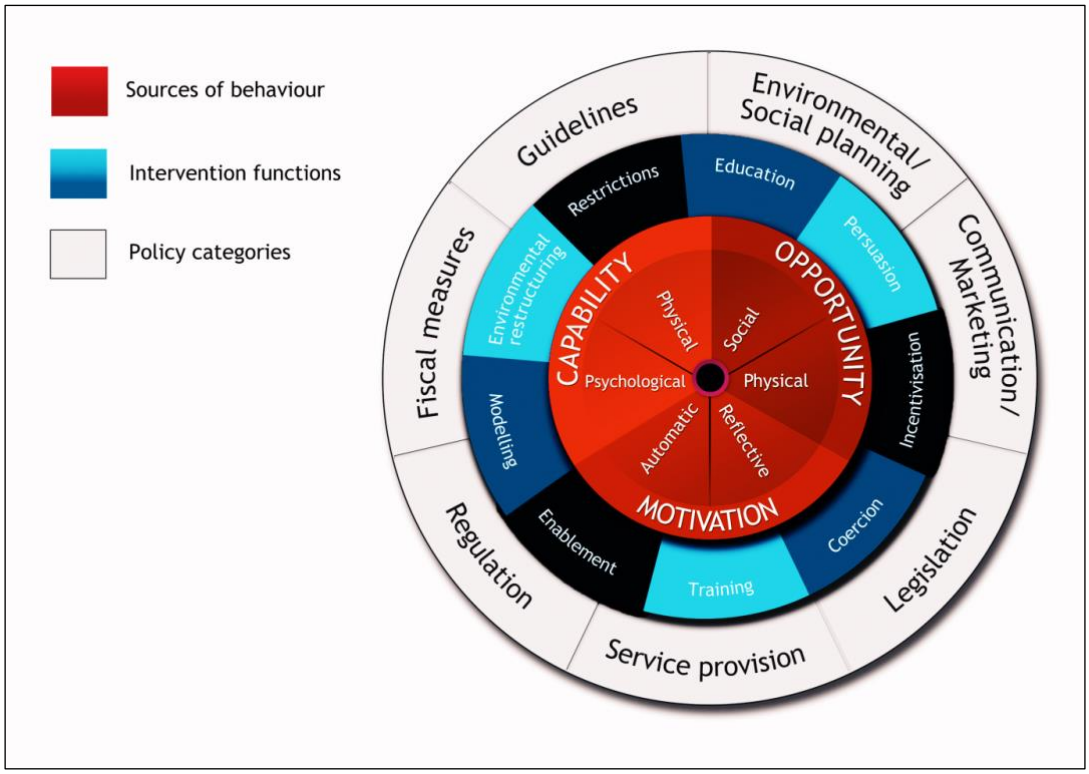

Figure 4: The Behaviour Change Wheel, adapted from (Michie et al., 2011b)

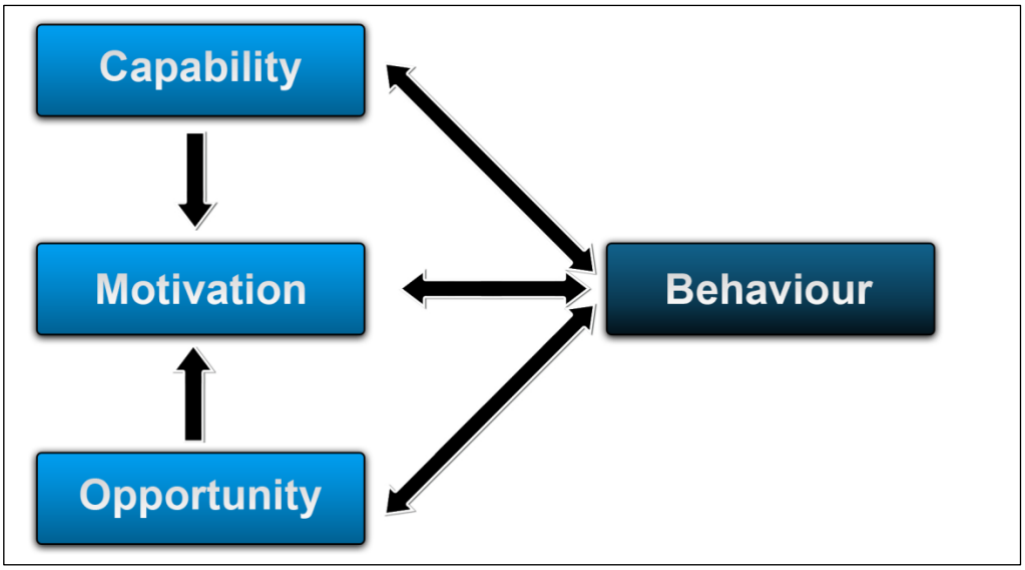

Figure 5: The COM-B model, adapted from (Michie et al., 2011b)

The BCW is an increasingly applied framework for designing and developing behaviour change interventions in various health-related problems and contexts (Band et al., 2017; Barker et al., 2016; Walsh et al., 2018; Gould et al., 2017); some interventions were delivered through apps (Curtis et al., 2015; Fulton et al., 2016; Robinson et al., 2013; Tombor et al., 2016). To the best of the author's knowledge, however, it has been never used in the context of supporting pain self-management for cancer patients. Koller et al. (2018), indeed, used only the BCTTv1 to code and describe their 'ANtiPain' intervention for cancer patients for reporting their randomized controlled pilot study (Koller et al., 2018).

To design the intended app, the intention was to link most of its active features to theory specified change processes since such links are not always clear in the descriptions of published interventions (Abraham and Michie, 2008; Michie and Abraham, 2004). Based on that and in light of what has been discussed above and in the previous sections, the BCW was selected to drive and inform the design of the app through understanding pain self-management as a behaviour using the COM-B model.

3.2.3 Aim of the study

The aim of the study is to utilise the BCW framework with insight into self-management of cancer pain to (1) establish the theoretical foundation for developing the app, and (2) to inform the design of the app. To the best of the researcher knowledge, this is the first systematic theory- and evidence-driven design for a pain app for patients with cancer.

3.3 Methods

According to the BCW framework, there are eight steps grouped into three stages for designing behaviour change interventions (see Figure 6). The steps can be conducted with flexibility according to the need and context for each individual study (Michie et al., 2014). For this study, they were adapted and conducted as detailed below.

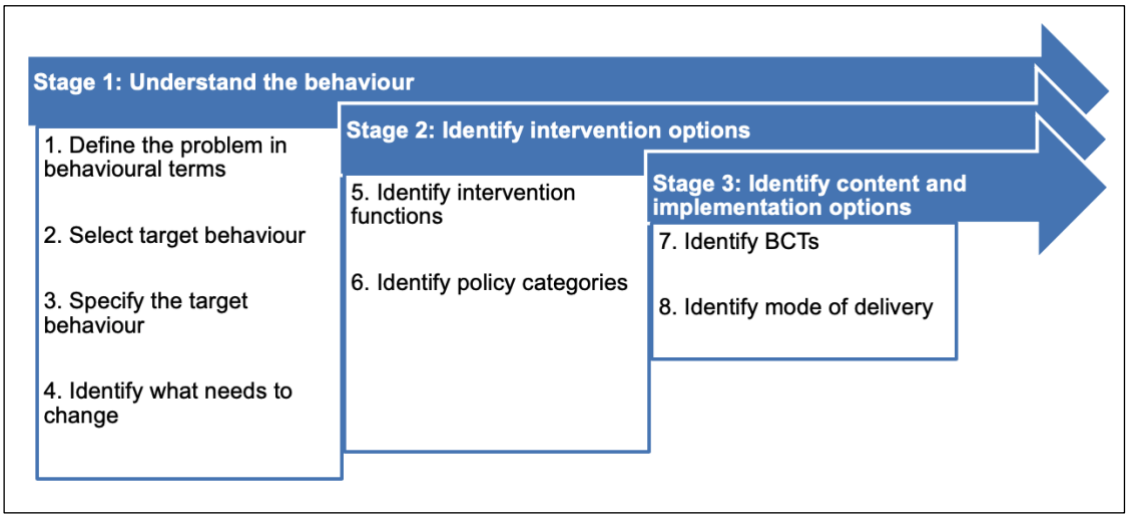

Figure 6: Behaviour change intervention design process, adapted from (Michie et al., 2014)

3.3.1 Stage 1: understanding the behaviour and what needs to change

3.3.1.1 Step 1: defining the problem in behavioural terms

This step aimed to define the problem of inadequate pain management for cancer patients in behavioural terms. This involved considering all behaviours from individuals, groups, or populations that potentially contribute to the problem.

3.3.1.2 Step 2: selecting target behaviour

The aim of this step was to select one target behaviour to be addressed by the intervention, as it is recommended limiting the intervention to just one or a few behaviours to increase the intensity and effectiveness of the intervention (Michie et al., 2014). The target behaviour was selected based on evidence discussed in the literature regarding factors hindering effective pain management (see Chapter 1, section 1.3.4). Since the app is oriented to the patient's use in the home setting, we focused on pain management behaviours attributed to patients. The behaviour that shows strongest supporting evidence for better pain management was selected as the target behaviour.

3.3.1.3 Step 3: specifying the target behaviours

In this step, the target behaviour was specified in terms of the context in which it occurs including who performs it, what needs to be performed to achieve the desired change, and when and where it is performed.

3.3.1.4 Step 4: identifying what needs to change

This step aimed to identify the determinants for the target behaviour specified from the previous steps, which involved pain self-management. A behavioural diagnosis was conducted to identify what needs to be changed in relation to the COM-B components for the selected target behaviour to be performed. This means exploring barriers to, and facilitators of, patients' capability, opportunity, and motivation to perform pain self-management as it is defined earlier (see section 3.2.1). The Medline database was searched using a combination of keywords and relevant MeSH terms, such as '*pain management*', '*self-management*', '*cancer*', '*pain*', '*barriers*', '*facilitators*', and '*patient-related barriers*' (see Appendix 4, Table 21 for the search strategy). The search was restricted to reviewing articles to identify the evidence-based barriers to and facilitators of the target behaviours. The identified relevant articles were analysed to extract all the barriers and facilitators relevant to pain self-management. The barriers and facilitators were coded and mapped to the COM-B components. This was represented in a table that served as the foundation for mapping theoretical components to app features.

3.3.2 Stage 2: identifying intervention options

3.3.2.1 Step 5: identifying intervention functions

There are nine BCW intervention functions; each function can serve multiple COM-B components, and each component can be served by different functions. They are education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling, and enablement (Michie et al., 2014; Michie et al., 2011b) (see Appendix 4, Table 22 for the definitions and Table 23 for linking the functions with COM-B). The COM-B components identified in the

previous stage were mapped to intervention functions that are likely to serve and bring about change according to the BCW's guidelines (Michie et al., 2014).

3.3.2.2 Step 6: identifying policy categories

The BCW identified seven policy categories that could effectively support the delivery of the intervention functions (see Appendix 4, Table 24 for the matrix of this). The possible policy categories include communication/marketing, guidelines, fiscal measures, regulation, legislation, environmental/social planning, and service provision (Michie et al., 2014; Michie et al., 2011b) (see Appendix 4, Table 25 for definitions). In this study, the intended app was conceptualised as a service provision policy, according to the BCW (Michie et al., 2014; Michie et al., 2011b). Therefore, this step was used only to refine the candidate intervention functions identified in the previous step to only the functions that could be delivered using this policy category.

Furthermore, the BCW framework emphasises the importance of considering the context of the intervention as all steps are implemented, and selecting what is most appropriate for the intervention to ensure effectiveness (Michie et al., 2014; Michie et al., 2011b). In line with that, the APEASE criteria (Affordability, Practicability, Effectiveness/cost-effectiveness, Acceptability, Side effects/safety, Equity; see Appendix 4, Table 26 for details), suggested by the BCW (Michie et al., 2014), were applied to the candidate intervention functions. This was to guide the judgment in selecting the most suitable functions that the intervention can serve within its context. The judgment was firstly made by the researcher based on the criteria application; then it was confirmed after a supervision meeting. The selected functions were then mapped to the original intervention table produced in the first stage.

3.3.3 Stage 3: identifying content and implementation options

3.3.3.1 Step 7: identifying behaviour change techniques

The contents of the intervention were identified in this step using the BCTTv1 (Michie et al., 2013) (see Appendix 4, Table 27). This was achieved, in accordance with the BCW guidelines (Michie et al., 2014), through mapping the

selected intervention functions from the previous steps to possible BCTs that are relevant to serve the functions and induce the desired change. The BCW identified a list of candidate BCTs for each intervention function and classified them into most and less frequently used BCTs. Both groups were considered for this intervention. Some BCTs are deemed appropriate for different intervention functions (see Appendix 4, Table 28 for the matrix of this). Online training[2] provided by the BCTTv1 developers was taken by the researcher to help in understanding BCT labels and definitions and in applying the taxonomy accurately and reliably. All the candidate BCTs for the intervention were considered with regard to their appropriateness to the context using the APEASE criteria. Then, evidence from the literature on BCTs used in effective interventions was considered to support the final selection of potentially effective and evidence-based BCTs to be incorporated into the app design. The database of BCTTv1-coded interventions[3] was searched for interventions that focused on self-management as the target behaviour. There was found to be a lack of interventions and reviews in supporting pain self-management for cancer patients using the BCTTv1. Therefore, BCTs serving effective interventions supporting self-management in any health condition were included. The selected BCTs were then mapped to the original intervention table with examples given on how these BCTs could be applied in the intervention context. Translating BCTs into app features was not guided by the BCW framework. Digital behaviour change interventions (Curtis et al., 2015; Fulton et al., 2016; Revenäs et al., 2015; Tombor et al., 2016; Walsh et al., 2018) that used some of the BCTs identified for the app, were reviewed to learn how the BCTs could be represented.

3.3.3.2 Step 8: identifying mode of delivery

The selected mode of delivery, as discussed earlier, is a mobile phone app. Therefore, this step of the framework was not considered.

[2] Available on http://www.bct-taxonomy.com/

[3] It is a database of published intervention papers and reviews in which BCTs have been coded using BCTTv1. It is provided by the BCTTv1 developers and available on http://www.bct-taxonomy.com/interventions

3.4 Results

3.4.1 Stage 1: understanding the behaviour and what need to change

3.4.1.1 Steps 1, 2, and 3: defining, selecting and specifying the target behaviours

In this stage, the first three required steps were achieved almost before the beginning of the current study, as they were informed by previous research and the literature review in preparation for this thesis as follows. **Step 1:** from a behavioural perspective, it is clear from Chapter 1, section 1.3.4 that the problem of unsatisfactory pain management is related to a combination of behaviours on HCP, healthcare system, and patient levels. **Step 2:** pain self-management was selected as the target behaviour for the app, as it shows strong supporting evidence for better pain management (Coward and Wilkie, 2000; Shute, 2013; Jacobsen et al., 2009b; Luckett et al., 2013; Oldenmenger et al., 2018b; Ward et al., 2001). **Step 3:** patients need to self-manage their pain at home and during the period of experiencing pain by incorporating pain-control strategies into daily life and communicating with HCPs.

3.4.1.2 Step 4: identifying what needs to change

Five relevant review articles (Jacobsen et al., 2009b; Luckett et al., 2013; Oldenmenger et al., 2018b; Ward et al., 2001; Kwon, 2014) were generated from the search and used for the behavioural diagnosis. The behavioural diagnosis shown in Table 6 indicated that physical and psychological capability, physical and social opportunity, and automatic and reflective motivation needed to change for the pain self-management to be performed. Table 6 serves as the intervention mapping table for the rest of the analysis results.

Table 6: Behavioural diagnosis for pain self-management using COM-B model

COM-B components		Barriers/facilitators to pain self-management	Intervention functions	BCT labels	Examples of application (BCT#)
Capability	Physical	• Barrier: sensory barriers such as side effects of pain medication (Jacobsen et al., 2009b) • Barrier: lack of skills for how to manage different patterns and types of pain (Luckett et al., 2013) • Facilitator: being able to use nonpharmacological strategies (Luckett et al., 2013)	• Training • Enablement	• 4.1. Instruction on how to perform a behaviour • 1.2. Problem solving • 12.6. Body changes	• Provide patients with information and instructions about pain and pain control strategies (4.1). • Using the app itself to record pain details over time has the potential to trigger problem solving (1.2). • Provide patients with information about how to physically cope with cancer and medication side effects such as the benefit of routine physical exercise (4.1, 12.6).
	Psychological	• Barrier: poor knowledge about pain medication and their side-effects (Oldenmenger et al., 2018b; Jacobsen et al., 2009b) • Barrier: lack of awareness of which services and management options are available and how to manage pain at home (Luckett et al., 2013)	• Education • Training • Enablement	• 2.2. Feedback on behaviour • 2.3. Self-monitoring of behaviour • 2.7. Feedback on outcome(s) of behaviour • 5.1. Information about health consequences • 7.1. Prompts/cues	• Inform patients about support services available for them and about nonpharmacological pain control strategies and remind them to consider using them (4.1, 7.1). • Inform patients about pain and pain medications and their effects (5.1, 11.1). • Ask patients to daily record their adherence to medication as prescribed and whether they have used any other pain control strategy. Provide them with

		• Barrier: lack of skills on how to manage different patterns and types of pain (Luckett et al., 2013) • Facilitator: being educated about the disease, pain and pain medication will facilitate changing knowledge, attitudes, and beliefs (Ward et al., 2001; Kwon, 2014; Luckett et al., 2013) • Facilitator: being aware of nonpharmacological strategies (Luckett et al., 2013)		• 2.4. Self-monitoring of outcome(s) of behaviour • 6.3. Information about others' approval • 5.3. Information about social and environmental consequences • 5.6. Information about emotional consequences • 4.1. Instruction on how to perform a behaviour • 11.1. Pharmacological support	a form for recording that and a method for reviewing it (2.3, 2.4) • Inform patients that HCPs approve conscious patients who self-manage their pain and keep partnership with them (6.3).
Opportunity	Physical	• Barrier: no access to specialist services are nearby and the need to travel with pain and being away from family and work (Luckett et al., 2013)	• Training • Enablement	• 2.3. Self-monitoring of behaviour • 2.4. Self-monitoring of outcome(s) of behaviour	• The app functions as an electronic diary and facilitates reporting pain to HCPs and identifying nearby support services (2.3, 2.4, 1.2, 3.1, 3.2).

		• Facilitator: being able to record pain and medication in diaries (Kwon, 2014)		• 1.2. Problem solving • 3.1. Social support (unspecified) • 3.2. Social support (practical)	
	Social	• Barrier: cultural norms regarding experience of cancer pain and attitudes toward its management (Luckett et al., 2013) • Facilitator: developing trust in HCPs makes patients more likely to report pain (Luckett et al., 2013)	• Enablement	• 2.3. Self-monitoring of behaviour • 2.4. Self-monitoring of outcome(s) of behaviour • 3.1. Social support (unspecified) • 3.2. Social support (practical) • 3.3. Social support (emotional) • 12.2. Restructuring the social environment	• The app provides patients with ways of getting social support, such as chatting with other patients, identifying nearby social support services (3.1, 3.2, 3.3, and 12.2). • The app facilitates reporting pain to HCPs, thus improving the partnership between the two (2.3, 2.4).
Motivation	Automatic	• Barrier: cognitive barriers to pain medication including fear of addiction, side effect, tolerance,	• Persuasion • Training • Enablement	• 5.1. Information about health consequences	• Explain to patients that self-management of pain through adherence to subscribed medication and adopting

		and being harmful for immune system (Oldenmenger et al., 2018b; Ward et al., 2001; Jacobsen et al., 2009b; Kwon, 2014; Luckett et al., 2013) • Barrier: mood disorders and emotional barriers, such as depression and mood fluctuations (Jacobsen et al., 2009b; Kwon, 2014) • Barrier: anxiety from the uncertainty and fear that the pain will get worse (Luckett et al., 2013)		• 5.3. Information about social and environmental consequences • 5.6. Information about emotional consequences • 11.1. Pharmacological support • 11.2. Reduce negative emotions	some pain control strategy can help in preventing pain deterioration and unscheduled visits to hospitals and lower the financial burden on healthcare system and increasing feeling in control of condition and well-being (5.1, 5.3, 5.6, 11.1). • Advise patients on ways of reducing negative emotions (11.2)
	Reflective	• Barrier: patients are reluctant to adhere to treatment recommendations (Oldenmenger et al., 2018b; Ward et al., 2001; Jacobsen et al., 2009b) • Barrier: belief that "good patients" do not complain about pain and should be stoic and endures pain (Ward et al., 2001; Jacobsen et al., 2009b; Kwon, 2014; Luckett et al., 2013)	• Education • Persuasion	• 2.2. Feedback on behaviour • 2.3. Self-monitoring of behaviour • 2.7. Feedback on outcome(s) of behaviour • 5.1. Information about health consequences • 7.1. Prompts/cues	• Inform patients that HCPs approve of keeping a good partnership with them. This helps HCPs to build a full pain record for better pain assessment, intervene more effectively in the right time preventing pain deterioration, unscheduled visits to hospitals and burden on healthcare system (6.3, 5.1 and 5.3). • Ask patients to report daily and record their pain level and provide them with some feedback about the pain pattern. Provide them with a method for

		• Barrier: belief that reporting pain distracts health care professional from treating cancer (Ward et al., 2001; Jacobsen et al., 2009b; Kwon, 2014; Luckett et al., 2013) • Barrier: perceived lack of trust in health care system and healthcare professionals (Jacobsen et al., 2009b; Luckett et al., 2013) • Barrier: belief that increased pain indicates a progression of the cancer and cancer pain is inevitable and cannot be managed (Ward et al., 2001; Jacobsen et al., 2009b; Kwon, 2014; Luckett et al., 2013)		• 2.4. Self-monitoring of outcome(s) of behaviour • 6.3. Information about others' approval • 5.3. Information about social and environmental consequences • 5.6. Information about emotional consequences	measuring pain and recording its scores, and a method for reviewing it (2.2, 2.3, 2.4 and 2.7). • Remind patients to record pain consistently and maintain the partnership with their HCPs (7.1).

* Numbering mentioned beside the BCT's labels refers to the classification labels in the BCTTv1

3.4.2 Stage 2: identifying intervention options

3.4.2.1 Steps 5 and 6: identifying and refining intervention functions

Mapping the intervention functions to the corresponding COM-B components indicated that all nine intervention functions were appropriate for addressing the identified determinants for pain self-management behaviour (see Table 7). Refining the functions to be delivered through the app (i.e., service provision policy category) however resulted in the following seven functions: education, persuasion, incentivisation, coercion, training, modelling, and enablement as shown in Table 7. Moreover, considering each candidate of the intervention functions using the APEASE criteria, four functions were selected: education, persuasion, training, and enablement; the reason for selecting these is detailed in Table 8. Table 6 illustrates mapping the selected functions to the previous results.

Table 7: Mapping intervention functions to COM-B components with consideration to the selected policy category

COM-B	Candidate intervention functions								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Physical capability					✓				✓
Psychological capability	✓				✓				✓
Physical opportunity					✓	✓	✓		✓
Social opportunity						✓	✓	✓	✓
Automatic motivation		✓	✓	✓	✓		✓	✓	✓
Reflective motivation	✓	✓	✓	✓					

*Shaded box = inappropriate intervention function to deliver through service provision policy category.

Table 8: Applying the APEASE criteria to guide the selection of intervention functions

Candidate intervention functions	Definition (Michie et al., 2014; Michie et al., 2011b)	Does the intervention function meet the APEASE criteria in the context of using an app to support pain self-management?
Education	*"Increasing knowledge or understanding"*	Yes
Persuasion	*"Using communication to induce positive or negative feelings or stimulate action"*	Yes
Incentivisation	*"Creating expectation of reward"*	Not practicable and unlikely to be effective in this context
Coercion	*"Creating expectation of punishment or cost"*	Not acceptable to patients and not practicable to deliver in this context
Training	*"Imparting skills"*	Yes
Modelling	*"Providing an example for people to aspire to or imitate"*	Not practicable or relevant to deliver in this context
Enablement	*"Increasing means/reducing barriers to increase capability or opportunity"*	Yes

3.4.3 Stage 3: identifying content and implementation options

3.4.3.1 Step 7: identifying behaviour change techniques

A total of 65 candidate BCTs were derived from linking the selected intervention functions to BCTs. This set was refined based on considering the context and applying the APEASE criteria to eighteen BCTs listed in Table 9 (see Appendix 4, Table 29 for the full analysis), fifteen of which were found to have been used in effective self-management interventions as specified in Table 9. Table 6 outlines how the eighteen BCTs were mapped to the previous analysis, along with examples of how they could be represented to bring about change and encourage patients to perform pain self-management.

Table 9: Mapping intervention functions to BCTs

Intervention function	BCT label*	BCT Definition (Michie et al., 2013)	Evidence for effectiveness
Education	2.2. Feedback on behaviour	*"Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity)"*	Yes (Wangberg, 2008; Koller et al., 2018)
	2.3. Self-monitoring of behaviour	*"Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy"*	Yes (Koller et al., 2018; Miller et al., 2017)
	2.7. Feedback on outcome(s) of behaviour	*"Monitor and provide feedback on the outcome of performance of the behaviour"*	Yes (Miller et al., 2017)
	5.1. Information about health consequences	*"Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour"*	Yes (Miller et al., 2017; Koller et al., 2018; Wangberg, 2008)
	5.3. Information about social and environmental consequences	*"Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour"*	No
	7.1. Prompts/cues	*"Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour"*	Yes (Miller et al., 2017)
	2.4. Self-monitoring of outcome(s) of behaviour	*"Establish a method for the person to monitor and record the outcome(s) of their behaviour as part of a behaviour change strategy"*	Yes (Koller et al., 2018)

	5.6. Information about emotional consequences	*"Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour"*	No
	6.3. Information about others' approval	*"Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do"*	No
Persuasion	2.2. Feedback on behaviour	Previously defined	See above
	2.7. Feedback on outcome(s) of behaviour	Previously defined	See above
	5.1. Information about health consequences	Previously defined	See above
	5.3. Information about social and environmental consequences	Previously defined	See above
	5.6. Information about emotional consequences	Previously defined	See above
	6.3. Information about others' approval	Previously defined	See above
Training	2.2. Feedback on behaviour	Previously defined	See above
	2.3. Self-monitoring of behaviour	Previously defined	See above
	2.7. Feedback on outcome(s) of behaviour	Previously defined	See above
	4.1. Instruction on how to perform a behaviour	*"Advise or agree on how to perform the behaviour"*	Yes (Miller et al., 2017; Lorig et al., 2003)

	2.4. Self-monitoring of outcome(s) of behaviour	Previously defined	See above
Enablement	1.2. Problem solving	*"Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators"*	Yes (Koller et al., 2018; Lorig et al., 2003; Lorig et al., 1999; Wangberg, 2008)
	2.3. Self-monitoring of behaviour	Previously defined	See above
	3.1. Social support (unspecified)	*"Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behaviour"*	Yes (Koller et al., 2018)
	3.2. Social support (practical)	*"Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour"*	Yes (Miller et al., 2017)
	2.4. Self-monitoring of outcome(s) of behaviour	Previously defined	See above
	3.3. Social support (emotional)	*"Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour"*	Yes (Koller et al., 2018)
	11.1. Pharmacological support	*"Provide, or encourage the use of or adherence to, drugs to facilitate behaviour change"*	Yes (Koller et al., 2018; Lorig et al., 2003; Lorig et al., 1999)
	11.2. Reduce negative emotions	*"Advise on ways of reducing negative emotions to facilitate performance of the behaviour"*	Yes (Koller et al., 2018; Lorig et al., 1999)

	12.2. Restructuring the social environment	*"Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour"*	Yes (Koller et al., 2018)
	12.6. Body changes	*"Alter body structure, functioning or support directly to facilitate behaviour change"*	Yes (Lorig et al., 2003)

* Numbering mentioned beside the BCT's labels refers to the classification labels in the BCTTv1
* Shaded box = less frequently used BCTs identified for the intervention function

3.5 Discussion

Much of the recent literature on evaluating pain apps has revealed the absence of any theoretical foundation and evidence-based features (Bhattarai et al., 2018; Lalloo et al., 2015; Wallace and Dhingra, 2014). The current study reports the theory- and evidence-driven design of an app, which is intended to support pain self-management, through the application of the BCW framework. This theoretical framework helps explain the mechanisms through which the intervention is likely to influence behaviour change (Tombor et al., 2016). This is in line with the UK MRC recommendation for developing and evaluating complex intervention (Craig et al., 2013).

In this study, the results of the fundamental phase of the BCW, the behavioural diagnosis based on the COM-B model, revealed that patients may have deficits in their capability, opportunity, and motivation preventing them from performing pain self-management (see Table 6). Consequently, the determinants derived from the literature in relation to the diagnosis were identified to be targeted by the app. They were in accordance with indicators that have been identified for nurses to assess whether patients with cancer pain can perform pain self-management (Yamanaka, 2018). These were labelled as physical functions, cognitive abilities, motivation, undergoing treatment for pain, receiving individual education, receiving family and HCPs' support, and health literacy (Yamanaka, 2018).

The app needs to use education, persuasion, training, and enablement intervention functions as, based on the analysis, they were found the most likely to address the specified factors. Incentivisation, coercion, and modelling intervention functions were also suggested by the BCW, but they were excluded (see Table 8). This was because the nature and complexity of the disease and pain do not allow this type of intervention functions to be practicable or acceptable; for example, it would be inappropriate to show any form of reward or punishment simply because pain was controlled or not respectively. In some cases, a patient’s effort to cope with pain might not be very successful.

Eighteen BCTs were selected to describe specifically how the intervention functions can be presented to induce the desired change regarding the intervention context (see Table 9). In other words, they were selected to form the active content of the app, which potentially serve to weaken the barriers and support patients to be pain self-managed while using the app, as the context examples illustrate in Table 6. For example, to increase patients' motivation, which could be affected by the belief that pain increases as the disease progresses and so cannot be managed; the app can serve to educate patients by explaining the health consequences of cancer, including pain, to correct the misconception. Additionally, the app can use a persuasion function, which could be presented through asking patients to monitor and record pain levels. This has the potential to improve self-efficacy through observing positive experiences and to trigger problem-solving through noting unsuccessful ones.

The results showed that the identified BCTs had previously been applied in effective self-management interventions except for three of them, namely, 'information about others' approval', 'information about emotional consequences' and 'information about social and environmental consequences', which had no evidence of earlier use. Despite the lack of evidence of the effectiveness to support the latter ones, it was decided to include them in the design of the app to provide evidence. Some BCTs proposed by the BCW were found inappropriate to the context, such as 'biofeedback', 'identification of self as role model', and 'social comparison'. Other promising BCTs cannot be delivered through the app, such as 'goal setting', 'review behaviour goal', and 'action planning'; these are likely to require nurse coaching to be better implemented, which was beyond the scope of this study (see Appendix 4, Table 29). For example, the aforementioned BCTs were successfully implemented by Koller et al. (2018) in their intervention that involved coaching nurses to support patients' pain self-management (Koller et al., 2018). In addition, not every face-to-face intervention can be translated to mobile technology but questioning whether it is possible is important (Roth et al., 2014).

The BCTs specified for the app needed to be carefully translated and implemented as meaningful app features since no guidance was provided by the BCW in relation to this matter. Indeed, this was one of the limitations

regarding behaviour change intervention frameworks including the BCW (Mohr et al., 2014; Curtis et al., 2015). Evidence of using these BCTs in digital health interventions (Curtis et al., 2015; Fulton et al., 2016; Revenäs et al., 2015; Tombor et al., 2016; Walsh et al., 2018) was sought to learn from. It was crucial that the BCTs are delivered in optimal ways that ensure patients' engagement; therefore, the user-centred design (UCD) approach was adopted for building the app in line with patients' preferences as discussed in the next chapter. BCTs, such as 'self-monitoring' and 'feedback', will not be effective if patients lose interest in using the app.

It is important to acknowledge that the application of behaviour change theory in digital health is still an emerging area of research, with development of an agenda to guide the development of research only started in recent years (Michie et al., 2017). There is, indeed, a recently produced guide for developing and evaluating digital behaviour change interventions (West and Michie, 2016) but it was not available at the time of current development. It adapted the MRC guidance on development and evaluation of complex interventions and overlapped the BCW framework in many aspects, but it is meant to address specific issues that arise with digital behaviour change interventions such as user engagement (West and Michie, 2016).

The Behavioural Intervention Technology (BIT) model is another conceptual framework that aims to integrate behavioural science and technology and to support the translation of the behaviour change strategies into features of BITs, such as apps (Mohr et al., 2014). Compared to the BCW framework, it does not consider understanding the target behaviour from the early stages, and it does not provide intervention designers with all the possible options for solving the problem, so they can systematically select the most appropriate for the context. In addition, it does not support the integration of the UCD method (Curtis et al., 2015). These aspects, indeed, were believed to be essential factors for increasing the likelihood of success of mHealth apps (Curtis et al., 2015).

Based on the above, the study provided a step-by-step theory- and evidence-based design for the intended app. Such clarity was considered minimal or even non-existent in the practice of interventions claiming that they are guided by

theory (Michie and Prestwich, 2010). Characterising the app by well-defined and evidence-based BCTs might allow replication and easier evidence synthesis regarding the effectiveness of intervention contents, which was difficult to achieve, as the evidence suggested (Allard et al., 2001; Bennett et al., 2009; Devine, 2003; Koller et al., 2012; Howell et al., 2017).

This piece of work has some limitations. The behavioural analysis was based on the literature, as the topic of patients' barriers to cancer pain management seemed well-investigated. Nevertheless, additional data from multiple sources, such as focus groups or interviews, could have revealed more and strengthened the understanding of cancer pain self-management behaviours. This, consequently, could have resulted in a more precise selection of BCTs and effective intervention. Another limitation was related to implementing the stepwise approach recommended by the BCW team (see Figure 6). Although it seems straightforward, it was, in practice, hard to follow, as it involved shifting back and forth between steps as issues were discovered. It required using a great amount of judgement regarding what is most appropriate for the context, which involved consultations with the framework developers as well as with some experts in pain management. This may make it necessary to revisit the earlier stages at times, and this might not be clearly documented.

3.6 Conclusion

There has been increasing emphasis on the need for underpinning theory and evidence for mHealth interventions to ensure their success and facilitate their appraisal. The work in this study demonstrated the application of the BCW framework in designing and developing an app for supporting pain self-management for patients with cancer. The app design will be based on education, persuasion, training, and enablement intervention functions which will be presented by eighteen BCTs. To the best of the author's knowledge, this is the first systematic theory- and evidence-driven design for a pain app for cancer patients. This systematic approach can support clarity in the evaluating of underlying mechanisms of the intervention and support future replication.

3.7 Chapter summary

In this chapter, the active contents, BCTs, of the intended app as part of the Pain Recording System were identified. The study reported in this chapter addressed the second objective of the thesis which is ‘to establish the theoretical foundation’. The next chapter integrates the outcomes from both this Chapter and the previous Chapter (systematic review) with other methods from which insights were derived to inform the functional requirements and the design of the system.

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Chapter 4
Design of the pain recording system: requirements and modelling

4.1 Chapter overview

This chapter covers the third and fourth objectives of the thesis, which are:

- to model the system functionalities
- to conduct usability testing

It reports the methods used to design the system and identify its workflow, informed by the outcomes from both Chapter 2 (systematic review) and Chapter 3 (BCW analysis) from which insights were derived to inform the functional requirements of a system for pain recording by patients with cancer. This chapter reports the system modelling and usability testing along with the methods used to build the system prototypes.

4.2 Review of existing pain apps

When designing a new product, it is recommended that designers review existing competitors' products and learn from their strengths and weaknesses (Farrell, 2017). Several reviews have discussed in detail the characteristics and quality of the pain apps already in existence (Portelli and Eldred, 2016; Rosser and Eccleston, 2011; Lalloo et al., 2015; Wallace and Dhingra, 2014; Reynoldson et al., 2014) as mentioned in Chapter 1, section 1.3.8. In addition, reviewing and critiquing existing products can inform a new product design and structure (Jeffroy and Lambert, 1992). This level of detail however could not be derived from the available pain app reviews. The majority of existing reviews simply evaluated apps based on app descriptions and the authors typically did not actually download and install apps for their review, as also observed by recent critical reviews (Zhao et al., 2019; McKay et al., 2018). Therefore, a scoping review of available pain apps was conducted with the aim of identifying common pain app structures and workflows, as well as providing insight into their quality.

4.2.1 Methods

The UK iTunes App Store (Apple, 2017) for Apple iOS, one of the leading mobile operating systems (International Data Corporation, 2020), was searched between 27th June and 5th July 2017 using the following keywords: '*cancer pain'*, '*pain*', '*pain diary'*, '*pain log'* and '*pain record'*. Furthermore, another search was conducted using the search terms in the NHS Apps library for assessed and recommended health apps (NHS, 2017). The search could have been widened by including Google Play store (Google, 2017) for Android, a leading mobile operating system beside iOS (International Data Corporation, 2020), however, this was not undertaken mainly because of resource limitations. No Android devices were accessible for the researcher to use for testing apps and more time would have been needed for this.

4.2.1.1 App inclusion and exclusion criteria

Apps were included in the review if they:

- Provide tools for recording pain, whether the pain is related to cancer or pain in general
- Are designed for patient use
- Are free of charge
- Are in the English language

Apps limited to pain related to health conditions other than cancer were excluded. The review excluded paid apps, as there were sufficient free apps for the purpose of this review.

4.2.1.2 Apps selection

As it was not possible to review all of the apps identified from a search of the app store, it was decided to use a systematic process to identify ten apps to be included and reviewed. This number was considered to be sufficient to provide an overview and a feasible number to test. iTunes app ranking is based on popularity involving number of downloads and positive reviews (Wilson, 2018), therefore the selection of apps for the current review was conducted in batches of ten apps starting from the top of the search results. Apps were first screened based on their name and description and assessed against the inclusion criteria. Then, the first ten potentially relevant apps were installed on an iPhone 6s Plus (iOS version 10.3.2) for a further inclusion criteria assessment. Apps

which did not meet the eligibility criteria in the second stage were uninstalled and another batch of potentially eligible apps were installed. This was repeated until the target number of eligible apps (i.e., ten) was reached. In respect of the apps resulting from the NHS Apps library search, all identified eligible apps were installed after removing any duplicates.

4.2.1.3 Quality assessment and data extraction

The quality of the apps was evaluated using the Mobile App Rating Scale (MARS), a reliable tool for assessing the quality of mobile health apps (Stoyanov et al., 2015). According to McKay et al. (2018) who systematically reviewed the methods used in the evaluation of health apps, there is no single best practice approach that can be suggested. The review highlighted that MARS is a more recent method and it is considered a multidimensional measure for rating the quality of health apps (McKay et al., 2018). The scale contains 19 items grouped into 4 domains representing the objective app qualities: engagement (5 items), functionality (4 items), aesthetics (3 items), and information quality (7 items) (see Appendix 5). It also includes a subjective app quality subscale with an extra 4 items. The latter subscale is excluded from the overall mean app quality score due to its subjective nature (Stoyanov et al., 2015); therefore, it was ignored by studies that used the scale (Bardus et al., 2016). All MARS items are scored on a 5-point scale[4] (Stoyanov et al., 2015). The researcher completed Online training[5] in using the MARS tool efficiently prior to use as recommended by the scale developer (Stoyanov et al., 2015). The installed apps were tested thoroughly for 10-15 minutes and rated. For each domain in the MARS tool, a mean score was calculated. A MARS total score for each app was obtained by calculating the mean score for the objective quality domains. The mean (M) and standard deviation (SD) were calculated for the apps' MARS scores as well as the subscale quality scores to draw conclusions about apps quality. During testing of the apps, all identified favourable features were noted for consideration in the intended app design. A workflow of the apps was identified gradually by reviewing the included apps.

[4] 1-Inadequate, 2-Poor, 3-Acceptable, 4-Good, 5-Excellent
[5] Training slides available from: https://psyberguide.org/mars-rating-scale/, accessed on 7th July 2017.

4.2.2 Results and interpretations

In total, 11 apps were included. 10 were selected from the iTunes App Store alongside one eligible app (Px HealthCare Ltd, 2017) from the NHS Apps library search.

4.2.2.1 Quality assessment

Table 10 outlines all of the included apps and their calculated MARS scores assessed by the scale's domains; however, one app (Ringful LLC, 2017) could not be evaluated due to consistent crashes. Most of the apps (9/10) scored acceptable to good quality on the 5-point MARS scale (M = 3.64, SD = 0.45). The engagement domain had the lowest rating in most of the apps, with the mean score being 2.66 (SD = 0.61), representing poor to acceptable quality. This was mainly due to the lack of entertainment, interest and customisation aspects in MARS scale. Low user engagement could adversely affect the continuity of using health apps and consequently reduce their effectiveness, as discussed in the Introduction Chapter (see section 1.3.9). The information quality was slightly better with a mean score of 3.61(SD = 0.60), ranging from 2.25 (Merc App Solution, 2017) to 4.57 scored by OWise Breast Cancer app recommended by the NHS (Px HealthCare Ltd, 2017). The items of the information domain revealed that 9/10 apps did not contain any sort of information relevant to the goal of the apps including how to manage pain. In addition, 7/10 apps were not clearly developed by trusted bodies (i.e., government, university), had no stakeholder involvement during development, and have not been tested and verified in terms of acceptability, usability or effectiveness by evidence (i.e., in published scientific literature) thereby questioning their credibility. Both functionality (M = 4.28) and aesthetics (M = 4) were the highest scoring quality domains, showing good quality with a slight difference.

Table 10: The MARS scores for the included apps

#	App Name	MARS objective domains				MARS total score
		Engagement	Functionality	Aesthetics	Information	
1	OWise Breast Cancer [a] (Px HealthCare Ltd, 2017)	3.8	4.75	3.67	4.57	4.2
2	CatchMyPain (Sanovation AG, 2017)	3.4	4.25	4.67	4	4.08
3	Chronic Pain Tracker Lite (Chronic Stimulation LLC, 2017)	3	4	4.67	4	3.92
4	My Pain Logs (Subinprara Infotech Inc, 2017)	2.8	4.5	4.33	3.75	3.85
5	PainTrakr (Black Slate Software Inc., 2017)	2.2	4.75	4.67	3.5	3.78
6	Symptom Diary (Stuart Harris, 2017)	2.6	4.75	4	3.75	3.78
7	PainTrackr (Involution Studios Boston LLC, 2017)	2.2	4.5	4.33	3.5	3.63
8	ACPA Pain Logs (The American Chronic Pain Association Inc., 2017)	2.2	4	3.33	3.5	3.26
9	Chronic Pain Diary Lite (Ben Delaporte, 2017)	1.8	3.5	3.67	3.25	3.05
10	MyPainTracker (Merc App Solution, 2017)	2.6	3.75	2.67	2.25	2.82
M (SD)		2.66 (0.61)	4.28 (0.45)	4.00 (0.67)	3.61 (0.60)	3.64 (0.45)

[a] Recommended by the NHS.

The quality assessment of the apps indicated that they could provide an assured foundation for learning from their design in terms of appearance, flow logic, and navigation. More focus, however, needs to be oriented towards enhancing the engagement and information domains in new pain apps. This could be achieved by considering the items of each domain and attempting to fulfil them. The items associated with the information domain, including accuracy of app description and goals, quality and quantity of information, visual information, credibility, and evidence base, are deemed achievable. On the other hand, given that the app topic is pain, it is questionable whether all the items specified for the engagement domain can be attained. Specifically, providing entertainment and gamification as engagement aspects within such an area would be challenging. It seems, however, practical to deliver other aspects of engagement based on MARS, including presenting the app content in an interesting way, providing customised and interactive features, and considering the target group in relation to the design. For example, OWise Breast Cancer app recommended by the NHS was rated (4.2) better than all of the others in terms of the MARS total score and had the highest engagement score (3.8) but it is still less than good (i.e., score 4).

In addition, given that engagement with digital behaviour change interventions (DBCIs) is a multidimensional construct as discussed previously (see Chapter 1, section 1.3.9), it is important to note that ‘Engagement’ measured by MARS seems to represent the user experience (UX) dimension only. The latter can be captured from a momentary interaction with an app/system which is meant by MARS. On the other hand, the second dimension, the extent of usage such as frequency and duration, would need to be captured in a prolonged testing. It is almost certain that using MARS alone is not adequate to fully evaluate engagement with DBCIs. This suggests, therefore, that the results related to engagement reported for the reviewed apps need to be interpreted with caution.

4.2.2.2 Features and design

All apps featured a Visual Analog Scale (VAS) to record pain severity. The common presentation of the scale was a slider of numbered format. This was in

line with a study that reviewed 12 apps for pain self-management (Reynoldson et al., 2014). Most of the apps (9/10) used graphical methods, mainly line graphs, to show pain severity over time. Three apps included a useful feature allowing users to switch between a week, month, or year view to display the graph for that period. The majority of the apps (9/10) provided a method for editing/deleting old pain entries and other recorded data. This does not seem appropriate given that pain experience can be difficult to recall accurately, and retrospective scoring of pain intensity could be imprecise (Linton, 1991; Linton and Melin, 1982; Lewandowski et al., 2009), as discussed in Chapter 1, section 1.3.2. Apps featured a variety of ways to input data, such as: a list of answers to select from, used to describe pain and other symptoms; and a free text box that was mostly used to record medications, treatments and entry notes. Six apps included recording and tracking of other aspects and symptoms apart from pain, including weather, blood pressure, sleep quality, fatigue and mental state etc. Although that might be seen as provision of extra functionality, it made such apps look busy and confusing. Literature in usability of health apps recommends that apps should be easily understood and confusing terms or actions should be avoided (Zapata et al., 2015). Different presentations of app menus were used, ranging from displaying the menu content on the first screen to using the 'hamburger' menu (≡) button. The last method, however, along with using the add (+) button to record a new entry, which was featured by five apps, was found confusing for the elderly (Cousins, 2018; Isaković et al., 2016). One app provided a user video guide and three others featured a reminder function to enable users to set an alarm for logging a record. Both mentioned features were considered useful for inclusion in the intended app.

An initial set of features that were common to most apps were selected and workflows that were associated with higher MARS scores (≥ 4) were utilised to identify the general workflow for the intended app illustrated in Figure 7.

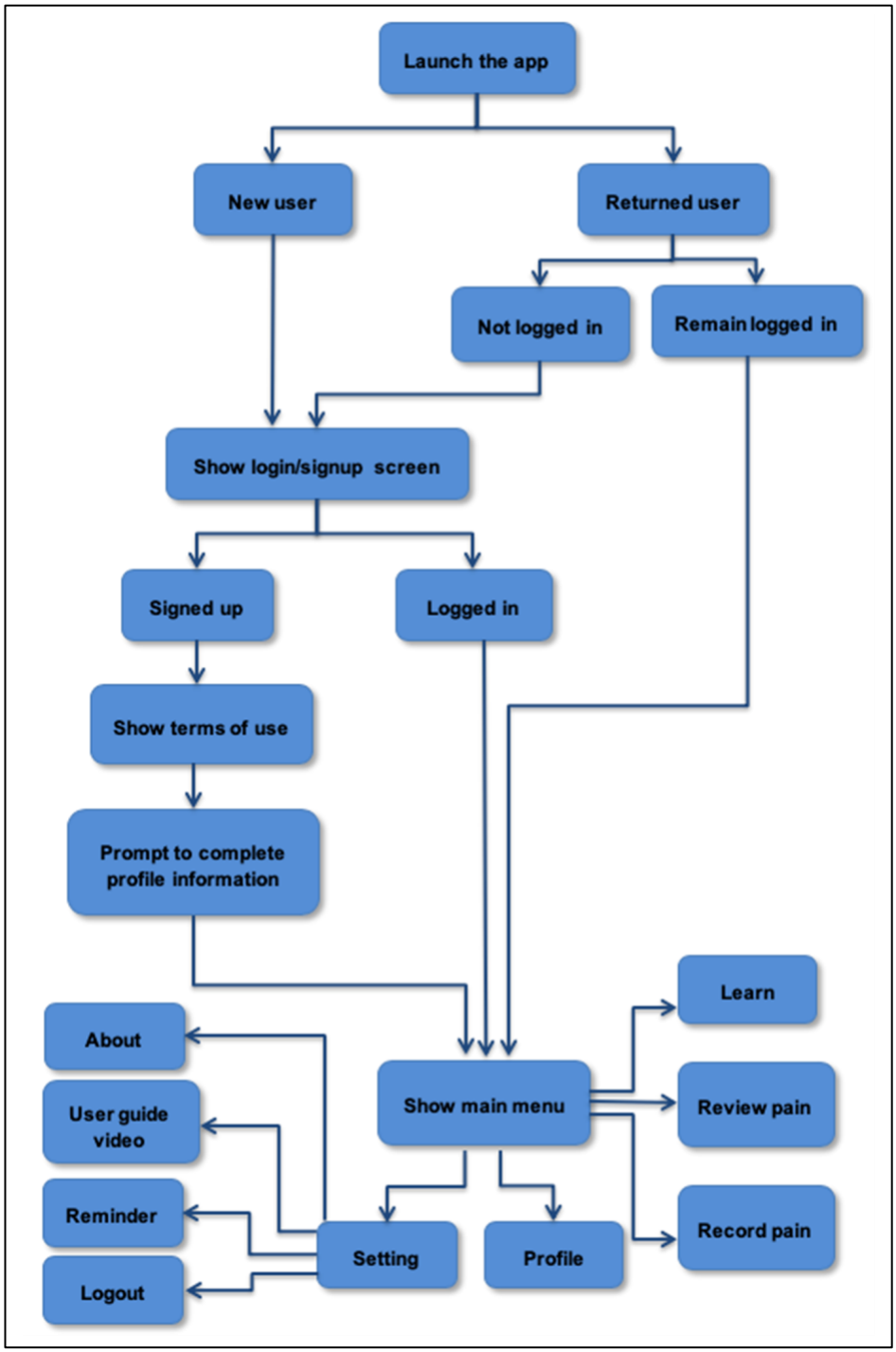

Figure 7: General workflow for the intended app

4.3 User-Centred Design (UCD)

It is essential to design a system in line with potential user requirements and preferences to increase engagement and continuity of use, as highlighted previously in Chapter 1, section 1.3.9. In response to this need, the User-Centred Design (UCD) framework was integrated with the UK Medical

Research Council (MRC) guidelines (see Chapter 1, section 1.2.1) and employed to design and develop the intended system. UCD is defined as "*an approach to systems design and development that aims to make interactive systems more usable by focusing on the use of the system and applying human factors/ergonomics and usability knowledge and techniques*" (ISO 9241-210, 2010).

The framework is based on an iterative and incremental design process that involves users in the early phases of the design, using design representations and techniques that users can understand. Each iteration should include three main phases: (1) an analysis of the users' needs and the context of use, (2) prototype design and development phase, and (3) an evaluation in a real-life context, feeding back specified suggestions for modifications that should be considered in planning the next design iteration. Iterations start with a simple prototype and continue until system usability objectives have been achieved in a complete executable system (Gulliksen et al., 2003). Active involvement of potential users (i.e., HCPs, patients and researchers) early and throughout the design process shapes the system in agreement with user expectations, ensures system usability, and reduces errors and the need for redesigning, thus saving time and cost (Gulliksen et al., 2003; Johnson et al., 2005). Two UCD cycles were feasible within the timeframe and resources of this project. Figure 8 illustrates the UCD phases as applied in the first cycle which was published (Abahussin et al., 2020). The first cycle was solely focused on the design and gathering the user requirements for the intended pain recording system. The phases of this cycle were planned and conducted carefully to acquire most of them and minimise the need for further design iterations, as detailed below. The second cycle aimed to develop the fully functional system prototype. Its phases were reported throughout the next two Chapters (i.e., 5 and 6).

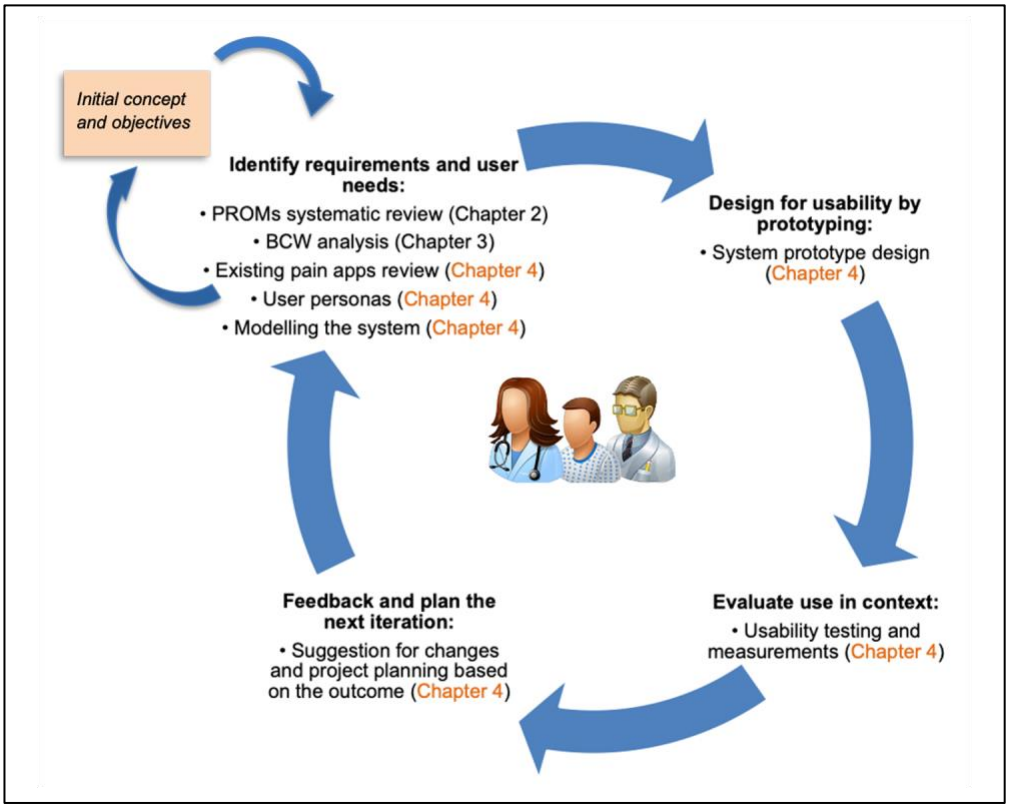

Figure 8: Phases of the UCD first cycle focused in designing the pain recording system, adapted from Gulliksen et al. (2003, p. 5)

4.3.1 User needs and requirements identification

4.3.1.1 User personas of the system

Developing user personas for a product is a recommended UCD technique that aims to focus the design effort effectively towards users' needs and build appealing features (Harley, 2015; Pruitt and Adlin, 2006). Personas are detailed descriptions of imaginary people representing target users of a product, focusing on their goals, motivations and behavioural details in relation to using the product (Laubheimer, 2017; Pruitt and Adlin, 2006). They are constructed out of well-understood, highly specified data about real people (Harley, 2015; Pruitt and Adlin, 2006). Personas can be created either through an empirical approach based on data-intensive efforts combining qualitative and quantitative data sources, or through a non-empirical approach based on assumption-based efforts that rely on existing knowledge about the user population (Flaherty, 2015). The latter was the feasible and appropriate approach for the current project as it is usually adopted in projects with limited resources and a tight

schedule to maintain the advantages of a user-centred focus (Flaherty, 2015). Following that, three user personas were created to model the needs of the pain recording system's potential users (i.e., HCPs, patients and researchers) as shown in Table 11. Professionals in palliative care and research were also consulted about the created personas and further refinements were conducted based on their input.

Table 11: The system's user personas

User role	Description
Patient	A 50-year-old female recently diagnosed with breast cancer is experiencing pain due to surgery. She needs to learn how to control her pain. She also needs to assess her pain on a regular basis and keep a log of it to communicate with her doctor at follow-up appointments. She avoids using opioids to minimise negative side effects and instead tries different nonpharmacological pain management strategies. She has a basic knowledge of smart devices, including how to use social media apps and how to read eBooks on an iPad.
HCP	A 58-year-old male is working as oncologist in the palliative care unit at a large teaching tertiary hospital. Patients with chronic pain are transferred to him so he can assess their pain, prescribe medications and advise them on appropriate treatments and pain management strategies. He needs to see the pain history of patients to achieve better pain assessment. He uses a computer most of the time as a part of his job is to access patients' records and so on.
Researcher	A 40-year-old research fellow in the Academic Unit of Palliative Care, at a leading research University undertakes research that is aimed at improving pain management for cancer patients. He needs to follow-up with participants in the Randomised Controlled Trials (RCTs) that are undertaken to assess the effectiveness of pain management interventions. He needs to see patients' histories for pain both with and without applying an intervention. He is quite confident in computer use and an excellent internet user.

4.3.1.2 Modelling the system

Modelling is important in the field of software development as it helps with specifying, constructing and documenting the structure and behaviour of a

system's architecture (Kruchten, 2004). A system's model is defined as a simplification of reality that describes the system from a particular perspective (Kruchten, 2004). Figure 9 illustrates the intended system architecture based on the main concept of the project. The system was designed to have three main components: a mobile app for the patients' use, a web-based application (i.e., portal) for the HCPs' and researchers' use, and a database hosted in a server connecting the two. The proposed app was intended to be used on a regular basis by patients to log pain details, for one or more of the following functionalities: (1) as a stand-alone application to support pain self-management, assisting patients to monitor pain and reflect on what could help to ease pain or avoid triggering pain, (2) as a means of communicating patient self-reported pain scores and attempted pain control strategies to HCPs to support pain assessment and management, (3) as a means of reporting pain scores to researchers when participating in pain intervention studies, especially longitudinal studies. After patients have submitted data via the app, HCPs and researchers can access and view the patient's data via the system portal. Figure 10 represents the data flow diagram for the system, a traditional tool for illustrating the information flow within a system (Jukić et al., 2013). The main data flow (i.e., inputs and outputs) for the intended system was identified as:

- Patient records and reviews pain entries
- HCP reviews patient record using the patient's date of birth or system identification number (ID)
- Researcher registers study details and reviews records of anonymous patients participating in that study

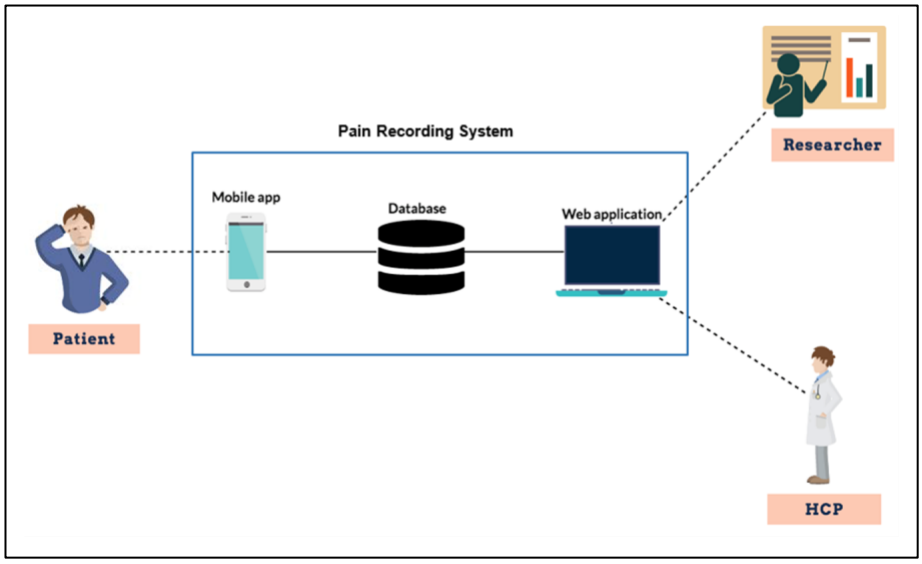

Figure 9: The architecture of the Pain Recording System

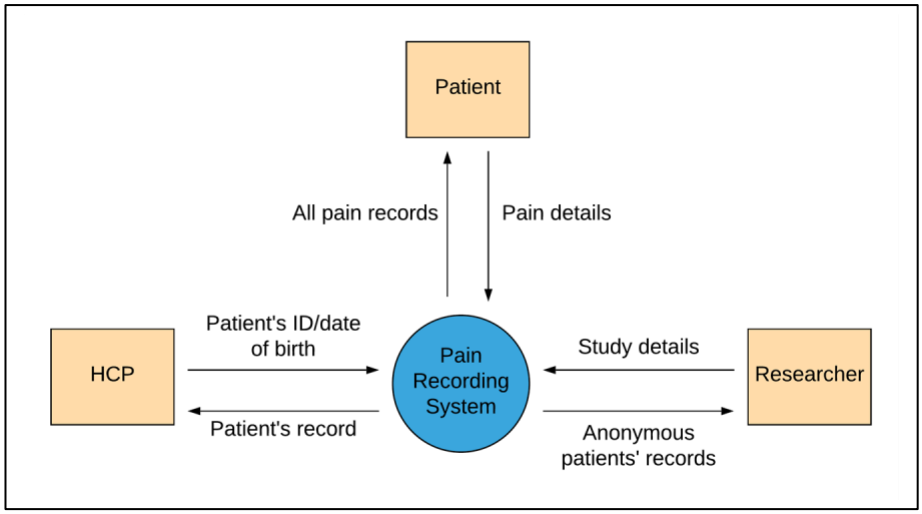

Figure 10: Data flow diagram for the Pain Recording System

The functional requirements for the system were derived from the multiple research activities discussed previously and highlighted in Figure 8. Figure 11 represents the main identified requirements using a use case diagram. The use case diagram is a widely used technique in software engineering for specifying user requirements (Gulliksen et al., 2003). Use cases are used to represent end

users of a system achieving specific goals within the system (Pratt and Nunes, 2012) and each use case is represented by a blue circle in the figure.

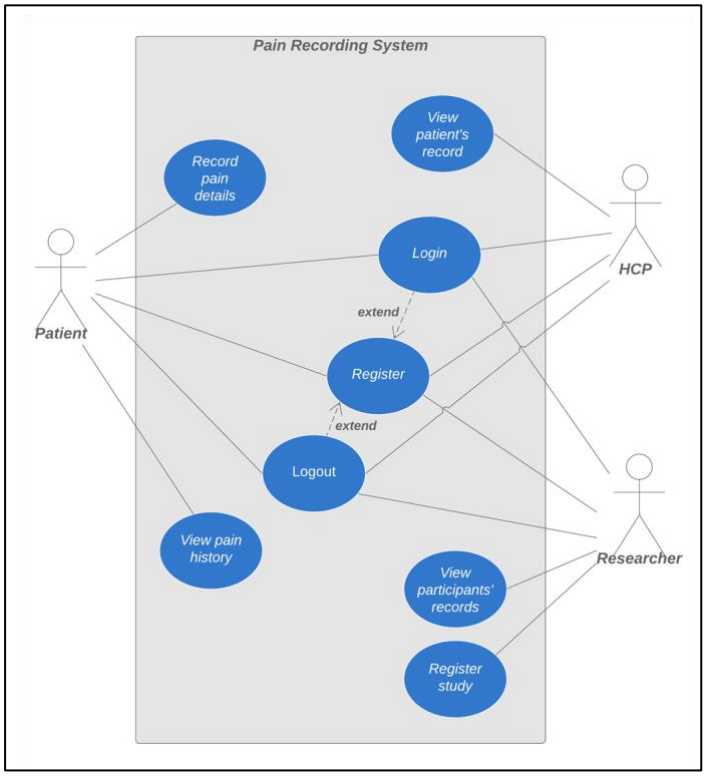

Figure 11: Use case diagram for the Pain Recording System

4.3.1.3 System integrated requirements

The identified requirements for the system are grouped based on the end user products, which are mobile app and web-based portal, as outlined in Table 12 and Table 13 respectively. Other features were specified as favourable to implement for both the app and portal as shown in Tables 14 and 15 respectively.

Table 12: The intended mobile app functional requirements

#	Requirement	Derived from	Design specification	Simulated in prototype design
1	Creating user account capturing basic personal and medical information, as well as study ID, should the user wish to take part in a study registered in the system	User persona identification, modelling the system, and pain app review	Create a form to capture login details, study ID, demographic data and clinical information including first cancer diagnosis, date of diagnosis, current treatment stage, and current prescribed pain medication	Yes
2	Recording pain score daily using the BPI-SF eleven questions for both pain severity (4 questions) and interference (7 questions) and displaying pain scores using a line chart	Systematic review, BCW analysis (BCT 2.3, 2.4), pain app review, user persona identification, and modelling the system	• Display the questions for each subscale in a separate screen and use radio buttons for selecting answers • Using a dual line chart, display the calculated average score for each subscale for each day with completed pain entry	Yes
3	Recording adherence to medication as prescribed and whether they have used any other pain control strategy (i.e., non-pharmacological) on daily basis; and displaying this information on the pain score line chart	BCW analysis (BCT 1.2, 2.3, 2.4), user persona identification, and modelling the system	• Create a form to capture these data in a separate screen following the BPI questions • In the pain graph, display these data alongside the pain scores using tooltips	Partially
4	Allowing user to switch between a week, month, or year view to display the pain	BCW analysis (BCT 2.7), and pain app review	A switch at the top of the pain graph showing week, month, year	Partially

	graph for that period but for the year view, show the average of pain score for each month			
5	Providing information and instructions about: • Pain and pain control strategies including non-pharmacological strategies and remind the user to consider using them • Pain medications and their effects • How to physically cope with cancer and medication side effects • Available support services • Ways of reducing negative emotions • Pain self-management and how it can help in preventing pain deterioration and unscheduled visits to hospitals and increasing feeling of being in control of condition and well-being • HCPs' approval given to conscious patients who self-manage their pain and maintain partnership with them	BCW analysis (BCT 4.1, 5.1, 5.3, 5.6, 6.3, 7.1, 11.1, 11.2, 12.6)	• Links to carefully selected resources that provide information about all the mentioned topics. Resources were limited to Cancer Research UK and Macmillan organisations' websites as they are well-known highly credible sources of information oriented toward cancer patients (see the list of topics/links in Appendix 6). • The app randomly selects a topic and suggests that the user learn about it when they submit a pain entry	Partially
6	Providing some feedback about the user's pattern of pain	BCW analysis (BCT 2.2, 2.7)	Alert pops up when the user has consistent or increasing pain layout for three days or more in 5 to	No

			10 scores, to advise them to seek medical consultation	
7	Reminding the user to complete pain entry if some days are missed	BCW analysis (BCT 2.2, 7.1)	Notification pops up when the user misses completing pain entry for more than three days, to advise them to do so	No
8	Allowing user to set and customise a reminder for completing pain entry	BCW analysis (BCT 7.1), and pain app review	Reminder option can be toggled on and off. When reminder is on, allow selecting a specific time for each day and use notification feature to alert the user at the times selected	Partially
9	Allowing user to access social support and identify nearby support services	BCW analysis (BCT 3.1, 3.2, 3.3, and 12.2)	• Links to selected resources that provide information about available support services for cancer patients (see the list of these in Appendix 6) • Link to Cancer Research UK (CRUK) Forum	Yes
10	Allowing user to edit information captured during registration	User persona identification, modelling the system, and pain app review	Display the registered information in a form with the ability to change any field and save changes	Yes

Table 13: The intended portal functional requirements

#	Requirement	Derived from	Design specification	Simulated in prototype design
1	Creating user account capturing basic information including the role of the user (i.e., HCP, researcher, or joint clinician-researcher)	User persona identification and modelling the system	Create a form to capture login details and the mentioned information	Yes
2	Controlling access to functionalities and contents based on the user role		Create a top bar navigation menu where items are hidden/displayed based on the logged in user role	No
3	Allowing user (i.e., HCP) to search the system for a registered patient by system ID or date of birth and displaying all the patient's information recorded by the patient using the intended app including the pain chart		• Use two searching boxes to allow searching by any of the two mentioned fields • Using another screen, display the results showing all the information grouped in categories: patient information, clinical information, and pain trajectory	Yes
4	Allowing user (i.e., HCP) to monitor a selected group of patients		• Add a button within the result screen showing a patient's record, which the user can use to add the patient to a monitored group • Using another screen, display a list of patients added to the monitored group along with a summary of their pain status, which the user can navigate to view the full record of each one or remove from the list	No

5	Allowing user (i.e., researcher) to register study details and obtain the study system ID		Create a form to capture the study details including study title, start date, end date and number of participants required	Yes
6	Allowing user (i.e., researcher) to view the details of registered study, an update of recruitments and anonymous patients' records showing their pain entries		• Display a list of studies registered by the user with the ability to view, edit, and delete each one • Using another screen, display the details of a selected study from the list and a table showing a list of patients' anonymous pain records	Partially
7	Allowing user (i.e., researcher) to download anonymous patients' pain records for a registered study		Create an Excel sheet compiling patients' anonymous pain records for each study	Partially
8	Allowing user to edit information captured during registration		Display the registered information in a form with the ability to change any field and save changes	Yes

Table 14: The intended app preferable features

#	Feature	Simulated in prototype design
1	Providing user guide video	Partially
2	Providing description of the app	Partially
3	Providing prompts and hints interacting with user activities	Yes
4	Allowing the app to work offline and synchronise data to the server once connected to the internet	No
5	The app can be accessed by Apple and Android users	No

Table 15: The intended portal preferable features

#	Feature	Simulated in prototype design
1	Providing prompts and hints interacting with user activities	Yes
2	Allowing user (i.e., researcher) to add/remove a registered patient to/from a study as a participant	No
3	Allowing user to send prompts to patients and study participants	No

By analysing the identified requirements, a preliminary schema for the system backend database was produced and represented in an entity relationship (ER) diagram illustrated in Figure 12. The ER modelling is the traditional and most generally accepted method of data requirement description at the conceptual phase (Jukić et al., 2013). The main outlines of the schema were:

- A patient could have many pain records and many episodes. The latter represents the period of a treatment phase. An episode could contain many groups of medication used within it. A pain record denotes the pain scores captured from the BPI-SF on a specified date. It could be associated with many pain control strategies used within that date.
- A professional could be in association with many patient records and many studies.
- A study could include many patients (i.e., participants).

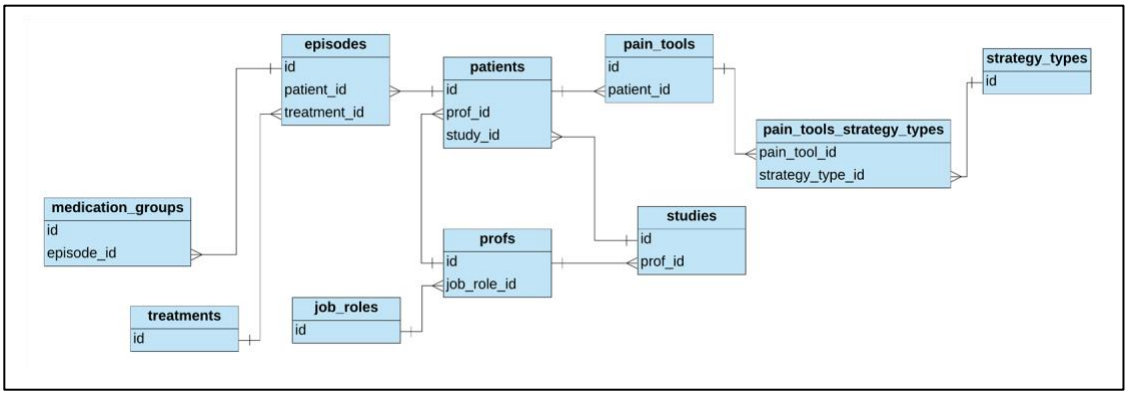

Figure 12: Entity relationship diagram for the Pain Recording System

4.3.2 Prototype design and development

The design for both the app and portal was specified based on the identified requirements. The core design specifications alongside some favourable features were simulated in the system prototypes where feasible, as illustrated in Tables 12-15. Some design aspects were not fully simulated, as this was not possible, but were partially simulated. To demonstrate as much as possible of the design specification, high fidelity clickable prototypes for the system were built. Such prototypes require more skill and time than traditional paper-based and low-fidelity prototypes (Walker et al., 2002). They, however, represent more realistic and detailed design allowing realistic user interaction and consequently better outcome of user testing (Babich, 2017).

There are a number of tools available in the market, such as InVision, Figma, Adobe XD, that can be leveraged to build and provide interactive prototypes (UserTesting, 2019). They vary in terms of subscription charge and features provided; however, InVision was ranked first in the lists of best prototyping tools (Heaton, 2018; UserTesting, 2019). InVision has several standout features including the best way to share design mock-ups with project team members and clients and having its own app for UI design, prototypes and animations (Bogawat, 2019). It allows syncing with Sketch files, a well-known design program, facilitating a real-time update to prototype (Bogawat, 2019; Heaton, 2018). Therefore, Sketch software was used in combination with the InVision platform to design and build the prototypes for the intended system (InVision Platform, 2018; Sketch Software, 2018). The former was utilised to design and

link the screens for each application prototype. Prototypes were then synchronised to the InVision platform where they were ready for the usability testing[6]. The InVision app was installed on an iPad which was used to access the designed app prototype simulating the real app for the system. The latter was given the name 'PainRecord'. Using a laptop, the portal prototype was directly accessed via the platform website simulating the real portal application. The iPad and the laptop were used by the participants during the test. Figures 13 and 14 demonstrate some screenshots of the app and the portal prototypes, respectively.

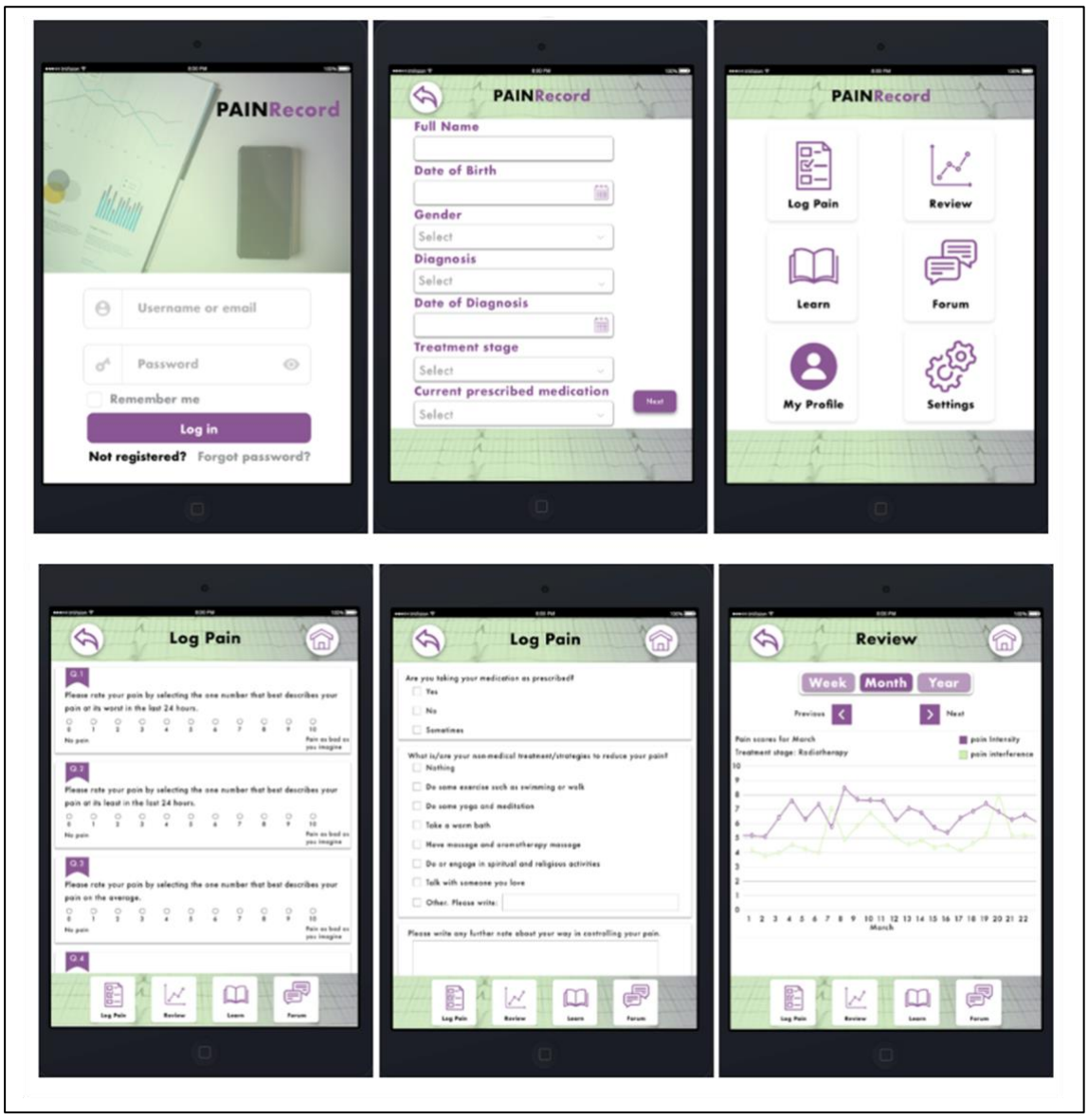

Figure 13: Screenshots of the app prototype

[6] The prototypes can be accessed from:
The portal: https://invis.io/QSK1T8UXVFR
The app: https://invis.io/Q7I7XPUY4U6

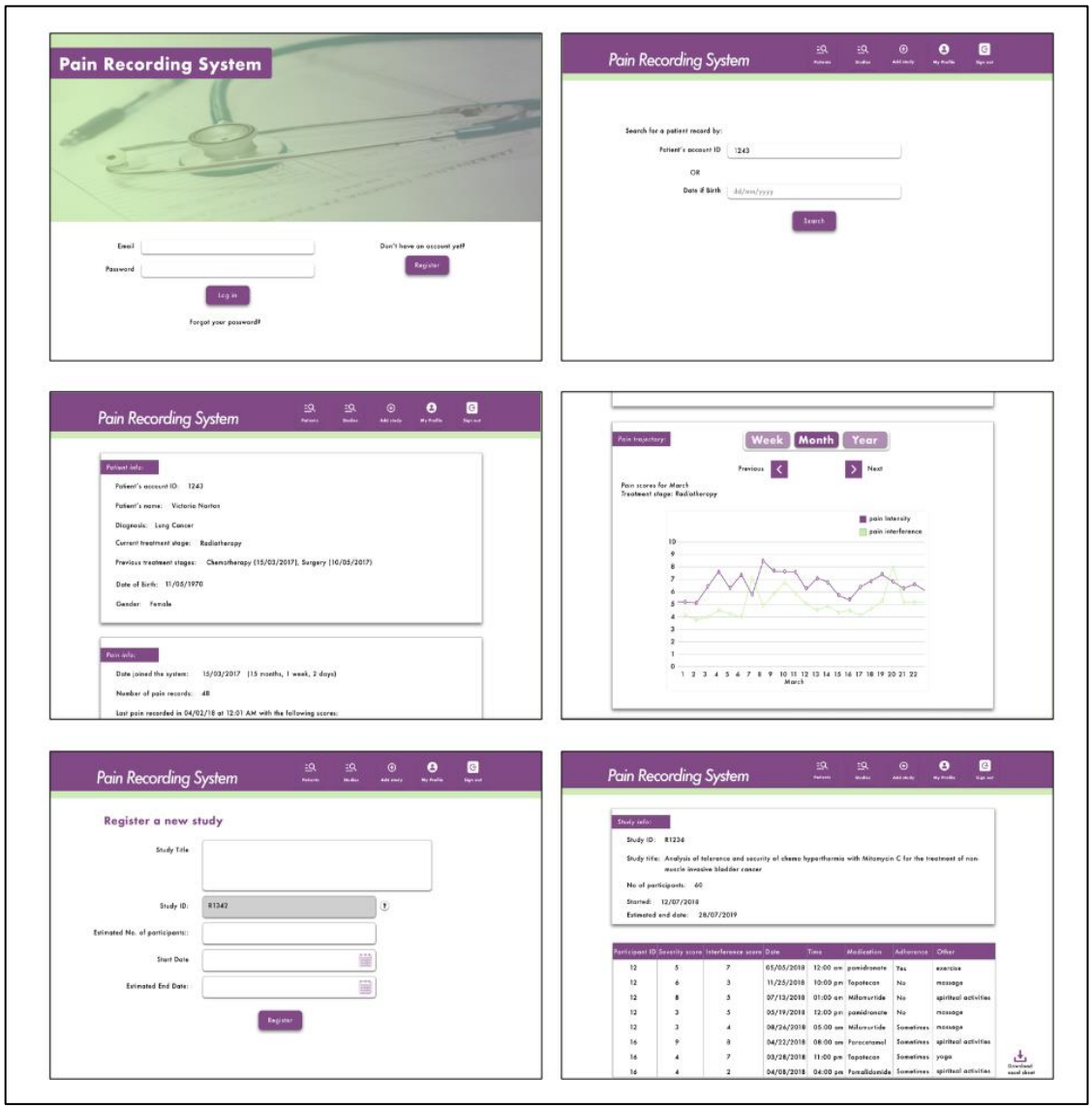

Figure 14: Screenshots of the portal prototype

4.3.3 Usability evaluation

4.3.3.1 Usability testing approaches

Usability testing, which is an essential process of UCD (Bertaggia et al., 1992; Pratt and Nunes, 2012), involves three important components: representative participants, representative tasks, and representative environments. At least one observer is required to monitor participants' interactions with the evaluated software or website (Lewis, 2006).

Usability testing is typically conducted by means of either a qualitative or quantitative approach, which is determined based on the initial aim of the test (Lewis, 2006; Sauro, 2010; Moran, 2019). The qualitative approach is used to discover and fix usability problems in order to improve the user interface as part of an iterative design process (Bertaggia et al., 1992; Nielsen, 1993; Sauro, 2010). On the other hand, the quantitative approach is usually adopted to assess the overall quality of an application interface and describe the usability of the application through usability metrics (Nielsen, 1993; Sauro, 2010). It is normally used to compare designs and decide between alternatives or as a part of competitive analysis (Bertaggia et al., 1992; Nielsen, 1993).

Typical data collection methods used in qualitative usability testing include think-aloud protocol, observation, focus group, and semi-structured interviews (Nielsen, 1993; Cato, 2001; Jibb et al., 2017; Pratt and Nunes, 2012). These methods are intended to supplement each other since they can reveal different aspects of the usability problems, and their advantages and disadvantages can partly compensate for each other. Therefore, the recommended practice is to choose a few of these methods based on the availability of resources for the test instead of relying on just one (Nielsen, 1993).

The data collection methods for the quantitative usability testing are based on measurement of usability aspects. According to the ISO, the usability of a product is specified by the extent of effectiveness, efficiency and satisfaction in achieving specified goals by specified users in a specified context of use (ISO 9241-210, 2010). Each of the mentioned usability attributes is quantified by different usability metrics as recommended by field experts and detailed below:

- Effectiveness is quantified through the task completion rates and the number of user errors (Nielsen, 1993; Sauro, 2010). Errors are defined as incidences of unintended actions or omissions (Sauro, 2010).
- Efficiency is represented by the time the user takes to complete tasks (i.e. task time) (Nielsen, 1993; Sauro, 2010).
- Satisfaction is measured either at task level or at test level; or both if possible, using reliable questionnaires (Nielsen, 1993; Sauro, 2010). The System Usability Scale (SUS) (Brooke, 1996) is a standard that has been used heavily for this purpose as a post-test questionnaire

(Lewis and Sauro, 2009; Sauro, 2010). The Single Ease Question (SEQ), which is a validated 7-point rating scale where 7 is ‘very easy’, is recommended as a post-task question (Sauro and Dumas, 2009; Sauro, 2010).

As expected, the qualitative usability testing approach is the common practice in usability testing conducted in the early stages of developing health apps and systems as part of the iterative design process. Most reported usability studies for such interventions have focused on use of the ‘think-aloud’ technique combined with semi-structured interviews or focus groups to disclose problems in their product design and improve it (Stinson et al., 2013; Jibb et al., 2017; Taylor et al., 2017b; Cai et al., 2017).

There is, however, scope to explore collection of both qualitative and quantitative data in usability testing associated with the early stages of development of mHealth interventions. Combining and linking qualitative and quantitative approaches in the so-called mixed methods approach can provide a more holistic understanding than can be achieved by one method alone (Fetaji et al., 2008; Fetters and Molina-Azorin, 2017). In addition, the advantages and disadvantages of the two data collection methods can supplement each other. For example, the response bias through which interview participants tend to give answers that are more socially accepted could be resolved by objective measurement of the usability attributes (Fetaji et al., 2008; Zapata et al., 2015).

Indeed, there is a recent growing interest in adopting the mixed methods approach in conducting usability testing studies for health apps at the design stage (Amann et al., 2020; Korpershoek et al., 2020). Moreover, a recent study has introduced iterative convergent mixed methods design as a novel framework for creating insight into health app usability (Alwashmi et al., 2019). The approach involves simultaneous qualitative and quantitative data collection and analysis that continues through the development iterations of the app. In cyclical iterations, early development is more qualitatively focused but gradually becomes more quantitatively focused with an increased number of participants (Alwashmi et al., 2019).

Furthermore, Sauro (2010), a usability expert, supports the mixed methods approach, naming it the 'quantitative formative approach'. He emphasises that quantifying usability as part of an iterative design and test strategy can support the qualitative results, allowing testers to describe usability problems in numbers and establish a usability benchmark. Such numbers may not be statistically reliable due to the small sample size, but they can support testers' interpretations and claims given the testing goal (i.e. iterative design) (Sauro, 2010).

In the current usability testing, a mixed-methods approach was adopted in which quantitative and qualitative data were collected. Qualitative data were used to identify and characterise usability problems and to capture recommendations for improvement. Some usability metrics were collected to manifest the perceived usability of the system prototypes in numbers, allowing numerical tracking of design usability in future testing.

4.3.3.2 Participant sampling and recruitment

Two groups of representative participants were required to test the system prototypes: a group of patients with cancer and a professional group representing HCPs and researchers. Purposive sampling was employed to produce the study samples for both groups of participants. This technique involves selecting participants who are likely to generate useful data, and it is the aim of most qualitative research that uses non-probabilistic samples (Green and Thorogood, 2014). The appropriate method for the current study was to recruit the maximum variation of samples in terms of demographic characteristics, such as age, sex, role (for the professional group), and patients' diagnoses. It is, in fact, widely used and recommended in studies related to mHealth applications to maximise the possibility that the participants' feedback will apply to many types of people (Hilliard et al., 2014; Cai et al., 2017; Jibb et al., 2017).

A sample size of six for each group of participants was estimated with the intention of continuing sampling until saturation point is reached. Data saturation occurs when no new information is being generated (Green and

Thorogood, 2014). Saturation is considered the gold standard by which purposive sample sizes are determined in health sciences research (Guest et al., 2006). Furthermore, experts in usability engineering have found that testing 5 potential users in each iterative cycle can be cost effective and is sufficient to reveal most of the usability problems and improve the design (Lewis, 2006; Nielsen and Landauer, 1993; Sauro, 2010; Nielsen, 2000; Nielsen, 1993; Molich, 2010). Moreover, usability testing studies for mHealth applications indicate that testing with four to six participants in each testing cycle is the typical number needed to reach data saturation in each cycle and refine the prototype (Jibb et al., 2017; Stinson et al., 2013).

Patients were recruited from the Yorkshire Cancer Community Organisation (YCCO), a support and advice network for people affected by cancer in the Yorkshire and Humber area, U.K. (https://yorkshirecancercommunity.co.uk/) and from two patients and public involvement groups affiliated with the School of Medicine at the University of Leeds. The coordinators of these sites were first approached by email, in which the study was briefly explained and assistance in sharing this with their members was requested. Once approval was indicated, a participation invitation email, along with the participant information sheet and participant consent form (see Appendix 7), was sent to the coordinators who circulated them via their internal members' mailing lists. Reminder and follow-up emails were sent when no adequate responses were received. The researcher also had the opportunity to introduce the study and distribute copies of the participant information sheet at the annual general meeting of the YCCO held on 29th June 2018 in Leeds, where a group of the attendees consisted of cancer patients.

Researchers and HCPs were approached and recruited from the University of Leeds and St James's University Hospital in Leeds. A group of names with relevant expertise were identified through their public online profiles. An invitation email with two attachments – a participant information sheet designed specifically for this group and the participant consent form (Appendix 7) – was sent by the researcher to all the identified names.

People from both groups (i.e., patients and professionals) interested in taking part were invited to contact the researcher by using the contact details provided in the invitation email or the information sheet. Participation was voluntary and time spent during the testing session was not to be compensated. Participants were eligible to claim any travel expenses incurred in order to take part in this study.

4.3.3.3 Participant eligibility criteria

For the patient group, participants were required to (1) be ≥ 18 years old, (2) be able to speak and read the English language, (3) be diagnosed with cancer, (4) have experienced at least one episode of pain after diagnosis, (5) have no severe physical or cognitive impairments or psychiatric illnesses, and (6) be smart device users and familiar with mobile apps. For the professional group, HCPs and researchers were eligible if they had an interest in or experience of working in the field of oncology and palliative care.

4.3.3.4 Ethical approval and considerations

The study was reviewed by the School of Medicine Research Ethics Committee at the University of Leeds and ethical approval was granted on 16th May 2018 (Ref no: MREC17-059, see Appendix 8).

All the participants were fully informed of the study by being provided with the participant information sheet and consent form. Completed and signed consent forms were collected at the beginning of each testing session. The participants had the right to withdraw from the study at any time before the start of data analysis. Identifiable data were only collected through the consent forms. Other collected data were anonymised using a coding system. Any contact details collected while arranging participation were kept only if participants were happy to be contacted again for future phases of the research. The data were retained securely by the researcher; paper records of the study were kept in two separate locked cabinets within an office at the University of Leeds, while the electronic records were stored in the University server (i.e., the researcher's M drive).

4.3.3.5 Usability testing tasks

Specific tasks were identified based on the system use cases which would be performed by potential users (i.e., patient, HCP, or researcher). The tasks were created by the researcher and discussed with the academic supervisor D.W. to ensure their effectiveness and precision (see Appendix 9).

4.3.3.6 Usability testing procedure

The testing sessions were conducted separately for the participants in a quiet room at either the University of Leeds or St James's University Hospital in Leeds. The sessions were led by the researcher alone and lasted between 60-90 minutes. A session guide was used in all sessions (Appendix 10). At the beginning of each session, a brief introduction to the test's purpose and process along with a minimal explanation of the Pain Recording System were provided. After the signed consent forms were collected, participants were asked to complete a short questionnaire that asked to provide demographic data as well as information on usage of mobile apps (see Appendix 11). The 'think aloud' technique was employed in this testing. It involves asking participants to verbalise their thoughts as they complete tasks and move through the user interface (Nielsen, 1993). A demo[7] of the think aloud protocol was displayed to all participants before starting the test, to ensure full understanding of the process. Participants were asked to think aloud while testing the prototype and to carry out the group of tasks that was appropriate to their role. The tasks were written on separate papers and handed to each participant one at a time. The professional group was given the chance to randomly explore the app prototype before testing the portal prototype to grasp the entire system. The researcher observed each participant's interactions with the system prototypes and documented certain usability metrics, including task completion times and rates, and numbers of user errors. An observation sheet was designed to facilitate this (see Appendix 12). The audio and touch-screen interactions were recorded to support the field notes. After completion of each task, the participants were asked to rate the task's difficulty using the Single Ease Question (SEQ). After

[7] Provided by the Nielsen Norman Group (NN/g) on: https://www.nngroup.com/articles/thinking-aloud-demo-video/

finishing the test, the participants were asked to complete the System Usability Scale (SUS) (see Appendix 13). Finally, participants were involved in a brief semi-structured interview to capture any requirements and thoughts that had not been articulated during the test. The interviews were audio recorded and an interview topic guide was used in all of them (see Appendix 14). At the end of each session, participants were thanked for their time and were asked whether they were happy to be contacted again for further testing.

4.3.3.7 Data analysis

Data analysis began from the first usability testing session in order to recognise when data saturation was reached. The recordings of the semi-structured interviews were transcribed by the researcher. The transcripts, along with the session field notes, were analysed using the thematic content analysis approach (Green and Thorogood, 2014). This approach is the most common one for analysing qualitative data produced from usability testing (Cai et al., 2017; Jibb et al., 2017; Stinson et al., 2013). The data obtained from the current study were reviewed, and a coding system was created to reflect perceptions, recommendations and usability issues in the system prototypes. The data were coded, and the codes were then grouped into meaningful categories. Finally, similar categories were organised and grouped to represent overarching themes. NVivo software (QSR International, 2019) was utilised to assist in the analysis process. The researcher came up with suggestions on how the system could be improved to reflect the identified themes (i.e., requirements and usability issues) wherever feasible. The suggestions were then discussed within supervision meetings until consensus was achieved.

Descriptive statistics were used to summarise the demographics and the usability metric data. For calculating the task completion rate ($\frac{\text{number of successful completed tasks}}{\text{taken number of tasks}}$), codes one and zero were used for successful and unsuccessful completion respectively. To ease the analysis of user errors, a code system was used as follows: one for at least one error committed and zero for no error committed for each task, following Sauro's (2010) suggestions. Each usability metric on a task level, including completion rate, number of user errors, SEQ, and time on task, was calculated to obtain the average for each

participant separately. Then, the aggregate mean and 95% confidence interval (CI) were calculated for each participant group (i.e., patients and professionals) to draw a conclusion about a metric. The mean and 95% CI were calculated for the SUS scores for each participant group. Both SPSS (IBM Corporation, 2019) and Microsoft Excel software were used to conduct the analyses.

4.3.3.8 Results and interpretations

4.3.3.8.1 Participant Characteristics

Data saturation was reached after testing and interviewing eleven participants as follows: five cancer patients and six palliative care professionals. Patient participants were aged ≥ 41; 80% were female; all were using smart devices and all stated they were confident (60%) or very confident (40%) in using them; none had tried any pain app previously and 60% stated that they were using some health-related apps (see Table 16). Participants who were professionals were aged 18-40; 67% were female; three had a combined clinical and academic role and three had a predominantly research role; 50% had work experience of >3 years; all were confident in using computer-based applications and 67% were health apps users (see Table 16).

Table 16: Participant characteristics

Patients	**n = 5**
Range of age in years (n, %)	41-65 (2, 40%) >65 (3, 60%)
Gender (n, %)	Female (4, 80%) Male (1, 20%)
Using smart devices (yes %)	100%
Level of confidence in using smart devices (%)	Confident (60%) Very confident (40%)
Tried any pain app before (Yes %)	0%
Using health related apps (Yes %)	60%
Professionals	**n = 6**
Range of age in years (n, %)	18-40 (6, 100%)

Gender (n, %)	Female (4, 67%) Male (2, 33%)
Role (n, %)	Clinician-researcher (3, 50%) Researcher (3, 50%)
Years of work experience (n, %)	>3 (3, 50%) 1-3 (2, 33%) <1 (1, 17%)
Level of confidence in using computer-based applications (%)	Confident (50%) Very confident (50%)
Using health related apps (Yes %)	67%

4.3.3.8.2 Qualitative results

Three overarching themes were identified from the qualitative analysis: (1) appreciation of the system; (2) clarifying certain design aspects and functionalities; and (3) enhancing the quality and usage of captured clinical data. Each theme covered several categories, as elaborated below, along with the identified feasible reflection in the design of the functioning system.

Theme 1: Appreciation of the system

- Intuitive layout and navigation: Simplicity of the design was well-liked by participants. All participants found the app and the portal easy to use and understand. There were minimal problems navigating between screens and finding a way to accomplish an aim. For the app prototype, patients said:

"I like the fact that it was very simple; the visuals are very simple and there was nothing complicated." (Patient 3)

"I like the simple way to slide out and the explanation for each part that you need to use and was very clear. I liked the whole pages' layouts and the colours used. I do not have anything that I dislike as I find it very easy to use." (Patient 4)

For the portal prototype, one of the professional group members commented:

"I think it was very easy and very clear; the layout is very clear, and all the processes are well linked to each other." (Professional 5, clinician-researcher)

- Effectiveness of the system's main functions: The participants recognised the usefulness of reporting and reviewing the history of pain for effective pain management.

"We tend to ask patients just to measure outcomes like pain in one quick snapshot of time, and that does not capture their whole experience, so measurements like this are really helpful and allow you to kind of look over time and look in more detail at how different outcomes fluctuate." (Professional 2, researcher)

"If I had it, I would use it. I think it would have helped me if I had kept a diary of how I was every day . . . so having an app like this would be very useful because I used to use a diary, which does not allow much space. With this, you can put in a lot of information about how you are, and I think it's very good." (Patient 5)

"It is useful to see the graph and to track things . . . to see what happens when asking a patient to use new medicine because, if I have this information, it is great to incorporate this with the pain scores. As a clinician, I am constantly asking patients after we started if they noticed any benefits. Sometimes, people cannot remember very well because they have been busy recently, so that would be useful from the point of view of tracking things." (Professional 6, clinician-researcher)

In addition, the researchers appreciated the ease of collecting pain data through the app and found it a novel approach, with one researcher stating the following:

"For me, as a researcher, I can see that would help me capture pain data easily from patients . . . I could log a couple of different studies on there, and I could make the app work for two or three different studies . . . I think it has really good

function and is something not seen before. Normally, you would see a web app designed for a specific study, and it is only used for that study. I like the fact that this is generic, simple and easy to use." (Professional 3, researcher)

Theme 2: Clarifying design aspects and functionalities

- Explaining the aim of the app and how it is useful: The participants indicated that it might be useful to provide either some explanation or a video guide for the potential benefits of recording pain, using the app for the long term. They thought that people might not see how useful this format is at the start of using the app, which raises the risk of early discontinuance.

"I think it probably needs to be shown how it could be helpful. Otherwise, they will not risk inputting their stuff . . . you can have a video guide or a tutorial to show them how to use it." (Professional 6, clinician-researcher)

This recommendation was already considered and addressed in the app prototype by two subsections of the 'Settings' section: 'About PainRecord' and 'User guide video'. The subsections, however, were not active in the prototype. This confirmed the need to implement these sections so as to provide some explanation of the app and the potential benefits of using it, as well as to showcase the functionality of the app via a video guide.

- Explaining the reason for having two lines in the pain graph: The participants expected to see one line in the pain graph (see Figure 13, Review screen); there are two lines: one for severity and one for interference of pain based on how the BPI-SF captures pain (Cleeland, 2009).

"Make it clear why there are two lines in the graph because people expect to see one line for pain." (Patient 3)

This issue was addressed in the 'Log pain' section by using some design touches to explain that there are two sub-measures for pain. For example, we matched the colours that were used in the questions for each of the sections to the lines in the graph.

- Data protection and use policy: The participants expressed concern about where the data were stored and who had access to them. They requested clarification of the policy of data use in the app.

"My only other thing is about the GDPR [the General Data Protection Regulation] stuff. I just . . . having a little something somewhere just for people to understand how to log in to this and how your pain diaries are being kept . . . who is doing what whilst it's there?" (Patient 3)

This concern was appreciated and will be considered when the system is adopted and implemented. It was not feasible, however, to provide a valid data policy during the developmental stage. The data collection for the development stage was in-line with the GDPR but a data policy for the functional system would be required for active clinical use.

- Simplification of wording and terminologies: The participants noted some terminologies and wording in the app that seemed complicated for the general public.

"I think that's a bit of a complicated sentence. I think you could restructure that sentence to make it a little easier to understand." (Patient 5)

All the issues with wording that were mentioned by the participants were noted and simplified. The simplified forms of the wording were based on participants' suggestions and/or discussions by the research team.

- The forum's usefulness: The participants questioned the use of an external forum because the app provides a link to the Cancer Research UK online forum. They suggested the provision of explanations about the benefits that they might obtain from using it.

"I think I dislike the forum being linked to me. I think it is unnecessary. It did not tell me what I may gain from it. Maybe an explanation of speaking to other people in similar situations could be helpful and would motivate people to sign

up. Again, you have another sign-in page, different logins and different passwords, so I am just not sure that would work for many people." (Patient 1)

This recommendation was addressed by adding an induction screen before linking to the external forum, to highlight the potential benefit from sharing thoughts with others in the same situations and to provide hints for a better user experience. There might have been better impressions of the forum if it had been developed internally. This is currently out of the system's scope and resources.

Theme 3: Enhancing the quality and usage of captured clinical data

- Capturing used pain-control strategies: Because the app requires users to log pain data once a day, including pain level and strategies used to control their pain, the participants were not sure whether users would be able to recognise the connection between what they do during the day and their pain levels.

"I am not sure how the patients or people always know the strategies that they have taken necessarily . . . they might be quite habitual . . . But I think capturing an overall pattern might be helpful if you're capturing the different types of things that people are doing. So, if everyone is doing exercise or something, but doing something like taking a warm bath is better, that might be helpful to know." (Professional 2, researcher)

"You might find that people will get confused with that . . . people who are religious might pray every day, but whether they feel that this reduces their pain every time, I do not know . . . it doesn't work in sessions in an accurate way. Maybe it could be the same with talking with someone you love – it might be helpful, but it doesn't really reduce your pain . . . so, I don't know. It depends on how each person looks at these questions differently." (Professional 4, researcher)

In responding to this, the app aims to help patients recognise their practices in relation to their pain levels and to provide hints to try something different to

ease pain. The effectiveness of this, and whether patients can recognise the connection, will be confirmed by the long-term trial.

- Using notifications: The participants suggested sending a notification to patients when their pain level shows a consistent or increasing layout or when they fail to log pain details for a few days.

"Is it possible to say your pain is consistent? The layout should have your GP or consultant review your medication, so if one has pain every day at a level of 10, the app will alert him to see his consultant." (Patient 4)

"You want to set times at which your patients are prompted to put in their scores because, if you give the patients the app to use and they barely use it, then you are not collecting enough data as a researcher." (Professional 6, clinician-researcher)

These suggestions confirmed the importance of providing users with feedback regarding their interaction with the app. This had already been documented in the requirements list of the app (see Table 12; requirements # 6 and 7), but it was not feasible to integrate it into the prototype's design as this need input data from the user.

- Capturing reliable and updated clinical data: The participants, especially the professionals, raised the concern that patients might struggle to specify the treatment stage or might not provide reliable data for it.

"People get confused between stage and grade . . . I do not think you will necessarily get reliable data for the stage." (Professional 2, researcher)

"I think it (treatment stages data) would be valuable, but it would depend on how and what options are provided in the dropdown menu. There are different ways in which you can interpret different stages. In my research, I did not ask this, but I checked for it anyway in the medical records because, for example, some people will say that their diseases are stable, but they are still receiving

chemotherapy or immunotherapy. Whether that is considered stable or under treatment depends on how you define it." (Professional 4, researcher)

The professionals also indicated that it is quite challenging to find a practical method for capturing accurate and precise data about current prescribed pain medication that could work with patients.

"I think that, potentially, a dropdown box describing different types of medicine could become very big because . . . are you going to summarise for them, for example, opioids . . . the patient may not know what an opioid is." (Professional 6, clinician-researcher)

"Patients find it easier to select from an alphabetical list of medications rather than classifying them . . . some do not grasp that they are in the morphine category of drugs, and some do not want to think that they are on this drug!" (Professional 1, clinician-researcher)

"If you just have a whole list of different medications, that could be quite burdensome for the patient, particularly if they're not necessarily words that we come across in everyday life . . . if you ask people in an open text box to fill in what they are taking, they would spell it wrong, and they wouldn't remember. It is really difficult . . . I don't have a standard way of collecting that information (i.e., medication)." (Professional 2, researcher)

They suggested integrating a method with which to instruct patients to review and update their recorded treatment stage and medications.

"I would say the only thing that I dislike about it is some of the information that the patients are being asked to collect and find. I think there has to be a way of ensuring that it's up-to-date information and there are good prompts and sufficient patient information in order for them to accurately write down what treatment they are receiving or what pain they are having." (Professional 6, clinician-researcher)

These issues were addressed by using two dropdown menus with a start typing functionality to refine the list. This solution is in line with evidence related to usability of apps (Zapata et al., 2015). One menu presents a list of general cancer treatment stages, and the second lists standard categories of pain medications. The list of treatments[8] was specified based on the feedback of HCPs. The medication categories were identified from Cancer Research UK (2018). To encourage patients to regularly review the data that were provided when they registered, this is displayed at the top of the pain graph with a link for updating the information.

- Providing summaries of the collected data: The professionals asked to see summaries of patients' demographic data and how often they logged pain data.

"You are probably wanting something to say how often they are completing it so that there is compliance with the instructions of the app." (Professional 6, clinician-researcher)

"It would be good to have various simple summaries of the data that patients have entered . . . so, number of patients currently active, number of patients completed . . . maybe a pie chart of males and females and a quick graph of the different age ranges. You know, the kind of demographic data that the patient entered on the app." (Professional 3, researcher)

These recommendations were added to the portal's requirements list and were incorporated in the developed system.

Overall, these results indicated that the system was well-received, and all participants found it promising and easy to use. A few required changes and usability issues with the design were identified by the participants and were incorporated into the developed system.

[8] Surgery, Chemotherapy (IV), Chemotherapy oral, Surgery and Chemotherapy, Radiotherapy, Hormone therapy, Immunotherapy, No treatment, Other.

4.3.3.8.3 Quantitative results

The captured usability testing metrics confirmed the qualitative findings and suggested that participants had found the system prototype usable, as outlined in Table 17. The figures represented adequate usability objectives (i.e. effectiveness, efficiency and satisfaction; discussed in section 4.3.3). Task completion rates were 95% and 100% for patient and professional groups respectively. Number of user errors was 0.13 and 0.04 in testing the app and portal prototypes respectively. Both metrics' scores representing effectiveness were in line with the recommended figures, which are a >78% completion rate and a <0.66 average of user errors (Sauro, 2010). The same was found for the metrics that were used to represent system satisfaction, where the average SEQ and SUS scores showed figures (see Table 17) higher than the recommendation of >4 points and >68 points, respectively (Sauro, 2010; Sauro, 2011). Furthermore, the average time to complete a task in the system prototypes was only between 33 seconds and 1 minute and 7 seconds (see Table 17), which can be seen as a good level of efficiency. Taken together, these results showed that the intended system has the potential to be effective, efficient and satisfying for users. The recorded usability metrics provided a baseline for future usability testing, where system improvements in usability objectives can be tracked.

Table 17: Usability metrics

Usability metrics	In testing Patients	In testing Professionals
Mean completion rate, (95% CI[a])	95% (90%, 100%)	100% (100%, 100%)
Mean number of user errors, (95% CI[a])	0.13 (0.05, 0.20)	0.04 (0.00, 0.13)
Mean SEQ, (95% CI[a])	6 (5, 7)	7 (6, 7)
Mean Task time mm:ss, (95% CI[a])	01:07 (00:57, 01:21)	00:33 (00:19, 00:47)
Mean SUS (95% CI[a])	90 (83, 97)	85 (76, 92)

[a] Based on 1000 bootstrap samples

4.3.3.9 Study reflection

The study set out with the aim of testing the usability of the proposed prototypes of the pain recording system and collecting recommendations for design improvements. The mixed methods approach which is a relatively new methodology in this context was explored in conducting the testing. Collective findings derived from both qualitative and quantitative data provided insight into the needs of the system's potential users and informed the extent of usability of the suggested design. There are, however, several challenges and considerations that need to be taken into account in future studies.

Firstly, the testing sessions were conducted and observed by the researcher alone. Although the sessions were well-planned[9] (see section 4.3.3.6), it was challenging in some cases for a single observer to control the testing conditions, which might have affected the accuracy of the results. Indeed, it is recommended that at least two evaluators be present in usability testing sessions to help with observation and interpretation of the perceived information (Zapata et al., 2015). In some cases, precise capture of some usability metrics such as task-time while participants were applying the think-aloud technique was challenging. This was because some participants had a greater desire to pause while performing a task, or to talk or ask questions. Although referring back to the screen recordings in such cases was significantly helpful in extracting the data, the presence of more than one observer could have helped in controlling the testing sessions and enhancing the credibility of study results. The author's observation is in line with evidence from previous observations that found the noise in usability measurements is likely to increase due to some people being more talkative than others (Amann et al., 2020; Budiu, 2017).

Another source of uncertainty is that all the participants from the patient group had experienced at least one episode of pain previously (see section 4.3.3.3) but had no pain while performing the test. It is important to consider that their

[9] Beside reviewing the literature, the researcher attended three highly regarded training courses to help with designing and conducting the usability testing study. The courses involved practical aspects of usability testing and measuring user experience and were held in London in March 2018 by the NN/group https://www.nngroup.com/, a well-known group interested in evidence-based user experience research and training.

performance might have differed if they had been in pain; for instance, they might have made more errors. Therefore, the results from this group need to be interpreted with caution. Involving cancer patients in pain in a future study would present more representative results, although it is questionable whether it would be ethically and practically feasible to do that.

In addition, in consistent with the literature (Adam et al., 2021; LeBlanc et al., 2013; Reid et al., 2015), the recruitment of the patient group was challenging and time-consuming despite the small sample size required for this study. As the intended system is oriented towards cancer patients in community settings, it was thought that a typical group of these patients would be easily reached through the sites discussed in section 4.3.3.2, which maintain several communication channels with people affected by cancer in the Yorkshire area. Although the arrangers of the sites were thankfully cooperative in advertising the study, there was low interest in participating. Therefore, the recruitment period was expanded to more than three months (starting on 4/6/2018 and ending on 21/9/2018). Other recruiting approaches need to be explored with the mentioned population in future studies to speed up the requirement period.

Finally, it is important to stress that the patients who participated in this study were selected purposively and were required to be smart device users and familiar with mobile apps, as discussed before (see sections 4.3.3.2 and 4.3.3.3). Therefore, the study findings including the perspectives of app users cannot be extrapolated to the whole patient population, and a larger usability study with representative samples will be needed in future to draw decisive conclusions about the usability of the app.

4.4 Chapter summary

The aim of this chapter was to shape the design of the pain recording system, which was published, addressing the third and fourth objectives of the thesis (see Chapter 1, section 1.2.1). A review of 11 available pain apps was reported here and contributed to identification of the workflow of the intended app (i.e. PainRecord) along with useful app features to be considered. The UCD approach was employed to guide the design and development of the entire

system, focusing on involving potential users (i.e., HCPs, patients and researchers) from the early stages of development. The involvement of end users and HCPs in pain app development is minimal in existing pain apps, which affects their clinical utility (Zhao et al., 2019). The outcomes from the previous two chapters (i.e., 2 and 3) as well as the pain app review were integrated within the first phase of the UCD that aimed to identify user needs and system requirements. High-fidelity clickable prototypes were developed representing most of the system functionalities. Eleven usability testing sessions were conducted by employing an innovative approach, the developed prototypes and representative system users. The findings suggested that the system has the potential to be easy to use and well-aligned with users' needs. They identified usability measurements to be utilised in tracking improvements to the system. There were a few recommendations and addressable usability issues reported by the participants. This supported the intention to directly convert the identified system design, with serious consideration to all of the required changes, to a working system prototype through the second iteration of the UCD discussed in the forthcoming two Chapters; Chapter 5 (the system development) and Chapter 6 (the system feasibility evaluation).

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Chapter 5

Development of the pain recording system

5.1 Chapter overview

This chapter reports the development process of a working prototype of the intended system, addressing the fifth objective of the thesis which is 'to build the system'. The outcomes of the first iteration of the User Centred Design (UCD) discussed in the previous chapter, informed the system design and requirements. The second iteration of UCD, reported in this chapter, focuses on converting the design into a fully functioning prototype, as illustrated in Figure 15.

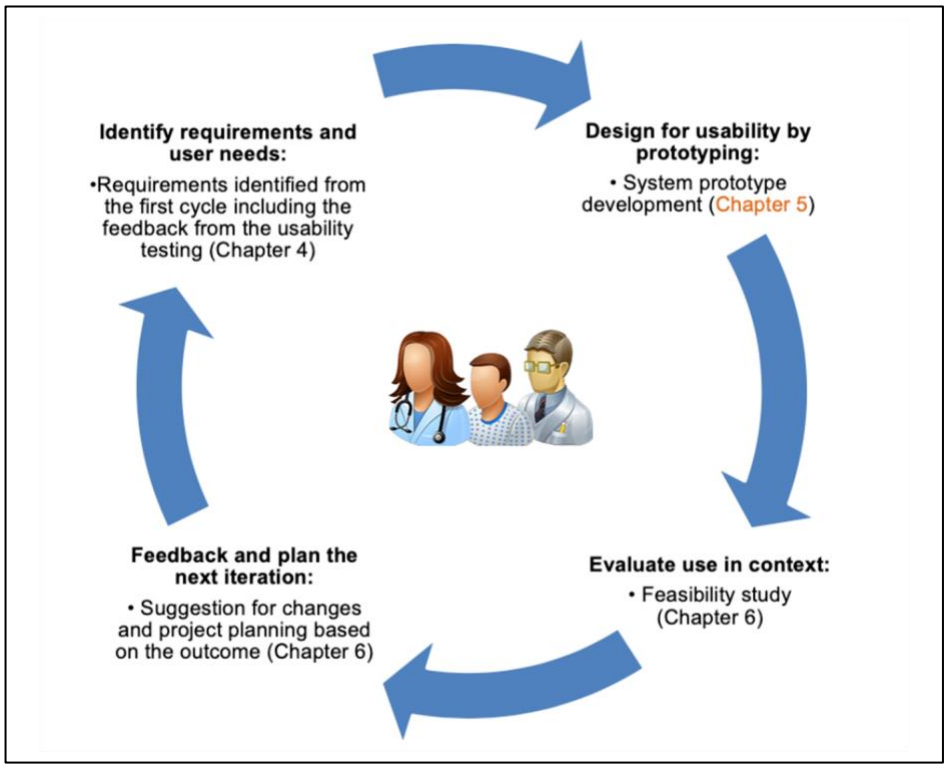


Figure 15: Second cycle of the UCD aimed to develop the fully functional system prototype, adapted from Gulliksen et al. (2003, p. 5)

5.2 System development: general procedure

An iterative and incremental approach was adopted to develop the system's working prototype demonstrated in Figure 16. It is a practical and well-established model for software and system development that can be easily integrated with UCD (Basil and Turner, 1975; Dhandapani, 2016). The method was first introduced by Basil and Turner (1975) and is now deemed the predecessor of the Agile model, the most successful and commonly used model in the industry (Dhandapani, 2016). It necessitates having a list of the project tasks (i.e., requirements) needed to achieve the final implementation. Then it starts by building and testing a simple implementation of a small subset of the tasks, iteratively enhancing existing versions and adding new features, that is, another subset of tasks, until the full system is implemented (Basil and Turner, 1975; Dhandapani, 2016).

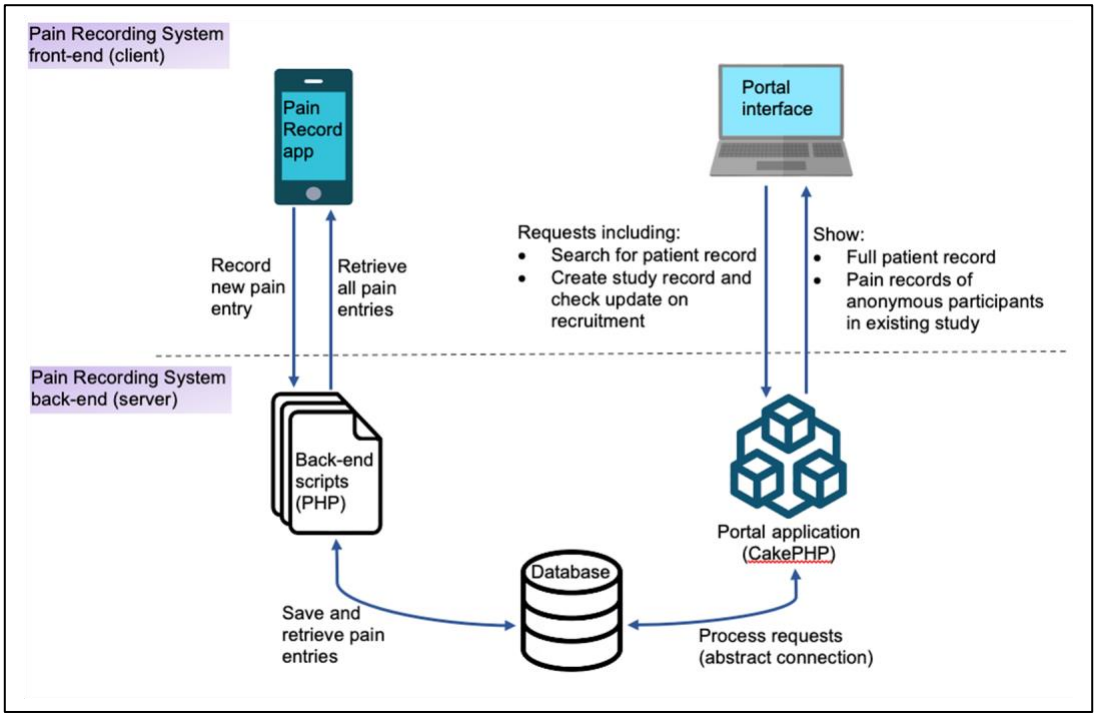


Figure 16: The architecture of the Pain Recording System's working prototype

The identified requirements for the Pain Recording System components, as discussed in the previous chapter, were iteratively and incrementally built into codebases by the researcher, starting with the PainRecord app as detailed

below (see the project code hosted in a GitHub repository[10]). The code was written with two key considerations, which are critical to obtaining maintainable code: the code should be readable, and the requirements might be changed or extended. This implied using comments efficiently, avoiding duplicated code, naming things appropriately, and structuring the code discernibly (Miller, 2006; Boro, 2018). Implemented functionalities were reviewed and tested in regular meetings with the research team, where any problem in the implemented design was discussed until a design solution was reached by consensus, on the basis of which consequent modifications were made by the researcher. Once implementation of all the features for each system component was completed, the working prototype was tested individually by the principal researcher and research colleagues (that is the 3 supervisors) on their own devices. Any further recommendations or design issues were addressed in the final prototype version before moving to the 'evaluate use in context' phase of the second cycle of UCD, discussed in the following chapter.

5.3 Development of the PainRecord app

5.3.1 Approaches for developing the app

One of the requirements was to deliver the intended app for the two leading platforms (i.e. operating system [OS]) for mobile apps, Apple iOS and Android (International Data Corporation, 2020). The purpose of this requirement was to increase the accessibility of the app by ensuring it could be available to the large number of mobile app users. Such an aim led to the selection of the technical approach adopted to develop the app, as discussed below.

There are mainly three approaches to mobile app development, referred to as mobile app types: Native, Web, and Hybrid (Jabangwe et al., 2018; Anglin, 2017). Native app development necessitates using each platform's specific programming language, software development kit (SDK), and a development

[10] The GitHub repository created for the project can be access via https://github.com/amhzjm/Pain-Recording-System using the following sign in details:
Username: myguests
Password: asma2guests

tool to build apps that are specific to that platform (Anglin, 2017). It implies the need for a significant amount of resources, specifically time, effort and money, to build an app that can be deployed on both the aforementioned platforms, as it involves writing the code twice for the same app to run on two different runtime environments (Shah et al., 2019). For example, an extensive knowledge of Java or Kotlin is required for Android, while Objective-C or Swift is required for iOS (Shah et al., 2019). Interestingly, Apple introduced ResearchKit, an open-source framework providing iOS app developers with tools designed for medical research (Apple, 2021). The native app development approach allows developers to leverage native technologies and application program interfaces (API) for a specific OS such as accessing the location, filesystem, and camera (Jabangwe et al., 2018; Fling, 2009). As a result, native or platform apps, as they are referred to in some literature, have the advantages of providing the richest design and user experience (UX), that is usability, along with fast performance and consistent look and feel compared to other app types (Jabangwe et al., 2018; Xanthopoulos and Xinogalos, 2013; Heitkötter et al., 2013; Fling, 2009).

Web apps, unlike natives apps that require certification and distribution from a third party in order to get on users' devices (Fling, 2009), rely only on the internet browser of a mobile device to run. No installation is required and there is accessibility across platforms providing the same UX (Shah et al., 2019; Jabangwe et al., 2018; Xanthopoulos and Xinogalos, 2013). They resemble websites in that they are inaccessible when there is a network failure. In addition, they have limited access to the underlying technologies of the mobile device (Shah et al., 2019; Xanthopoulos and Xinogalos, 2013). Such apps are developed simply by using standard web technologies, such as HyperText Markup Language (HTML) and JavaScript accompanied by frameworks like Angular, jQuery, Ruby on Rails etc., but are designed specifically for mobile devices' browsers to provide 'application-like' experience (Shah et al., 2019; Jabangwe et al., 2018; Fling, 2009).

Hybrid apps, as the name suggests, integrate aspects from both web and native mobile app development (Anglin, 2017). They are built with web technologies but embed the code inside native web containers which are platform specific

(Anglin, 2017; Shah et al., 2019). The containers allow the apps to be installed on devices, access the devices' APIs, and sometimes look and feel like native apps (Lauer, 2016; Xanthopoulos and Xinogalos, 2013). Hybrid apps can be deployed for multiple platforms with fewer resources compared to native apps, as most of the codebase can be shared (Anglin, 2017; Lauer, 2016). The main disadvantage of such apps, however, is that their performance, including speed, is limited to the performance of the web container on the device they run on, causing different UX across devices (Anglin, 2017; Lauer, 2016).

Selecting a mobile app development approach depends mainly on marrying resources and the requirements of an app to the capabilities of an approach (a mobile app type) (Anglin, 2017). To develop the PainRecord app, use of native devices' APIs and features such as push notifications were required, eliminating the web app approach. Building the intended app as a native app was considered the appropriate approach, as high performance and rich UX were necessary to maintain user engagement. Regular engagement with the app would contribute into optimal pain monitoring meant by the app leading to potentially better pain management (see Chapter 1, section 1.3.9). The extensive resources required for an approach that targeted both iOS and Android platforms created a problem. With the rapid growth of the mobile industry and technology (Shah et al., 2019), such problems have been solved by emerging technologies and frameworks that allow the building of native apps for both the aforementioned platforms with one language instead of two (Schwarzmüller, 2019b). These frameworks compile the application source code using an engine to implement platform-specific user interface (UI) components, providing real native apps (Schwarzmüller, 2019b; Shah et al., 2019; Danielsson, 2016). These native apps are also called interpreted apps, indicating the way they are produced and distinguishing them from native apps built by the platform specific language (Shah et al., 2019). Popular frameworks in this field are React Native, NativeScript, and Flutter (Schwarzmüller, 2019b).

Among the three, React Native (RN) was selected to develop the PainRecord app for several reasons. Firstly, Flutter was eliminated from the beginning because it uses a specific programming language, called Dart created by Google, compared to the other two that use JavaScript, a widespread web

development language (Schwarzmüller, 2019b; Shah et al., 2019). In addition, there was uncertainty about its success because it was very new. The first stable version was released in December 2018 (SPEC, 2018), just at the start of the app development phase in February 2019. Moreover, evidence has suggested that RN is the leading and the most commonly used framework compared to others including NativeScript (Schwarzmüller, 2019b; Shah et al., 2019; The State of JavaScript, 2017). RN, which was developed by Facebook as an open source framework, has been used to build well-known and successful apps for popular and big companies such as Facebook itself, Airbnb, Uber and Instagram (Schwarzmüller, 2019b; React Native, 2020g). Furthermore, it relies on React.js which is an extremely popular JavaScript library for creating interactive component-based UIs (React, 2020b; Peal, 2018a); also it has a vibrant community, enabling help to be obtained when needed (Schwarzmüller, 2019b). Since RN was released in 2015, the developer and RN community have been working on a large-scale reconstruction of the framework to improve its flexibility. It is considered one of the top open source projects on GitHub, a development platform to host projects and review code built and collaborated on by millions of developers (GitHub, 2020), so that in 2018, it had the second highest number of contributors for any repository in GitHub (React Native, 2020g; SPEC, 2018). In fact, RN has its flaws and problems (Schwarzmüller, 2019b; Peal, 2018a) as discussed below (section 5.3.2), but overall its advantages outweighed its downside compared to the other available technologies.

5.3.2 Insight into React Native and development challenges

The basic concept of RN is that the app code is written in JavaScript and split into two parts: UI components, as explained shortly, and the other code which includes the business logic. When the app runs on a platform, the UI components are compiled and translated into native views corresponding to the platform language. The other code however is not compiled; it runs inside a JavaScript engine and uses the ‘Bridge’, a core RN abstraction layer, to communicate with native APIs and views responding to user interaction (Schwarzmüller, 2019a; Shah et al., 2019).

RN uses components (i.e., building blocks) to build the UI, following the React.js approach. It provides developers with only some core components and features to start building complex custom components. An RN app is typically structured to render one root component, with other components required by the app nested inside it.

Components can be built as a function or as a class. Class components should have a special function called ‘render’. The outputs of such function and a functional component are nested components inside each other, describing what is displayed on the screen. A special JavaScript syntax called JSX is used to write the outputs, representing components as tags/elements that look similar to HTML tags, such as <*Text*> *Hello world* </*Text*>. RN uses styling syntax that is similar to Cascading Style Sheets (CSS) and its naming conventions. Both types of components accept arguments called properties (props); thus, they should be built and treated as blueprints and reusable components that can be customised with these props. Class components use something called ‘state’ which is a personal data storage for each component. ‘State’ is useful for handling data that comes from user interaction or changes over time. Any change in the state’s data of a component causes the component to be re-rendered and consequently updates the UI. The hierarchy of components in RN is maintained whereby each component depends only on its parent and its own internal state.

This overview of RN (extracted from React, 2020b; React Native, 2019b; Schwarzmüller, 2019a), was based on RN version 0.59.1 and React.js version 16.8.4, which were used in building the PainRecord app. These versions were the latest during the app development period, but several updates have since been issued (React, 2020a; React Native, 2020f). There is a new version of RN published almost every month along with its documentation (React Native, 2020f; Schwarzmüller, 2019a). This indicates the fast-paced progress of these technologies and confirms that the RN community is energetic considering that RN is open source, which leads to development challenges.

During development, adoption of a new update revealed flaws in the previous version. These flaws caused, in some cases, a series of errors in the existing

code that had worked before the update. This was in line with other developers' experience (Peal, 2018c; Schwarzmüller, 2019a). In addition, a typical RN project needs three development environments: RN, Android, and iOS as detailed below (section 5.3.3), requiring a significant amount of time to set up, learn and update them (React Native, 2020h; React Native, 2019b; Peal, 2018a). In fact, updating one of the environments led in many cases to crashes due to compatibility issues within the app project.

Furthermore, RN apps depend highly on third-party packages to achieve specific functionalities, as RN only provides a set of built-in basic components and APIs (React Native, 2020b; Schwarzmüller, 2019a; Kaushik et al., 2018). In practice, this contributed to some challenges which included: (1) searching for suitable packages with no previous knowledge as to whether they exist or not; this seems to have been recently guided by the RN developer (React Native, 2020e); (2) some packages had inconsistency issues (Peal, 2018c), in that they worked smoothly with one platform but caused errors in the other one; (3) some packages were built to only support one of the platforms (React Native, 2020e); (4) some packages contain native code (i.e. not pure JavaScript) and installing them into the app project required further steps in each platform environment (React Native, 2020b), which were not always clear; (5) packages need to be consistently maintained by the developers to be up to date with RN and React.js versions, besides which, they need to follow updates in both platforms to avoid any compatibility issues (Schwarzmüller, 2019a; Peal, 2018c). Therefore, finding a useful package and adapting it to working code was not always a seamless process.

Apart from that, RN is still immature and has bugs. There were some incidents of code being expected to work but not working, taking from hours to many days to work around, as also confirmed by developers (Peal, 2018a; Schwarzmüller, 2019a; Peal, 2018c). In addition, although the idea of RN is to write one code in JavaScript so as to run it on both platforms, actually, it was still necessary to write different code, with the same language, for the different platforms (React Native, 2020d). Usually, this was required to variably adjust the position of elements or to use different UI components, as in fact not all UI elements exist

on both platforms (Schwarzmüller, 2019b). To successfully achieve that, prior expertise on both platforms was required (Peal, 2018a).

Moreover, RN error messages were mostly ambiguous, since an error message could denote different problems. Sometimes, it was not obvious which issue it should be ascribed to or whether the problem was inherent to RN (Peal, 2018a). Difficulties debugging RN apps were commonplace and different tools were provided to assist with this task (Yuan, 2017; React Native, 2020a). This was attributed to the fact that debugging JavaScript code is not supported by the two platform environments (Yuan, 2017). All of the aforementioned issues made finding the root cause of crashes and debugging errors incredibly difficult and time consuming. This required frequently engaging with community discussions and trying different workarounds which sometimes included debugging the native platforms (React Native, 2020a) in order to make all the project parties work together flawlessly. These challenges were in line with other developers' experiences (Schwarzmüller, 2019b; Schwarzmüller, 2019a).

Airbnb, one of the giant companies that used RN, as mentioned previously, has recently moved away from it, having reported their two-year experience (Schwarzmüller, 2019b; Peal, 2018b). The report highlighted most of the issues experienced in the current project, including the frustration of engineers because working with RN required a balance of expertise on all three platforms (RN, iOS, and Android), which is remarkably rare. In addition, the frequent technical issues and the difficulty of root cause attribution added to the frustrations of the experience and brought unexpected delays to many projects (Peal, 2018a; Peal, 2018b; Peal, 2018c; Peal, 2018d). The following quote, from the Airbnb experience, summarises the current experience: "*It [RN] is a paradigm shift for mobile and we were able to reap the benefits of many of its goals. However, its benefits didn't come without significant pain points*" (Peal, 2018c).

As indicated previously, the ambition was to develop the PainRecord app for both platforms. Unfortunately, the complex development challenges and time involved in resolving them meant working across both platforms became unsustainable. After five months the decision was made to continue with the

iOS platform and cease work on the Android platform. This decision enabled the researcher to accelerate the development process and meet the timeline of the project by focusing only on resolving the technical issues related to development of the iOS platform. Over the course of five months, the Android platform caused crashes more frequently than iOS. This was consistent with the experience of Airbnb, who found iOS less problematic (Peal, 2018c). In addition, the researcher (that is developer) has more experience with iOS, since a good level of expertise on both platforms was found to be necessary, as discussed above. In fact, it is well known that software development timelines are difficult to anticipate before further development, but a general agreement on the technical scope and timeline should be established before the start of the development (Roth et al., 2014). In addition, developers with RN experience found that it was highly convenient to primarily develop one platform before the other (Peal, 2018a). Therefore, the development of the PainRecord app for iOS was continued with the intention of rebuilding it to support Android in future work.

5.3.3 Development environment and setups

The development of the PainRecord app involved client-side (that is the app itself) and server-side development, as can be discerned from the architecture of the working system prototype shown in Figure 16. The setup for the server-side is explained below (section 5.5). For building the app, there are different setups required, based on the development operating system, prior to the installation of RN using the Command Line Interface (CLI) (React Native, 2019b). The app was developed on macOS using the researcher's MacBook Pro laptop (OS 10.14). The setup for that consisted of installing: (1) some system packages including Node, Watchman, and JDK using Homebrew package manager (Homebrew, 2019); (2) the React Native CLI using Node's package manager (npm); (3) Xcode, Integrated Development Environment (IDE) for iOS (Apple, 2019b); (4) Android Studio, IDE for Android (Android, 2019); and (5) any text editor - the Atom was used, as it is free and popular (Atom, 2019). Xcode and Android Studio were configured as guided by RN (React Native, 2019b). They were required to set up the tooling needed to build and run the app for iOS on a simulator and for Android on a virtual device

(React Native, 2019b). Moreover, they facilitated testing and debugging the app on real devices following specific configurations (React Native, 2019c).

For debugging, different tools were used, as recommended (React Native, 2020a; Schwarzmüller, 2019a; Yuan, 2017), at different points of the development process including:

- the in-App Developer Menu which allowed automatic app reloading at any time the code changed.
- Chrome Developer Tools, including breakpoints and console.log, which were useful in debugging the logic flow and unexpected behaviours.
- React Native Debugger (Hong, 2019) which facilitated analysing and inspecting each component in relation to style, 'props' and 'state'.
- the standalone version of React Developer Tools (Facebook, 2019), which allowed debugging the React component hierarchy.

5.3.4 Development process

5.3.4.1 Structuring the app

After setting up the development environment, a new RN project was initiated and named 'PainRecord'. This subsequently initiated two related projects for Xcode and Android development environments. The RN project (see the GitHub repository mentioned above in section 5.2) was structured to run the app from the main component 'App.js' as it is typically named (React Native, 2019b) (see Figure 17). The latter was built to encapsulate the rest of the app's created components. A total of 24 custom components were created and categorised into two main groups:

1. components representing the app's screens (n = 18). Figure 18 illustrates an example of this, namely the app's main menu screen.
2. reusable components (n = 6) representing either customisable UI elements such as buttons and texts, or segments of JSX code that needed to be invoked multiple times across the app. Figures 19 and 20 show examples of both, respectively.

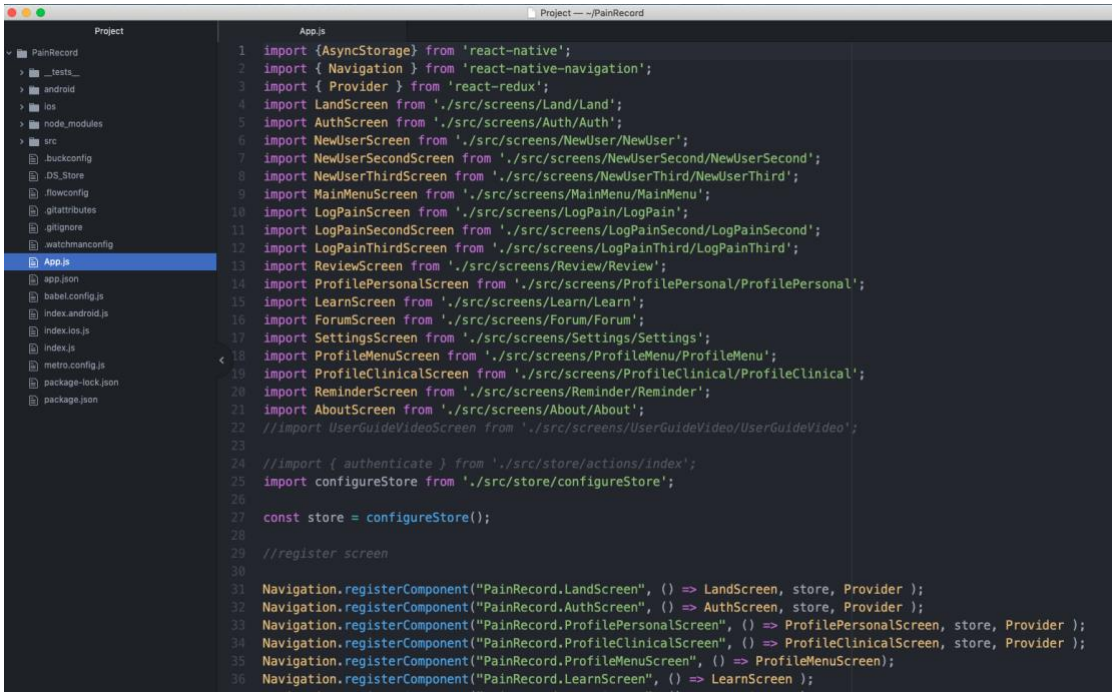


Figure 17: An excerpt of the app main component, App.js.

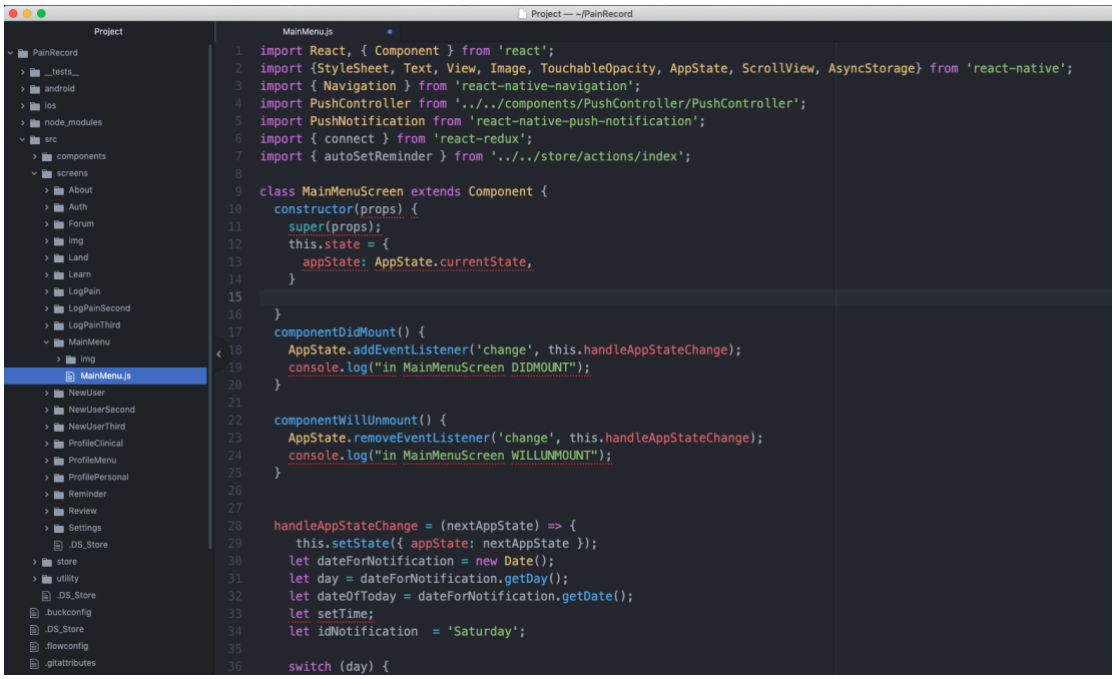


Figure 18: The app main menu screen, represented by MainMenu.js.

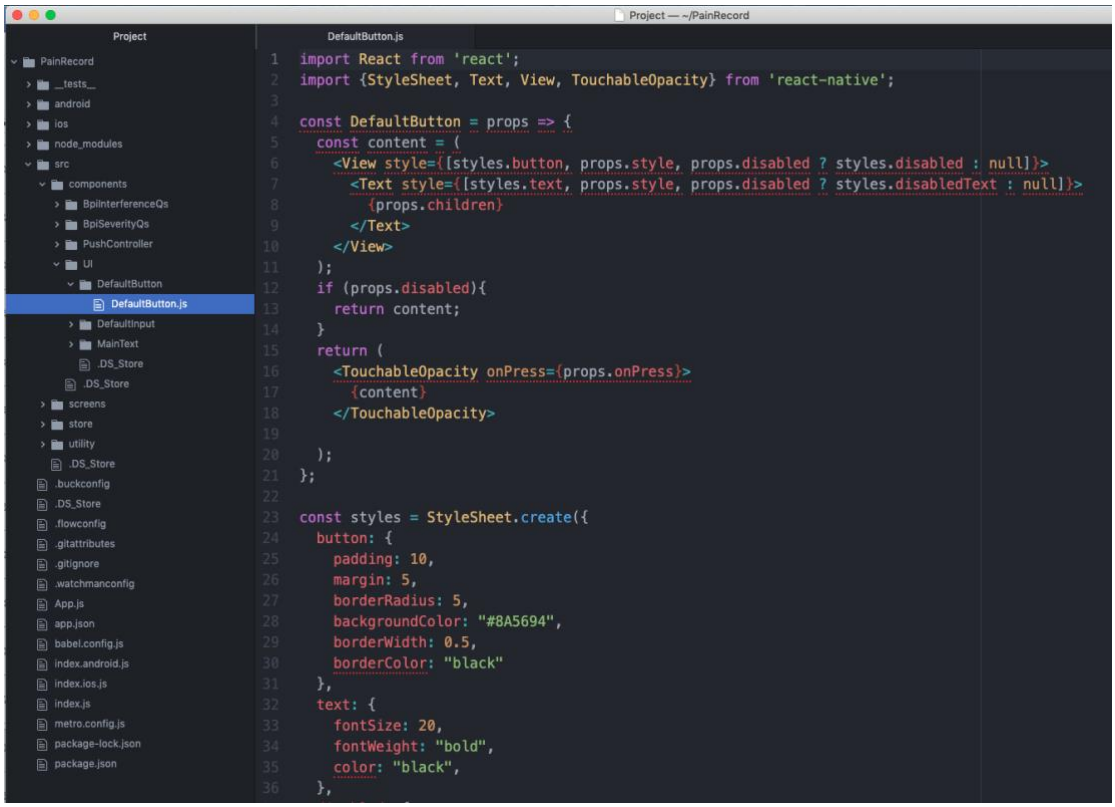


Figure 19: A customisable button used across the app screens, represented by DefaultButton.js.

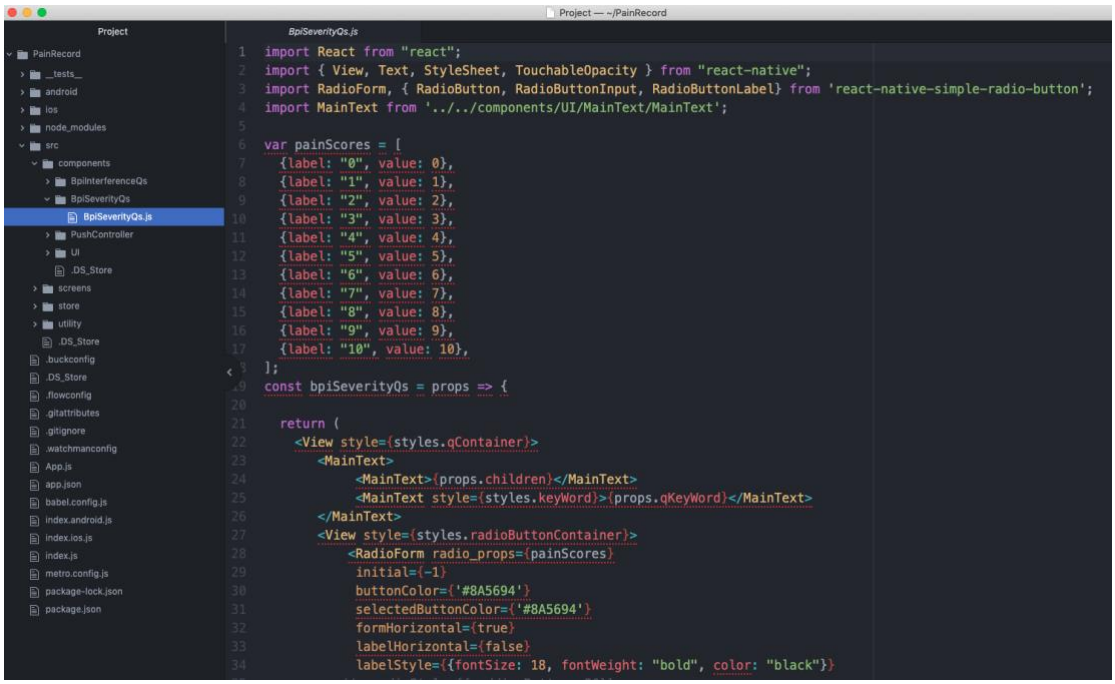


Figure 20: A reusable component, BpiSeverityQs.js, for presenting the BPI severity questions.

As mentioned before (section 5.2), the app was developed incrementally by breaking the work into small segments presenting the app's screens and reflecting the requirements discussed in Chapter 4 (see Tables 12 and 14). Fourteen selected third-party libraries were utilised to achieve a number of the app's functionalities and features. The app's dependencies and examples of how they were leveraged are listed below:

- React Native Navigation (Wix, 2018) was used in almost all the app's screens (i.e. components) to facilitate pushing screens over each other as well as navigating back to previous ones. Figure 21 shows an example of this, navigating from the 'Main menu' screen to the 'Settings' menu screen and returning back.

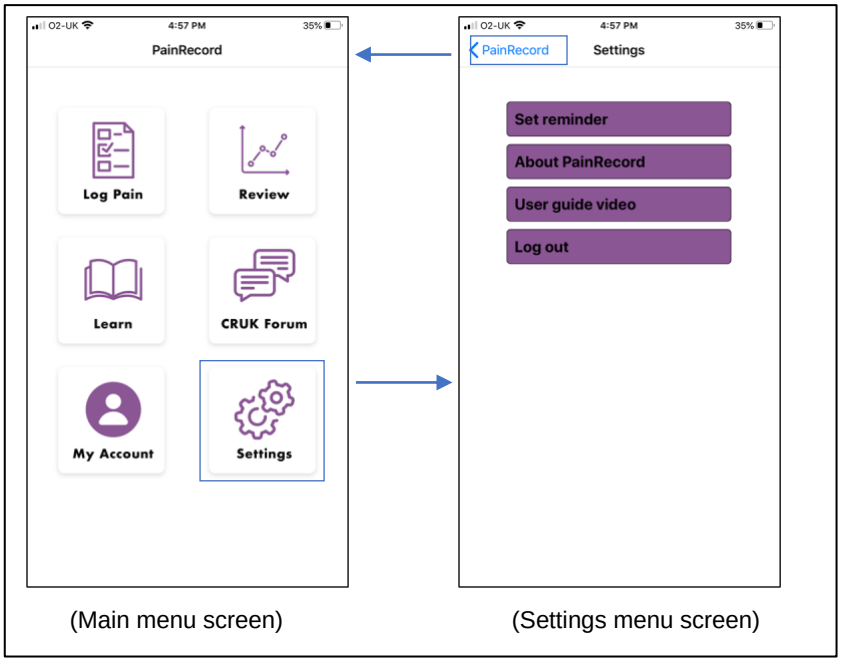
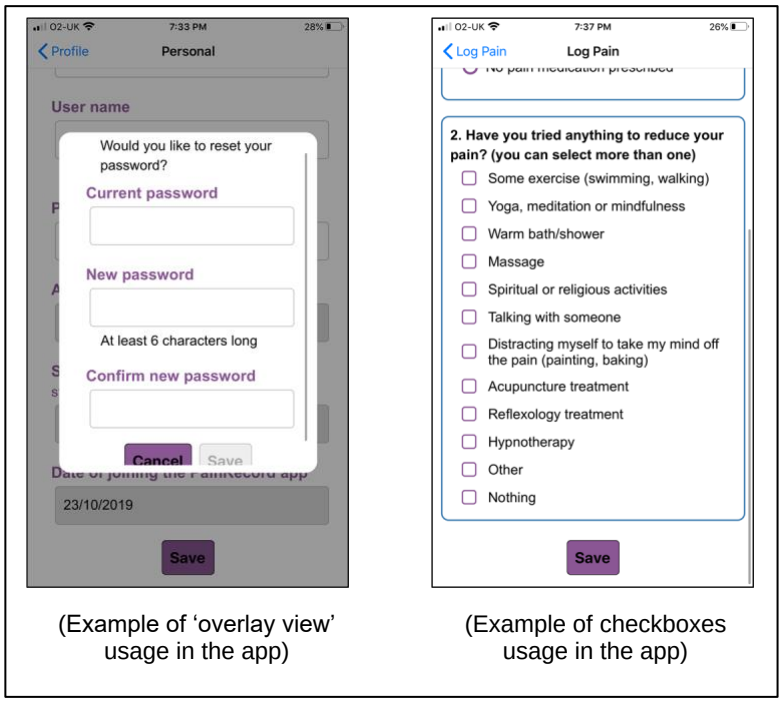


Figure 21: Navigations between Main menu and Settings menu screens facilitated by using the React Native Navigation package

- Redux (Redux, 2019b) and other related packages, including React Redux (Redux, 2019a) and Redux Thunk (Redux, 2019c), were collectively used to provide a memory store for the app's public 'state' and facilitate handling the state's data. In other words, the app needed data that can be accessed by several components. Such a requirement cannot be easily met within the ecosystem of a typical RN app, where

each component has a local ‘state’ and passing its ‘props’ to multiple components would be complicated (Schwarzmüller, 2019a). Redux is the most popular library for handling the ‘state’ of an RN app (React Native, 2020c). An obvious use of this was to maintain the user login details and settings.

- Victory Native (Formidable, 2019) and its dependency React Native SVG (React Native Community, 2019b) were required to build the visualisation contents of the app including the pain chart.
- React Native Elements (React Native Elements, 2019) and its dependency React Native Vector Icons (Arvidsson, 2019) were leveraged to present different UI elements in the app, such as the ‘overlay view’ used to confirm changing user password and the checkboxes utilised for answering a question related to pain management strategies (see Figure 22).



(Example of ‘overlay view’ usage in the app)

(Example of checkboxes usage in the app)

Figure 22: Presenting different UI elements utilising React Native Elements package

- React Native Simple Radio Button (Moschan, 2019) was used mainly to present the rating questions related to the Brief Pain Inventory-Short Form (BPI-SF) tool (Cleeland and Ryan, 1994) (see Figure 23).

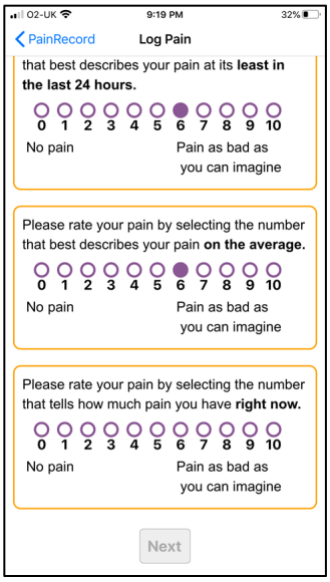


Figure 23: Usage of radio buttons in presenting the BPI questions in the app

- React Native Searchable Dropdown (Ibrahim, 2019) was utilised to provide dropdown menus with a start typing functionality so as to refine the list of potential answers to several questions on matters such as medications or cancer diagnosis[11], as Figure 24 illustrates.

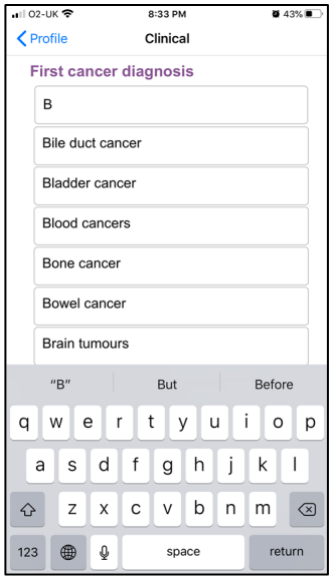


Figure 24: Example of utilising React Native Searchable Dropdown package

[11] The Cancer diagnosis list was identified from Cancer Research UK https://www.cancerresearchuk.org/about-cancer/type, accessed 4th January 2019.

- React Native Datepicker (Yue, 2018) was used to capture a date in several places in the app, such as the date of birth in the registration form or in the user profile, as shown in Figure 25.

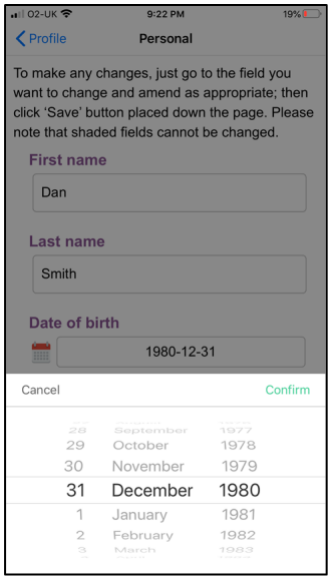


Figure 25: Example of using the React Native Datepicker package

- Toggle Switch React Native (Benkeroum, 2019) was utilised to visualise the on/off option to settings, including a setting reminder as illustrated in Figure 26.

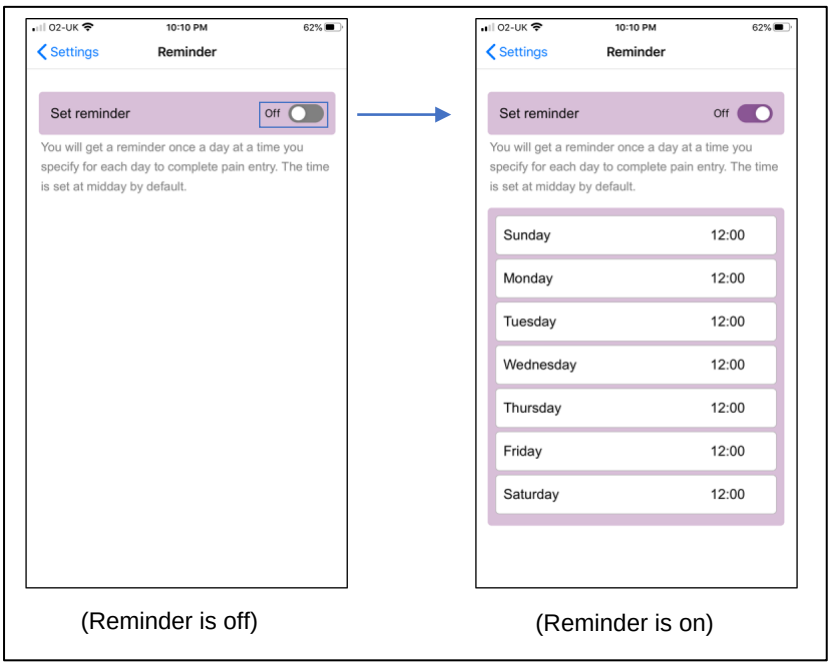


Figure 26: Example of utilising Toggle Switch React Native package for presenting reminder settings

- React Native Push Notifications (Trujillo, 2019) and its dependency Push Notification iOS (React Native Community, 2019a) were used to achieve several functionalities that required firing notifications, such as the reminder feature shown in Figure 27.

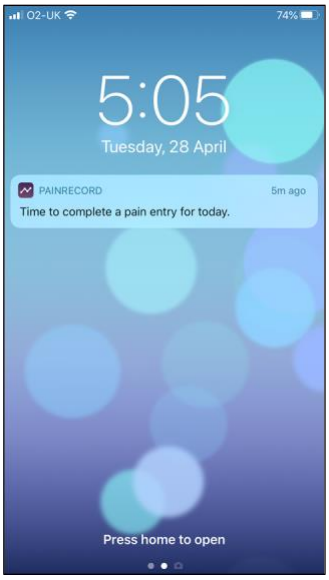


Figure 27: Example of utilising the React Native Push Notification package to implement the notifications required for the reminder feature

5.3.4.2 Linking the app to the server

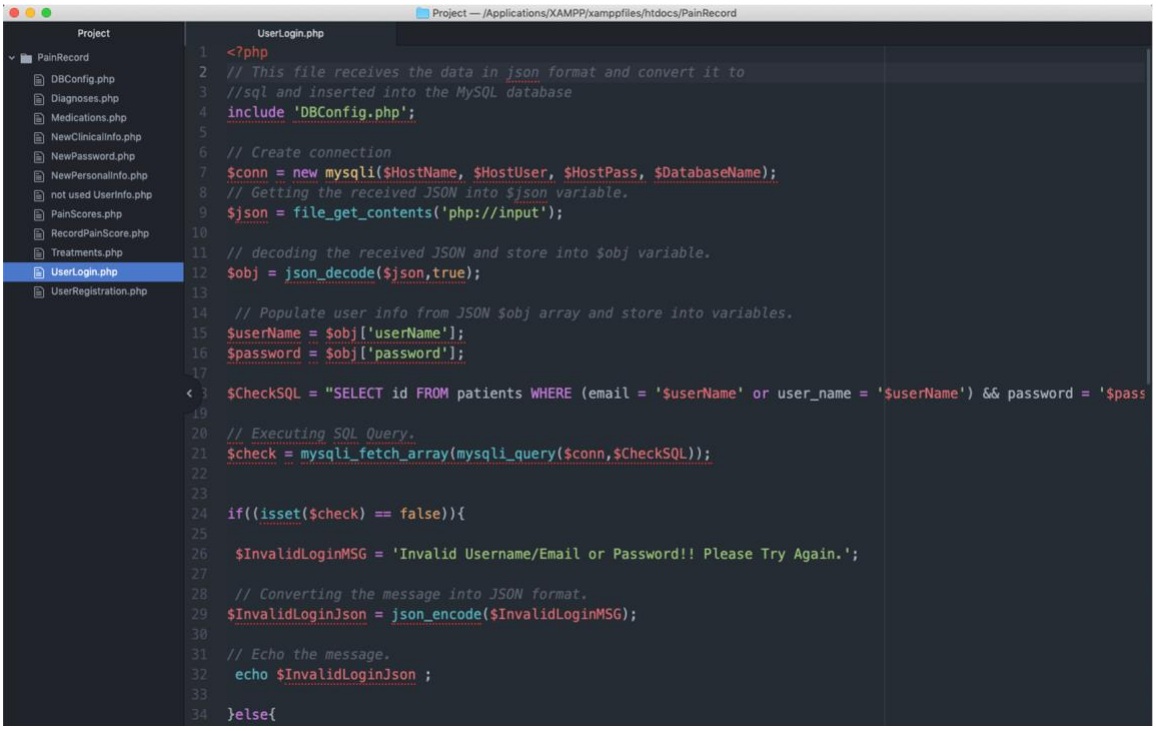
The app used Fetch API provided by RN to communicate with the server and make an HTTP (Hypertext Transfer Protocol) request using the POST method (React Native, 2019a). Where this was required, a request was created to be made to a specific scripted PHP (Hypertext Preprocessor) file stored in the server (see Figure 16). For example, for user authentication, username and password entered by the user are fetched to the server, where a PHP script has been built to handle this, as Figure 28 demonstrates (see the full code in the GitHub repository mentioned above in section 5.2). The latter performs a query using this data on the database and the result is presented as a response to the request. The app then handles the response and acts accordingly. In addition to

authentication, there were another nine places in the app that required the creation of server requests and corresponding PHP scripts, as listed below:

- To register a new user, where the registration includes providing personal and clinical information
- To provide a list of diagnoses
- To provide a list of cancer treatments
- To provide a list of pain medications
- To record pain data
- To retrieve pain data
- To update clinical information
- To update personal information
- To change the user password

```
export const authenticate = (userName, password) => {
  return dispatch => {
    let medList = [];
    fetch('https://painrecordingsystem.co.uk/PainRecord/UserLogin.php', {
    method: 'POST',
    // convert object of the data to JSON string to be sent to the db through body key
    body: JSON.stringify({
      userName: userName,
      password: password,
    })

  }).then((response) => response.json())
        .then((responseJson) => {

  // Showing response message coming from server after inserting records.
          if (responseJson == 'Invalid Username/Email or Password!! Please Try Again.'){

            Alert.alert(responseJson);

          }
          else if (responseJson == 'Something went wrong! Please try Again.'){
            Alert.alert(responseJson);
          }else {
```

(An excerpt of the code used in the app to create a user authentication request)



(An excerpt of the PHP script used in the server to handle the authentication request)

Figure 28: Example of implementing communication between the app and the server

5.3.4.3 Data validation

Several client-side and server-side validation techniques were implemented, mainly in the user registration form and in the BPI questions. Validation involves ensuring that user input is in the correct format and meets the pre-set requirements for the field. If this is conducted in the frontend, it is called client-side validation; if conducted in the backend, it is called server-side validation and it is best practice to consider both (MDN, 2020). The 11 rating questions for both subsections of the BPI were all designed to require answers; thus, the user cannot move to the next section or submit without completing all of them (that is client-side validation), as Figure 29 demonstrates.

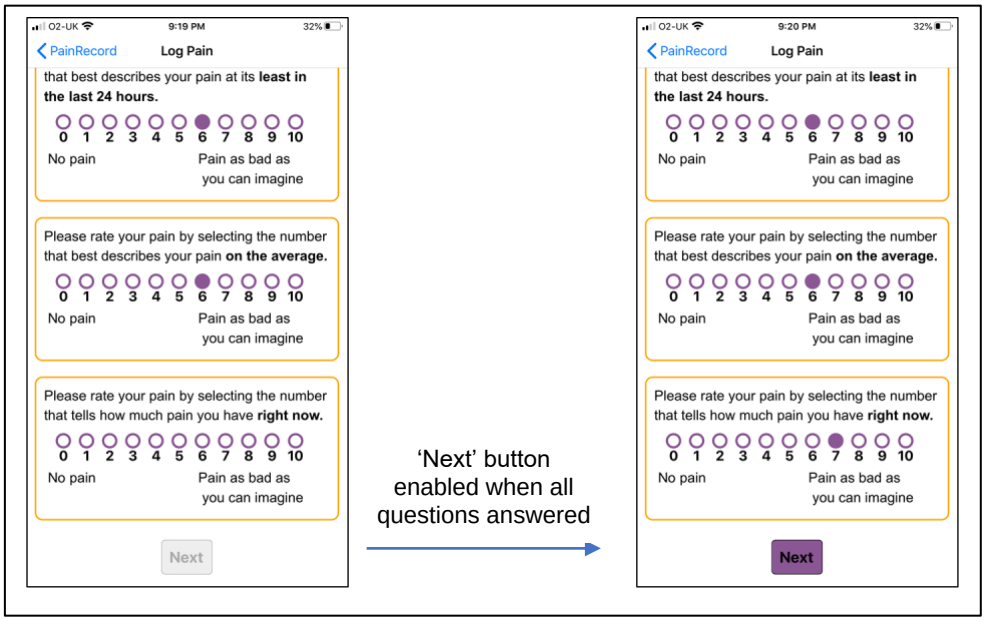


Figure 29: Example of the implementation of client-side validation in capturing the level of pain using the BPI

For the registration form, implemented server-side validation included preventing user registration if the entered username/email is already in use or if the user provides an invalid study ID (that is no registered study has the entered ID), as illustrated in Figure 30. From the client-side, 'username', 'password' and 'confirm password' fields were designed to require completion in a specific format (see Figure 31). In addition, completion of both the 'first cancer diagnosis' and 'current cancer treatment' fields was set to be required for registration, as it was believed that these are the minimum clinical data needed

by HCPs to develop an understanding of the patient's pain, especially if they have no other access to the patient's clinical data (see Figure 31).

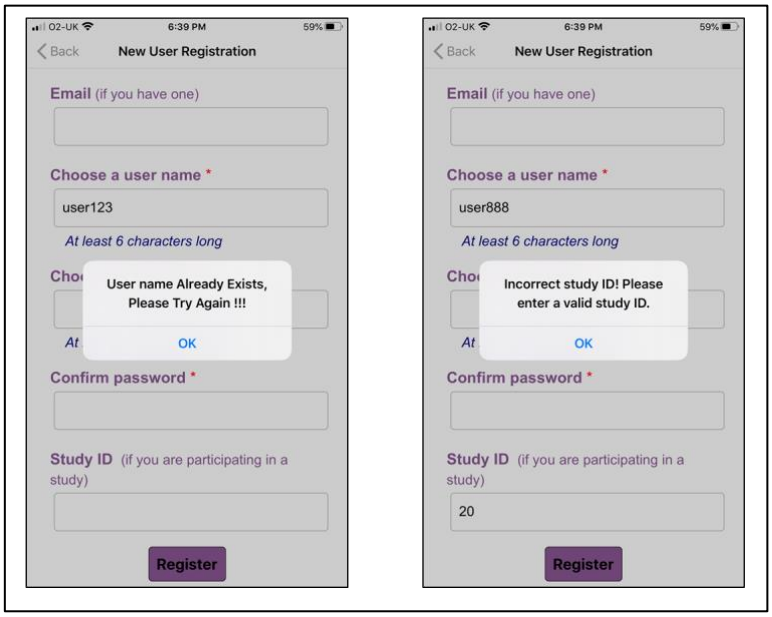
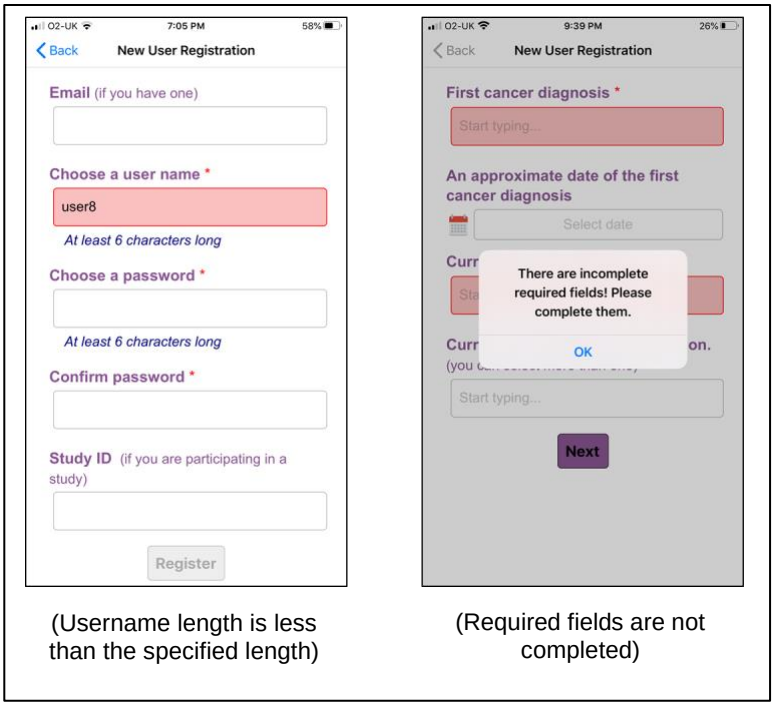


Figure 30: Implementation of the server-side validation in the app registration



(Username length is less than the specified length)

(Required fields are not completed)

Figure 31: Implementation of the client-side validation in the app registration

5.3.4.4 Security measures

As preparation for the app's production and testing, all the HTTP requests within the app were secured (that is HTTPS) by optimising the security of the server, as discussed in section 5.6 below. The App Transport Security (ATP) feature provided by iOS, which blocks any HTTP traffic, was enabled prior to building the app for production, as recommended (React Native, 2019c).

5.3.4.5 Testing the app beta version internally

Following Apple's instructions for testing a developed app in iOS devices (Apple, 2019a), Apple Developer Program Membership was obtained by the researcher at a charge, using her Apple ID. This allowed creation of an ad hoc provisioning profile and consequently a Distribution Certificate for the app. Any tester's iOS device was registered, using its unique device ID (UDID), in the app's profile. The development environment (that is Xcode) facilitated identifying the UDID and registering the device once the latter was connected to the researcher's laptop. Registering the device was obligatory prior to building and creating the app bundle file (IPA) that was required to launch the app on the device.

The app was tested internally by the researcher in two stages, with app testing support from research colleagues in the second stage. First, it was tested thoroughly by the researcher on two iOS devices with different screen sizes: iPad Air 2 and iPhone 6s Plus, applying a number of main use cases (see Chapter 4, Figure 11). All the app features were tested using the ad hoc testing technique (Writer, 2020) to check for any errors, or any deficiencies related to UI or UX. In addition, the content of the app was checked against the app requirements, incorporating feedback from the usability testing discussed in the previous chapter (see Tables 12 and 14, and section 4.3.3.8). This was to ensure that all of the requirements were implemented precisely as planned.

In the second stage, the app was tested individually by three research colleagues. The app was installed in the colleagues' own iOS devices. They were asked to use the app and test it thoroughly for at least 10 minutes and then complete the user version of MARS (uMARS) (see Appendix 15). The

latter is a reliable scale that can be used by end-users to assess the quality of mHealth apps (Stoyanov et al., 2016). It is a simplified version of MARS, which requires training and expertise in mHealth to administer, as mentioned in the previous chapter; it has however the same domains and applies the same scoring system (see section 4.2.1.3) (Stoyanov et al., 2016). The aim of this stage was mainly to finalise the implementation phase of the app prototype by using a systematic method for ensuring that the app works efficiently in different types/sizes of iOS devices and within the borders set for it. The assessment indicated that the app had a good (M = 4) objective quality. The lowest score was in the engagement domain (M = 3.4) with consideration to the defect of MARS in relation to evaluating engagement discussed previously (see Chapter 4, section 4.2.2.1). On the other hand, the information domain had the highest score (M = 4.4). Both functionality and aesthetics had almost equal scores in the app, representing good quality (M = 4.1 and M = 4.0 respectively). Specific comments received from the members were also incorporated into the app as preparation for moving to the next phase of the second UCD cycle, discussed in the next chapter.

5.3.5 Final PainRecord app features and design

5.3.5.1 Layout and registration

The general layout of the app consists of a plain white background with mainly two colours, purple and black, used for most of the UI elements. A purple icon with the name of the app, ‘PainRecord’, was designed by the researcher to be used for launching the app. The icon has a white zigzag line as a denotation of monitoring pain (see Figure 32). The app starts up with the landing screen, with the user given two buttons with which to proceed as ‘New user’ or ‘Existing user’, as illustrated in Figure 32. The app was designed to be responsive to different screen sizes and rotations (see Figure 33). The ‘New user’ button leads to the registration form displayed across three screens, as Figure 34 shows. In each screen the user is asked to complete a few fields and click the ‘Next’ button in order to move to the following screen. The form fields were carefully identified and designed to minimise registration effort and time, with a few fields set as ‘required’, as mentioned before (see section 5.3.4.3). At the

last screen, the user is required to click the ‘Register’ button, at which point a confirming message will pop up, as illustrated in Figure 34. After a successful registration, the login screen shown in Figure 35 is displayed. The ‘Existing user’ button takes the user straight to this screen. If incorrect login details are entered, the app notifies the user, as Figure 35 shows. Once valid login details are submitted, the main menu screen is displayed, as illustrated in Figure 35. Following that, this screen will be directly shown for any subsequent use of the app unless the user chooses to logout.

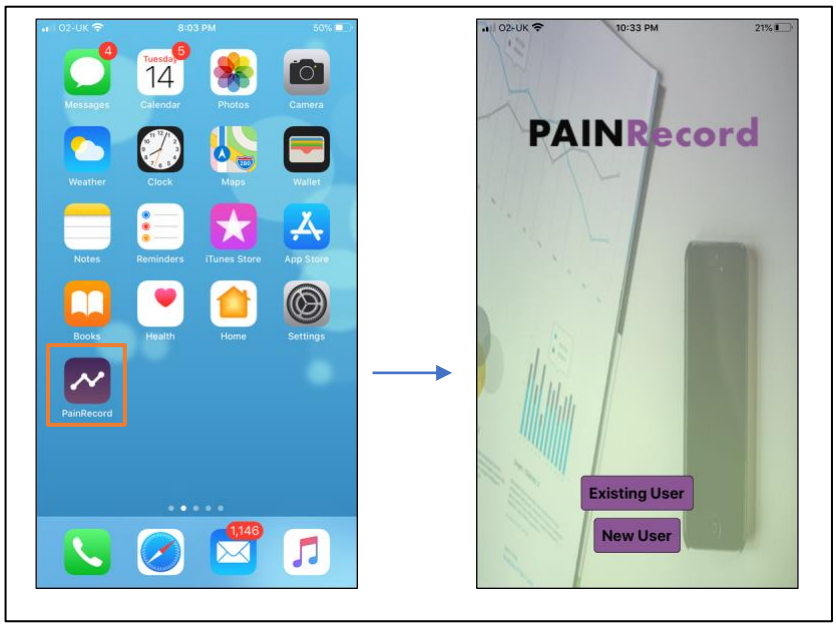
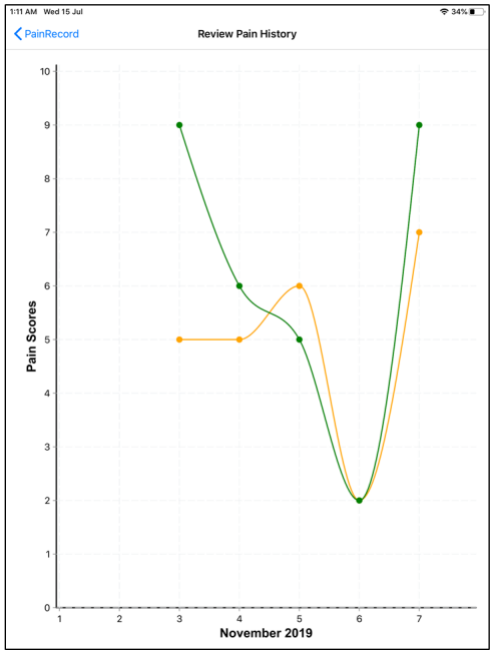
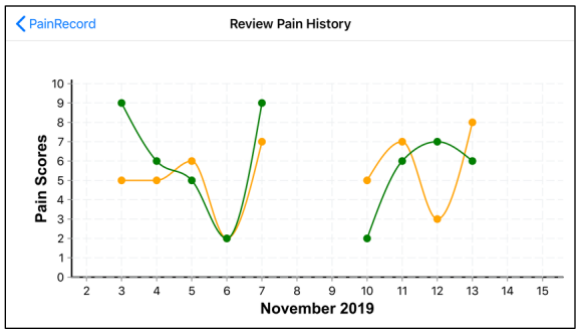


Figure 32: The PainRecord app icon and the landing screen



(Screenshot of the app on iPad)



(Screenshot of the app on iPhone and with landscape orientation)

Figure 33: Screenshots of the app showing its responsiveness to different screen sizes and rotations

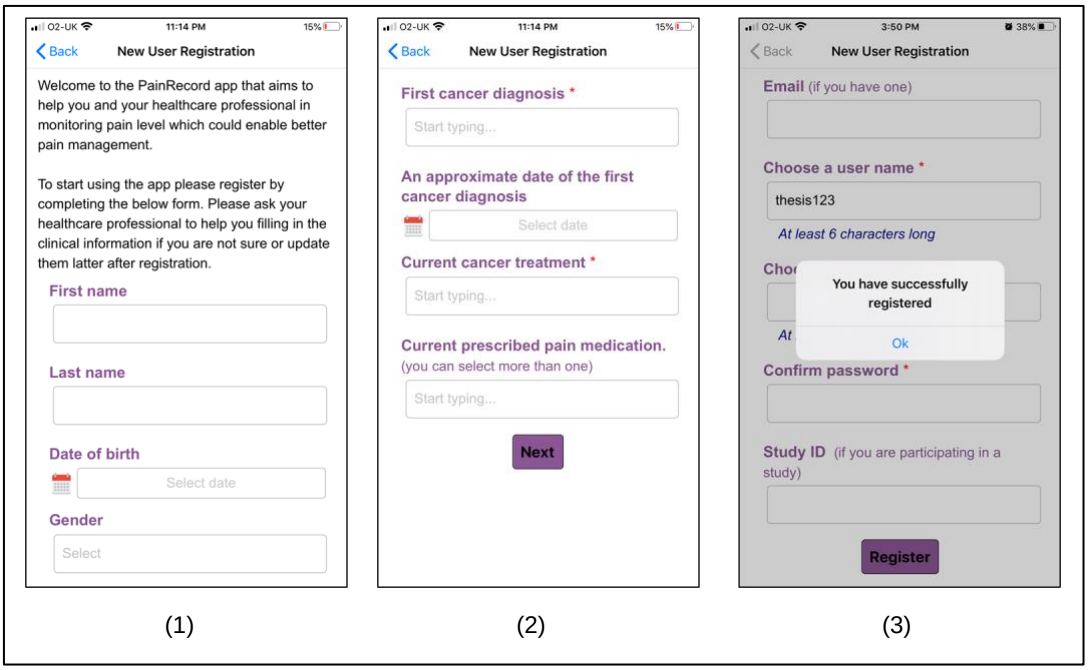


Figure 34: Screenshots of the app registration process

Note: passwords fields are automatically blanked out in iOS screenshots

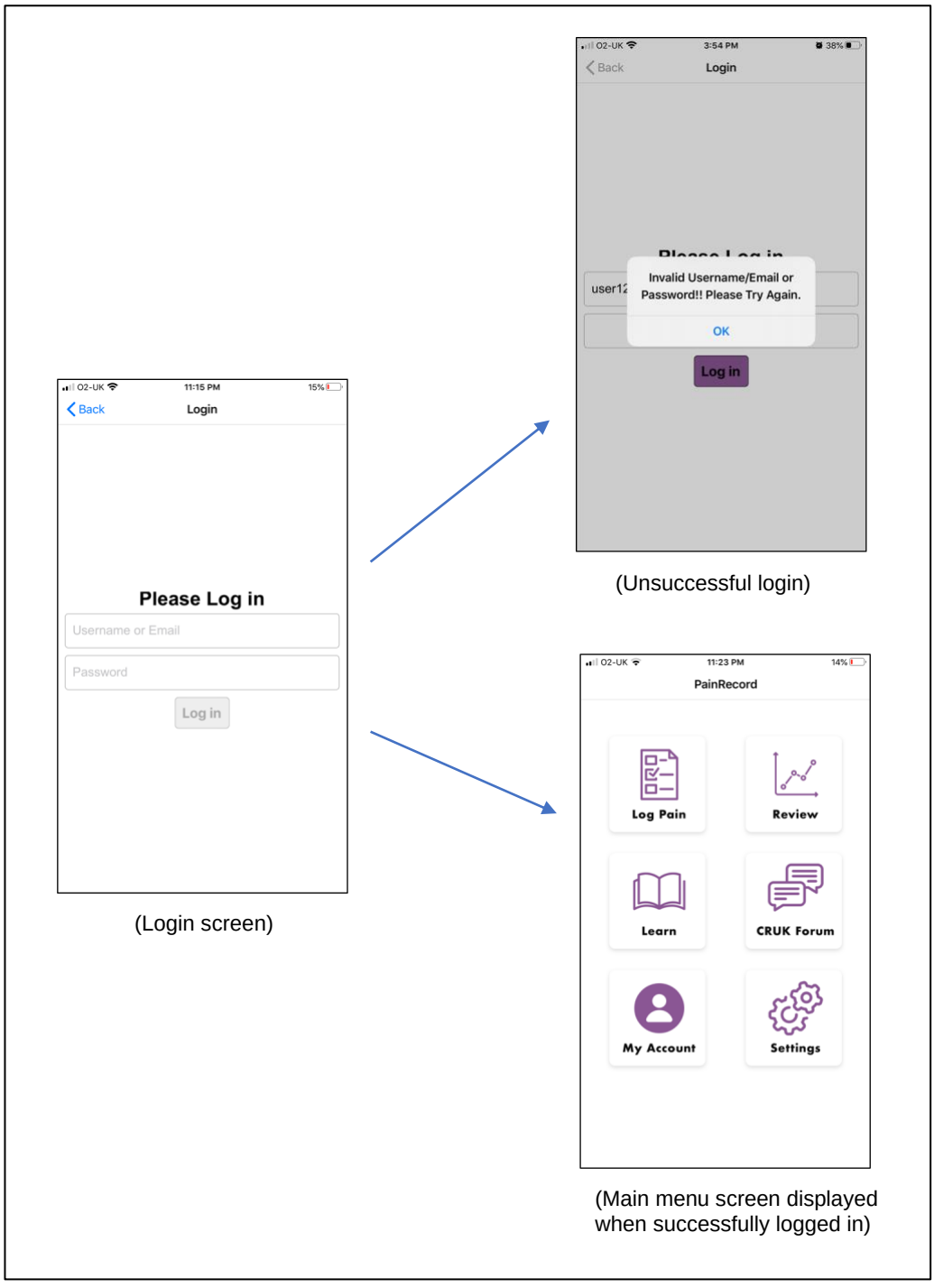


Figure 35: The app Login process and its main menu

5.3.5.2 The app main menu

The main menu screen provides the user with the entire content and functionalities of the app, classified into six sections (see Figure 35) as detailed below:

1. The ‘Log Pain’ section can be used to enter pain details including: (1) the pain level, by answering the questions on the Brief Pain Inventory-Short Form (BPI-SF) two subscales (Cleeland, 2009), and (2) the extent of medication adherence and pain-control strategies used[12] (i.e. non-pharmacological) within the past 24 hours. The latter was captured by a special form designed by the researcher and incorporated into the app (see Appendix 16). The details are captured through three screens, where the user is asked to complete a couple of questions in each screen and click the ‘Next’ button to move to the following screen (see Figure 36). Once the user clicks the ‘Save’ button on the third screen, a confirmation message will appear alongside an option for the user to follow an external link to learn about a pain self-management technique. There are links to different topics and approaches to pain self-management available within the app in the ‘Learn’ section as discussed below. The app randomly selects one of these each time the user submits pain entry. Figure 37 gives an example of this.

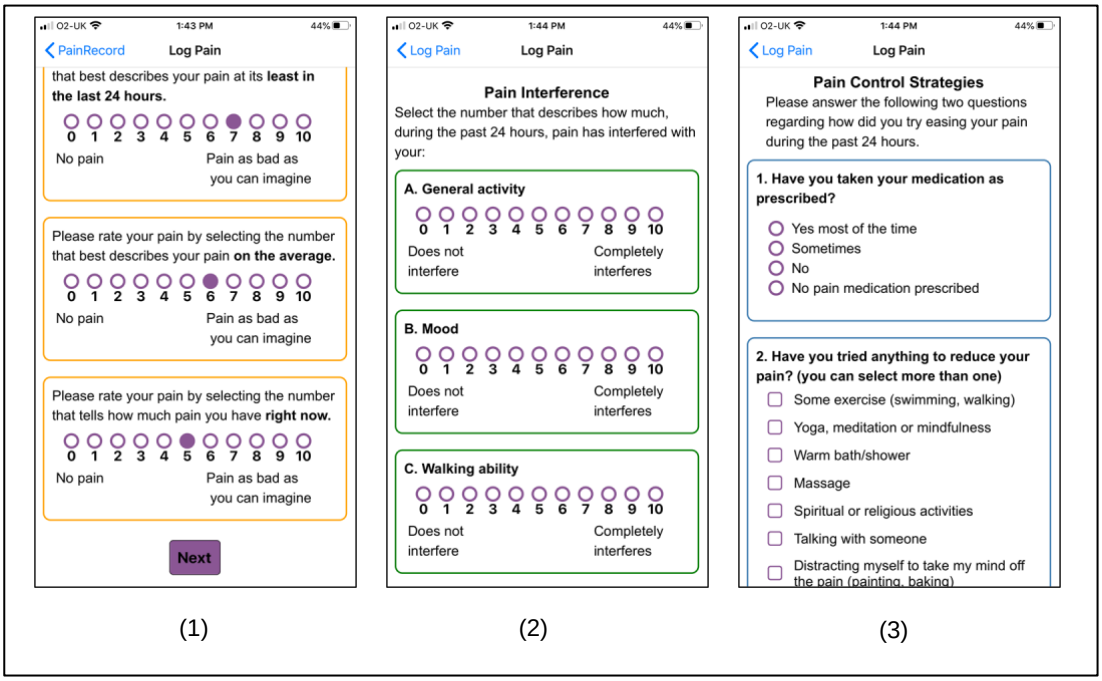


Figure 36: Screenshots of the ‘Log Pain’ section in the app

[12] A list of pain-control strategies was identified by exploring the CRUK and Macmillan websites and was refined based on the participants’ feedback on the usability testing discussed in Chapter 4.

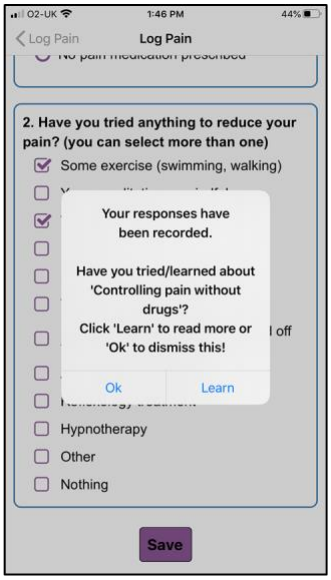
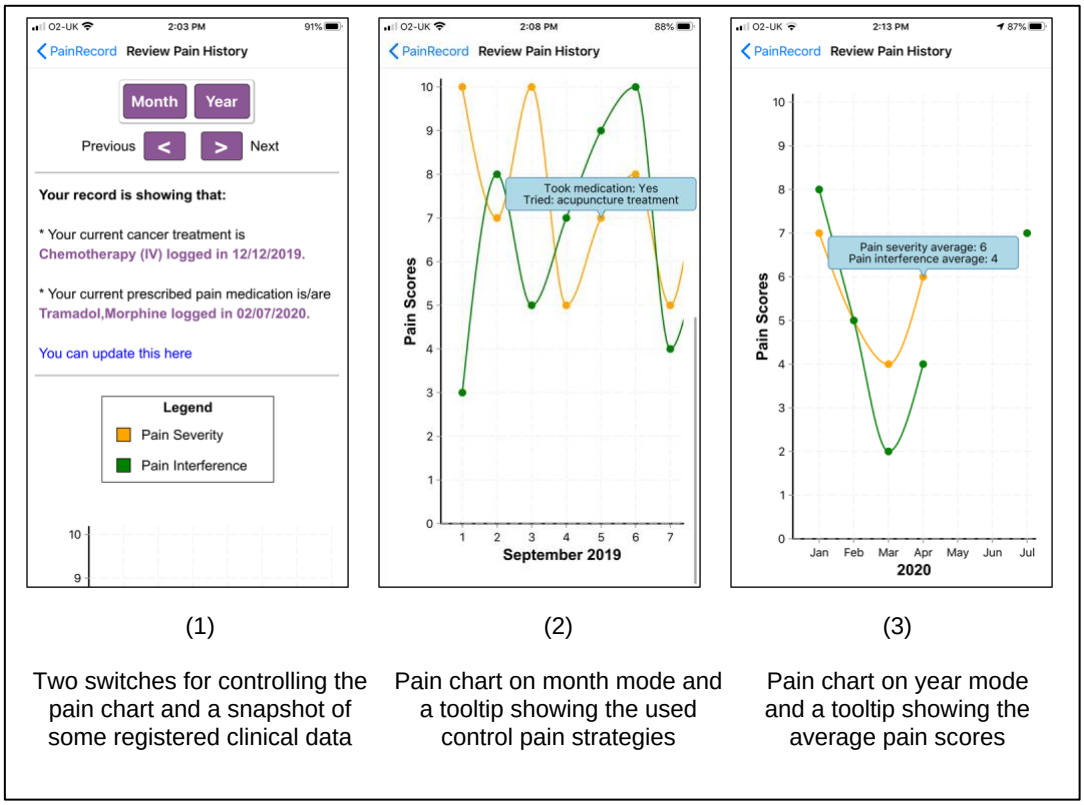


Figure 37: Confirmation message for logging pain details with a suggestion about a pain management related topic

2. The ‘Review’ section allows the user to view the recorded pain details for each day of the current month, plotted in a dual line chart representing the BPI’s two subscales. The subscale points denote the average scores for the related subscale’s items as usually scored by the BPI-SF (Cleeland, 2009). The user can hold a tab on each point/day in the chart to reveal the recorded details about pain control strategies represented as a tooltip, as illustrated in Figure 38, screenshot 2. At the top of the chart’s screen, the user is given two switches to control the chart view, as Figure 38, screenshot 1 clarifies. There is a month/year switch to change the view mode to year chart or back to month chart. The year chart represents the average score for each subscale (that is severity and interference) for each month (see Figure 38, screenshot 3). The other switch allows going back or forward in months or years based on the selected chart view mode. The chart is slidable, enabling the user to view the days/months for the whole month/year. As Figure 38, screenshot 1 shows, the user is also reminded about their registered data in relation to current cancer treatment and pain medication prescribed for them, with a link for updating the information if needed. The link takes the user to the appropriate fields in the ‘My Account’ section, discussed later.



(1) Two switches for controlling the pain chart and a snapshot of some registered clinical data

(2) Pain chart on month mode and a tooltip showing the used control pain strategies

(3) Pain chart on year mode and a tooltip showing the average pain scores

Figure 38: Screenshots of the 'Review' section

3. The 'Learn' section offers a list of external resource links providing a variety of information related to pain, pain management and support services (see Figure 39). Users will be able to fully explore the recommended resources once they follow the links. The resources were categorised and selected carefully from legitimate websites to reflect a group of requirements specified previously (see Table 12 in Chapter 4).

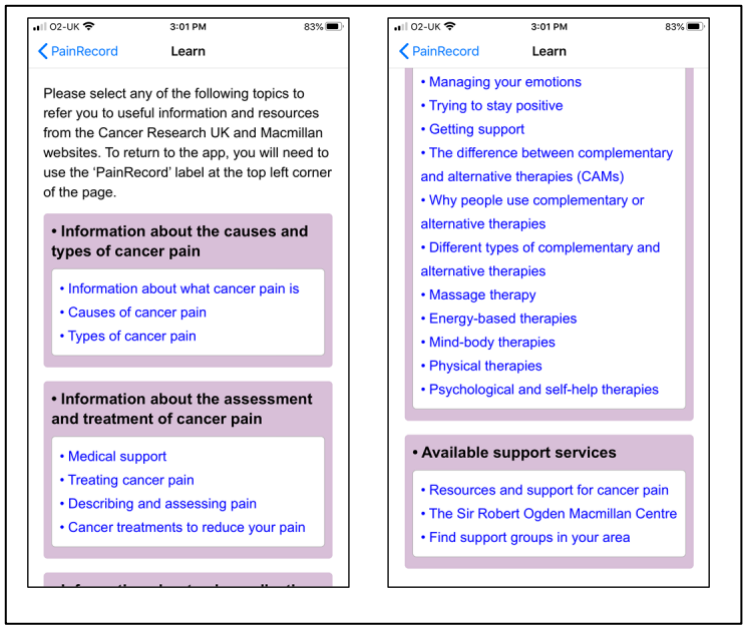


Figure 39: Screenshots of the 'Learn' section

4. The 'CRUK Forum' section introduces the CRUK online forum and provides a link to it as a means of obtaining social support (see Figure 40).

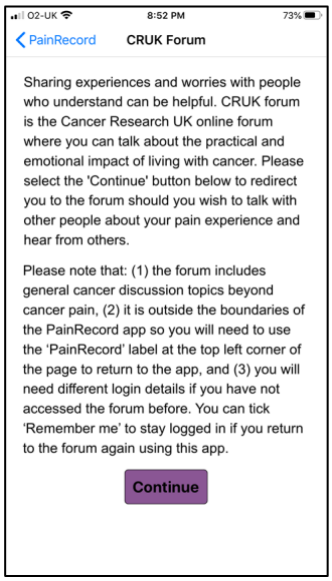


Figure 40: Screenshot of the 'CRUK Forum' section

5. The 'My Account' section can be used to update registered data, which was partitioned into two types, personal and clinical, as illustrated in Figure 41.

Once the user selects the type of data, the related fields are displayed in another screen. The user can then change any field and click ‘Save’ at the end of the screen where a confirming message pops up, as shown in Figure 42.

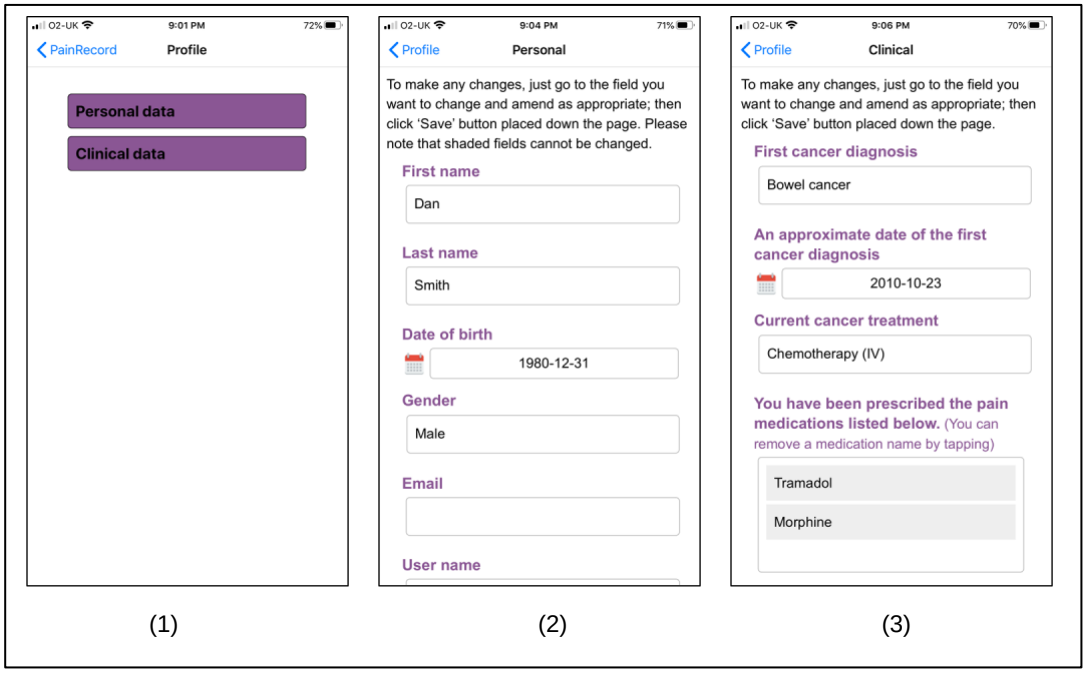


Figure 41: Screenshots of the ‘My Account’ section

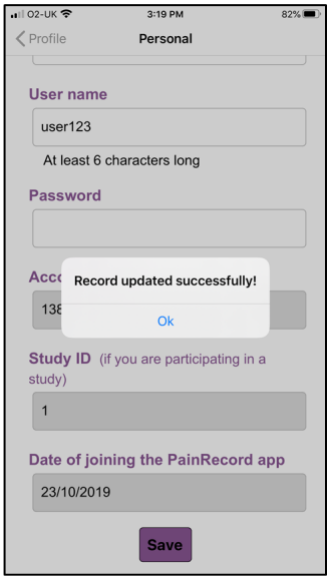


Figure 42: Confirmation message for updating user profile

6. The ‘Settings’ section encompasses four options as illustrated in Figure 43, screenshot 1:
   - ‘Set reminder’ can be used to turn the reminder on and specify the time preferred for each day in order to receive a notification to complete a pain entry. The reminder is set by default to midday for all days when it is turned on (see Figures 26, 27 and 43, screenshot 2).
   - ‘About PainRecord’ provides a brief introduction to the app and the potential benefits of using it (see Figure 43, screenshot 3).
   - The ‘User guide video’ delivers a video guide[13] designed to showcase the functionality of the app.
   - ‘Log out’ allows the user to log out from the app; thus, when opening the app later, the user will need to enter the login details again.

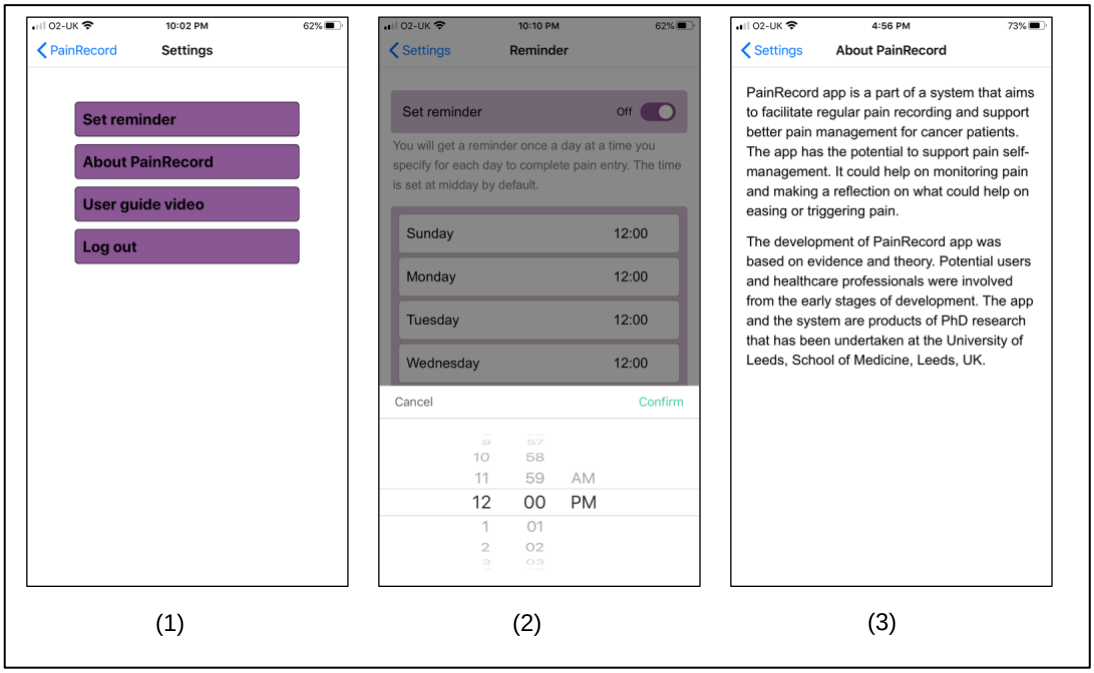


Figure 43: Screenshots of the ‘Settings’ section

5.3.5.3 App feedback to users

The app was designed to observe the entered pain scores and act accordingly. If the pain levels are at 5 to 10 for three days or more, relying on the BPI severity scores and show increasing or consistent layout, a corresponding alert

[13] The video guide can be accessed from https://painrecordingsystem.co.uk/Guide.mp4

message will be triggered asking the user to seek medical consultation. The latter appears when the user opens the ‘Review’ section as illustrated in Figure 44, screenshots 1 and 2. In addition, if no pain details are entered for more than three days, a notification will pop up to encourage the user to do so, as Figure 44, screenshot 3 demonstrates. The period of three days was specified as a threshold to trigger feedback, as it was considered a reasonable period for this purpose.

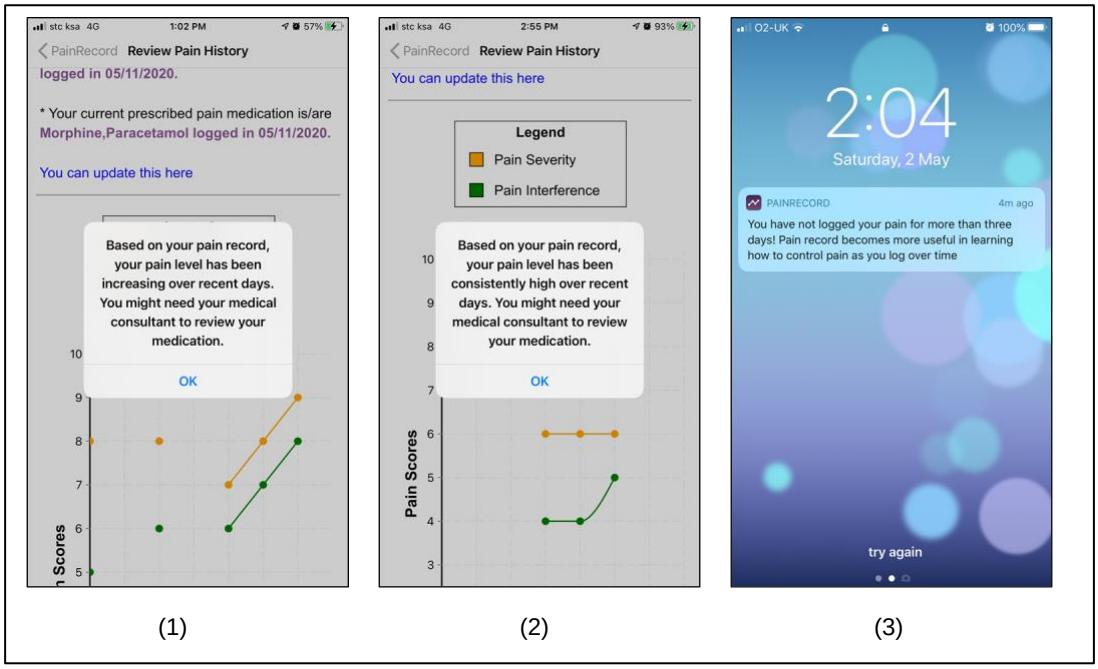


Figure 44: Screenshots of the sort of feedbacks provided by the app

5.3.5.4 Design decision justification

Some design decisions were made in an attempt to attain the optimal design that could serve the aim of the app. Therefore, it is important to explain them, as in the following points:

- Relying on the BPI-SF that was meant to capture pain experience over 24 hours (see the scale in Appendix 17), the app was designed to record only one observation of pain details each day. The user can log in pain details multiple times during the day; but the app records and only displays the most recent attempt during that day. This is because asking about the experience of pain during 24 hours is likely to induce similar answers if repeated. In addition, the app does not allow the user to record pain for a day other than the current day. Therefore, when a day is missed there is no

way to record the details for that day, or to edit earlier recorded ones. This is mainly to ensure the accuracy of the data captured, by encouraging immediate recording of pain experience and preventing recollection. There has been an emphasis on designers of digital health interventions to employ all the measures that can guarantee reliable data collection (Velardo et al., 2017). Retrospective scoring of pain level was found inflated compared with daily measures (Linton and Melin, 1982; Lewandowski et al., 2009) as mentioned before (see Chapter 1, section 1.3.2). Furthermore, evidence suggests that filling paper diaries, which does not ensure immediate and real-time feedback, may not truly reflect adherence to self-monitoring as patients may falsify the time and frequency of self-monitoring (Burke et al., 2008; Yu et al., 2015).

- Capturing pain medications and cancer treatment stage at registration and encouraging the user to review and update them if changed at the 'Review' section could not be of clear benefit to the user according to the current design. This was important for the desired long-term outcomes of the system. In other words, collecting this sort of data alongside pain scores and cancer type for longitudinal studies does not seem to have been previously investigated or implemented. The availability of such data could lead to greater insight into pain management; for example, by identifying a type of medication that works for a certain group of cancer patients or a pattern of pain associated with a specific treatment stage, and so on. In addition, designing the backend, the database, of the app to capture these data allowed the developed system, including the app, to be scalable.

5.3.5.5 The app's limitations

All the identified requirements discussed in Chapter 4 were implemented, except two of the preferable features. These were 'allowing the app to work offline' and 'delivering the app for Android platform' besides Apple iOS (see features #4 & 5, Table 14, Chapter 4) which were not implemented largely due to the project's time constraints and the unexpected delay that occurred at the beginning of the development phase. Absence of the former feature could cause frustration to the user in some places while using the app. For instance,

in the ‘Review’ section there will be no data displayed in the pain chart if there is no connection to the internet. This could have been implemented by retrieving the user’s pain details from the server when the phone was connected to the internet and temporarily storing them locally. There are a variety of mechanisms allowing storage of data in a local database for an RN app, including WatermelonDB, SQLite, FireBase, and Realm (Acharya, 2019).

The work presented here is an initial minimum viable product prototype. As such, a few data security measures were considered. However, securing user data is a necessity for the app’s deployment in the future and further security features must be employed in a future version of the app. The modular approach does mean inclusion of additional security measures should be straightforward. For example, encrypting login details was not employed, which could have been implemented by using a third-party library such as Bases64 (Kogai, 2020).

The design of the ‘Set Reminder’ feature does not allow the user to disable the reminder for specific days. In other words, once the user turns the reminder on, they will have the option to change the time of the reminder for each day which is set by default to 12 p.m. (see Figure 43, screenshot 2). Lack of flexibility in setting the reminder could be inconvenient for some users who wish to be prompted only on a few days of the week. This was not noticed in the early stages of implementation and could have been easily fixed by a more ingenious design. There is always scope for improvement throughout the iterations of the UCD; thus, this needs to be fixed in a future cycle.

5.4 Development of the portal

5.4.1 Selected development approach

Using a successful PHP framework, such as CakePHP, Laravel and CodeIgnite, for web application development can considerably speed up the development process and optimise the performance of an application (Li et al., 2017; Fayyaz and Munir, 2014). PHP frameworks provide the developer with a variety of common functionalities and classes in the form of helpers,

components and plug-ins, reducing the development time (Fayyaz and Munir, 2014). They help to reinforce the security of a website and reduce repetitive and complex tasks, which means that developers can do less writing and more production of high quality applications (Yadav et al., 2019).

The CakePHP framework (CakePHP, 2020a) was chosen to build the web application for the Pain Recording System (i.e. portal) (see Figure 16). It is more appropriate for large level applications compared to CodeIgnite, as it performs better under stress conditions (Fayyaz and Munir, 2014). Laravel is also designed for enormous applications; its advantages are more oriented towards E-commerce (Electronic commerce) applications (Yadav et al., 2019). Furthermore, CakePHP has a higher reusability score than the other two considered here (Li et al., 2017).

CakePHP, which was released in 2005 (Houghton, 2020), is one of the popular open source frameworks based on the Model View Controller (MVC) design pattern (CakePHP, 2020a; Li et al., 2017). The latter has proven its effectiveness in generating organised modular web applications that allow better scalability and maintainability (Li et al., 2017; Sarker and Apu, 2014). It is considered a standard design pattern for web applications (Yadav et al., 2019) where the application is broken into three modules (CakePHP, 2020a; Sweat, 2005) as illustrated in Figure 45 alongside Figure 16:

- Models represent the part of the application that implement the business logic and handle its data.
- Views are responsible for the presentational interfaces of the application using the model data.
- Controllers handle a request from the user and are responsible for rendering a response with the help of both mentioned modules.

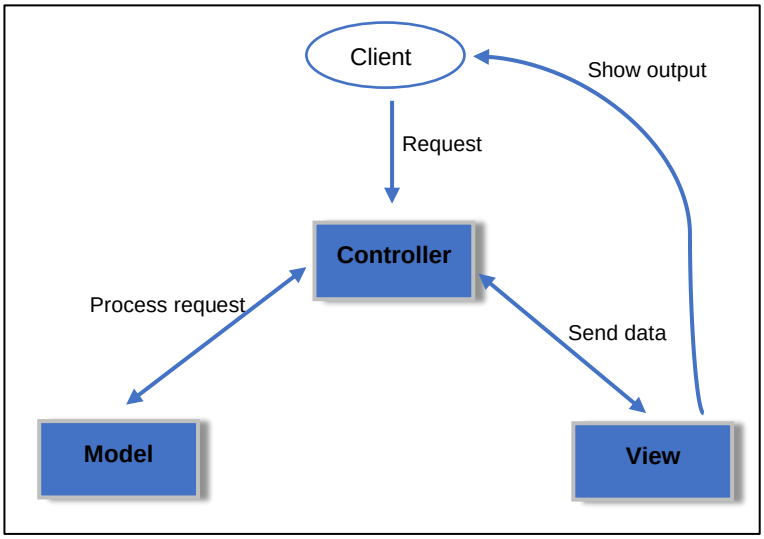


Figure 45: MVC structure, adapted from Yadav et al. (2019, p. 506)

While CakePHP has a steep learning curve, once mastered its development can be easier as it provides features that allow developers to achieve great functionalities with less effort (Demblani, 2016). Developers need to follow CakePHP conventions in which a standard set of rules are already put in place. This enables the developer to obtain great functionality, avoid unnecessary configuration, and build a consistent application structure (CakePHP, 2020a; Houghton, 2020). For example, CakePHP has certain assumptions for naming in its database schema, such as the assumption that table names must correspond to CakePHP models, and must be plural and underscored if they contain more than one word (CakePHP, 2020b).

CakePHP has a built-in Object-Relational Mapping (ORM) (CakePHP, 2020d), which is a programming technique that facilitates connections between Object-Oriented Programming (OOP) languages and relational databases by mapping objects in the code into tables in the relational database (Fayyaz and Munir, 2014; Walek et al., 2012). CakePHP's ORM benefits greatly from the framework conventions for database tables, in that a few lines of code can replace the need for writing complex SQL (Structured Query Language) statements (CakePHP, 2020d; Houghton, 2020; Fayyaz and Munir, 2014).

5.4.2 Supporting technology stack

CSS and Javascript were used in combination with standard libraries such as jQuery (2020) and Bootstrap (2020), to enhance the UI. In addition, the Chart.js (2020) package was leveraged to build the charting component of the portal. Font Awesome toolkit (2020) was used to obtain representative icons for the portal interface.

5.4.3 Development process

A CakePHP (version 3.9) framework was installed and a new CakePHP application with the name ‘Portal’ was created by the researcher inside a local server (discussed below in section 5.5) set up on her personal laptop. The application was connected to the system database (discussed below in section 5.5.1) following the required configurations (see Figure 16). The database was built in accordance with the CakePHP naming conventions, allowing automatic construction of the CakePHP Skeleton (i.e., MVC) for the application. In other words, the CLI was used to run specific CakePHP commands on each database table to create the associated model, view and controller in the application along with basic database functions including create, read, update and delete (CRUD) a record.

The portal (see the GitHub repository mentioned above in section 5.2) was developed incrementally, as mentioned before (section 5.2), by breaking the work into small segments presenting the portal’s pages and reflecting the requirements discussed previously in Chapter 4 (see Tables 13 and 15). The work was mainly focused on three controllers associated with the ‘Profs’, ‘Patients’, and ‘Studies’ database tables. Several functions were created for these controllers along with their corresponding views, to handle the specified requirements. Furthermore, a specific code was implemented in the ‘AppController’ to control the user authentication and active usage session for accessing the portal contents (see Figure 46). The ‘AppController’ is the main controller class in CakePHP, while other created controllers for the application are extended from it (CakePHP, 2020c).

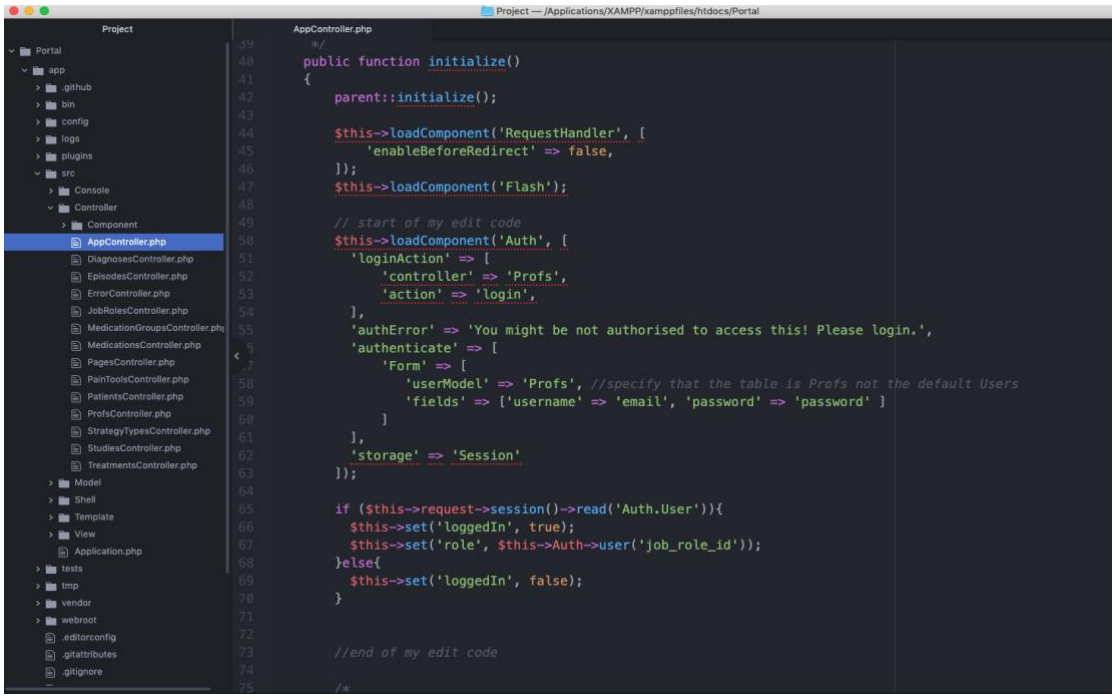


Figure 46: Excerpt from the code used in the 'AppController' to control user authentication while using the portal

Note: see the full code in the GitHub repository mentioned in section 5.2

5.4.3.1 Testing the portal beta version internally

The portal was tested internally in two stages. First, it was tested thoroughly by the researcher, applying a number of key use cases (see Chapter 4, Figure 11). All the portal features were tested using the ad hoc testing technique (Writer, 2020) to check for any errors, or any flaws related to UI or UX. In addition, the content of the portal was checked against the app requirements, incorporating feedback from the usability testing discussed in the previous chapter (see Tables 13 and 15 and section 4.3.3.8). This was to ensure that all of the requirements were implemented exactly as planned.

The second stage was carried out after uploading the application into an external server, as reported later in section 5.5. The portal was tested individually by three research colleagues. Any comments received from them were considered before moving to the next phase of the second UCD cycle, to be reported in the next chapter.

5.4.4 Final portal features

5.4.4.1 Layout and registration

The portal layout was designed to be simple and have a classical appearance like clinical record systems. A plain white background was used for the portal pages along with a turquoise navbar at the top (Figure 47). The landing page of the portal shows a login box which also contains a ‘Register’ button, as illustrated in Figure 47. The ‘Register’ button takes the user to a simple registration page. Once the user is successfully registered, the landing page will be displayed, allowing the user to log in.

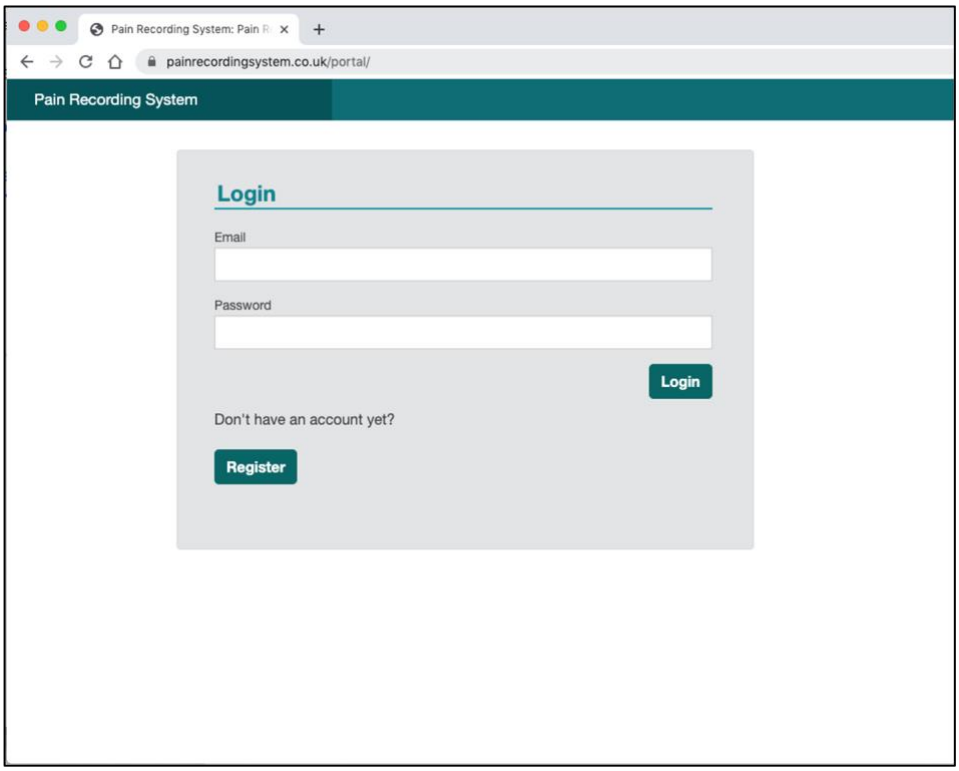


Figure 47: The portal landing page

5.4.4.2 The portal features and functionalities

The developed portal provides the user with the following functionalities which can be accessed from the navbar when they are successfully logged in (see Figure 48):

- ‘Patients search’ allows the user to search registered patients (i.e. registered in the system through the ‘PainRecord’ app) by using the patient’s system ID or date of birth to view their information along with

the pain history as illustrated in Figures 48, 49 and 50. The pain history is presented through a chart that contains the same features as those provided for the pain chart in the 'PainRecord' app (see section 5.3.5.2), as shown in Figure 50. The user can click on the 'Add patient to my monitoring list' button shown in Figure 49 to be able to directly access the patient information in future without searching.

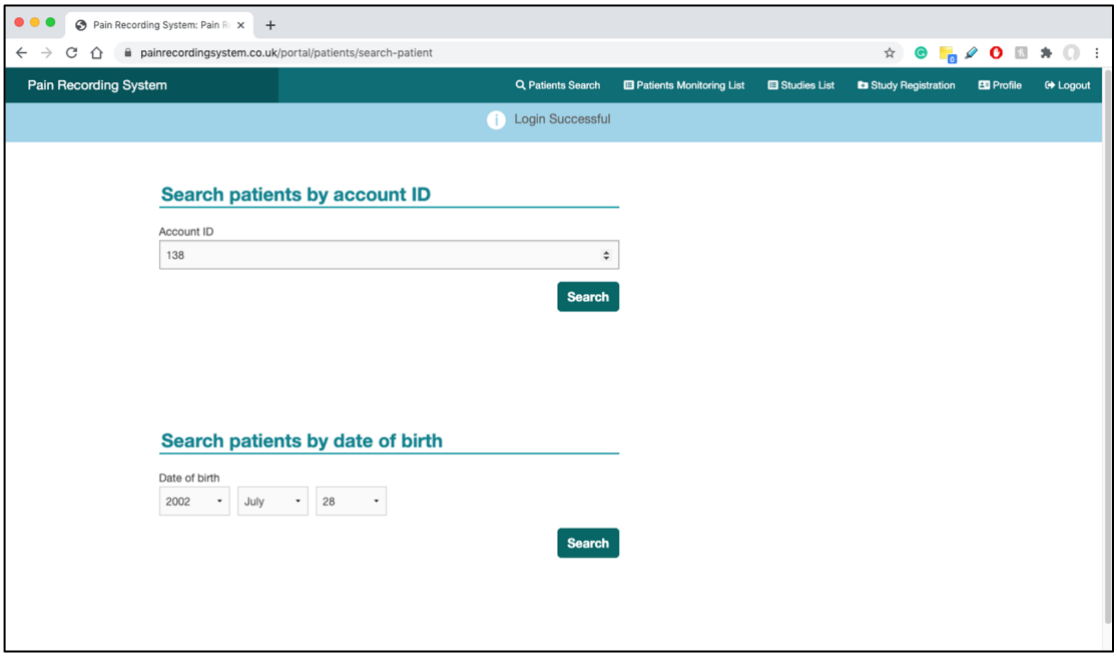


Figure 48: A screenshot of the patients search page showing the portal navbar at the top

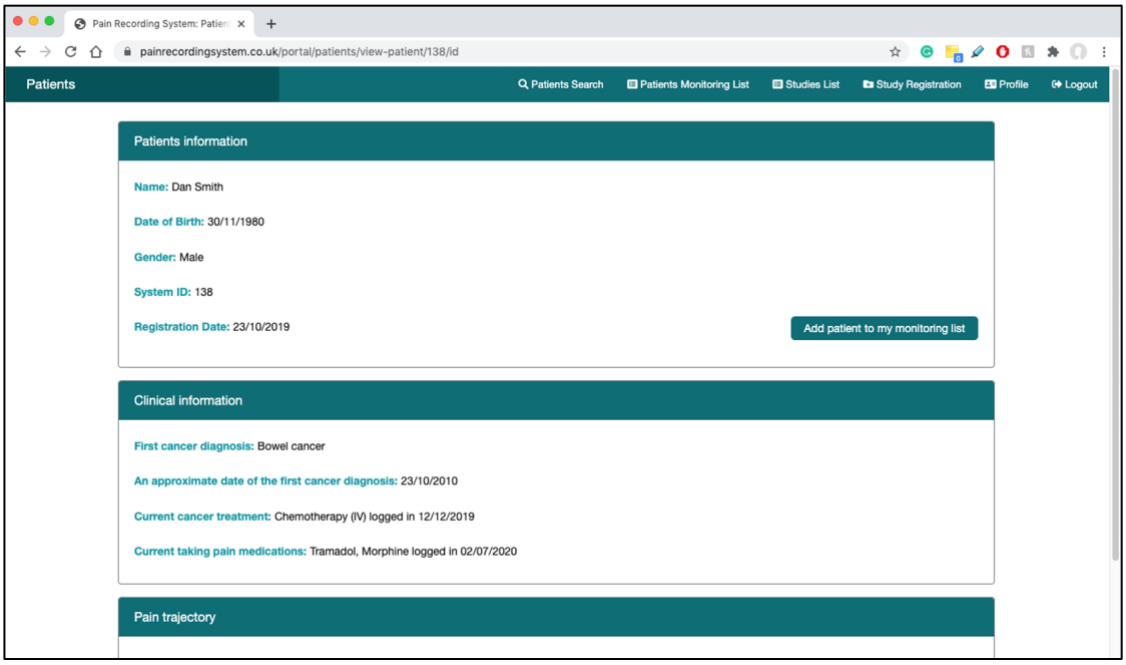


Figure 49: A screenshot of the patient search result showing information for a dummy patient registered in the system

Figure 50: A screenshot of the patient search result showing the pain history chart for the dummy patient registered in the system

- The ‘Patients monitoring list’ shows a group of patients whom the user decided to monitor. As Figure 51 illustrates, the page was designed to display the list of patients in a table containing: (1) an excerpt from the patients’ data, (2) a summary of their pain status represented as the averages of pain severity and interference scores[14] with highlighting scores ≥ 5, (3) calculated rate of patient compliance with logging pain details daily ($\frac{number\ of\ days\ with\ logged\ pain\ details}{number\ of\ days\ since\ registration\ date} \times 100$), and (4) two actions to do in relation to a patient, including viewing the full record of the patient, as in Figures 49 and 50, and removing the patient from the table (i.e. monitoring list).

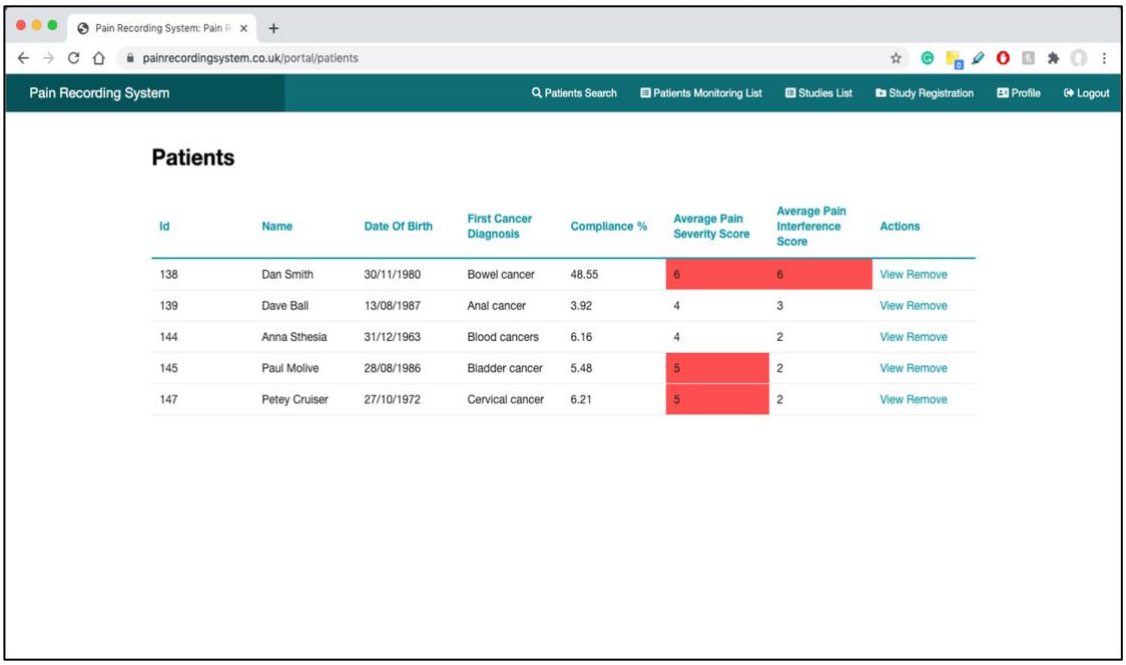


Figure 51: A screenshot of the patient monitoring list page showing dummy patients added by the user

- ‘Study registration’ is the place where the user can register a study as illustrated in Figure 52. This adds the study to the user studies list and allows the system to generate an ID for the study as shown in Figure 53.

[14] Average pain severity = $\frac{total\ of\ pain\ severity\ scores}{number\ of\ days\ with\ logged\ pain\ details}$

Average pain interference = $\frac{total\ of\ pain\ interference\ scores}{number\ of\ days\ with\ logged\ pain\ details}$

The user can provide the study ID to the study's potential participants for use when registering on the PainRecord app, allowing the system to link them to this study.

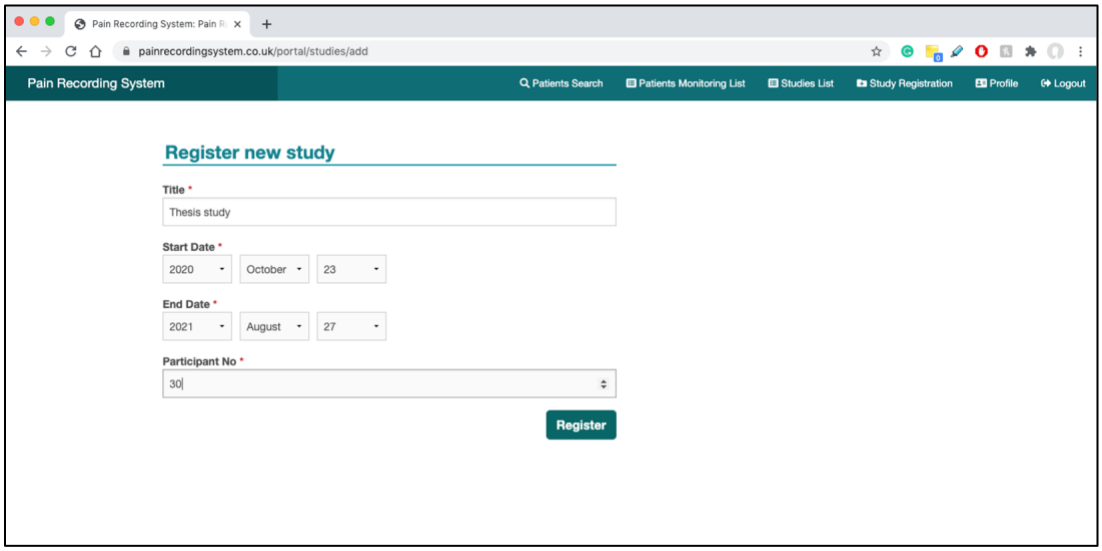


Figure 52: A screenshot of the study registration page

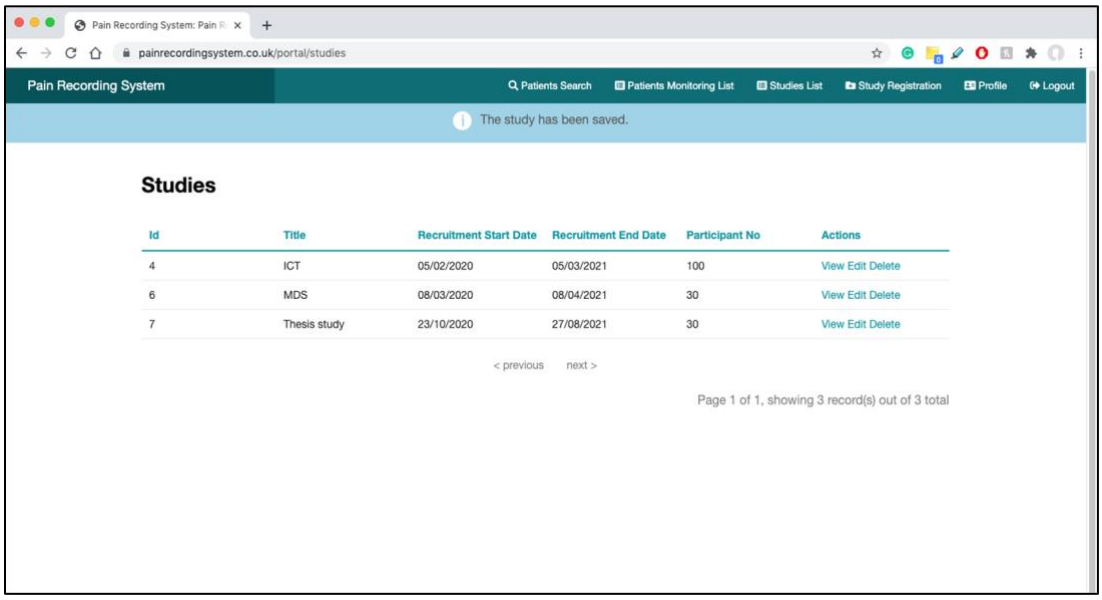


Figure 53: A screenshot of the study list page showing dummy list of studies added by the user

- The 'Studies list' shows a list of studies added by the user. As illustrated in Figure 53, the list is presented in a table arranged to summarise the studies' registered details and to provide the user with three actions to take on each study. Using the provided actions, the user can:

(1) view the full record of a study, including update on recruitment status and list of anonymous participants, organised in a table briefing their details including average of pain and compliance rate (see Figure 54). Furthermore, the user can obtain the participants' summary table and their raw pain data as Excel sheets by using the 'Download The Table' and 'Download Raw Pain Data' buttons respectively, located at the bottom of the page, as shown in Figures 54 and 55.

(2) edit the registered details of a study.

(3) delete the study record from the system and consequently disconnect the participants' records from the study.

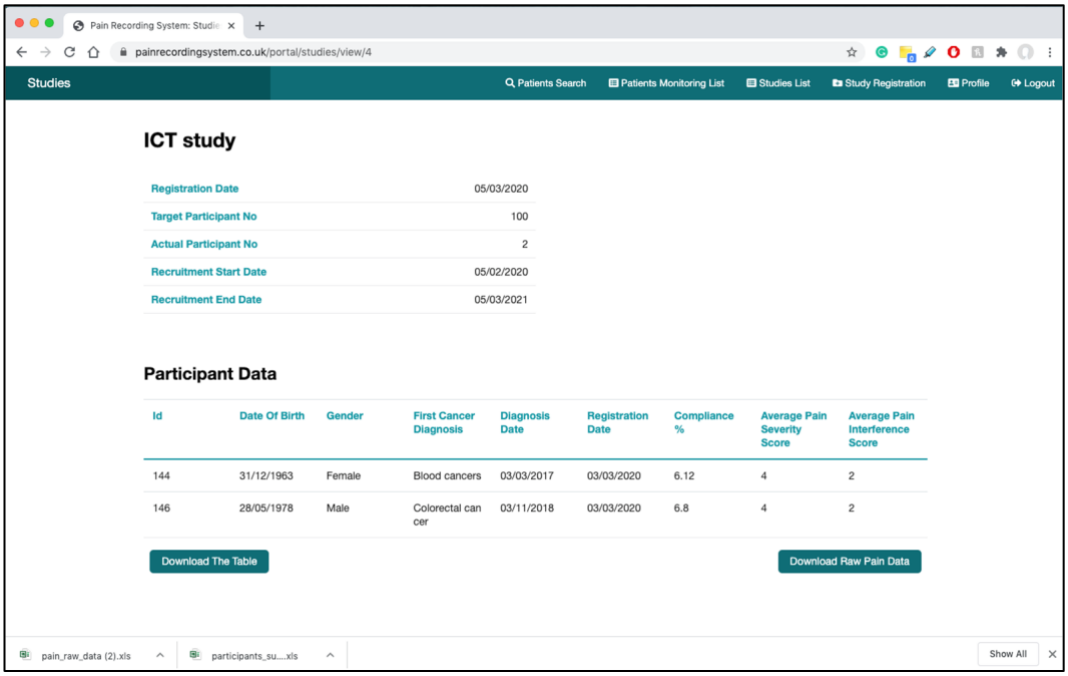


Figure 54: A screenshot of the study view page showing details of a dummy study

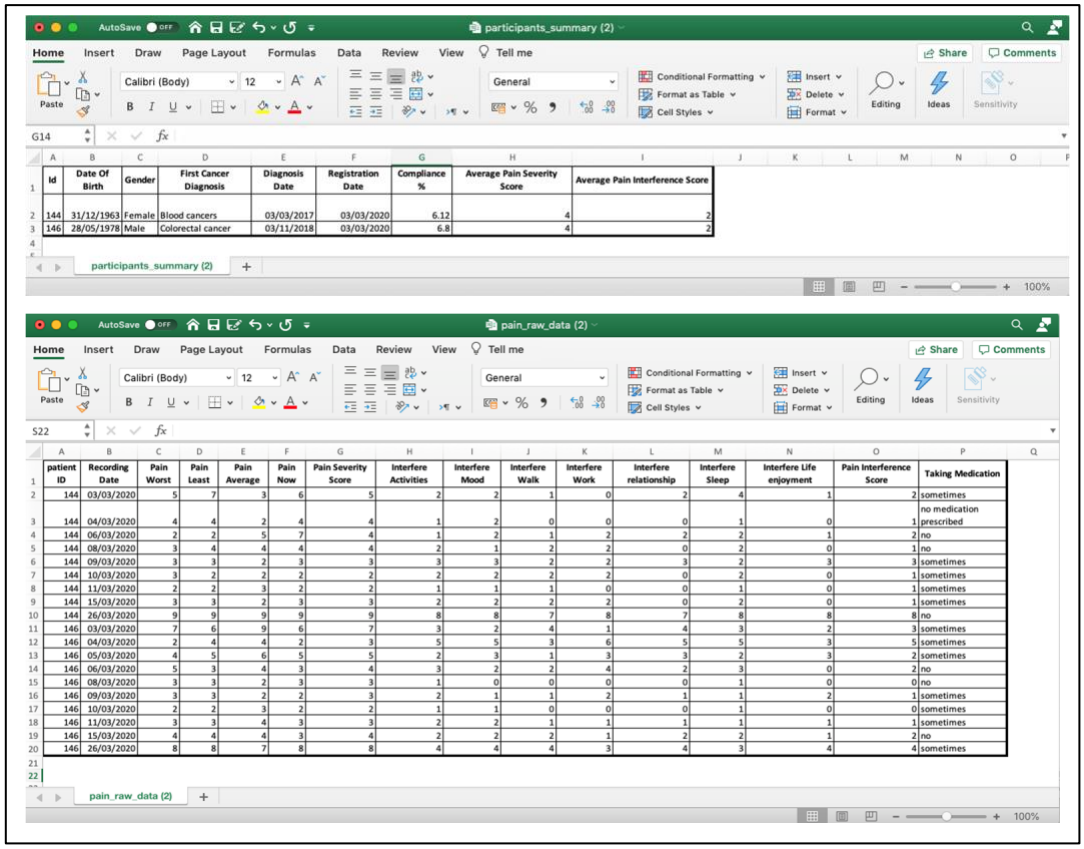


Figure 55: Screenshots of downloaded Excel sheets from the portal related to a dummy study data

- 'Profile' is where the user can edit their registered data as shown in Figure 56.
- 'Logout' allows the user to log out from the system.

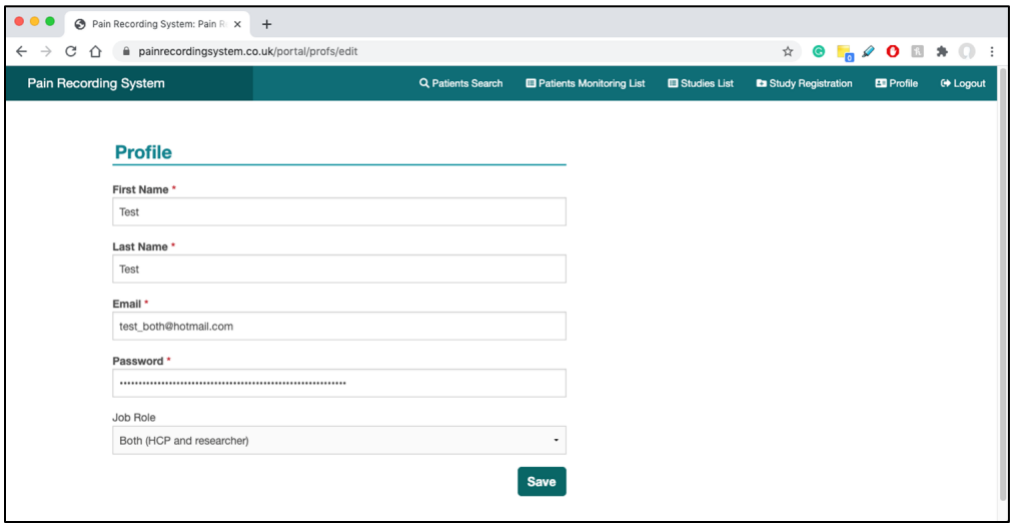


Figure 56: A screenshot from the user profile page showing dummy user data

The access to the portal contents and functionalities is controlled by the user's job role. In other words, the portal's navbar is controlled to display the appropriate activities in relation to the user's registered role when they are successfully logged in as detailed below:

- HCPs can only access activities related to patients, including searching patients and viewing patients' monitoring list.
- Researchers can only access activities related to studies, including registering studies and viewing studies' details.
- Users who have a combined clinical and academic role can access all the aforementioned activities provided by the portal.

For enhancing the security of the data in the portal, the system was designed to automatically log the user out once they become inactive for a while and show a flashing notification bar below the navbar asking the user to log in again. The portal, in addition, uses this type of notification along with pop-up alert messages to interact with the user's activities, optimising the UX. Figure 57 illustrates some of these.

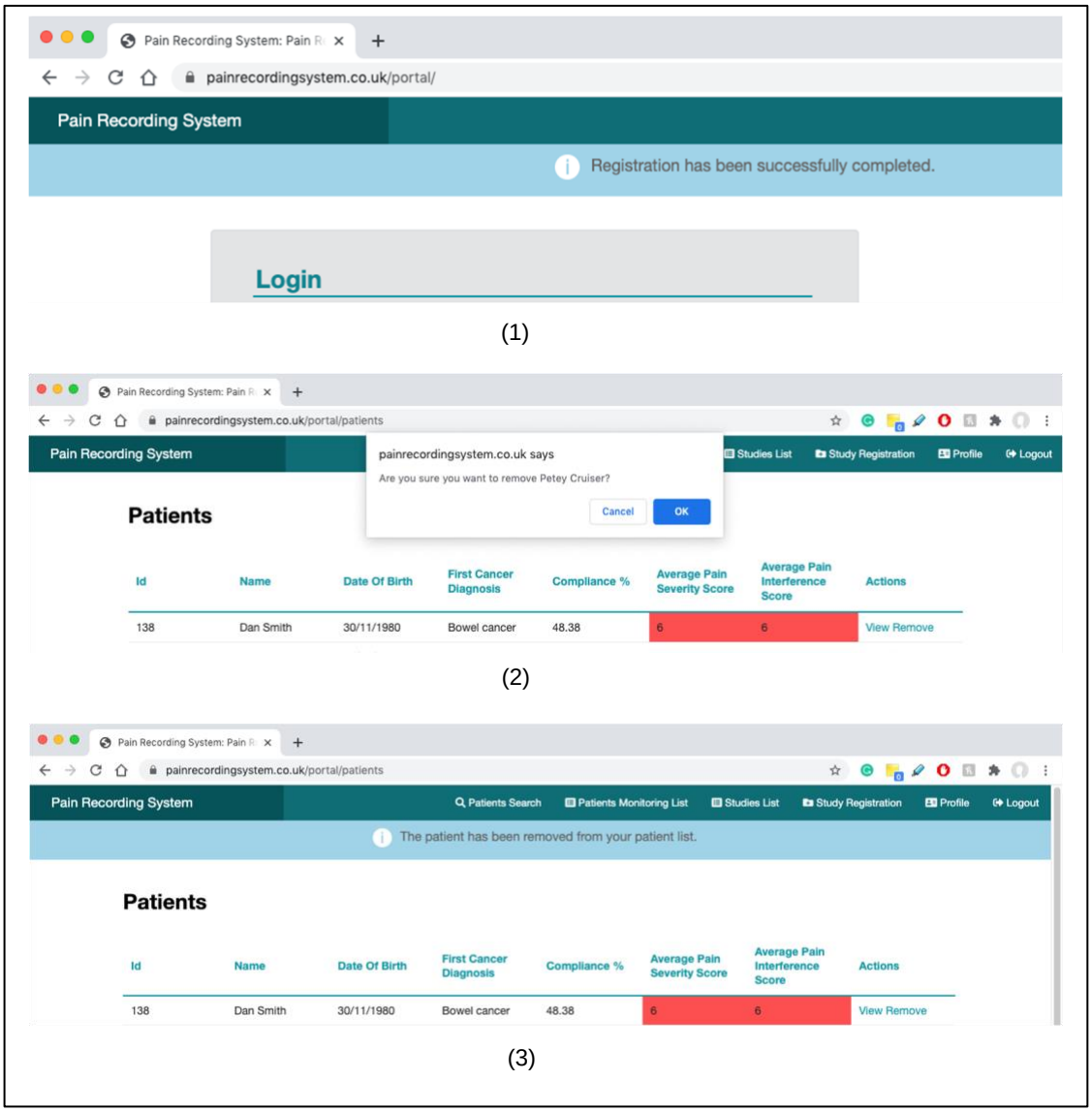


Figure 57: Screenshots of type of notification employed in the portal

5.4.4.3 The portal's limitations

All the identified requirements discussed in Chapter 4 were fulfilled in the final portal prototype, except for two of the preferable features: 'allowing user to add/remove a registered patient to/from a study as a participant' and 'allowing user to send prompts to patients and study participants through the PainRecord app' (see features #2 and 3, Table 15, Chapter 4). Implementing the former feature would provide the user with more flexibility in managing recruitment. Allowing portal users to reach the other end of the Pain Recording System (that is PainRecord app) would improve the efficiency of the system. Time constraints of the project and the unexpected delay caused at the beginning of the development phase were the main reasons for dismissing the mentioned

features from the current version, with the aim of incorporating them in a future UCD cycle.

5.5 Database/server-side development

MySQL database was selected for the system as it is one of the commonly used Relational Database Management Systems (RDBMS) (Ongo and Kusuma, 2018), which fits well with the other technical choices determined for the other parts of the system. For example, CakePHP's ORM requires a relational database in order to work appropriately with it (CakePHP, 2020d). MySQL has a faster query execution compared to other RDBMS such as Oracle and PostgreSQL (Ongo and Kusuma, 2018). It has shown significantly better performance when compared to other popular open source databases, including MariaDB (Tongkaw and Tongkaw, 2016). Furthermore, MySQL is appropriate for storing sensitive data and has a low implementation cost (Ongo and Kusuma, 2018).

The researcher used her personal laptop to set up a local development server, XAMMP (version 7.3.1) (Apache Friends, 2020), and to build the required database for the system. The server was also utilised to store and process the server-side scripts required by the other parts of the system during the development phase. XAMMP is a popular PHP development environment and open source package that was developed by Apache Friends to provide developers with the Apache web server (Apache Friends, 2020).

5.5.1 Final database schema

The preliminary design outlined for the system database (see Chapter 4, section 4.3.1.3 and Figure 12) was implemented. Three extra tables were added to the schema to allow further system scaling in future. The additional tables were (see Figure 58):

- 'diagnoses' for listing the cancer diagnoses' names.
- 'medications' for listing the pain medications' names.
- an associative table named 'medication_groups_medications', as a 'medication_groups' table, which represents dates when groups of

medications were first used within an episode of treatment; it could include many names of medications (that is 'medications' table) and *vice versa*.

Adding these tables would allow updating the lists of diagnoses and medications easily and handling any future changes more efficiently.

The system database (see Figure 16), named 'PainRecords', was built with consideration of the CakePHP naming conventions as mentioned in section 5.4.3. Figure 58 illustrates the developed database schema for the final system prototype.

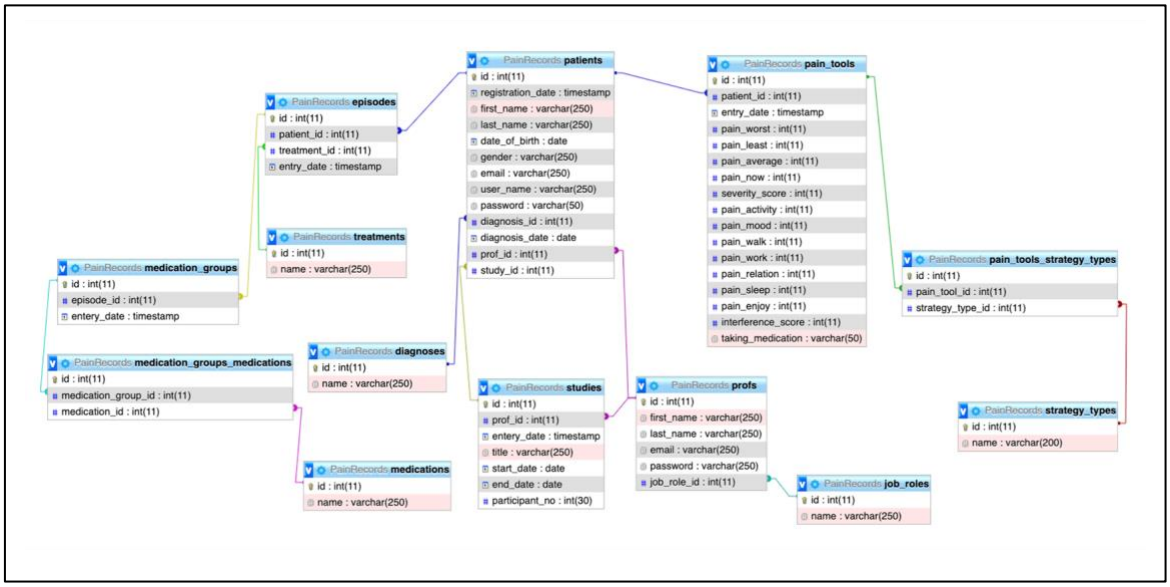


Figure 58: A screenshot of the 'PainRecords' database developed for the Pain Recording System

5.6 Deployment of the Pain Recording System

The developed system prototype was deployed and uploaded by the researcher to an external server to allow potential users to test the system, as reported in the next chapter, providing them with more real experience. A virtual private server (VPS) along with a domain name were purchased for a year from the OVHcloud hosting service company [15]. A firewall was created and configured for the server using the rules and settings recommended by OVHcloud (OVHcloud,

[15] Available from https://www.ovhcloud.com/en-gb/

2020a; OVHcloud, 2020b). A one-year licence of the Plesk Web Admin Edition was purchased from the Plesk hosting platform[16] and installed in the server. Plesk was leveraged to obtain a web-based control panel for the server, allowing more flexibility in managing the system, including the portal website hosted on https://painrecordingsystem.co.uk/portal/ [17]. The connection to the server was encrypted and secured by employing an SSL/TLS certificate from Let's Encrypt, an open certificate authority, following Plesk security recommendations (Plesk, 2020).

The deployment of the system with the aforementioned temporary setup was considered appropriate for the current phase of development, inasmuch as future cycles of UCD were expected. Distributing the PainRecord app beta version with the setup mentioned in section 5.3.4.5 for the purpose of testing it on potential users was also deemed practical for this phase of project. Publishing the app on Apple store would require time-consuming steps including an approval process for making changes to the app (Roth et al., 2014); therefore, this was left to more advanced phases of the project in future, when the app will become more stable and ready for large-scale testing and use.

5.7 Chapter summary

This chapter reported the achievement of the fifth objective of the thesis, 'to build the system'. It described the process of developing the working prototype of the Pain Recording System including the PainRecord app, the web-based portal and the server hosting the system database (see Figure 16). This was the second cycle of the UCD, the 'prototype development' phase. The following chapter presents the next phase of this cycle, which is 'evaluate use in context', represented by a feasibility study.

……..

[16] Available from https://www.plesk.com/
[17] For login credentials for dummy user accounts, please see Appendix 28

Chapter 6

Evaluation of the Pain Recording System: a feasibility study

6.1 Chapter overview

This chapter presents the final phase of the second cycle of the User Centred Design (UCD) established in the previous chapter for the Pain Recording System as shown in Figure 59. The chapter reports the procedures used to examine the functioning system prototype in context, addressing the sixth and last objective of this thesis, which is 'to test the system feasibility'. It concludes with suggestions informing future iterations of the UCD for the system (see Figure 59).

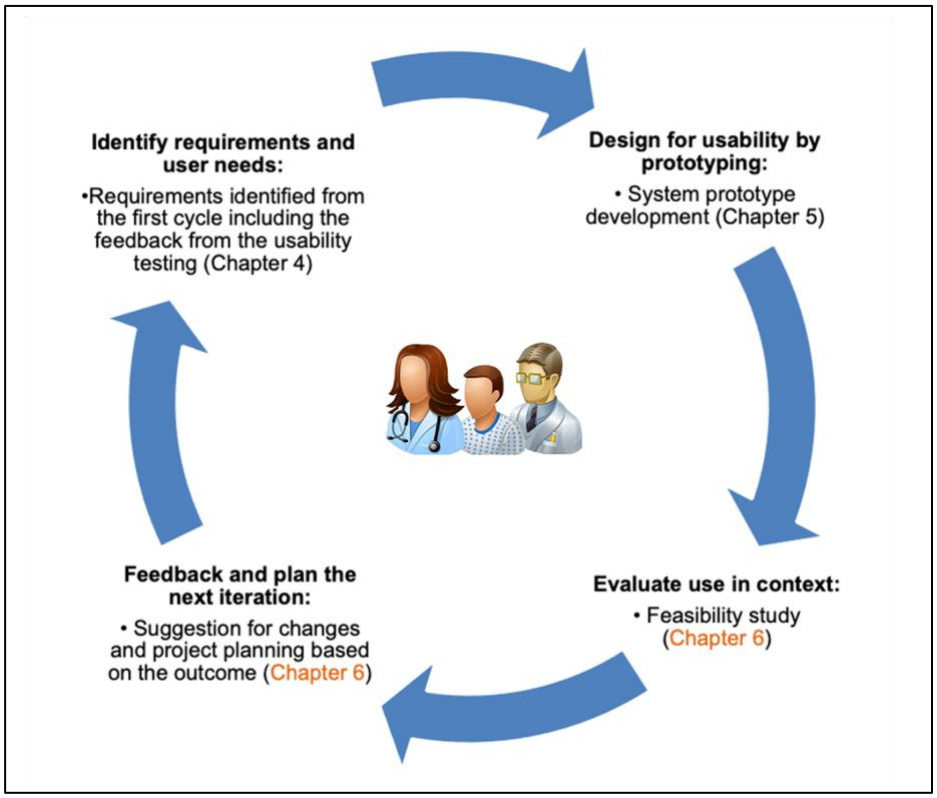


Figure 59: Second cycle of the UCD aimed to develop the fully functional system prototype, adapted from Gulliksen et al. (2003, p. 5)

6.2 Aim and objectives

Feasibility studies in the field of health promotion can focus on different aspects of an intervention's feasibility to determine its acceptability and readiness for further testing (Bowen et al., 2009). Therefore, it was deemed important to clarify the aim of the current feasibility study at this stage of the iterative development of the Pain Recording System. The overall aim of the study was to test the system's working prototype with the following underlying objectives:

- To obtain initial insight into the feasibility and acceptability of the system
- To obtain initial insight into implementation scopes
- To test the usability and practicality of the system and gather suggestions for improvement
- To test the technical integrity of the system components.

6.3 Methods

A mixed-methods approach was adopted whereby qualitative and quantitative study data were collected to address the aim and objectives of the study. The strength of this approach and the appropriateness of its adoption in iterative development of mHealth interventions were discussed previously in Chapter 4 (section 4.3.3.1). The main data collection methods employed in this study included semi-structured interviews, questionnaires, and usability scales, as discussed in detail below.

6.3.1 Study design

The system was tested in two phases conducted in parallel: (1) testing the PainRecord app and (2) testing the Pain Record System portal. For the first phase, community-based cancer patients were recruited to complete a two-week test of the developed app. After the test, they were asked to provide feedback by completing a self-reported usability questionnaire and participating in a semi-structured interview. Given the time constraints of the project, the specified test period was thought applicable to the study's objectives. It would allow the patients to realise the potential long-term benefit of using the app, thus enabling them to judge it appropriately. Evaluating the effectiveness of

behaviour change interventions requires tests of longer periods (Sangelaji et al., 2016; NICE, 2020), but this was not the scope of the current study and will be considered in future work.

For testing the system portal, a group of professionals (i.e., HCPs and researchers) were recruited. Participants were asked to test the portal online in a one-off session and then complete a standard usability questionnaire and open-ended questionnaire designed for the study. They were invited to a brief follow-up interview after submitting their feedback online.

6.3.2 Ethical approval

An amendment application for the previously granted ethical approval (see Chapter 4, section 4.3.3.4) was submitted on 18th October 2019 to the School of Medicine Research Ethics Committee at the University of Leeds in order to include this study. The changes were approved on 19th December 2019 with reference number MREC 17-059 Amd 1 Oct 2019 (see Appendix 18).

6.3.3 Ethical considerations

To ensure participants were fully informed of what participation in the study involved, they were provided with the participant information sheet and consent form to read prior to participation. In addition, they were given the opportunity to ask questions. Completed and signed consent forms were collected before the participant started to test the system (i.e., the app or the portal). The participants were made aware that their participation was voluntary, and they had the right to withdraw from the study at any time before the start of data analysis. Identifiable data were only collected through the consent forms and an administrative sheet. Other collected data were anonymised using a coding system. The data were retained securely by the researcher; paper records of the study were kept in locked cabinets, while the electronic records were stored in the University server (i.e., the researcher's M drive).

For the purpose of this study and for the security of the participants' data, the system was intended to be hosted by the University of Leeds and the IT team

was approached by the researcher to facilitate this. They lacked however the capability to meet this request at the required time. Their advice was sought about the OVHcloud hosting service (see Chapter 5, section 5.6) as an alternative and they approved using it within the classification of data that had been defined (see Appendix 19). Participants were provided with anonymised names to use and asked to use anonymised personal information for sign-up.

The University of Leeds Jisc online survey service was used, and each participant was provided with a numeric identifier to use when completing the study's surveys. The data held in the external servers was accessed only by the researcher.

Participants were made aware that the PainRecord app installed in their devices was expected to stop working after the study finished, as it is still in a testing phase and will be available to install from the App Store when it is verified. Until then, they were advised of the availability of some pain apps that could help.

6.3.4 Participant sampling and recruitment

In line with the first cycle of the system development and testing (see Chapter 4, section 4.3.3.2), two types of potential end-users were approached to participate in the second testing: patients with cancer living in the community and professionals, including HCPs and researchers. The participants from each group were selected purposively. Sample size was determined following a qualitative method rather than a formal statistical test. Thus, four to six participants were to be recruited for each group as in the previous testing, until saturation was reached: that is until no further themes arose. More details on the employed sampling technique and size, along with the justification for their selection, were discussed earlier (see Chapter 4, section 4.3.3.2).

Participants from the patient group were approached via cancer support groups, organisations and charities, as well as patients' and public involvement groups affiliated with the School of Medicine at the University of Leeds. To speed up the recruitment process, the coordinators of five of these sites (see Appendix 20) were contacted by the researcher and an agreement to help in advertising

the study was reached prior to the start of the study. Once ethical approval was granted (see section 6.3.2), the details of the study, including the participant information sheet and participant consent form (Appendix 21), were sent to the coordinators. Different approaches were used to advertise the study, including:

- circulating invitation emails to the internal members' mailing lists of the organisation
- posting invitations to participate on the organisations' Facebook pages and websites
- adding invitations to participate in the organisations' newsletters or bulletins
- displaying a poster about the study at the organisations' centres.

The advertisement materials were designed by the researcher and made available to the coordinators (see Appendix 22). The study was advertised at least twice at each site in periods when recruitment was slow.

After more than a month from the beginning of the recruitment process (which started on 20/12/2019), only two patients had participated, who kindly shared the study details with their personal contacts. Through this, another 15 sites were identified and contacted by the researcher by email and/or phone in February 2020 with the request to help with recruitment. Out of the 15 sites, one agreed to help and advertised the study, two declined, and 12 sites did not respond despite at least one follow-up (see Appendix 20). The low interest could be attributed to the fact that the timing of recruitment process coincided with the beginning of the Coronavirus (Covid-19) outbreak as discussed in detail in section 6.3.7.

Patients interested in taking part were invited to contact the researcher by using the contact details provided in the invitation materials (i.e., email, poster etc.), in which the researcher identified their eligibility. Participants were offered a £20 Amazon voucher as a 'thank you' for their time and were eligible to claim any travel expenses incurred in order to take part in the study.

For the professional group, researchers and HCPs were approached and recruited from the University of Leeds and St James's University Hospital in Leeds. The group of professionals who participated in the first testing (Chapter

4, section 4.3.3) and consented to be contacted again were invited to participate in this study. In addition, more professional names with relevant expertise were identified through their public online profiles. An invitation email with two attachments – a participant information sheet and a participant consent form designed specifically for this group (Appendix 21) – was sent by the researcher to all the identified names. They were invited to contact the researcher if they were interested in taking part.

6.3.5 Participant eligibility criteria

Criteria for selecting the participants were the same as in the first testing (see Chapter 4, section 4.3.3.3) apart from the addition of two more specific inclusion criteria for patient participants: (1) they had to have experienced at least one episode of pain within the last six months, and (2) they were required to own an iOS smart device (iPad or iPhone) in which the researcher could install the PainRecord app for them to use.

6.3.6 Testing procedures

6.3.6.1 Testing the PainRecord app

An introductory session was arranged with each eligible patient, during which a brief explanation of the concept of the Pain Recording System, the nature of participation, and what the test was expected to achieve, was provided. After collecting the completed and signed consent forms, participants were asked to complete: (1) a short questionnaire that requested demographic data as well as information on usage of mobile apps (see Appendix 23), and (2) a separate administrative sheet designed to collect contact details including home address, email, and mobile phone number (see Appendix 23). Then, they were asked to unlock the iOS smart devices on which they wished to test the app and hand it in to the researcher. The devices were connected to the researcher's laptop, where the required process for installing a version of the app was completed by the researcher and facilitated by the development settings in the laptop. The process for installing a beta version of the app was described previously in Chapter 5, section 5.3.4.5. Once the installation was complete, the device was

returned to the participant. With the researcher's assistance if needed, the participant was asked to open the app and set up an account using anonymised personal data including the unique name for each participant assigned by the researcher, as mentioned earlier (see section 6.3.3). Only minimal explanation of the app was provided as the participants were asked to explore it themselves during the test period. Participants were invited, but not mandated, to complete one pain entry daily for a period of two weeks.

After two weeks, the researcher sent the participants by post a copy of the mHealth App Usability Questionnaire (MAUQ) (Zhou et al., 2019). The MAUQ is a recent and validated usability questionnaire designed specifically to evaluate mHealth app usability. It was created in four versions depending on the type of app assessed (interactive or standalone) and target user of the app (patient or provider) (Zhou et al., 2019). The version used in this study was for interactive apps used by patients. It contains 21 statements with a 7-point Likert scale for each, where 7 is 'strongly agree' (see Appendix 24). Participants were then contacted to ensure that they received and completed the questionnaire and to arrange for a brief semi-structured interview.

Each participant was interviewed individually. The aim of the interview was mainly to investigate ways of improving the system and to discuss the participant's perceptions around: (1) the feasibility and acceptability of the app specifically and of the system in general, (2) scopes of implementation. Completed MAUQs were collected at the beginning of the interviews. The interviews were audio recorded and a topic guide was used in all of them (Appendix 25), but in addition, some questions were derived from the participant's answers to the MAUQ. At the end of each interview, the participant was thanked, and a £20 Amazon voucher was emailed to them.

Both the introductory sessions and the interviews lasted between 20 and 30 minutes. They were conducted in a quiet room at the University of Leeds at times convenient for the participants.

6.3.6.2 Testing the portal of the Pain Record System

Dummy patient accounts were created using mock pain data to demonstrate how the data captured via the PainRecord app would be displayed. In addition, dummy studies were registered and linked with groups of dummy participant accounts. This was to simulate the working system and provide professionals, such as HCPs or researchers, with a better representation of the way the system can display patient/participant data. As access to the portal's content and functionalities is controlled by the user's registered role (i.e., HCP, researcher, or clinician-researcher) as discussed in Chapter 5 (section 5.4.4.2), three types of fake accounts were created to facilitate testing the system by participants in different roles.

Professionals who accepted the invitation to participate and signed the consent form received an email from the researcher that walked them through the way to test the system and to provide their responses and feedback online, quoting a reference number provided in the email (see Appendix 26). They were required to take the following three steps in sequence:

1. Complete a short online questionnaire to report demographic data (see Appendix 27).
2. Visit and explore the portal developed for the Pain Recording System (https://painrecordingsystem.co.uk/portal/) using a one-page sheet created by the researcher to help in testing the system. The sheet included login credentials, minimal information about how the system worked, and some tasks to help with recognising the portal's functionalities (see Appendix 28).
3. Evaluate the system by completing an online survey. The survey encompassed: (1) the System Usability Scale (SUS) (Brooke, 1996) which was mentioned and used previously (see Chapter 4, section 4.3.3.1), and (2) seven open-ended questions such as "To what extent do you think the system would be useful in the management of patients with cancer pain?" (see Appendix 27), designed to allow participants to articulate their perceptions of the system feasibility and their suggestions for improvement.

After completing the three steps, the researcher emailed participants to thank them and invite them to a brief follow-up interview which aimed to discuss the participant trials of the system's usage, guided by their submitted feedback. The interviews were conducted either by phone or by online meetings platforms such as Microsoft Teams and Skype, based on the participants' preference. These were audio recorded and lasted, on average, 9 minutes.

6.3.7 Impact of Covid-19 pandemic

Conduct of the study coincided with the beginning of the Coronavirus (Covid-19) outbreak in Europe in late January 2020 (ECDC, 2020). In that period, the feeling of confusion and being overwhelmed started to arise among people in relation to the virus. The study also coincided with the period in which the UK government responded to the rapid spread of the virus and put certain restrictions into effect to contain it. On 16th March 2020, the British authorities enforced the application of 'social distancing', avoidance of 'non-essential' travel and contact with others and working from home if possible. There was a particular emphasis on compliance in the case of high-risk people, namely those who were over 70 years old and had serious health conditions (GOV.UK, 2020). In response to these measures, the University of Leeds moved to online delivery of services and academic activities and closed several buildings, asking staff and researchers to work remotely starting from 20th March for an unforeseeable period of time. Furthermore, it was requested that nonessential research activities, along with any research activity that could not be completed remotely, be suspended. This included recruitment and fieldwork undertaken with external partner bodies (Student Communications, 2020; Stroud, 2020) (see Appendix 29).

In light of these conditions, the current study was affected in relation to participant recruitment, in particular for the patient group. Considering that patients with cancer were a high-risk group (Salunke et al., 2020) and taking part in the study required two face-to-face meetings (see section 6.3.6.1), recruiting them was not feasible during this difficult time. It should be noted that recruitment efforts had been ongoing for almost three months (i.e., 20/12/2019 – 16/3/2020) before the aforementioned measures were announced and

although recruitment was proving challenging, persistence was beginning to pay off and potential participants were being identified. Unfortunately this coincided with an increasing feeling of uncertainty surrounding the virus, along with the observed growth of infected cases and related deaths locally and globally (ECDC, 2020; World Health Organisation, 2020) which likely impacted on patients willingness to commit to the study in the weeks prior to the first formal lockdown being announced on 16 March 2020. The disruption caused by Covid-19 to the progress of studies and research activities has been well recognised (Paula, 2020; Goldstone, 2020).

Nevertheless, the researcher tried to amend the study procedure to enable participants from the patient group to take part remotely. This essentially meant finding a method through which participants could access the beta version of the PainRecord app and install it in their devices by themselves. Apple provides a way of distributing beta versions of apps to external testers via the App Store Connect platform which sends the tester an invitation by email to test the app (Apple Developer, 2020). A search of Apple documentation however left it unclear whether installing the app via the email would be straightforward. Therefore, the researcher decided to try that and triggered the required processes (Apple Developer, 2020; Katz, 2020). Consequently, the PainRecord app was submitted to Apple for two phases of technical review. In the first review, it was accepted after the second submission, where some fixes including the use of suggested alternative libraries were completed based on the reviewer's comments (see Appendix 30 and 31). Then, the app was approved immediately in the subsequent review (see Appendix 32), enabling the researcher to use the service (i.e., App Store Connect) and invite people by email to test the app. Through this pilot, it became evident that the recipient of the email would need to follow three steps to install the app: (1) accept the invitation by installing an app called 'TestFlight' produced by Apple and designed to support installation of beta versions, (2) quote a specific code given within the instruction, (3) open the TestFlight app, find the 'Redeem' button and enter the given code, which would then take the tester to a preview page for the tested app to install it. The beta version would be controlled by the TestFlight app; therefore, on the first launch of the tested app there would be some instructions on how to take screenshots and submit them along with feedback

via TestFlight. The mentioned process for installing the app remotely was considered overwhelming to the tester, given the target testers of the current app.

In addition, it was questionable whether it was morally acceptable to approach patients with cancer for such a study within the current uncertain conditions. Evidence has shown that the presence of cancer in Covid-19 patients is associated with development of serious events including ICU admission, mechanical ventilation and mortality (Salunke et al., 2020). In addition, a high prevalence of mental health problems in patients affected with cancer has been reported during the pandemic and has been attributed to high distress over Covid-19-elevated risk and fear of disease progression due to treatment delay or interruption (Wang et al., 2020; Chen et al., 2020).

Another source of concern was that any changes in the study procedures due to the current situation would need amendments to the existing ethical approval. As part of the disruption caused by Covid-19, the School of Medicine Research Ethics Committee at the University of Leeds experienced a period of suspension during which priority was given to ethics applications related to Covid-19 (see Appendix 33). This meant a further expected delay in finishing the study.

In view of the existing time constraints on the project, and all the above-mentioned factors, the decision was made in collaboration with the supervision team that despite the researcher's attempts to modify the way participants could engage with the study ongoing recruitment was not going to be feasible. The decision was taken that the study should be completed with the participants already recruited. It was however borne in mind that there was a need for future iterations of the UCD through which the app could be further improved and tested in better conditions and with a higher number of participants.

6.3.8 Data analysis

The recordings of the semi-structured interviews were transcribed by the researcher. The transcripts, along with the answers to the open questions

collected via the online questionnaire, were analysed using the thematic content analysis approach (Green and Thorogood, 2014). The latter is a commonly used approach in analysis of health research data (Vaismoradi et al., 2013). The researcher read all the transcripts and responses to become familiar with the collected data. Initial categories were identified that reflected areas prespecified in the questionnaire and the interview topic guide. The data were then coded deductively, and the codes grouped into meaningful subcategories. Any particular issue within the data that did not fit with the initial categories was considered an emergent category and coded inductively. The codes were revised and refined several times to ensure that the finally developed overarching themes presented all the data sufficiently and efficiently. NVivo software (QSR International, 2019) was leveraged in the analysis process.

The quantitative data derived from the usability scales and demographic questionnaires were analysed descriptively. The number of pain entries logged by each participant over the two-week period of the test was retrieved from the system database and analysed. Both SPSS (IBM Corporation, 2019) and Microsoft Excel software were used to facilitate the analyses.

6.4 Results

18 professionals (9 clinician-researchers, 3 HCPs, 6 researchers) were invited to participate, of whom eventually 10 accepted and participated, as illustrated in the recruitment flowchart in Figure 60. Participants were in the age ranges of 20 to 40 (50%) and 41 to 60 (50%) and the majority were female (70%). Of the 10 participants, four had a clinical-research role, one was an HCP and five had a mainly research role; all had an average of 13.3 $\pm$ 9.2 years of work experience (see Table 18).

11 patients showed an interest in testing the PainRecord app; of whom 5 were not eligible, 4 dropped out, and 2 completed the test (one participated in the first testing), as Figure 60 shows. As Table 18 shows, the two participants were > 41 in age; were male and female; both were using smart devices and were very confident in using them; neither had tried any pain app previously; and one was using some health-related apps. In terms of adherence to the need to record

one pain entry over the test period, the completed days for both participants were 14 and 9 out of 14 days.

All participants (n = 12) from both groups completed the usability scales used for each system component, indicating a high level of system usability. The average rate on the MAUQ scale completed by the patients (n = 2) was 6, where the optimal usability on the scale was 7 (range 1 to 7) (Zhou et al., 2019). In addition, the average score for the SUS scale used by the professionals (n = 10) was 80, which was considered far above the acceptable average score of 68 (Sauro, 2010; Sauro, 2011) (see Table 19).

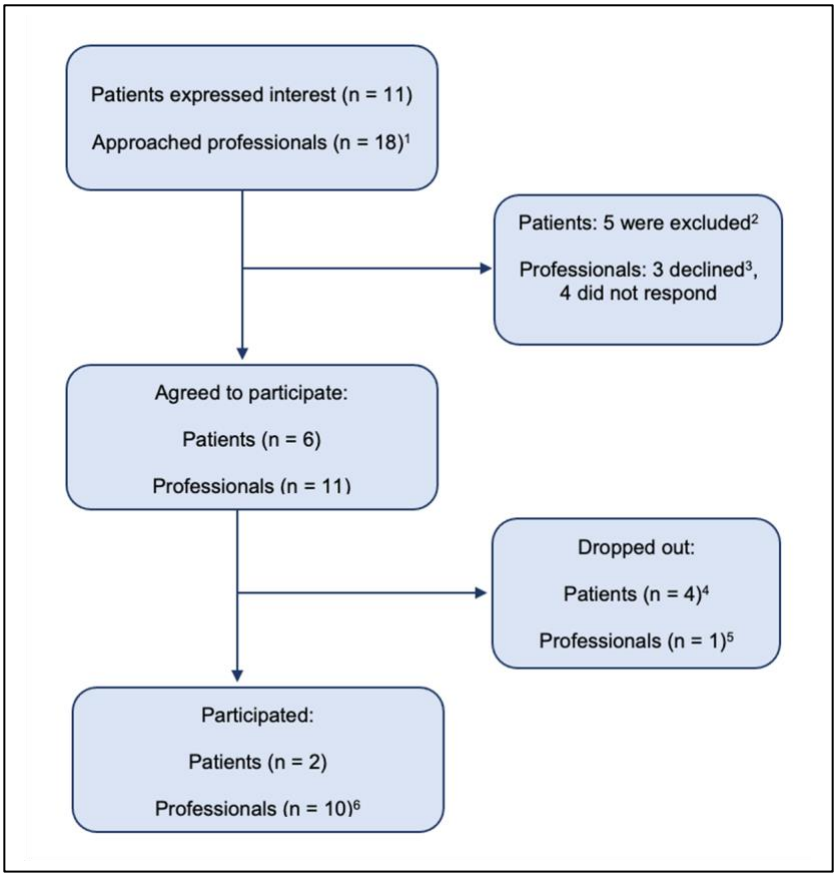


Figure 60: Recruitment flowchart for patients and professionals

[1] Clinician-researcher (9), HCP (3), researcher (6)

[2] have not experienced pain (2), did not have iOS device (3)

[3] were too busy (3)

[4] was too unwell (1), did not respond after showing interest (3)

[5] did not respond after consenting

[6] Clinician-researcher (4), HCP (1), researcher (5)

Table 18: Participant characteristics

Patients	**n = 2**
Range of age in years (n, %)	41-65 (1, 50%) >65 (1, 50%)
Gender (n, %)	Female (1, 50%) Male (1, 50%)
Using smart devices (yes %)	100%
Level of confidence in using smart devices (%)	Very confident (100%)
Tried any pain app before (Yes %)	0%
Using health related apps (Yes %)	50%
Professionals	**n = 10**
Range of age in years (n, %)	20-40 (5, 50%) 41-60 (5, 50%)
Gender (n, %)	Female (7, 70%) Male (3, 30%)
Role (n, %)	Clinician-researcher (4, 40%) Researcher (5, 50%) HCP (1, 10%)
Years of work experience (mean ± SD)	13.3 ± 9.2

SD = standard deviation

Table 19: Usability scales

Usability scales	**Mean (95% CI[a])**
SUS scale (professionals)	80 (73, 86)
MAUQ scale (patients)	6 (6, 6)

[a] Based on 1000 bootstrap samples

Five broad themes emerged from the qualitative data analysis: (1) extent of system usability and appreciation of the design; (2) the system's potential to optimise pain management; (3) the system's potential to facilitate pain data collection; (4) suggestions for improvement; (5) potential scope and challenges of the system's implementation.

Theme 1: Extent of system usability and appreciation of the design

A common view amongst participants was that the system, implying the portal and the PainRecord app, was easy to use and intuitive, enabling the user to navigate easily without guidance, as participants commented:

"*How was easy to use is good … it was less than 5-minutes … I would say 2 minutes … was easy to go*" (Patient 1)

"*Easy to see where to look and click for everything you needed … everything was clear and not too complicated … I liked the minimalist design*" (Professional 4, researcher)

"*It was fine and easy to use*" (Professional 3, clinician-researcher)

One participant, a practitioner, mentioned that training would be required to use the system effectively. This could require training to enable interpretation of the results displayed in the system and integrate them into the current practice in planning patient care:

"*I would need some training to use effectively in practice*" (Professional 8, HCP)

The majority of the participants liked the uncluttered design of the system and appreciated the content and the provision of several useful features. The excerpts below, for example, referred to the portal design:

"*Very professional looking*" (Professional 1, researcher)

"*The diagram format made the pain experience of the patient that month clear*" (Professional 8, HCP)

"*I liked the extra detail while hovering over the datapoints e.g. 'tried a warm bath'…*" (Professional 6, researcher)

"*The system was simple to use, particularly downloading the data*" (Professional 10, researcher)

In terms of the design of the PainRecord app, one patient commented on the simplicity of completing pain entry in reply to efficient questions:

"*It has simple questions that cover up everything … it highlights the worst and least… for me the worst in the morning and least at night so I used to get better during the day … the ability and interference questions are good … covered important areas … it does affect your mood and going out and getting with people … I don't take so many medications it does cause me problems … those [list in tried things question] are self-explanatory … it gives you full of thoughts … it is a good list*" (Patient 1)

Another patient found the learning section in the app beneficial:

"*I found the links …you got various links from there going to … I could go to various websites … that is good*" (Patient 2)

In all cases, when asked whether they experienced any problem using the system, the majority of participants emphasised that they had no issues, whether technical problems or misunderstandings:

"*No particular difficulties or issues*" (Professional 2, clinician-researcher)

"*No technical issues*" (Professional 6, researcher)

"*No, it was easy to use*" (Patient 2)

Only one clinician-researcher reported experiencing a problem with the display of the pain chart in the portal, which seemed mainly to arise because of some restrictions or lack of supportive tools in the browser used to access the portal:

"*Not all aspects work/display on the hospital internet explorer browser… it was mainly the graphs – IT would have to make changes to computers*" (Professional 11, clinician-researcher)

One patient, also, commented on one incident in which the data chart was not displayed. This probably occurred because of a loss of internet access, as the current version of the app does not work offline. The need for an internet connection to enable the app to work properly had been discussed previously

and documented as a limitation to be considered in a future version (see Chapter 5, section 5.3.5.5):

"*In the review … there was a tricky sort of move about the chart where it was not showing anything … and I kept moving it around until I was able to see … it did that once for me*" (Patient 1)

Another issue was mentioned by one patient regarding the notification used to implement the reminder functionality in the app:

"*There was an issue with the notification … it did work for two days then stopped! … I put my own reminder and it was fine*" (Patient 1)

Theme 2: The system's potential to optimise pain management

There was a clear sense amongst participants of how the system would be beneficial in facilitating better pain management. Participants mentioned that displaying the daily report of pain as a line chart was very useful. They indicated that it would help in pain assessment and inform the consultation as well as the change of treatment plan when the patient visited the clinician. In particular, this would be very helpful for a practitioner who sees the patient infrequently or for the first time, by providing a quick overview and update of the patient's pain.

"*Display the graph for clinicians; that would be a good demonstration of how useful the tool is to track people pain … clinicians need some visual feedback of the routine pain assessment over time and that helps them to track pain and manage pain over time*" (Professional 10, researcher)

"*Info displayed is useful … having an accurate record of pain would be helpful to planning care within existing management pathways, especially in metastatic or end of life*" (Professional 11, clinician-researcher)

"*It is really valuable prior to a clinician reviewing a patient so if the patient is reporting in remotely at home and then they receive a telephone consultation or actually coming to the hospital to see the clinician … I think if the clinician can see it prior to them … it kind of helps inform the conversation when they actually*

see them they can focus on what the particular issue is painwise … have a plan in place regarding pain medication and it could be they find it valuable if a patient says struggling with pain … changing the medication that they're on so that could actually … maybe inform the change of treatment … that [pain chart] is really interesting for clinician to be able to look back retrospectively and see where there is particular points in the patient pathway where pain is an issue and knowing medication as well" (Professional 2, clinician-researcher)

"*A use could be in helping communication between patient and HCP – we can see your score has changed, use that as a basis for a conversation as to why and what might be done. It may also be useful as a quick way for an HCP who is not familiar with the patient to get an update on their history and what has been going on recently. For example, a CNS [Cancer Nurse Specialist] who has not visited the person before can see how pain is usually*" (Professional 7, researcher)

"*Could be a good accessible way to monitor pain*" (Professional 8, HCP)

Patients suggested that using the app to report pain would accurately portray the experience of pain, minimising the need to describe it when they meet the clinician. One patient highlighted that patients might not tell the truth about their pain experience when they actually see the clinician. This could be because of the long periods between follow-up appointments during which the patient might forget the days of pain.

"*I mean when I was in treatment, if the doctor could see, I could say here we go then he can see I am suffering and had really bad days … because must people when go to doctor say I am alright … so I think it is very good ... I mean I used to go to doctor, and he used to say are you feeling good I used to say I am fine but actually I am not*" (Patient 1)

"*I think it [reporting pain] would be very useful to keep it on perhaps until your 6 monthly check-ups*" (Patient 2)

Despite participants' awareness of paper pain diaries and other web-based systems designed to report different cancer symptoms including pain, they appreciated the PainRecord app's being highly interactive and focused on pain. They suggested that it would engage more people in using it for reporting pain because of its presence as an app in patients' phones, thus enabling quick access to it.

"*I actually like the fact that it is focused on one thing because I think pain is a very distressing symptom and it can get lost in everything else … I think it is really useful to have that one checker on pain so it could be looked at and managed separately … it is good … definitely people are always on their phone … so I think it is brilliant that it is mobile-based … I think people would like the interactive aspect of it as they get a place where they can put their data. I think there must be something of therapy to calm yourself so when you feel pain you can register it and log it and you know that someone looking at it*" (Professional 4, researcher)

"*I think it would be very useful because I kept a diary … I found that ok ... the diary was ok but if I went to the hospital sometimes I have not got it with me perhaps, whereas most of the time you have got your phone with you … if you go for your treatment and it is on your phone so it is useful to have that … a lot of patients will be given [paper-based diary] but you have to remember to take it with you every time … if you got a book [paper-based diary] and you are on chemo and you become forgetful … you can forget where you put it where you usually do remember where is your phone*" (Patient 2)

"*So many things are changing so quickly from an IT point of view and one of the things that we were really lacked with the […] was being web-based and it not being an app and we certainly had a lot of patients who asked could it be an app, so the fact that you've got it as an app I think is a really good positive and I think that will help a lot of patients engaged with it*" (Professional 2, clinician-researcher)

In addition to the engagement aspect, there was a sense that the app could support self-management alongside appreciation of the system having been

designed to support both clinicians and patients. One patient reported that the trial of the app made him think about the pain differently and do something about it rather than taking tablets:

"*The two lines [in the pain chart] are great because it gives you … you can see it is going down or going along or it is up until to date … it gave me lots to think about when I was doing it … well there is Hypnotherapy, Acupuncture and talking to people so why not looking of something like that if I was in so much pain … so it does give you actually ideas as well as I think … It made me think ... why I am in pain … why I am still feeling this problem … what can I do … so it did made me do stretches in the morning because I used to be in a lot of discomfort every morning so I do stretches and then go back to that neck massage for oedema and stuff like that ... so it did get me keeping doing that rather than go to massage … so same day same day [pain scores] it made me looking to it and go actually that it beats down or it is constant but does not need to be constant ... can I get it down to one without taking tablets ... it makes me not forget it but not take paracetamol or something like that and avoid tablets and do something different … and to be fair I do think it [pain] is a little bit less by doing sort of things differently ... so I tried do stretching and revert back to the neck massage which I get oedema out of it which … I used to stop doing that because I would be uncomfortable … so now I think I am actually feeling some benefit of this*" (Patient 1)

"I think if you can do something where it is not only a benefit for patients but also for clinicians as well … I think it is a well win really" (Professional 2, clinician-researcher)

"*It would help patients to self-manage*" (Professional 11, clinician-researcher)

One practitioner however was concerned about the need for patients to have mobile apps literacy to enable the system to succeed:

"*I think that there is potential for this to be useful, particularly in the community field and with the ability for the practitioner to monitor patients' pain, but this*

would also require the patient to be computer literate and able to use the app" (Professional 8, HCP)

Theme 3: The system's potential to facilitate pain data collection

The professionals collectively agreed that the system would be very useful in research and pain data collection. They suggested that it would be helpful in collecting accurate data remotely. Some felt that patients might like using it, while only one considered that the usage might be limited to people who have no problem using apps.

"*I think it would be useful, and would provide accurate data*" (Professional 1, researcher)

"*Could be very useful for remote collection of pain data for studies … very useful indeed*" (Professional 3, clinician-researcher)

"*I bet patients would like to put their data into a phone app, and this interface is good. So I think it will be good for research*" (Professional 4, researcher)

"*An effective data collection tool for research … I think this could be very useful, but it may be limited to certain demographics of patients due to accessibility or problems in using the app*" (Professional 8, HCP)

Professionals could see the benefits of the system in tracking pain from the research side and evaluating interventions, especially for longitudinal studies. They felt that it would provide insight into pain trends associated with a specific group of patients.

"*It would be good to track this over time from a research perspective to see how pain, and actions taken to improve pain, change over time*" (Professional 9, clinician-researcher)

"I think if I was doing something more longitudinal, it would really be useful … I think definitely for interventions because it is such an instant tool for monitoring

… it can be time stamped when people getting pain" (Professional 4, researcher)

"*Would be useful prior to reviewing a patient but also to look back retrospectively at particular trends with a particular group of patients … I think being able to collect any kind of patient data is valuable full stop*" (Professional 2, clinician-researcher)

"*I can see a use in research to show changes before or after an intervention or a typical pattern of scores for a person or disease population*" (Professional 7, researcher)

Theme 4: Suggestions for improvement

When asked about the scope for improving the system, participants offered different suggestions which they believed would, if followed, meet their particular needs in practice, thus enabling more engagement with the system. A few clinicians, for example, requested more clinical information such as secondary diagnosis, comorbidities, the place of pain, and fuller description of pain medications (i.e., doses and frequency) to provide a wider picture of the patient's pain. Others preferred to search for a patient by name or by NHS (National Health Service) number. One participant felt that more hints might be needed regarding the usage of hovering over some aspects of the interface including the pain chart.

"*Could there be a feature where more of a link to what analgesics (both background and PRN [as needed]) or interventions had been used or introduced*?" (Professional 8, HCP)

"*If you just got the scores, yes, you may see how it is changing over the time, but how would you know where the pain is … do they log any comorbidities … other health problems something like arthritis and something like that … if you are not aware of that, the pain could be completely irrelevant to the cancer they have*" (Professional 11, clinician-researcher)

"*It was only by accident I realized hovering over gave more detail. I would suggest adding some text to clarify this*" (Professional 2, clinician-researcher)

It was suggested that patients be enabled to add free text and notes with each pain entry. This was mentioned by one patient but supported by a few professionals as well. Patients could use this method to report other activities carried on during the day which might affect the pain level. A free text box, also, was recommended to help patients indicate why pain medication was not taken that day, which could help clinicians to understand the sort of complications patients were experiencing with some types of medication.

"*I think it needed somewhere where we could put a note for the day … because it asks you how tired you have been and things like that … it would be good to be able to put there whether you did extra things that day to make you tired … I think that would be useful because then when you are looking at it and if you are looking at it with the hospital professional … when you are having chemo you often cannot remember the day before if you got a note there and they may ask you, oh why were you so tired that day … you know from the notes if you been for a long walk or you have done extra housework … if you were looking back at it, it would give you something to the reason why you were like that on that day*" (Patient 2)

"*Can patient add free texting as well?*" (Professional 2, clinician-researcher)

"*When they say no you want then a little pop-up box to say why you did not take it … you could put in the box I didn't take it because I was sick because of this or that and that your oncologist or nurse needs to know why you did not take it*" (Patient 2)

Although the app provides some feedback that appears mainly when the user visits the review section (see Chapter 5, section 5.3.5.3), one patient argued that instant feedback after submitting the pain entry would be valuable:

"*It tells you've completed it for the day, but I wonder if it could say like your pain is improved on yesterday without even go back to review section … it would be*

good if it tells you once you fill that … something like you seems to be in more pain today or your pain seems decreasing or increasing" (Patient 1)

For the researchers' interface in the system, a few participants mentioned suggestions regarding some wordings, and one asked for a clearer formatting of the downloaded data. A minority of researchers preferred to see pain data in a chart, but one argued that they could use the raw pain data downloaded from the system to create the chart.

"*I wasn't clear when registering a new study what you meant by 'participant no'? I assume you meant the target sample, but this could be worded more clearly*" (Professional 6, researcher)

"*When downloading the study data it would have been nice if information from the different participants were made clearer such as by alternating coloured text or shading*" (Professional 7, researcher)

"*The ability to view pain scores as a chart would be useful to see change over time or before or after an intervention*" (Professional 7, researcher)

"*I think that would be useful for the researchers, but the researchers can make the graph themselves*" (Professional 10, researcher)

In addition, there were some recommendations in relation to tracking the recruitment process. The current version of the system displays the total number of recruited participants so far. It was suggested however that an update about this be displayed per a period specified by the researcher (i.e. week or month) using a chart or table. Besides that, the recommendations included enabling the researcher to track participants' progress by featuring a reminder tool in the system which would be triggered according to the researcher's preferences. This was only mentioned by a very small number of participants.

"*Could you display recruitment to the study per month? ... a chart or a table just to give the ability to know how many people you are having per month ... I*

guess maybe if you can adjust it so it can be per month or per week or per quarter … whatever you need for your study … it might be quite useful for some researchers … I wondered if there could be a 'tracker' element to the system … a researcher could use the system to highlight data collection timepoints, trigger reminders to participants … you are collecting routine pain measurements … or participants, from home, are entering measurements for a certain time, it might be quite nice to have a feature that sort of told you when you should be contacting them and trying to remind them to kind of take part in the research or when they need that point of scheduling ... that kind of thing so you can track their progress actively throughout the study … and perhaps when they miss certain date of data collection point or when they are due for appointment and that kind of things" (Professional 6, researcher)

Theme 5: Potential scope and challenges of the system's implementation

In all cases, participants agreed on how valuable it would be for a clinician to review the pain records reported by the patient to promote pain management. There was uncertainty amongst participants however as to how and where the system could be effectively implemented. This was due to several factors reported by the participants. In current practice, for instance, cancer patients might be seen by different bodies depending on the type and stage of the disease as well as on the treatment. When considering the best way to implement the system, one clinician-researcher commented:

"*It is so difficult ... there are so many different organisations that are involved in patients' care … you know, the hospice, the GP and hospital, but then you also have other areas like you know outside of the medical area like the Maggie's centre and various people work where patients are able to get information regarding managing pain, and obviously there is the pain management team as well that's associated with the hospital … it's difficult … it's knowing where that gap is really … it's knowing where patients are less supported and this would be the benefit; really it is a difficult one … I think it is ideal as I mentioned for the clinicians to be able to see the results prior to seeing a patient I think that is a really good idea*" (Professional 2, clinician-researcher)

This was also visualised from the patient side, as one patient stated:

"*It is a long-term illness really even if you are not on treatment you are asked to be seen by doctor because the whole body is changed and it [pain] is a lot harder to do … I think it is a great thing that you record it privately and on the back of that anyone you contact with for your treatment should be able to see that including dietitian, speech therapist, consultant, cancer nurse, and GP ... everybody … so the patient is given it and everyone within the cancer nurse specialist and the GP can see it because I hear all these different things when I do things at Macmillan but I just see my GP but I do not see the other … so I see my GP every 6 to 8 weeks but also I see my consultant every 8 weeks so he should be able to see it and also the cancer nurse team so all of them should be able to see it*" (Patient 1)

In addition, there was a sense that the system could be suitable for supporting patients who have infrequent contact with the health care system. This, indeed, was in line with the population targeted by the system in the first place, namely the community-based cancer patients. As one participant put it:

"*I think it is great … I think it would be great if it could be used in an area where possibly patients are getting missed so the fact they are on app and they can do it remotely, so those kind of patients who kind of fallen between primary and secondary care and kind of tend to be forgotten about, so it mostly would be valuable for that group definitely … certainly those who are not getting regular kind of contact with clinical teams and getting advice and etc.*" (Professional 2, clinician-researcher)

These views meant that implementing the system as a standalone system would be a positive approach. This would amplify the potential benefit and facilitate the system's usage by any organisation involved in patient care. On the other hand, a group of clinicians were concerned that it might be overwhelming to use a new piece of software that was not integrated within the existing system that they were accustomed to using. It was suggested that the Pain Record System be integrated with existing electronic systems within both primary and secondary care.

"*Would be really good if it could be incorporated into the clinical system so the HCP wouldn't have to make much effort to look at it*" (Professional 9, clinician-researcher)

"*Would be good to have this data available, but if the results could not be integrated with hospital systems, probably wouldn't be used extensively … clinicians don't like having to use multiple systems at same time*" (Professional 11, clinician-researcher)

"*This might be a useful addition to systm1 data collection so that they could monitor for issues, and in the ability to pass on pain information to IPUs [The Integrated Procedures Unit] during admissions, or other involved HCP*" (Professional 8, HCP)

Others felt that the system could be more useful if it were focused on certain settings rather than on cancer pain in general. They argued that pain is a broad field in which types of pain and settings would need different types of consideration in terms of how pain was reported by patients and how it was assessed and managed by clinicians. This was mentioned by a minority of participants:

"*Pain is quite a broad-spectrum topic and I think you need to think about the type of pain you are collecting, whether it's something you are looking at acutely wise, so if it's somebody who had an acute event or had a surgery and it is post-surgery pain as opposed to chronic pain and it is possibly chronic cancer pain. I think they're kind of two different things and how they're managed are very different and I think how patients would report them would be very different as well so I'm not sure whether you can look at it just generalising cancer pain or whether you are looking specifically at a particular area … I just don't know if it's better focusing on rather than making it generally cancer pain … whether it would be better focusing on a particular area so whether that be pain for patients who are palliative care or a particular disease side I am not sure whether that would be a good area to focus on or whether just to stick to generally cancer pain … I'm not sure; I mean that obviously would limit your*

number, then if you just picked from particular area, not sure" (Professional 2, clinician-researcher)

6.5 Discussion and conclusion

This study set out with the aim of testing the Pain Recording System working prototype as a part of the second iteration of the UCD adopted for the system's development. The testing in this iteration was focused on obtaining preliminary insight into the system feasibility and scope of implementation along with evaluating the system's usability and technical reliability. In total, 12 people participated in this testing, representing the potential end-users of the system who would be patients, researchers, or HCPs. Their perceptions were mainly obtained via standardised usability scales and an open-ended questionnaire designed for the study, accompanied by semi-structured interviews.

The results from both usability scales and qualitative data showed that the system was well-received and easy to use, with participants mostly finding no issues in navigating through it. Compared with the first testing (Chapter 4), this testing showed fewer usability scores based on SUS scale by 2 and 10 points for the app[18] and the portal respectively. This was, indeed, considered a minimal difference between the design and the working prototype. Despite the minimal information provided about the system, participants were able to easily interact with its interfaces and understand how it works. There were, however, a few suggestions for optimising the system's functionalities and interfaces. Clinicians asked for more clinical information and preferences when searching patients. Enabling patients to add free text when completing pain entry along with immediate feedback after submitting were suggestions that were highlighted. There was a mix of simple suggestions for improving the researchers' interface, mostly reflecting personal preferences. Sensible recommendations will be considered in future iterations of the UCD in which the system will be further upgraded.

[18] The MAUQ average score obtained from this testing (6) was converted to SUS score (83) to be able to compare.

Patients and clinicians were able to recognise the clinical applicability of the Pain Recording System. They could see how it might assist them in monitoring pain and facilitating communication, leading potentially to improvements in pain management. Clinicians' perceptions about the possible benefit of electronic pain monitoring as identified in this study were in line with previous palliative care studies (Taylor et al., 2017a). Clinicians who tested the system highly appreciated the ability to view patients' pain history as a line chart of daily self-reported pain scores along with notes reporting the extent of adherence to pain medications and whether other (i.e., non-pharmacological) pain-control strategies were used. Self-reporting is crucial for optimal pain management, as patients experience pain uniquely and its effects on their daily life and activities vary (Zhao et al., 2019). A systematic review and meta-analysis indicated that the feedback based on patient reported outcomes measurements (PROMs) of pain tended to prompt discussion between patients and HCPs, leading to reduction in pain intensity (Adam et al., 2017). In addition, evidence suggested that pain charts had been acknowledged by HCPs as useful audit tools, helping them to reflect on practice and improve future patient care (Luckett et al., 2013).

Patients could see how the system might help in presenting their experience of pain accurately to the HCPs. Asking patients with cancer about pain by a simple question in spaced visits does not convey the true picture of pain, while daily pain fluctuations are very common (Zhao et al., 2019; Hochstenbach et al., 2015). Patients in this study mentioned that they might not tell the truth about their pain when they see the HCP. This could be how patient reluctance in reporting pain, a well-documented barrier to pain assessment and management (Luckett et al., 2013), manifests. On the other hand, completing pain entry privately via the PainRecord app seemed satisfying to patients who tried the app.

The PainRecord app was perceived as an electronic pain diary and instant data collection tool which participants agreed would be helpful in research. There was a slight concern about the app literacy expected of patients but the majority of participants valued the app and felt it would be more engaging and better favoured than paper-based diaries and questionnaires. Patients showed satisfactory compliance in using the app over the test period, as they were able

to complete 11 out of 14 days on average. Cancer patients' willingness to engage with technology as part of their pain management was reported by another study (Allsop et al., 2019). In addition, evidence suggested that electronic data capture and self-report is increasingly preferred either in clinical settings in general (Lane et al., 2006) or in clinical pain studies in particular (Jibb et al., 2020).

Although behaviour change was not a primary outcome in this study due to the short test period (i.e., two weeks), the findings were promising in relation to that. To evaluate the short-term effectiveness of behaviour change interventions a test of longer duration, between 8–12 weeks (Sangelaji et al., 2016; NICE, 2020), would be needed. Patients were able to see the benefit of monitoring pain and reflecting on their daily activities and attitudes towards pain management. The provision of educational resources in the app, besides the suggestions about different non-pharmacological strategies available for easing pain, were highly regarded. Qualitative studies suggested that increasing the sense of control may be among the greatest psychological needs, with positive consequences not only for pain but also for cancer (Luckett et al., 2013). Clinicians saw how patients' use of the app would be useful for the patients as well as for themselves.

Participants, mainly clinicians, raised some points with regard to the current practice of cancer patient care and pain management, showing uncertainty about the effective approach to system implementation. Clinicians believed that the system should be incorporated with existing electronic health records (EHR) in order to be used efficiently. This was recommended mostly to reduce the effort spent in accessing different systems. The same observation by HCPs regarding new systems was captured in other palliative care studies (Taylor et al., 2017a). It might be that embedding the Pain Recording System in existing EHRs would reduce duplication of work and of clinical patient information. Such an approach, however, could limit researchers' usage of the system. In addition, it could deviate from the system's initial aim, the main targets of which were the less supported and community-based patients. This population might not contact the NHS frequently, instead communicating with other organisations where they could receive support with cancer and pain management. This was

mentioned by a number of participants who discussed the complications of cancer patient care, in which patients can be seen by different bodies. The complex needs of cancer patients and the fragmented care and support services provided to them have been reported within the NHS (Buckland, 2016; NHS, 2020b; NHS, 2020a).

A further source of uncertainty, as a few clinicians hesitantly argued, was the fact that because pain is a broad-spectrum topic, tailoring and implementing the system to serve a specific cancer patient setting might be more useful than taking a general approach. Obviously, this would limit the benefits of the system and might not cover the targeted community-based patients. Clinicians' scepticism about implementing new digital health interventions was discussed previously in pain management studies (Taylor et al., 2017a). Indeed, the problems of implementing and integrating digital health interventions in general within the existing health system in the UK have been discussed intensively in the literature. Interoperability, cost, and difficulties in understanding how best to adopt and implement such interventions were identified as factors hindering their use (Ross et al., 2018; Ross et al., 2016; NHS, 2014; Murray et al., 2011).

Another possible approach to implementing the Pain Recording System could be the provision of a standalone system. This would facilitate the accessibility of the system by researchers as well as any organisation involved in providing support and care to cancer patients.

In general, the findings were encouraging although obtaining the perspectives of more patients would be beneficial. The small number of patients who participated in testing the PainRecord app was a situation mostly attributed to the global circumstance of the Covid-19 pandemic. The adverse impact of the pandemic on the progress of studies and research activities, including recruitment, have been reported (Paula, 2020; Goldstone, 2020). In addition, it is important to mention that prior to the pandemic, recruiting cancer patients was already challenging, as discussed previously regarding the first testing of the system (see Chapter 4, section 4.3.3.9), and as also experienced by other feasibility studies of pain control interventions (Adam et al., 2021). This limited the ability to draw richer conclusions from the patient population in relation to

the acceptability of the system and the usage of the app. It is certainly the perspectives of the two patients who participated in the study, but they do not represent the patient population. Despite this, patients' perspectives captured in the study were consistent with other studies that explored and reported the viability of using technology in improving cancer patient care (Allsop et al., 2019; Blakely et al., 2019; Berlangieri, 2018). A further large-scale feasibility study of the system will be considered in a future cycle of UCD involving a higher number of patients and gathering richer insights into the system's practicability and effective implementation.

6.6 Chapter summary

In this chapter, the feasibility study conducted for the Pain Recording system was reported, presenting the final phase of the second cycle of the UCD. The study addressed the sixth and concluding objective of the thesis which was 'to test the system feasibility'. It concluded with some recommendations for optimising the system and highlighted the need for a larger scope study to overcome the limitations of this one. The outcomes feed into future research. In the next chapter, the overall principal findings of the thesis are presented and discussed.

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Chapter 7
General discussion and conclusion

7.1 Chapter overview

This chapter presents a general discussion of the thesis outcomes and their implications. It highlights the contribution of the thesis, considering the limitations and strengths of the methods used. The chapter then concludes with plans and recommendations for future research.

7.2 Summary of the thesis

In reviewing the literature, it was apparent that undertreatment of pain in cancer patients persists as a multifaceted public health issue. The widespread use of mobile phones, advances in such technologies and people's attachment to their phones meant it was timely to explore innovative approach to the improvement of cancer pain management, particularly in community-based patients. This thesis, therefore, designed and developed a mobile app-based system, in an attempt to optimise cancer pain management through three mechanisms: (1) providing patients with a means of supporting pain self-management, (2) providing HCPs with a means of facilitating effective pain assessment with routine reporting of pain data, and (3) providing researchers with a means of remotely collecting pain data. The focus in the thesis was to develop the Pain Recording system methodically, based on evidence and theory and informed by end-users. The UK Medical Research Council (MRC) framework for developing and evaluating complex interventions (Chapter 1, section 1.2.1), integrated with the iterative process of User-Centred Design (UCD) (Chapter 4, section 4.3), was employed to guide the work. The thesis identified and formed the first (Development) and partially the second (Feasibility/piloting) phases of the MRC framework in which six mapping research objectives were accomplished (see Chapter 1, Figure 2).

Two UCD cycles were completed, encapsulating three stages in each. The work in the first cycle focused on designing the system (see Chapter 4, Figure 8). In

the first stage, ‘requirements identification’, of this cycle, the core contents and requirements of the system were gathered and identified via five research activities representing the first four objectives of the thesis. The first activity was a systematic review of Patient-Reported Outcome Measures (PROMs) (Chapter 2) which identified the Brief Pain Inventory-short form (BPI-SF) as the best validated measure to be incorporated in the app, PainRecord. The review also established that the work I proposed was novel, as no study identified had used a pain measurement instrument in an app for adult cancer patients. The second activity was a behavioural analysis of pain self-management in cancer patients (Chapter 3). This identified eighteen behaviour change techniques (BCTs) selected for translation into app features (see Chapter 3, Table 9). The third activity was a scoping review of existing commercial pain apps (Chapter 4, section 4.2). The review helped in discerning the workflow of the PainRecord app and drew attention to a few interface features that were either useful and so should be included, or useless or distracting and so should be avoided, with the emphasis on enriching the user experience (UX) and information aspects. The fourth activity consisted of creating three user personas which model the needs of the three potential types of users of the systems: patients, HCPs, and researchers (Chapter 4, section 4.3.1.1). Finally, the fifth activity consisted of modelling the system architecture, data flow and use cases, which helped in envisaging the system’s functionality and the way its components interact (Chapter 4, section 4.3.1.2).

High fidelity clickable prototypes were then developed to simulate the integrated requirements representing the second stage, ‘prototypes design and development’, of the first UCD cycle (Chapter 4, section 4.3.2). The third stage, ‘evaluate use in context’, of the cycle was achieved by conducting usability testing sessions on the created prototypes with eleven participants representing a mixture of potential users (Chapter 4, section 4.3.3). The testing indicated that the system was found to be well-aligned with participants’ needs and intuitive, with some suggestions offered by participants to clarify certain design aspects and functionalities as well as to enhance the quality and usage of captured clinical data.

The outcomes of the first UCD iteration informed the system design and requirements. These were used to initiate the second UCD cycle, which focused on developing the operational prototypes for the Pain Recording system (see Chapter 5, Figure 15). Hence, the system was fully developed as a mobile app and web application, both linked and supported by a back-end cloud-based server (Chapter 5) and evaluated in a form of feasibility study (Chapter 6) representing the second and final stages, respectively, of the second cycle of the UCD. In this cycle of development, both the fifth and sixth objectives of the thesis were achieved. It concluded that the system was feasible and acceptable, and that potential users (patients, HCPs and researchers) could see the benefits they might reap from the system in relation to both practice of and research into pain management in patients with cancer. There were mixed recommendations for improvements, along with some uncertainty about the sustainable implementation of the system within the currently fragmented care provided to cancer patients.

7.3 Contributions to knowledge

The main contribution of the thesis is twofold: (1) the development of a mHealth-based intervention that is underpinned by evidence and theory and informed by potential users, and (2) the potential of mHealth-based interventions in optimising pain self-management and facilitating routine reporting of pain data, with the focus on UK-based adult cancer patients living in the community. The latter was made evident by the concluding study of the thesis, a feasibility study, which presented encouraging findings on the feasibility, usability and acceptability of the Pain Recording System and the related PainRecord app. The literature shows that mHealth apps have been increasingly explored in different health conditions and have shown promising benefits (Kosse et al., 2017; Whitehead and Seaton, 2016; Irvine et al., 2015; Lakshminarayana et al., 2014). There has, however, been a dearth of research investigating such technologies in oncology in general, and in pain management in particular, with a few attempts made (Adam et al., 2021; Jibb et al., 2017; Fortier et al., 2016) at a very early stage and in different settings. The thesis shows strength in other aspects which contribute to the means of

achieving the main output, as detailed in the following subsections and summarised in Figure 61.

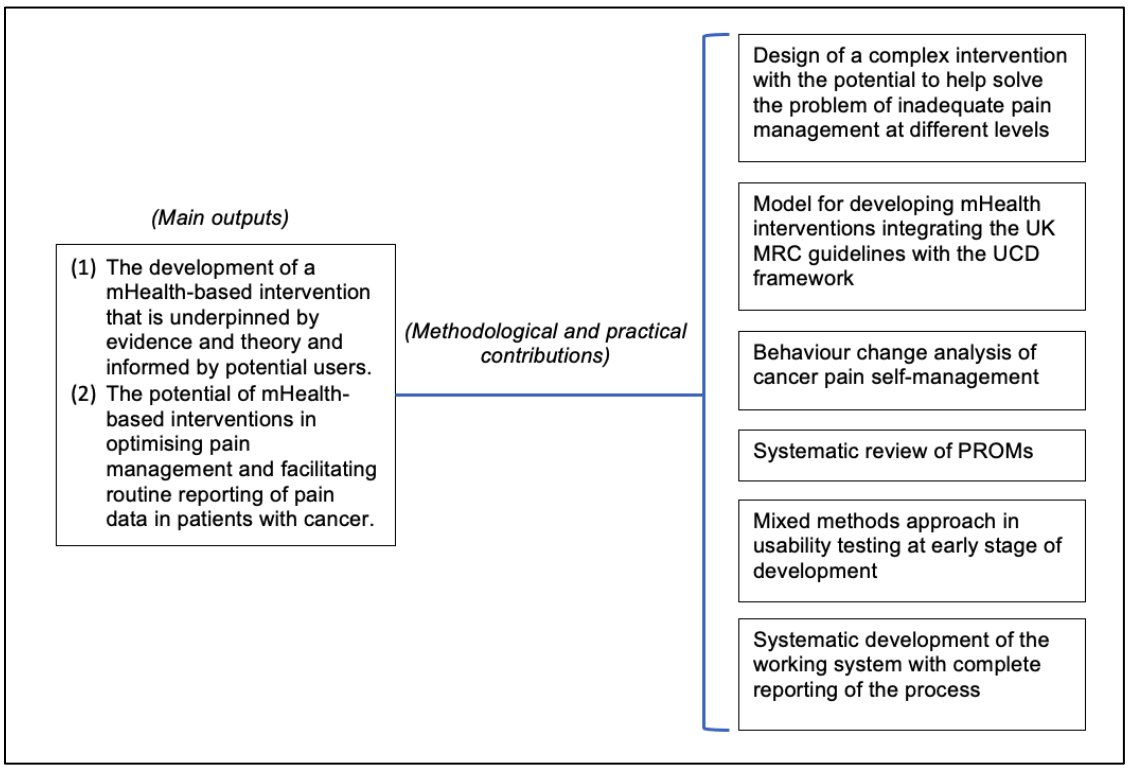

Figure 61: Summary of the thesis contributions to knowledge

7.3.1 Design of a complex intervention

This thesis has produced a fully working mHealth-based system designed to serve three types of users (patients, HCPs and researchers), with the potential to help solve the problem of inadequate pain management at different levels. This complex design is innovative and might be appropriate for such a complicated problem. Given that poor pain management in the community is a multifactorial problem rooted in issues operating at different levels, complex interventions that can act on several levels and tackle these issues in an effective and coordinated way are urgently required (Adam and Murchie, 2014). The majority of mHealth interventions were either oriented towards directly benefitting patients, supporting HCPs' clinical practice, or benefitting both patients and HCPs (Lane et al., 2020; Grist et al., 2017; Whitehead and Seaton, 2016). The design of the Pain Recording System is presented in such a way that the related PainRecord app can be used as a stand-alone application to support patients in self-managing their pain. Pain self-management

interventions for patients with cancer have been found effective (Howell et al., 2017; Koller et al., 2012; Bennett et al., 2009; Devine, 2003; Allard et al., 2001) but rarely delivered via mobile apps. Importantly, evidence shows that self-management interventions for patients delivered via mobile apps were effective compared with self-management interventions delivered via traditional methods or along with the usual care in chronic conditions such as diabetes and cardiovascular diseases (Whitehead and Seaton, 2016).

In addition, the developed system provides HCPs with a web-based portal to provide access to longitudinal and graphical pain data for each patient. The literature review showed the importance of and need for this type of data for effective pain assessment and better pain management (Chapman et al., 2020; NCCN, 2017; Shute, 2013), with no pain apps found that facilitated clinician access to graphical pain data visualisation (Zhao et al., 2019). The system, also, can be accessed by researchers as a platform for managing recruitment and pain data collected from participants using the PainRecord app. This has not been attempted before in the context of cancer pain and would likely enable the better quality pain studies and more insightful pain management strategies that are urgently needed (Hackett et al., 2016; Nekolaichuk et al., 2013; Laneader et al., 2007). The use of apps as a reliable and valid data collection method was reported when collecting symptoms, including pain, in different health conditions (Bromberg et al., 2014; Connelly et al., 2012).

7.3.2 Model for developing mHealth interventions

The thesis presented an innovative and detailed exemplar for developing mHealth interventions, considering important aspects that determine adoption and effectiveness. In other words, the way of integrating the UK MRC guidelines with the UCD framework showcased in this thesis is novel. The two frameworks might have been mentioned together (Cai et al., 2017; Jibb et al., 2014) but there was no transparency as to how they were jointly used. The integrated approach enabled systematic and iterative development of a system driven by evidence and theory besides being focused on user needs. As mentioned in the literature review, such features need to be borne in mind when developing high quality mHealth interventions that have the potential to be effective and

engaging (Portelli and Eldred, 2016; Rosser and Eccleston, 2011). Yet the majority of publicly available pain self-management apps failed to include these criteria (Zhao et al., 2019; Bhattarai et al., 2018; Lalloo et al., 2017).

7.3.3 Behaviour change analysis of cancer pain self-management

The application of the Behaviour Change Wheel (BCW) framework in the context of pain self-management for cancer patients is novel (Chapter 3). The developed PainRecord app incorporated eighteen standardised BCTs selected clearly and systematically, whereas there is a paucity of studies that sought such clarity in reporting the use of theory (Michie and Prestwich, 2010). A total of fifteen of these BCTs were used in effective self-management interventions developed for multiple health conditions, as mentioned before (see Chapter 3, section 3.4.3.1). The eighteen BCTs can be used to describe the current intervention and can be repeated in other interventions with similar contexts. This would enable tracking mechanisms, thus subsidising effectiveness across interventions, which is the inspiration of the BCW framework (Michie et al., 2013; Michie et al., 2011b). Indeed, there would seem to be a definite need for pain self-management interventions for cancer patients to be evidentially characterised. This is because studies have shown that these interventions are effective, but when synthesising evidence, no conclusion can be drawn to identify the efficacious components amongst these interventions (Howell et al., 2017; Koller et al., 2012) that are to be focused on and replicated in new interventions. Significantly, the step-by-step approach used to derive the BCTs for the PainRecord app provides an exemplar and a practical guide for developing the content of future mHealth interventions. It offers, also, the opportunity for other researchers to utilise the outcomes of any reported phase and to proceed to develop other cancer pain self-management interventions possibly using different delivery modes or policies. For example, the behavioural diagnosis that was based on the COM-B model delivered in this thesis can be used to study other intervention functions (see Chapter 3, sections 3.4.1.2 and 3.4.2) that might be more appropriate to another intervention context.

7.3.4 Systematic review of PROMs

Another significant contribution of the thesis is the published systematic review of PROMs (Abahussin et al., 2019). The review (Chapter 2) is the first attempt to systematically appraise the measurement properties of PROMs used to measure pain in cancer patients. The review combined the Cochrane guidelines for systematic review and the COSMIN framework. The latter is, in turn, the first reliable methodological guideline for conducting systematic reviews of PROMs (Mokkink et al., 2016; Terwee et al., 2011). The use of Cochrane guidelines in this review was particularly helpful for constructing a thorough search strategy, which was lacking in the COSMIN guidelines available at the time of conducting the review. In fact, this has been lately resolved in the new comprehensive methodological guideline produced by the COSMIN group (Prinsen et al., 2018). Interestingly, the new guideline clearly imitates the Cochrane guidelines in its conduct of the literature search. The review showed that BPI-SF is the best measure based on the available evidence, providing HCPs and researchers with an evidence-based selected PROM.

7.3.5 Mixed methods approach in usability testing

The use of mixed methods in the usability testing conducted at the first UCD iteration (Abahussin et al., 2020) is an innovative approach (Chapter 4). Adopting this approach in usability testing in the context of an early stage of development has just recently gained attention in developing mHealth interventions (Amann et al., 2020; Korpershoek et al., 2020), with qualitative methods being the common practice (Stinson et al., 2013; Jibb et al., 2017; Taylor et al., 2017b; Cai et al., 2017). The testing was extremely helpful in providing insight into the needs of the system's potential users and informed the extent of usability of the first prototype of the system, thus allowing future tracking of usability objectives. In addition, this testing, along with the feasibility testing performed in the second UCD iteration, both contributed to presenting the views and attitudes of patients with cancer, HCPs, and researchers towards mHealth interventions in the field of cancer pain management.

7.3.6 Systematic development of the working system

The process of building the working system, particularly the PainRecord app, was thoroughly conducted and reported in this thesis, enabling the learning of lessons as well as replications. Research evidence highlighted that descriptions of the technology used to build mHealth interventions are not always reported (Fiordelli et al., 2013). A possible explanation of failure to report is that these details are not always available or clear to the researchers. In other words, the development and technical part of interventions could be taken care of by a third party or a commercial software development company, sharing minimal details with the researchers. The process contributed to forming an understanding of the available technologies and approaches for developing the system components (see Chapter 5, sections 5.3.1 and 5.4.1), enabling selection of the appropriate means of featuring the intervention requirements within the constraints of the project. This will inform future intervention developments, bearing in mind rapid changes in technology. Inappropriate selection of technology might lead to undesired problems for the researcher to tackle and so affect adoption of the intervention. For example, Amann et al. (2020) developed a self-management app for people with spinal cord injury and reported facing a problem with the app being developed as a web app showing limited and impeded functionality. To avoid poorer evaluations, it was necessary to explain the limitations of the technology to the study participants prior to the usability test. Indeed, studies in the field of mHealth have notably focused on using web apps (Irvine et al., 2015; Adam et al., 2021; Amann et al., 2020; Oldenmenger et al., 2018a) which are relatively easier to build than other facilities, as discussed before (see Chapter 5, section 5.3.1). This establishes the novelty of using the React Native framework to build the PainRecord app as a native app.

7.4 Research reflections and limitations

Although specific limitations and considerations were discussed within the relevant chapters it is important to reflect on the thesis as a complete body of work in respect of both its limitations and the opportunity for learning the research process provided. Firstly, the UCD approach requires the ability to distinguish between, on the one hand, requirements and needs of users, which

can facilitate delivering the functionality intended by the intervention, and, on the other, entirely subjective preferences and needs. Otherwise, the developer might lose the focus, resulting in more unnecessary UCD iterations and a possibly incoherent tool. Achieving consensus among all users is not always attainable or compatible with the functional constraints of a digital health tool (Amann et al., 2020). In addition, the work presented in this thesis is an initial minimally viable product prototype. Therefore, the Pain Recording System and the related app are not yet fully stable and were deployed with a temporary and practical setup that require further security features to be enabled. The provisional deployment setting was, however, deemed appropriate to the limited resources available for this research. Importantly, it was suitable for the current stage of development as part of an iterative process in which a few iterations implying changes are to be expected.

Despite the tremendous effort and time spent in building the system, the fact that the researcher was also the developer was advantageous. This was more evident when translating the specified requirements, including the BCTs, into digital features with user personas and optimal user experience in mind. Although this process required the researcher to visit the literature to learn from existing interventions and observe how BCTs were expressed, it possibly caused less frustration in producing a design that ideally reflected the specified requirements, compared to experiences of using a third party to build the intervention. Tombor et al. (2016) and Curtis et al. (2015) reported that translating the content of their interventions into app features and implementing BCTs in an app involved liaising with the development company, holding repeated discussions between the research team and the development team, and producing several versions of the apps until agreement was reached.

Clearly, development of a digital behaviour change intervention requires adequate knowledge of different fields expressed by a multidisciplinary team whose members work very closely with each other. This type of intervention combines input from behavioural, software engineering and user experience as well as health sciences (Perski et al., 2017; Roth et al., 2014). Therefore, development of the current intervention by the primary researcher alone, who has limited background in the health, clinical and behavioural fields, presented

a limitation. This problem, however, was counteracted by regular meetings and discussions with the multidisciplinary supervision team and by advice sought and consultations held, whenever need arose, with experts including behavioural scientists.

With regard to research participants, there are limitations. Given the sample technique adopted, research samples were limited by region and number, besides the fact that people who agreed to take part might have a positive attitude toward digital solutions. This means that the results may not be fully generalisable, although the findings align with previous studies which provides some assurance (see Chapter 6, section 6.5). In addition, including the perspectives of more patients with cancer in the feasibility study would have strengthened confidence in the findings. It indeed cannot be assumed that generally the patient population is confident with technology, and variability in this aspect is expected. Therefore, testing the app with a representative patient sample in the future is necessary to provide more reliable insight into the patients' perspectives in relation to the app's usability and acceptability.

As discussed previously, the small sample of patients obtained in the feasibility study was mostly a consequence of the global circumstance of the Covid-19 pandemic (see Chapter 6, section 6.3.7). It is, however, worth reflecting on the difficulty experienced in recruiting this population even before the pandemic, as mentioned in regard to the first testing of the system (see Chapter 4, section 4.3.3.9). Initially, challenges including recruitment and retention, as well as ethical and methodological issues in conducting studies with this group, were well documented within the literature (Adam et al., 2021; Reid et al., 2015; LeBlanc et al., 2013; O'Mara et al., 2009; Laneader et al., 2007). Moreover, in this thesis, approaching patients mainly via cancer patients' support groups and charities proved challenging. Despite the much appreciated cooperation of some of the coordinators of these sites, others seemed to gate keep access to their members. A possible explanation for this is that the groups' primary focus is their members' (i.e., patients') comfort and so may try to protect them from any burden they perceived participation in research may involve.

Indeed, researchers are advised to avoid putting additional stress and discomfort on patients with serious illnesses by minimising the burden of data collection (Laneader et al., 2007). Considering this, and stressing the need to engage patients with cancer in research in order to build evidence-based policies, protocols and treatment (Reid et al., 2015), the developed system along with the app might contribute to the production of more research with a lighter burden on patients, thus motivating them to participate.

One barrier to taking part in this research might be that some patients with cancer do not own smart devices or have little interest in using mobile apps aimed to support their health and wellbeing. This is, however, not consistent with the statistical evidence showing high numbers and a rapid increase in ownership and usage of smartphones and apps (see Chapter 1, section 1.3.7). Furthermore, evidence from the literature emphasises that patients with cancer, as well as older adults, are receptive to the use of technology, including mobile phone apps, to support care and treatment, as long as it has a simple design and includes clear instructions (Adam et al., 2021; Allsop et al., 2019; Blakely et al., 2019; Kim and Choi, 2019; Berlangieri, 2018; Kessel et al., 2017; Andebe et al., 2017; Valenti et al., 2016; Enguidanos et al., 2014). Taken together, further approaches to recruitment of community-based cancer patients need to be explored in future phases of the research.

A final point concerns the fact that patients with cancer sometimes receive fragmented care and support especially when their needs are complex and multifaceted. This was highlighted in the literature (Hackett et al., 2018; Buckland, 2016; Mitchell et al., 2016) and also by participants in the feasibility study. This issue presents a potential obstacle to the sustainable implementation of the developed system, as discussed previously (see Chapter 6, section 6.5). On the other hand, the literature review also indicated that ineffective coordination, implying poor communication and information sharing, between different healthcare providers is a barrier to continuity of care and effective pain management (Hackett et al., 2018; Buckland, 2016; Mitchell et al., 2016). This could suggest that implementation of the system as a stand-alone system to be made accessible to all the parties involved in providing healthcare and support to cancer patients might help to overcome this barrier. It has been

found that sharing electronic palliative care summaries with out-of-hours services reduced the likelihood of hospital admission during the out-of-hours period for cancer patients (Ali et al., 2013). The NHS, however, in its attempts to digitalise the healthcare system, failed to achieve a balance between centralised implementation and maintenance of local engagement; besides which, it faced the problem of different local systems failing to talk to each other, thus losing the potentially shared benefits of interoperable systems (Wachter, 2016; NHS, 2014). In addition, the multi-level complexity of digital health implementation is acknowledged in the literature (Ross et al., 2018; Ross et al., 2016). This certainly highlights the need to consider thorough exploration of how best to plan for the implementation phase by clearly identifying obstacles and addressing them. This, in turn, would increase the likelihood of the system being adopted and engagement maintained.

7.5 Directions for future research

There is scope for further progress on the work presented in this thesis. Given the systematic and integrated approach (i.e., MRC and UCD) adopted to design and develop the Pain Recording System, future studies are clearly indicated. Specifically, further UCD iterations and tests of the system will be conducted to improve it, with more attention given to enlarging the sample size and increasing the diversity of participants. This will help to obtain better insight into the target population's perspectives on the system, shaping it to reflect the needs and preferences gleaned from wider end-user characteristics. In addition, further exploratory testing in real life and for a prolonged period of time will help to develop greater understanding of the usability, feasibility and engagement of the system and could contribute to identification of obstacles to suitability for implementation. Importantly, it will assist in establishing a protocol for important outcome measures, so as to move on to full evaluation.

As part of improving the system in future iterations, serious consideration will be given to meeting the requirements of national standards and formal regulations for digital health applications and health apps. Example of a regulatory body is the UK Medicines and Healthcare Products Regulatory Agency which provides guidance on medical device stand-alone software, including apps being placed

on the Great Britain market, to fulfil the UK Conformity Assessed mark (GOV.UK, 2021). In addition, both the evidence standards framework for digital technologies developed by NICE (the National Institute for Health and Care Excellence) (NICE, 2021) and the digital technology assessment criteria for health and social care (DTAC) set by the NHS (NHS, 2021) will be borne in mind. Reflecting on such requirements and criteria will strengthen the evidence underpinning the system and increase the likelihood of its adoption by decision-makers and funders in future, after its effectiveness is proven.

Once the system is stable, the research will move towards the third phase of the MRC framework (i.e., the Evaluation phase; see Chapter 1, Figure 1). A definitive testing in the form of a randomised controlled trial will be conducted to provide evidence of the effectiveness of the developed system. The trial will enable evaluation of real clinical practice, health outcomes, long-term engagement, and research benefits, as well as cost effectiveness. There is a definite need for a large, prolonged trial to evaluate the efficacy of the app for achieving the intended behaviour change and supporting pain self-management. Indeed, evidence has highlighted the lack of studies of this type regarding behaviour change interventions delivered via apps (McKay et al., 2018), considering that this approach is still an emerging area of research.

7.6 Conclusion

This thesis thoroughly reports the design, development, and early testing of a complex mHealth based intervention, the Pain Recording System, to support better pain management for UK-based adult cancer patients living in the community. The system sought to both support pain self-management and facilitate routine reporting of pain data to HCPs and researchers. To the best of the researcher's knowledge, this is the first digital solution serving three key stakeholders (patients, HCPs and researchers) in the context of enhancing the management of pain in adult cancer patients. With a systematic development process and both evidence and theory underpinning the design, alongside the involvement of potential users from the early stages of development, the thesis has shown that the developed system is scalable, usable and acceptable. Importantly, the thesis concludes that there is a potential for mHealth

interventions to be effective in optimising pain management for cancer patients. Further exploration, however, is necessary to provide conclusive evidence and to establish suitable approaches to implementation in the context of home-based palliative care.

In conclusion, completion of this thesis coincides with completion of the year since the global Covid-19 pandemic started, along with a period of national and local lockdown during which clinically vulnerable people are asked to shield. This situation emphasises the importance of investing in digital health and moving towards establishing effective ways to support patients and provide health services remotely, besides proceeding with research and building evidence-based practice and treatments. The work presented in this thesis represents a significant innovative and timely step towards achieving this.

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Appendices

Appendix 1: COSMIN's definitions of the measurement properties

Domain	Measurement property	Definition from Mokkink et al. (2010c)
Reliability		*"The degree to which the measurement is free from measurement error."*
Reliability (extended definition)		*"The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: for example, using different sets of items from the same HR-PROs (internal consistency), over time (testeretest) by different persons on the same occasion (interrater) or by the same persons (i.e., raters or responders) on different occasions (intrarater)."*
	Internal consistency	*"The degree of the interrelatedness among the items."*
	Reliability	*"The proportion of the total variance in the measurements which is because of "true" differences among patients."*
	Measurement error	*"The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured."*
Validity		*"The degree to which an HR-PRO instrument measures the construct(s) it purports to measure."*
	Content validity	*"The degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured."*
	Construct validity (or	*"The degree to which the scores of an HR-PRO instrument are consistent*

	hypotheses testing)	*with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the HR-PRO instrument validly measures the construct to be measured."*
	Structural validity	*"The degree to which the scores of an HR-PRO instrument are an adequate reflection of the dimensionality of the construct to be measured."*
	Cross-cultural validity	*"The degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument."*
	Criterion validity	*"The degree to which the scores of an HR-PRO instrument are an adequate reflection of a ''gold standard''."*
Responsiveness	Responsiveness	*"The ability of an HR-PRO instrument to detect change over time in the construct to be measured."*

Appendix 2: The search strategy applied on Medline, Embase, and CINAHL

Search strategy applied on Medline (Ovid 1996 to March 2018):

Concept	Search terms (number of records)
Population	1 exp Neoplasms/ (1844343) 2 (carcin*or cancer* or tumo?r* or neoplasm* or adenocarcino*).tw. (1022908) 3 exp Adult/ (4229928) 4 adult.tw. (435643) 5 1 or 2 (2056450) 6 3 or 4 (4459633) 7 5 and 6 (919871)
Intervention	8 *Pain Measurement/ (10338) 9 ((pain* or sore* or hurt* or discomfort* or uncomfort* or cramp* or irritat* or analges*) adj3 (measur* or assess* or scal* or scor* or rat* or self report* or self management or self rat* or validated measurement or evaluat* or quantif* or Inventory or inventories)).tw. (72972) 10 exp Pain/ (240689) 11 exp Analgesia/ (22756) 12 8 or 9 or 10 or 11 (280293) 13 exp Software/ (117330) 14 (tool* or electronic* or device* or app* or machine or instrument* or questionnaire*).tw. (4286417) 15 13 or 14 (4330910) 16 12 and 15 (99102)
Comparison	Not applicable
Outcome	17 (validat* or validity or reliab* or objectivit* or clinimetric* or evaluation or responsive* or (psychometr* and propert*) or (cronbach* and alpha) or correlation or coefficient or internal consistency or Cohen* kappa or test retest or variability or standard error of measurement or sensitivity or specificity or hypotheses testing).tw. (2311433) 18 ((minimal* or meaning* or detectabl* or important* or effectiv* or relevant*) and (difference* or change* or improv* or shift* or alteration* or deterioration* or respons* or efficacy or effectiveness)).tw. (1624912) 19 exp Psychometrics/ (52213)

	20 exp observer variation/ (34804) 21 17 or 18 or 19 or 20 (3591050)
Combining Population, Intervention & Outcome	22 7 and 16 and 21 (2803)
Adding the Oxford filter for PRO measures	23 (HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab. or quality of life.mp. or (health index* or health indices or health profile*).ti,ab. or health status.mp. or ((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating* or based or assessed or assessment*)).ti,ab. or ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab. (479242) 24 22 and 23 (1018)
Restricting to English language publications	25 limit 24 to English language (960)

Search strategy used on Embase (Ovid 1996 to March 2018):

Concept	Search terms (number of records)
Population	1 exp Neoplasms/ (2969135) 2 (carcin*or cancer* or tumo?r* or neoplasm* or adenocarcino*).tw. (1666438) 3 exp Adult/ (5284274) 4 adult.tw. (667901) 5 1 or 2 (3313902) 6 3 or 4 (5551551) 7 5 and 6 (1175115)
Intervention	8 *Pain Measurement/ (331) 9 ((pain* or sore* or hurt* or discomfort* or uncomfort* or cramp* or irritat* or analges*) adj3 (measur* or assess* or scal* or scor* or rat* or self report* or self management or

	self rat* or validated measurement or evaluat* or quantif* or Inventory or inventories)).tw. (130140) 10 exp Pain/ (971696) 11 exp Analgesia/ (116744) 12 8 or 9 or 10 or 11 (1039377) 13 exp Software/ (79567) 14 (tool* or electronic* or device* or app* or machine or instrument* or questionnaire*).tw. (6561576) 15 13 or 14 (6594765) 16 12 and 15 (370305)
Comparison	Not applicable
Outcome	17 (validat* or validity or reliab* or objectivit* or clinimetric* or evaluation or responsive* or (psychometr* and propert*) or (cronbach* and alpha) or correlation or coefficient or internal consistency or Cohen* kappa or test retest or variability or standard error of measurement or sensitivity or specificity or hypotheses testing).tw. (3670061) 18 ((minimal* or meaning* or detectabl* or important* or effectiv* or relevant*) and (difference* or change* or improv* or shift* or alteration* or deterioration* or respons* or efficacy or effectiveness)).tw. (2628261) 19 exp Psychometrics/ (70994) 20 exp observer variation/ (17021) 21 17 or 18 or 19 or 20 (5688685)
Combining Population, Intervention & Outcome	22 7 and 16 and 21 (11418)
Adding the Oxford filter for PRO measures	23 (HR-PRO or HRPRO or HRQL or HRQoL or QL or QoL).ti,ab. or quality of life.mp. or (health index* or health indices or health profile*).ti,ab. or health status.mp. or ((patient or self or child or parent or carer or proxy) adj (appraisal* or appraised or report or reported or reporting or rated or rating* or based or assessed or assessment*)).ti,ab. or ((disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) adj2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys)).ti,ab. (836690)

	24	22 and 23 (2876)
Restricting to English language publications	25	limit 24 to English language (2781)

Search strategy used on CINAHL (EBSCO 1981 to March 2018):

Concept	Search terms (number of records)
Population	1 (MH "Neoplasms+") (240,806) 2 AB carcin*or cancer* or tumo?r* or neoplasm* or adenocarcino* (15,929) 3 (MH "Adult+") (906,221) 4 AB adult* (136,853) 5 3 or 4 (954,466) 6 1 or 2 (244,321) 7 5 and 6 (98,192)
Intervention	8 MM "Pain Measurement" (4,749) 9 (pain* or sore* or hurt* or discomfort* or uncomfort* or cramp* or irritat* or analges*) n3 (measur* or assess* or scal* or scor* or rat* or self report* or self management or self rat* or validated measurement or evaluat* or quantif* or Inventory or inventories) (36,968) 10 MH "Pain+" (116,376) 11 MH "Analgesia+" (8,163) 12 8 or 9 or 10 or 11 (133,853) 13 MH "Software+" (251,111) 14 AB tool* or electronic* or device* or app* or machine or instrument* or questionnaire* (618,061) 15 13 or 14 (786,201) 16 12 and 15 (41,913)
Comparison	Not applicable
Outcome	17 AB (validat* or validity or reliab* or objectivit* or clinimetric* or evaluation or responsive* or (psychometr* and propert*) or (cronbach* and alpha) or correlation or coefficient or internal consistency or Cohen* kappa or test retest or variability or standard error of measurement or sensitivity or specificity or hypotheses testing) (283,917)

	18 AB ((minimal* or meaning* or detectabl* or important* or effectiv* or relevant*) and (difference* or change* or improv* or shift* or alteration* or deterioration* or respons* or efficacy or effectiveness)) (244,635) 19 MM "Psychometrics" (2,185) 20 17 or 18 or 19 (474,761)
Combining Population, Intervention & Outcome	21 7 and 16 and 20 (617)
Adding the adapted Oxford filter for PRO measures	22 AB HR-PRO or HRPRO or HRQL or HRQoL (3,643) 23 AB QL (176) 24 AB QoL (6,970) 25 AB quality of life (54,826) 26 AB (health index* or health indices or health profile (6,059) 27 AB health status (17,241) 28 AB (patient or self or child or parent or carer or proxy) n1 (appraisal* or appraised or report or reported or reporting or rated or rating* or based or assessed or assessment*) (83,702) 29 AB (disability or function or functional or functions or subjective or utility or utilities or wellbeing or well being) n2 (index or indices or instrument or instruments or measure or measures or questionnaire* or profile or profiles or scale or scales or score or scores or status or survey or surveys) (30,777) 30 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 (166,231) 31 21 and 30 (295)
Restricting to English language publications	32 limit 31 to English language (294)

Appendix 3: The quality criteria for good measurement properties

The quality criteria for good measurement properties modified from Terwee *et al.* (2007) and available on http://www.cosmin.nl/

Measurement property	Rating*	Criteria
Internal consistency	+	At least limited evidence for unidimensionality or positive structural validity AND Cronbach's alpha(s) ≥ 0.70 and ≤ 0.95
	?	Not all information for '+' reported OR conflicting evidence for unidimensionality or structural validity OR evidence for lack of unidimensionality or negative structural validity
	-	Criteria for '+' not met
Reliability	+	ICC or weighted Kappa ≥ 0.70
	?	ICC or weighted Kappa not reported
	-	Criteria for '+' not met
Measurement error	+	SDC or LoA < MIC
	?	MIC not defined
	-	Criteria for '+' not met
Content validity	+	All items refer to relevant aspects of the construct to be measured AND are relevant for the target population AND are relevant for the purpose of the measurement instrument AND together comprehensively reflect the construct to be measured
	?	Not all information for '+' reported
	-	Criteria for '+' not met
Construct validity (or hypotheses testing)	+	At least 75% of the results are in accordance with the hypotheses
	?	No correlations with instrument(s) measuring related construct(s) AND no differences between relevant groups reported
	-	Criteria for '+' not met
Structural validity	+	Unidimensionality: EFA: First factor accounts for at least 20% of the variability AND ratio of the variance explained by the first to the second factor greater than 4

		OR Bi-factor model: Standardized loadings on a common factor >0.30 AND correlation between individual scores under a bi-factor and unidimensional model >0.90 Structural validity: CFI or TLI or comparable measure >0.95 AND (Root Mean Square Error of Approximation (RMSEA) <0.06 OR Standardized Root Mean Residuals (SRMR)<0.08)
	?	Not all information for '+' reported
	-	Criteria for '+' not met
Cross-cultural validity	+	No important differences found between language versions in multiple group factor analysis or DIF analysis
	?	Multiple group factor analysis AND DIF analysis not performed
	-	One or more criteria for '+' not met
Criterion validity	+	Convincing arguments that gold standard is "gold" AND correlation with gold standard ≥ 0.70
	?	Not all information for '+' reported
	-	Criteria for '+' not met
Responsivenes	+	At least 75% of the results are in accordance with the hypotheses
	?	No correlations with changes in instrument(s) measuring related construct(s) AND no differences between changes in relevant groups reported
	-	Criteria for '+' not met

CFI = comparative fit index; DIF = differential item functioning; EFA= exploratory factor analysis; ICC = intraclass correlation coefficient; LoA = limits of agreement; MIC = minimal important change; SDC = smallest detectable change; TLI = Tucker-Lewis index

* + = positive rating, ? = indeterminate rating, – = negative rating

Appendix 4: The BCW related analysis and tables

Table 20: COM-B model components

COM-B model component	Definition (Michie et al., 2014)
Physical capability	*"Physical skills, strength or stamina"*
Psychological capability	*"Knowledge or psychological skills, strength or stamina to engage in the necessary mental process"*
Physical opportunity	*"Opportunity afforded by the environment involving time, resources, locations, cues, physical 'affordance'"*
Social opportunity	*"Opportunity afforded by interpersonal influences, social cues and cultural norms that influence the way that we think about things, e.g. the words and concepts that make up our language"*
Reflective motivation	*"Reflective processes involving plans (self-conscious intentions) and evaluations (beliefs about what is good and bad)"*
Automatic motivation	*"Automatic processes involving emotional desires (wants and needs), impulses, inhibitions, drive states and reflex responses "*

Table 21: Search strategy for the behavioural diagnosis

Database: Ovid MEDLINE(R) <1996 to September Week 1 2018>:	
Search #	**Search terms (number of records)**
1	cancer.mp. or exp Neoplasms/ (2093540)
2	'patient-related barriers '.mp. (123)
3	patient.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1680366)
4	barrier.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (103661)

5	facilitators.mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (8335)
6	4 or 5 (111463)
7	3 and 6 (11068)
8	2 or 7 (11159)
9	self management.mp. or exp Self Care/ or exp Self-Management/ (44869)
10	pain.mp. or exp PAIN/ (468849)
11	9 and 10 (3145)
12	pain management.mp. or exp Pain Management/ (30638)
13	11 or 12 (33134)
14	1 and 8 and 13 (81)
15	limit 14 to (english language and "review articles") (15)

Table 22: Definitions of the BCW's intervention functions

Intervention function	Definition (Michie et al., 2014; Michie et al., 2011b)
Education	*"Increasing knowledge or understanding"*
Persuasion	*"Using communication to induce positive or negative feelings or stimulate action"*
Incentivisation	*"Creating expectation of reward"*
Coercion	*"Creating expectation of punishment or cost"*
Training	*"Imparting skills"*
Restriction	*"Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)"*
Environmental restructuring	*"Changing the physical or social context"*
Modelling	*"Providing an example for people to aspire to or imitate"*
Enablement	*"Increasing means/reducing barriers to increase capability or opportunity"*

Table 23: Matrix of links between COM-B and the intervention functions adapted from (Michie et al., 2014)

COM-B components	Intervention functions								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Physical capability					✓				✓
Psychological capability	✓				✓				✓
Physical opportunity					✓	✓	✓		✓
Social opportunity						✓	✓	✓	✓
Automatic motivation		✓	✓	✓	✓		✓	✓	✓
Reflective motivation	✓	✓	✓	✓					

Table 24: Matrix of links between intervention functions and policy categories adapted from (Michie et al., 2014)

Policy categories	Intervention functions								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Communication /marketing	✓	✓	✓	✓				✓	
Guidelines	✓	✓	✓	✓	✓	✓	✓		✓
Fiscal measures			✓	✓	✓		✓		✓
Regulation	✓	✓	✓	✓	✓	✓	✓		✓
Legislation		✓	✓	✓	✓	✓	✓		✓
Environmental/ social planning							✓		✓
Service provision	✓	✓	✓	✓	✓			✓	✓

Table 25: Definitions of the BCW's policy categories

Policy category	Definition (Michie et al., 2014; Michie et al., 2011b)
Communication/marketing	*"Using print, electronic, telephonic or broadcast media"*
Guidelines	*"Creating documents that recommend or mandate practice. This includes all changes to service provision"*
Fiscal measures	*"Using the tax system to reduce or increase the financial cost"*
Regulation	*"Establishing rules or principles of behaviour or practice"*
Legislation	*"Making or changing laws"*
Environmental/social planning	*"Designing and/or controlling the physical or social environment"*
Service provision	*"Delivering a service"*

Table 26: The APEASE criteria

Criterion	Description (Michie et al., 2014)
Affordability	*"Interventions often have an implicit or explicit budget. It does not matter how effective, or even cost effective it may be if it cannot be afforded. An intervention is affordable if within an acceptable budget it can be delivered to, or accessed by, all for whom it could be relevant or of benefit"*
Practicability	*"An intervention is practicable to the extent that it can be delivered as designed through the means intended to the target population. For example, an intervention may be effective when delivered by highly trained staff with extensive resources but in routine practice this may not be achievable"*
Effectiveness and cost-effectiveness	*"Effectiveness refers to the effect size of the intervention in relation to the desired objectives in a real world context. It is distinct from efficacy which refers to the effect size of the intervention when delivered under optimal conditions in comparative evaluations. Cost-effectiveness*

	refers to the ratio of effect to cost. If two interventions are equally effective then clearly the most cost-effective should be chosen. If one is more effective but less cost-effective than another, other issues such as affordability come to the forefront of the decision-making process"
Acceptability	*"Acceptability refers to the extent to which an intervention is judged to be appropriate by relevant stakeholders (public, professional, and political). Acceptability may be different for different stakeholders"*
Side effects/safety	*"An intervention may be effective and practicable but have unwanted side-effects or unintended consequences. These need to be considered when deciding whether or not to proceed"*
Equity	*"An important consideration is the extent to which an intervention may reduce or increase the disparities in standard of living, wellbeing, or health between different sectors of society"*

Table 27: Labels of the BCTs within the taxonomy adapted from (Michie et al., 2013)

Grouping	BCTs
1. Goals and planning	1.1. Goal setting (behavior) 1.2. Problem solving 1.3. Goal setting (outcome) 1.4. Action planning 1.5. Review behavior goal(s) 1.6. Discrepancy between current behavior and goal 1.7. Review outcome goal(s) 1.8. Behavioral contract 1.9. Commitment
2. Feedback and monitoring	2.1. Monitoring of behavior by others without feedback 2.2. Feedback on behaviour 2.3. Self-monitoring of behaviour 2.4. Self-monitoring of outcome(s) of behaviour 2.5. Monitoring of outcome(s) of behavior without feedback

	2.6. Biofeedback 2.7. Feedback on outcome(s) of behavior
3. Social support	3.1. Social support (unspecified) 3.2. Social support (practical) 3.3. Social support (emotional)
4. Shaping knowledge	4.1. Instruction on how to perform the behavior 4.2. Information about Antecedents 4.3. Re-attribution 4.4. Behavioral experiments
5. Natural consequences	5.1. Information about health consequences 5.2. Salience of consequences 5.3. Information about social and environmental consequences 5.4. Monitoring of emotional consequences 5.5. Anticipated regret 5.6. Information about emotional consequences
6. Comparison of behaviour	6.1. Demonstration of the behavior 6.2. Social comparison 6.3. Information about others' approval
7. Associations	7.1. Prompts/cues 7.2. Cue signalling reward 7.3. Reduce prompts/cues 7.4. Remove access to the reward 7.5. Remove aversive stimulus 7.6. Satiation 7.7. Exposure 7.8. Associative learning
8. Repetition and substitution	8.1. Behavioral practice/rehearsal 8.2. Behavior substitution 8.3. Habit formation 8.4. Habit reversal 8.5. Overcorrection 8.6. Generalisation of target behavior 8.7. Graded tasks
9. Comparison of outcomes	9.1. Credible source 9.2. Pros and cons 9.3. Comparative imagining of future outcomes

10. Reward and threat	10.1. Material incentive (behavior) 10.2. Material reward (behavior) 10.3. Non-specific reward 10.4. Social reward 10.5. Social incentive 10.6. Non-specific incentive 10.7. Self-incentive 10.8. Incentive (outcome) 10.9. Self-reward 10.10. Reward (outcome) 10.11. Future punishment
11. Regulation	11.1. Pharmacological support 11.2. Reduce negative emotions 11.3. Conserving mental resources 11.4. Paradoxical instructions
12. Antecedents	12.1. Restructuring the physical environment 12.2. Restructuring the social environment 12.3. Avoidance/reducing exposure to cues for the behavior 12.4. Distraction 12.5. Adding objects to the environment 12.6. Body changes
13. Identity	13.1. Identification of self as role model 13.2. Framing/reframing 13.3. Incompatible beliefs 13.4. Valued self-identify 13.5. Identity associated with changed behavior
14. Scheduled consequences	14.1. Behavior cost 14.2. Punishment 14.3. Remove reward 14.4. Reward approximation 14.5. Rewarding completion 14.6. Situation-specific reward 14.7. Reward incompatible behavior 14.8. Reward alternative behavior 14.9. Reduce reward frequency 14.10. Remove punishment
15. Self-belief	15.1. Verbal persuasion about capability 15.2. Mental rehearsal of successful performance 15.3. Focus on past success 15.4. Self-talk
16. Covert learning	16.1. Imaginary punishment

	16.2. Imaginary reward 16.3. Vicarious consequences

Table 28: Linking intervention functions to BCTs (Michie et al., 2014)

Intervention function	BCTs
Education	**Most frequently used BCTs:** Information about social and environmental consequences Information about health consequences Feedback on behaviour Feedback on outcome(s) of the behaviour Prompts/cues Self-monitoring of behaviour **Less frequently used BCTs:** Biofeedback Self-monitoring of outcome(s) of behaviour Cue signalling reward Satiation Information about antecedents Re-attribution Behavioural experiments Information about emotional consequences Information about others' approval
Persuasion	**Most frequently used BCTs:** Credible source Information about social and environmental consequences Information about health consequences Feedback on behaviour Feedback on outcome(s) of the behaviour **Less frequently used BCTs:** Biofeedback Re-attribution Focus on past success Verbal persuasion about capability Framing/reframing Identity associated with changed behaviour Identification of self as role model Information about emotional consequences Salience of consequences Information about others' approval Social comparison
Incentivisation	**Most frequently used BCTs:** Feedback on behaviour

	Feedback on outcome(s) of behaviour Monitoring of behaviour by others without evidence of feedback Monitoring outcome of behaviour by others without evidence of feedback Self-monitoring of behaviour **Less frequently used BCTs:** Paradoxical instructions Biofeedback Self-monitoring of outcome(s) of behaviour Cue signalling reward Remove aversive stimulus Reward approximation Rewarding completion Situation-specify reward Reward incompatible behaviour Reduce reward frequency Reward alternate behaviour Remove punishment Social reward Material reward Material reward (outcome) Self-reward Non-specific reward Incentive Behavioural contract Commitment Discrepancy between current behaviour and goal Imaginary reward
Coercion	**Most frequently used BCTs:** Feedback on behaviour Feedback on outcome(s) of behaviour Monitoring of behaviour by others without evidence of feedback Monitoring outcome of behaviour by others without evidence of feedback Self-monitoring of behaviour **Less frequently used BCTs:** Biofeedback Self-monitoring of outcome(s) of behaviour Remove access to the reward Punishment Behaviour cost Remove reward Future punishment Behavioural contract Commitment Discrepancy between current behaviour and goal Incompatible beliefs

	Anticipated regret Imaginary punishment
Training	**Most frequently used BCTs:** Demonstration of the behaviour Instruction on how to perform a behaviour Feedback on the behaviour Feedback on outcome(s) of behaviour Self-monitoring of behaviour Behavioural practice/rehearsal **Less frequently used BCTs:** Biofeedback Self-monitoring of outcome(s) of behaviour Habit formation Habit reversal Graded tasks Behavioural experiments Mental rehearsal of successful performance Self-talk Self-reward
Restriction	*No BCTs in BCTTv1 are linked to this intervention function because they are focused on changing the way that people think, feel and react rather than the way the external environment limits their behaviour.*
Environmental restructuring	**Most frequently used BCTs:** Adding objects to the environment Prompts/cues Restructuring the physical environment **Less frequently used BCTs:** Cue signalling reward Remove access to the reward Remove aversive stimulus Satiation Exposure Associative learning Reduce prompt/cue Restructuring the social environment
Modelling	**Most frequently used BCTs:** Demonstration of the behaviour
Enablement	**Most frequently used BCTs:** Social support (unspecified) Social support (practical) Goal setting (behaviour) Goal setting (outcome) Adding objects to the environment Problem solving Action planning Self-monitoring of behaviour Restructuring the physical environment Review behaviour goal(s)

	Review outcome goal(s) **Less frequently used BCTs:** Social support (emotional) Reduce negative emotions Conserve mental resources Pharmacological support Self-monitoring of outcome(s) of behaviour Behaviour substitution Overcorrection Generalisation of a target behaviour Graded tasks Avoidance/reducing exposure to cues for the behaviour Restructuring the social environment Distraction Body changes Behavioural experiments Mental rehearsal of successful performance Focus on past success Self-talk Verbal persuasion about capability Self-reward Behavioural contract Commitment Discrepancy between current behaviour and goal Pros and cons Comparative imagining of future outcomes Valued self-identity Framing/reframing Incompatible beliefs Identity associated with changed behaviour Identification of self as role model Salience of consequences Monitoring of emotional consequences Anticipated regret Imaginary punishment Imaginary reward Vicarious consequences

Table 29: Mapping intervention functions to BCTs and applying APEASE criteria

Intervention function	BCT label*	BCT Definition (Michie et al., 2013)	Does the BCT meet the APEASE criteria in the context of using an app to support

			pain self-management?
Education	2.2. Feedback on behaviour	*"Monitor and provide informative or evaluative feedback on performance of the behaviour (e.g. form, frequency, duration, intensity)"*	Yes
	2.3. Self-monitoring of behaviour	*"Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy"*	Yes
	2.7. Feedback on outcome(s) of behaviour	*"Monitor and provide feedback on the outcome of performance of the behaviour"*	Yes
	5.1. Information about health consequences	*"Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour"*	Yes
	5.3. Information about social and environmental consequences	*"Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behaviour"*	Yes
	7.1. Prompts/cues	*"Introduce or define environmental or social stimulus with the purpose of prompting or*	Yes

		cueing the behaviour"	
	2.6. Biofeedback	*"Provide feedback about the body (e.g. physiological or biochemical state) using an external monitoring device as part of a behaviour change strategy"*	Not practicable or relevant in this context
	2.4. Self-monitoring of outcome(s) of behaviour	*"Establish a method for the person to monitor and record the outcome(s) of their behaviour as part of a behaviour change strategy"*	Yes
	7.2. Cue signalling reward	*"Identify an environmental stimulus that reliably predicts that reward will follow the behaviour (includes 'Discriminative cue')"*	Not practicable or relevant in this context
	7.6. Satiation	*"Advise or arrange repeated exposure to a stimulus that reduces or extinguishes a drive for the unwanted behaviour"*	Not relevant in this context
	4.2. Information about antecedents	*"Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict*	Not relevant in this context

		performance of the behaviour"	
	4.3. Re-attribution	*"Elicit perceived causes of behaviour and suggest alternative explanations (e.g. external or internal and stable or unstable)"*	Not practicable or relevant in this context
	4.4. Behavioural experiments	*"Advise on how to identify and test hypotheses about the behaviour, its causes and consequences, by collecting and interpreting data"*	Not practicable or relevant in this context
	5.6. Information about emotional consequences	*"Provide information (e.g. written, verbal, visual) about emotional consequences of performing the behaviour"*	Yes
	6.3. Information about others' approval	*"Provide information about what other people think about the behaviour. The information clarifies whether others will like, approve or disapprove of what the person is doing or will do"*	Yes
Persuasion	2.2. Feedback on behaviour	Previously defined	See above
	2.7. Feedback on outcome(s) of behaviour	Previously defined	See above
	5.1. Information about health consequences	Previously defined	See above

	5.3. Information about social and environmental consequences	Previously defined	See above
	9.1. Credible source	*"Present verbal or visual communication from a credible source in favour of or against the behaviour"*	Not practicable to deliver in this context
	2.6. Biofeedback	Previously defined	See above
	4.3. Re-attribution	Previously defined	See above
	5.2. Salience of consequences	*"Use methods specifically designed to emphasise the consequences of performing the behaviour with the aim of making them more memorable"*	Not practicable or relevant in this context
	5.6. Information about emotional consequences	Previously defined	See above
	6.2. Social comparison	*"Draw attention to others' performance to allow comparison with the person's own performance"*	Not practicable and acceptable to deliver in this context
	6.3. Information about others' approval	Previously defined	See above
	13.1. Identification of self as role model	*"Inform that one's own behaviour may be an example to others"*	Not relevant in this context
	13.2. Framing/reframing	*"Suggest the deliberate adoption of a perspective or new perspective on behaviour (e.g. its purpose) in order to change*	Not practicable or relevant in this context

		cognitions or emotions about performing the behaviour"	
	13.5. Identity associated with changed behaviour	*"Advise the person to construct a new self-identity as someone who 'used to engage with the unwanted behaviour'"*	Unlikely to be acceptable and effective in this context
	15.1. Verbal persuasion about capability	*"Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed"*	Not practicable or relevant in this context
	15.3. Focus on past success	*"Advise to think about or list previous successes in performing the behaviour (or parts of it)"*	Not practicable or relevant in this context
Training	2.2. Feedback on behaviour	Previously defined	See above
	2.3. Self-monitoring of behaviour	Previously defined	See above
	2.7. Feedback on outcome(s) of behaviour	Previously defined	See above
	4.1. Instruction on how to perform a behaviour	*"Advise or agree on how to perform the behaviour"*	Yes
	6.1. Demonstration of the behaviour	*"Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to*	Not practicable or relevant in this context

		aspire to or imitate"	
	8.1. Behavioural practice/rehearsal	*"Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill"*	Not practicable or relevant in this context
	2.4. Self-monitoring of outcome(s) of behaviour	Previously defined	See above
	2.6. Biofeedback	Previously defined	See above
	4.4. Behavioural experiments	Previously defined	See above
	8.3. Habit formation	*"Prompt rehearsal and repetition of the behaviour in the same context repeatedly so that the context elicits the behaviour"*	Unlikely to be acceptable and effective in this context
	8.4. Habit reversal	*"Prompt rehearsal and repetition of an alternative behaviour to replace an unwanted habitual behaviour"*	Not relevant in this context
	8.7. Graded tasks	*"Set easy-to-perform tasks, making them increasingly difficult, but achievable, until behaviour is performed"*	Not relevant in this context
	10.9. Self-reward	*"Prompt self-praise or self-reward if and only if there has been effort and/or progress in*	Unlikely to be acceptable and effective in this context

		performing the behaviour"	
	15.4. Self-talk	*"Prompt positive self-talk (aloud or silently) before and during the behaviour"*	Not practicable or relevant in this context
	15.2. Mental rehearsal of successful performance	*"Advise to practise imagining performing the behaviour successfully in relevant contexts"*	Unlikely to be acceptable and effective in this context
Enablement	1.1. Goal setting (behaviour)	*"Set or agree on a goal defined in terms of the behaviour to be achieved"*	Not practicable or relevant in this context
	1.2. Problem solving	*"Analyse, or prompt the person to analyse, factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators"*	Yes
	1.3. Goal setting (outcome)	*"Set or agree on a goal defined in terms of a positive outcome of wanted behaviour"*	Not practicable or relevant in this context
	1.4. Action planning	*"Prompt detailed planning of performance of the behaviour (must include at least one of context, frequency, duration and intensity)"*	Not practicable or relevant in this context

	1.5. Review behaviour goal(s)	*"Review behaviour goal(s) jointly with the person and consider modifying goal(s) or behaviour change strategy in light of achievement"*	Not practicable or relevant in this context
	1.7. Review outcome goal(s)	*"Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement"*	Not practicable or relevant in this context
	2.3. Self-monitoring of behaviour	Previously defined	See above
	3.1. Social support (unspecified)	*"Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behaviour"*	Yes
	3.2. Social support (practical)	*"Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour"*	Yes
	12.1. Restructuring the physical environment	*"Change, or advise to change the physical environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour"*	Not relevant in this context

	12.5. Adding objects to the environment	*"Add objects to the environment in order to facilitate performance of the behaviour"*	Not relevant in this context
	1.6. Discrepancy between current behaviour and goal	*"Draw attention to discrepancies between a person's current behaviour (in terms of the form, frequency, duration, or intensity of that behaviour) and the person's previously set outcome goals, behavioural goals or action plans (goes beyond self-monitoring of behaviour)"*	Not practicable or relevant in this context
	1.8. Behavioural contract	*"Create a written specification of the behaviour to be performed, agreed on by the person, and witnessed by another"*	Not practicable and unlikely to be acceptable in this context
	1.9. Commitment	*"Ask the person to affirm or reaffirm statements indicating commitment to change the behaviour"*	Not practicable and unlikely to be effective in this context
	2.4. Self-monitoring of outcome(s) of behaviour	Previously defined	See above
	3.3. Social support (emotional)	*"Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff)*	Yes

		for performance of the behaviour"	
	4.4. Behavioural experiments	Previously defined	See above
	5.2. Salience of consequences	Previously defined	See above
	5.4. Monitoring of emotional consequences	*"Prompt assessment of feelings after attempts at performing the behaviour"*	Not practicable or relevant in this context
	5.5. Anticipated regret	*"Induce or raise awareness of expectations of future regret about performance of the unwanted behaviour"*	Not practicable and unlikely to be effective in this context
	8.2. Behaviour substitution	*"Prompt substitution of the unwanted behaviour with a wanted or neutral behaviour"*	Not relevant in this context
	8.5. Overcorrection	*"Ask to repeat the wanted behaviour in an exaggerated way following an unwanted behaviour"*	Not relevant in this context
	8.6. Generalisation of a target behaviour	*"Advise to perform the wanted behaviour, which is already performed in a particular situation, in another situation"*	Not relevant in this context
	8.7. Graded tasks	Previously defined	See above
	9.2. Pros and cons	*"Advise the person to identify and compare reasons for wanting (pros) and not wanting to*	Not practicable and unlikely to be effective in this context

		(cons) change the behaviour"	
	9.3. Comparative imagining of future outcomes	*"Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour"*	Not practicable or relevant in this context
	10.9. Self-reward	Previously defined	See above
	11.1. Pharmacological support	*"Provide, or encourage the use of or adherence to, drugs to facilitate behaviour change"*	Yes
	11.2. Reduce negative emotions	*"Advise on ways of reducing negative emotions to facilitate performance of the behaviour"*	Yes
	11.3. Conserve mental resources	*"Advise on ways of minimising demands on mental resources to facilitate behaviour change"*	Not practicable or relevant in this context
	12.2. Restructuring the social environment	*"Change, or advise to change the social environment in order to facilitate performance of the wanted behaviour or create barriers to the unwanted behaviour"*	Yes
	12.3. Avoidance/reducing exposure to cues for the behaviour	*"Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines"*	Not relevant in this context

	12.4. Distraction	*"Advise or arrange to use an alternative focus for attention to avoid triggers for unwanted behaviour"*	Not relevant in this context
	12.6. Body changes	*"Alter body structure, functioning or support directly to facilitate behaviour change"*	Yes
	13.1. Identification of self as role model	Previously defined	See above
	13.2. Framing/reframing	Previously defined	See above
	13.3. Incompatible beliefs	*"Draw attention to discrepancies between current or past behaviour and self-image, in order to create discomfort"*	Not practicable or relevant in this context
	13.4. Valued self-identity	*"Advise the person to write or complete rating scales about a cherished value or personal strength as a means of affirming the person's identity as part of a behaviour change strategy"*	Not practicable or relevant in this context
	13.5. Identity associated with changed behaviour	Previously defined	See above
	15.1. Verbal persuasion about capability	Previously defined	See above
	15.2. Mental rehearsal of successful performance	Previously defined	See above

	15.3. Focus on past success	Previously defined	See above
	15.4. Self-talk	Previously defined	See above
	16.1. Imaginary punishment	*"Advise to imagine performing the unwanted behaviour in a real-life situation followed by imagining an unpleasant consequence"*	Unlikely to be acceptable and effective in this context
	16.2. Imaginary reward	*"Advise to imagine performing the wanted behaviour in a real-life situation followed by imagining a pleasant consequence"*	Not practicable and unlikely to be acceptable in this context
	16.3. Vicarious consequences	*"Prompt observation of the consequences (including rewards and punishments) for others when they perform the behaviour"*	Not practicable in this context

* Numbering mentioned beside the BCT's labels refers to the classification labels in the BCTTv1
* Shaded box = less frequent used BCTs identified for the intervention functions

Appendix 5: The MARS Scale

Mobile Application Rating Scale (MARS)

App Classification

The Classification section is used to collect descriptive and technical information about the app. Please review the app description in iTunes / Google Play to access this information.

App Name: _____

Rating this version: _____ **Rating all versions:** _____

Developer: _____

N ratings this version: _____ **N ratings all versions:** _____

Version: _____ **Last update:** _____

Cost - basic version: _____ **Cost - upgrade version:** _____

Platform: ☐ iPhone ☐ iPad ☐ Android

Brief description: _____

_____

Focus: what the app targets (select all that apply)

- ☐ Increase Happiness/Well-being
- ☐ Mindfulness/Meditation/Relaxation
- ☐ Reduce negative emotions
- ☐ Depression
- ☐ Anxiety/Stress
- ☐ Anger
- ☐ Behaviour Change
- ☐ Alcohol /Substance Use
- ☐ Goal Setting
- ☐ Entertainment
- ☐ Relationships
- ☐ Physical health
- ☐ Other _____

Theoretical background/Strategies (all that apply)

- ☐ Assessment
- ☐ Feedback
- ☐ Information/Education
- ☐ Monitoring/Tracking
- ☐ Goal setting
- ☐ Advice /Tips /Strategies /Skills training
- ☐ CBT - Behavioural (positive events)
- ☐ CBT – Cognitive (thought challenging)
- ☐ ACT - Acceptance commitment therapy
- ☐ Mindfulness/Meditation
- ☐ Relaxation
- ☐ Gratitude
- ☐ Strengths based
- ☐ Other _____

Affiliations:

☐ Unknown ☐ Commercial ☐ Government ☐ NGO ☐ University

Age group (all that apply)

- ☐ Children (under 12)
- ☐ Adolescents (13-17)
- ☐ Young Adults (18-25)
- ☐ Adults
- ☐ General

Technical aspects of app (all that apply)

- ☐ Allows sharing (Facebook, Twitter, etc.)
- ☐ Has an app community
- ☐ Allows password-protection
- ☐ Requires login
- ☐ Sends reminders
- ☐ Needs web access to function

QUT Queensland University of Technology

YOUNGANDWELL Cooperative Research Centre

App Quality Ratings

The Rating scale assesses app quality on four dimensions. All items are rated on a 5-point scale from "1.Inadequate" to "5.Excellent". Circle the number that most accurately represents the quality of the app component you are rating. Please use the descriptors provided for each response category.

SECTION A

Engagement – fun, interesting, customisable, interactive (e.g. sends alerts, messages, reminders, feedback, enables sharing), well-targeted to audience

1. **Entertainment: Is the app fun/entertaining to use? Does it use any strategies to increase engagement through entertainment (e.g. through gamification)?**
   - 1 Dull, not fun or entertaining at all
   - 2 Mostly boring
   - 3 OK, fun enough to entertain user for a brief time (< 5 minutes)
   - 4 Moderately fun and entertaining, would entertain user for some time (5-10 minutes total)
   - 5 Highly entertaining and fun, would stimulate repeat use

2. **Interest: Is the app interesting to use? Does it use any strategies to increase engagement by presenting its content in an interesting way?**
   - 1 Not interesting at all
   - 2 Mostly uninteresting
   - 3 OK, neither interesting nor uninteresting; would engage user for a brief time (< 5 minutes)
   - 4 Moderately interesting; would engage user for some time (5-10 minutes total)
   - 5 Very interesting, would engage user in repeat use

3. **Customisation: Does it provide/retain all necessary settings/preferences for apps features (e.g. sound, content, notifications, etc.)?**
   - 1 Does not allow any customisation or requires setting to be input every time
   - 2 Allows insufficient customisation limiting functions
   - 3 Allows basic customisation to function adequately
   - 4 Allows numerous options for customisation
   - 5 Allows complete tailoring to the individual's characteristics/preferences, retains all settings

4. **Interactivity: Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)? Note: these functions need to be customisable and not overwhelming in order to be perfect.**
   - 1 No interactive features and/or no response to user interaction
   - 2 Insufficient interactivity, or feedback, or user input options, limiting functions
   - 3 Basic interactive features to function adequately
   - 4 Offers a variety of interactive features/feedback/user input options
   - 5 Very high level of responsiveness through interactive features/feedback/user input options

5. **Target group: Is the app content (visual information, language, design) appropriate for your target audience?**
   - 1 Completely inappropriate/unclear/confusing
   - 2 Mostly inappropriate/unclear/confusing
   - 3 Acceptable but not targeted. May be inappropriate/unclear/confusing
   - 4 Well-targeted, with negligible issues
   - 5 Perfectly targeted, no issues found

A. Engagement mean score = _____

QUT Queensland University of Technology

YOUNGANDWELL Cooperative Research Centre

SECTION B

Functionality – app functioning, easy to learn, navigation, flow logic, and gestural design of app

6. **Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?**
   1 App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)
   2 Some functions work, but lagging or contains major technical problems
   3 App works overall. Some technical problems need fixing/Slow at times
   4 Mostly functional with minor/negligible problems
   5 Perfect/timely response; no technical bugs found/contains a 'loading time left' indicator

7. **Ease of use: How easy is it to learn how to use the app; how clear are the menu labels/icons and instructions?**
   1 No/limited instructions; menu labels/icons are confusing; complicated
   2 Useable after a lot of time/effort
   3 Useable after some time/effort
   4 Easy to learn how to use the app (or has clear instructions)
   5 Able to use app immediately; intuitive; simple

8. **Navigation: Is moving between screens logical/accurate/appropriate/ uninterrupted; are all necessary screen links present?**
   1 Different sections within the app seem logically disconnected and random/confusing/navigation is difficult
   2 Usable after a lot of time/effort
   3 Usable after some time/effort
   4 Easy to use or missing a negligible link
   5 Perfectly logical, easy, clear and intuitive screen flow throughout, or offers shortcuts

9. **Gestural design: Are interactions (taps/swipes/pinches/scrolls) consistent and intuitive across all components/screens?**
   1 Completely inconsistent/confusing
   2 Often inconsistent/confusing
   3 OK with some inconsistencies/confusing elements
   4 Mostly consistent/intuitive with negligible problems
   5 Perfectly consistent and intuitive

B. Functionality mean score = _____

SECTION C

Aesthetics – graphic design, overall visual appeal, colour scheme, and stylistic consistency

10. **Layout: Is arrangement and size of buttons/icons/menus/content on the screen appropriate or zoomable if needed?**
    1 Very bad design, cluttered, some options impossible to select/locate/see/read device display not optimised
    2 Bad design, random, unclear, some options difficult to select/locate/see/read
    3 Satisfactory, few problems with selecting/locating/seeing/reading items or with minor screen-size problems
    4 Mostly clear, able to select/locate/see/read items
    5 Professional, simple, clear, orderly, logically organised, device display optimised. Every design component has a purpose

11. Graphics: How high is the quality/resolution of graphics used for buttons/icons/menus/content?

1 Graphics appear amateur, very poor visual design - disproportionate, completely stylistically inconsistent
2 Low quality/low resolution graphics; low quality visual design – disproportionate, stylistically inconsistent
3 Moderate quality graphics and visual design (generally consistent in style)
4 High quality/resolution graphics and visual design – mostly proportionate, stylistically consistent
5 Very high quality/resolution graphics and visual design - proportionate, stylistically consistent throughout

12. Visual appeal: How good does the app look?

1 No visual appeal, unpleasant to look at, poorly designed, clashing/mismatched colours
2 Little visual appeal – poorly designed, bad use of colour, visually boring
3 Some visual appeal – average, neither pleasant, nor unpleasant
4 High level of visual appeal – seamless graphics – consistent and professionally designed
5 As above + very attractive, memorable, stands out; use of colour enhances app features/menus

C. Aesthetics mean score = _____

SECTION D

Information – Contains high quality information (e.g. text, feedback, measures, references) from a credible source. Select N/A if the app component is irrelevant.

13. Accuracy of app description (in app store): Does app contain what is described?

1 Misleading. App does not contain the described components/functions. Or has no description
2 Inaccurate. App contains very few of the described components/functions
3 OK. App contains some of the described components/functions
4 Accurate. App contains most of the described components/functions
5 Highly accurate description of the app components/functions

14. Goals: Does app have specific, measurable and achievable goals (specified in app store description or within the app itself)?

N/A Description does not list goals, or app goals are irrelevant to research goal (e.g. using a game for educational purposes)
1 App has no chance of achieving its stated goals
2 Description lists some goals, but app has very little chance of achieving them
3 OK. App has clear goals, which may be achievable.
4 App has clearly specified goals, which are measurable and achievable
5 App has specific and measurable goals, which are highly likely to be achieved

15. Quality of information: Is app content correct, well written, and relevant to the goal/topic of the app?

N/A There is no information within the app
1 Irrelevant/inappropriate/incoherent/incorrect
2 Poor. Barely relevant/appropriate/coherent/may be incorrect
3 Moderately relevant/appropriate/coherent/and appears correct
4 Relevant/appropriate/coherent/correct
5 Highly relevant, appropriate, coherent, and correct

16. **Quantity of information: Is the extent coverage within the scope of the app; and comprehensive but concise?**

    N/A There is no information within the app
    1 Minimal or overwhelming
    2 Insufficient or possibly overwhelming
    3 OK but not comprehensive or concise
    4 Offers a broad range of information, has some gaps or unnecessary detail; or has no links to more information and resources
    5 Comprehensive and concise; contains links to more information and resources

17. **Visual information: Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct?**

    N/A There is no visual information within the app (e.g. it only contains audio, or text)
    1 Completely unclear/confusing/wrong or necessary but missing
    2 Mostly unclear/confusing/wrong
    3 OK but often unclear/confusing/wrong
    4 Mostly clear/logical/correct with negligible issues
    5 Perfectly clear/logical/correct

18. **Credibility: Does the app come from a legitimate source (specified in app store description or within the app itself)?**

    1 Source identified but legitimacy/trustworthiness of source is questionable (e.g. commercial business with vested interest)
    2 Appears to come from a legitimate source, but it cannot be verified (e.g. has no webpage)
    3 Developed by small NGO/institution (hospital/centre, etc.) /specialised commercial business, funding body
    4 Developed by government, university or as above but larger in scale
    5 Developed using nationally competitive government or research funding (e.g. Australian Research Council, NHMRC)

19. **Evidence base: Has the app been trialled/tested; must be verified by evidence (in published scientific literature)?**

    N/A The app has not been trialled/tested
    1 The evidence suggests the app does not work
    2 App has been trialled (e.g., acceptability, usability, satisfaction ratings) and has partially positive outcomes in studies that are not randomised controlled trials (RCTs), or there is little or no contradictory evidence.
    3 App has been trialled (e.g., acceptability, usability, satisfaction ratings) and has positive outcomes in studies that are not RCTs, and there is no contradictory evidence.
    4 App has been trialled and outcome tested in 1-2 RCTs indicating positive results
    5 App has been trialled and outcome tested in $\geq$ 3 high quality RCTs indicating positive results

D. Information mean score = _____ *

* Exclude questions rated as "N/A" from the mean score calculation.

App subjective quality

SECTION E

20. Would you recommend this app to people who might benefit from it?

1	**Not at all**	I would not recommend this app to anyone
2		There are very few people I would recommend this app to
3	**Maybe**	There are several people whom I would recommend it to
4		There are many people I would recommend this app to
5	**Definitely**	I would recommend this app to everyone

21. How many times do you think you would use this app in the next 12 months if it was relevant to you?

1 **None**
2 1-2
3 3-10
4 10-50
5 >50

22. Would you pay for this app?

1 No
3 Maybe
5 Yes

23. What is your overall star rating of the app?

1	★	One of the worst apps I've used
2	★★	
3	★★★	Average
4	★★★★	
5	★★★★★	One of the best apps I've used

Scoring

App quality scores for

SECTION

A: Engagement Mean Score = _____

B: Functionality Mean Score = _____

C: Aesthetics Mean Score = _____

D: Information Mean Score = _____

App quality mean Score = _____

App subjective quality Score = _____

Appendix 6: List of topics and resources provided in the app

- **Information about the causes and types of cancer pain**
    - Information about what cancer pain is

http://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/about-cancer-pain

    - Causes of cancer pain

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/what-is-pain-and-what-causes-it.html#45790

    - Types of cancer pain

https://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/causes-and-types

- **Information about the assessment and treatment of cancer pain**
    - Medical support

https://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/support-when-you-have-pain

    - Treating cancer pain

https://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/treating-pain

    - Describing and assessing pain

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/different-types-pain-describe.html#45794

    - Cancer treatments to reduce your pain

https://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/treating-pain/cancer-treatments-reduce-pain

- **Information about pain medication and how to take them**
    - Painkillers and ways of taking them

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/painkillers-and-how-they-are-taken.html#45879

- Different types of painkillers

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/levels-pain-different-strengths-painkillers.html#45802

- Other medicines to help control pain

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/other-types-of-drugs-used-in-pain-control.html#45866

- Common questions about painkillers

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/common-questions-about-painkilling-drugs.html#45931

- Practical tips for using your medicines

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/storing-and-remembering-your-medicines.html#45845

- **Things, other than medications, that might help you cope with cancer and pain**
  - Things you can do to help with pain

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/what-else-can-help-with-pain.html#45887

  - Controlling pain without drugs

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/controlling-pain-without-drugs.html#45874

  - Emotional and practical support with cancer pain

https://www.macmillan.org.uk/information-and-support/coping/side-effects-and-symptoms/pain/getting-emotional-and-practical-support.html#45894

  - Managing your emotions

https://www.cancerresearchuk.org/about-cancer/coping/emotionally/cancer-and-your-emotions/managing-your-emotions

  - Trying to stay positive

https://www.cancerresearchuk.org/about-cancer/coping/emotionally/cancer-and-your-emotions/trying-to-stay-positive

- Getting support

https://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/support-when-you-have-pain

- The difference between complementary and alternative therapies (CAMs)

https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/complementary-alternative-therapies/about/difference-between-therapies

- Why people use complementary or alternative therapies

https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/complementary-alternative-therapies/about/why-used

- Different types of complementary and alternative therapies

https://www.cancerresearchuk.org/about-cancer/cancer-in-general/treatment/complementary-alternative-therapies/individual-therapies

- Massage therapy

https://www.macmillan.org.uk/information-and-support/coping/complementary-therapies/complementary-therapies-explained/massage-therapies.html

- Energy-based therapies

https://www.macmillan.org.uk/information-and-support/coping/complementary-therapies/complementary-therapies-explained/energy-based-therapies.html

- Mind-body therapies

https://www.macmillan.org.uk/information-and-support/coping/complementary-therapies/complementary-therapies-explained/mind-body-therapies.html

- Physical therapies

https://www.macmillan.org.uk/information-and-support/coping/complementary-therapies/complementary-therapies-explained/physical-therapies.html#309182

- Psychological and self-help therapies

https://www.macmillan.org.uk/information-and-support/coping/complementary-therapies/complementary-therapies-explained/psychological-self-help-therapies.html

- **Available support services**
  - Resources and support for cancer pain

https://www.cancerresearchuk.org/about-cancer/coping/physically/cancer-and-pain-control/resources-and-support

  - The Sir Robert Ogden Macmillan Centre

http://www.leedsth.nhs.uk/a-z-of-services/leeds-cancer-centre/leeds-cancer-support/the-sir-robert-ogden-macmillan-centre/

  - Find support groups in your area

https://www.macmillan.org.uk/in-your-area/choose-location.html

Appendix 7: The usability testing recruitment documents

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School of Medicine

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Participant Information Sheet

Designing and developing a pain recording system for adult cancer patients
Version (2) 12/03/2018

You are being invited to take part in a research study conducted at the University of Leeds as a part of a PhD project. Before you make a decision about whether you would like to take part, we would like to explain why the research is being done and what it will involve. Please take the time to read the following information and 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.

What is the purpose of the study?
Pain is one of the most devastating symptoms for cancer patients. One third of cancer patients who experience pain may not receive effective treatment. One of the barriers to effective pain management is that cancer pain is not routinely monitored or measured.
The purpose of the study is to develop a pain recording system for adult cancer patients to support better pain management and to provide a secure means for collecting pain data for research purposes. The system consists of three main components: app used for the patients' use, database, and web application for the Healthcare Professionals' (HCPs') and researchers' use.

Why have I been invited?
The main group of users of the intended system will be cancer patients. Therefore, we would like input from this group to help us build the system. We would like to invite you to participate by testing an app prototype as a part of the system and providing feedback about what you think works well and how you think it could be improved. This will help us to tailor the system to make sure it works well and is acceptable to its intended users.

What do I have to do if I take part?
If you decide to participate, you will take part in 3 related research activities that will be completed in one session lasting approximately 90 minutes. The session will be held at a place most convenient to you which may be a quiet room at your own home or at the venue where your cancer support group meets. During the session you will be asked to:

- **Provide written consent:** the researcher will discuss the content of this information sheet with you and then you will be asked to sign the consent form attached to this document.
- **Completing a questionnaire:** you will be required to complete a brief questionnaire that asks some basic information about yourself and your views on using a smartphone application for health promotion, your level of technical expertise.
- **Testing an app.** You will be asked to try out an app. The app will be a prototype and will be developed further and improved from participants' feedback that we gather from each research iteration. You will only be involved in one iteration (i.e. one feedback session), unless you express

an interest to be contacted again for future system testing. You will be given a smartphone or tablet for the duration of the session with the app prototype installed on it. You will be required to try out the app through performing a list of written tasks and while explaining to the researcher your thoughts about the app. With your permission, the test will be audio and screen recorded (i.e. your voice and the device screen will be recorded). Also, we will be observing your interaction with the system and taking some notes during the session. After performing each task, you will be asked to rate the level of difficulty. You do not need to have had any prior experience apart from very basic skills of smart devices use.

- **Completing a post-test questionnaire and a brief interview**. After trying out the app, you will be required to complete a one page questionnaire that rates your overall satisfaction with the app. You will then be asked some further questions about your experience of the app and how you think it can be improved. With your permission, the brief interview will be audio recorded and notes will be taken if needed.

At the end of the session, you may be asked if you would like to take part in future feedback sessions after the app is further developed; this could be in a few weeks or months. If you agree we will keep your contact details so we can get back in touch with you.

Do I have to take part?

It is up to you to decide whether you would like to take part in the study as participation is voluntary. If you agree to take part, we will go through this information sheet with you again and ask you to sign a consent form. You can change your mind about taking part at any time, without giving a reason. If you do decide to not take part or withdraw after accepting or taking part, this will have no consequences in any way. In that case, any information held about you will be destroyed. However, you may not be able to withdraw information you have contributed once data analysis starts which will be 3 days after taking part.

What are the possible advantages and disadvantages of taking part?

There will be no immediate benefits for you, but the information we collect from you will help us establish the requirements for, and inform the development of the app which is part of a pain recording system to enhance the pain management for cancer patients.

The study will not involve any type of payments or incentives. Participation is voluntary and time spent during the testing session will not be compensated. However, if needed, any travel expenses to attend the feedback session will be paid for you.

Will my taking part in the study be kept confidential?

Any information we have about you or from you will be kept confidential in accordance with the Data Protection Act 1998. The recorded audio and video clips as well as the field notes took during the session will be transcribed. Your name and contact details will be kept separately from the transcript and any details that could be used to identify you will be removed from the transcript. We will use a code number to identify audio and video files (screen recording), transcripts, and questionnaires belong to you. Only aggregated and anonymised responses from you and from other participants will be shared through reports and publications derived from the study. We might use direct quotes from your responses to explain or interpret the findings but these will not be attributed to you and will be entirely anonymous. You will not be identified or identifiable in any reports/publications resulting from this study.

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School of Medicine

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All electronic data will be stored on a password protected computer used within the University of Leeds servers. Any paper copies will be kept in a locked filing cabinet within a locked office in a secure building at the university. Any sort of data will not be disclosed to anyone outside of the research team. We will keep information relating to the study according to the University of Leeds's data protection policies.

What will happen to the results of the study?
The findings will be written at the end of the project within a PhD thesis. You may, if you wish, have a summary of the findings to read for yourself once the study is complete. We will publish our findings in academic journals and conferences throughout the project. You will not be personally identified in any report or publication.

Who is organizing and funding the research?
The study is supported by a governmental scholarship for PhD studies at University of Leeds.

Who has reviewed the study?
This study has been reviewed by the School of Medicine Research Ethics Committee at University of Leeds on [16/5/2018] and given a favourable opinion [SoMREC project number 17-059].

Who can I contact for further information?

If you have any questions or concerns regarding this study, or would like additional information to assist you in reaching a decision about participation, please contact me, the principal investigator, Asma Abahussin at +44 113 343 4572 or by email at umaab@leeds.ac.uk.

Institution:
School of medicine / Leeds Institute of Health sciences
University of Leeds

Worsley Building, Level 10
Clarendon Way
Leeds LS2 9NL, UK

Also, you can contact my supervisors, Dr. Lucy Ziegler at +44 113 343 7351 or email L.E.Ziegler@leeds.ac.uk or Dr. David Wong at +44 113 343 9671 or email D.C.Wong@leeds.ac.uk or Prof Robert West at +44 113 343 2735 or email R.M.West@leeds.ac.uk .

Thank you for taking time to read this information sheet and consider this study. If you are willing to take part in this research project, please contact me in my contact details above.

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School of Medicine

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Participant Information Sheet

Designing and developing a pain recording system for adult cancer patients

Version (2) 12/03/2018

You are being invited to take part in a research study conducted at the University of Leeds as a part of a PhD project. Before you make a decision about whether you would like to take part, we would like to explain why the research is being done and what it will involve. Please take the time to read the following information and 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.

What is the purpose of the study?

Pain is one of the most devastating symptoms for cancer patients. One third of cancer patients who experience pain may not receive effective treatment. One of the barriers to effective pain management is that cancer pain is not routinely monitored or measured.

The purpose of the study is to develop a pain recording system for adult cancer patients to support better pain management and to provide a secure means for collecting pain data for research purposes. The system consists of three main components: app used for the patients' use, database, and web application for the Healthcare Professionals' (HCPs') and researchers' use.

Why have I been invited?

One of the user groups of the intended system will be HCPs and researchers. Therefore, we would like input from this group to help us build the system. We would like to invite you to participate by testing the system prototype and providing feedback about what you think works well and how you think it could be improved. This will help us to tailor the system to make sure it works well and is acceptable to its intended users.

What do I have to do if I take part?

If you decide to participate, you will take part in 3 related research activities that will be completed in one session lasting approximately 90 minutes. The session will be held at a place most convenient to you which may be a quiet room at your workplace. During the session you will be asked to:

- **Provide written consent:** the researcher will discuss the content of this information sheet with you and then you will be asked to sign the consent form attached to this document.
- **Completing a questionnaire:** you will be required to complete a brief questionnaire that asks some basic information about yourself and your role.
- **Testing a web application as an interface to the system.** You will be asked first to familiarise yourself with an app that will be used by the patients and then complete a web application trial. The system will be a prototype and will be developed further and improved from participants' feedback that we gather from each research iteration. You will only be involved in one iteration (i.e. one feedback session), unless you express an interest to be contacted again for future system testing. You will be given a laptop for the duration of the session with the system prototype of the web application

installed on it. You will be required to try out the system through performing a list of written tasks and while explaining to the researcher your thoughts about the system. With your permission, the test will be audio and screen recorded (i.e. your voice and the device screen will be recorded). Also, we will be observing your interaction with the system and taking some notes during the session. After performing each task, you will be asked to rate the level of difficulty. You do not need to have had any prior experience apart from very basic skills of computer use.

- **Completing a post-test questionnaire and a brief interview**. After trying out the system, you will be required to complete a one page questionnaire that rates your overall satisfaction with the system. You will then be asked some further questions about your experience of the system and how you think the system can be improved. With your permission, the brief interview will be audio recorded and notes will be taken if needed.

At the end of the session, you may be asked if you would like to take part in future feedback sessions after the system is further developed; this could be in a few weeks or months. If you agree we will keep your contact details so we can get back in touch with you.

Do I have to take part?

It is up to you to decide whether you would like to take part in the study as participation is voluntary. If you agree to take part, we will go through this information sheet with you again and ask you to sign a consent form. You can change your mind about taking part at any time, without giving a reason. If you do decide to not take part or withdraw after accepting or taking part, this will have no consequences in any way. In that case, any information held about you will be destroyed. However, you may not be able to withdraw information you have contributed once data analysis starts which will be 3 days after taking part.

What are the possible advantages and disadvantages of taking part?

There will be no immediate benefits for you, but the information we collect from you will help us establish the requirements for, and inform the development of a pain recording system to enhance the pain management for cancer patients.

The study will not involve any type of payments or incentives. Participation is voluntary and time spent during the testing session will not be compensated. However, if needed, any travel expenses to attend the feedback session will be paid for you.

Will my taking part in the study be kept confidential?

Any information we have about you or from you will be kept confidential in accordance with the Data Protection Act 1998. The recorded audio and video clips as well as the field notes took during the session will be transcribed. Your name and contact details will be kept separately from the transcript and any details that could be used to identify you will be removed from the transcript. We will use a code number to identify audio and video files (screen recording), transcripts, and questionnaires belong to you. Only aggregated and anonymised responses from you and from other participants will be shared through reports and publications derived from the study. We might use direct quotes from your responses to explain or interpret the findings but these will not be attributed to you and will be entirely anonymous. You will not be identified or identifiable in any reports/publications resulting from this study.

All electronic data will be stored on a password protected computer used within the University of Leeds servers. Any paper copies will be kept in a locked filing cabinet within a locked office in a secure building at

the university. Any sort of data will not be disclosed to anyone outside of the research team. We will keep information relating to the study according to the University of Leeds's data protection policies.

What will happen to the results of the study?
The findings will be written at the end of the project within a PhD thesis. You may, if you wish, have a summary of the findings to read for yourself once the study is complete. We will publish our findings in academic journals and conferences throughout the project. You will not be personally identified in any report or publication.

Who is organizing and funding the research?
The study is supported by a governmental scholarship for PhD studies at University of Leeds.

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Who can I contact for further information?

If you have any questions or concerns regarding this study, or would like additional information to assist you in reaching a decision about participation, please contact me, the principal investigator, Asma Abahussin at +44 113 343 4572 or by email at umaab@leeds.ac.uk.

Institution:
School of medicine / Leeds Institute of Health sciences
University of Leeds

Worsley Building, Level 10
Clarendon Way
Leeds LS2 9NL, UK

Also, you can contact my supervisors, Dr. Lucy Ziegler at +44 113 343 7351 or email L.E.Ziegler@leeds.ac.uk or Dr. David Wong at +44 113 343 9671 or email D.C.Wong@leeds.ac.uk or Prof Robert West at +44 113 343 2735 or email R.M.West@leeds.ac.uk .

Thank you for taking time to read this information sheet and consider this study. If you are willing to take part in this research project, please contact me in my contact details above.

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School of Medicine

UNIVERSITY OF LEEDS

Consent to take part in a study of designing and developing pain recording system for adult cancer patients	Add your initials next to the statement if you agree
I confirm that I have read and understand the information sheet dated 12.03.2018 explaining the above research project and I have had the opportunity to ask questions.	
I understand that my participation is voluntary and that I am free to withdraw at any time before data analysis starts (3 days after taking part) without giving any reason and without there being any negative consequences. If I do not wish to answer/perform any particular question/task, I am free to decline. I understand it may not be possible to withdraw data that I have provided once data analysis starts.	
I agree that my interaction with the smartphone or tablet/laptop is audio and screen recorded and the brief interview is audio recorded; and transcribed for the research purposes.	
I give permission for members of the research team to use, share and maintain the responses and information I provide as described in the information sheet dated 12.03.2018. I understand that I will not be identified or identifiable in any reports/publications result from the research.	
I give permission for direct quotes to be used in research reports and publications. All quotations will be anonymised.	
I agree to take part in the above research project.	

After taking part in the study, please consider your decision for the following:	Sign next to the statement if you agree
I agree to be contacted again (if needed) for the purposes of this research (provide additional information after participation or for invitation to participate again after updating the system prototype).	

Name of participant	Date (dd/mm/yyyy)	Signature of participant
Name of researcher	Date (dd/mm/yyyy)	Signature of researcher

Thank you for agreeing to take part in this study.
Your contribution is very much appreciated.

Research title	*Document type*	*Version #*	*Date*
Pain recording system design and development	Consent form	2	12/03/2018

Appendix 8: The usability testing ethical approval letter

UNIVERSITY OF LEEDS

Faculty of Medicine and Health Research Office
School of Medicine Research Ethics Committee (SoMREC)

Room 9.29, level 9
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Clarendon Way
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16 May 2018

Asma Abahussin
Leeds Institute of Health Sciences
Leeds University School of Medicine
Level 10, Worsley Building
Clarendon Way
LEEDS LS2 9NL

Dear Asma

Ref no: **MREC17-059**

Title: **Designing and developing pain recording system for adult cancer patients**

Your research application has been reviewed by the School of Medicine Ethics Committee (SoMREC) and I can confirm that ethics approval is granted based on the following documentation received from you and subject to the following conditions:

- **The box in 4.4 should be unticked as this indicates that the study data is to be submitted to a journal to support a publication, which does not seem to be the case**
- **The Participants Information Sheets should be checked for missing words and typographical errors**
- **Acronyms should be avoided in the Information Sheet/s, or provide the full version of the words when they are first mentioned, i.e. HCP**

Document	*Version*	*Date Submitted*
Asma Abahussin_ethical_review_form_V2	2.0	29/03/2018
Asma Abahussin_Participant_Consent_Form _V2	2.0	29/03/2018
Asma Abahussin_Participant_Info_Sheet_HCPs_Researchers_V2	2.0	29/03/2018
Asma Abahussin_Participant_Info_Sheet_Patients_V2	2.0	29/03/2018
Asma Abahussin_Post-test_questionnaire_V1	1.0	29/03/2018
Asma Abahussin_Questionnaires and Interviews_V2	2.0	29/03/2018
Asma Abahussin_Recruitment_Reminder_Emails_ HCPs_Researchers_V1	1.0	29/03/2018
Asma Abahussin_Recruitment_Reminder_Emails_ Patients_V1	1.0	29/03/2018
Asma Abahussin_Study_Protocol_V1	1.0	29/03/2018
Asma Abahussin_Fieldwork_Assessment_Form_low_risk_V1	1.0	09/02/2018

Please notify the committee if you intend to make any amendments to the original research ethics application or documentation. All changes must receive ethics approval prior to implementation. Please contact the Faculty Research Ethics Administrator for further information (fmhuniethics@leeds.ac.uk)

Ethics approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisation, including clinical areas. The committee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research activities.

Please note: You are expected to keep a record of all your approved documentation, as well as documents such as sample consent forms, risk assessments and all other documents relating to the study. This should be kept in your

study file, which should be readily available for audit purposes. You will be given a two week notice period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protection and any other legal and/or professional guidelines there may be.

We wish you every success with the project.

Yours sincerely

Dr Naomi Quinton, Co-Chair, SoMREC, University of Leeds
(Approval granted by Co-Chair Dr Naomi Quinton on behalf of the committee).

Appendix 9: The usability testing tasks

Tasks for participants (patients)

You were looking for an app that can support pain self-management and help in keeping record of pain to ease communicating this to your doctor in your follow-up appointments. You found PAINRecord app and you installed it in your smart device.

1. See if you can start using the app
2. See if you can record pain score
   Probe:
   a. Any comments – did anything you see not make sense to you?
3. Imagine you have used the app over a long period of time. See if you can view the history of pain
   Probe:
   a. Any comments – did anything you see not make sense to you?
4. Imagine you have already logged some pain scores. See if you can now record how you controlled that pain
   Probe:
   a. Any comments – did anything you see not make sense to you?
5. See if you can find out information about a topic related to cancer and cancer pain you would be interested in
6. See if you can reset your password and change the study ID
7. See if you can chat with other people
8. See if you can use the app to help you remember to log pain details

Tasks for participants (HCPs)

You are introduced to a new system intended to facilitate tracking the history of your patients' pain for better pain assessment and management. The pain data will be collected through a mobile app used by the patients.

0. First, take a few minutes to familiarise yourself with the app and how it works
   Probe:
   a. Any comments – did anything you see not make sense to you? And do you think it would be easy or difficult for patients?

1. Now, see if you can start using the system
2. Assume you have a patient and need to view his/her pain record. See if you can access a patient record

   Probe:

   a. Any comments – did anything you see not make sense to you?
3. See if you can reset your password and change your account type (role)

Task for participants (researcher)

You are introduced to a new system intended to facilitate collecting pain data for research purpose. The data will be collected through a mobile app used by the patients.

0. First, take a few minutes to familiarise yourself with the app and how it works

   Probe:

   a. Any comments – did anything you see not make sense to you? And do you think it would be easy or difficult for patients?
1. Now, see if you can start using the system
2. Assume you have a study registered on the system. Use the system to view the data collected

   Probe:

   a. Any comments – did anything you see not make sense to you?
3. Assume you have a study and need to track the pain scores for your participants. See if you can register this study on the system
4. See if you can reset your password and change your account type (role)

Tasks for both (HCP and researcher)

You are introduced to a new system intended to facilitate tracking the history of your patients' pain for better pain assessment and management. Also, the system is intended to facilitate collecting pain data for research purpose. The pain data will be collected through a mobile app used by the patients.

0. First, take a few minutes to familiarise yourself with the app and how it works

   Probe:

a. Any comments – did anything you see not make sense to you? And do you think it would be easy or difficult for patients?

1. Now, see if you can start using the system
2. Assume you have a patient and need to view his/her pain record. See if you can access a patient record

   Probe:

   a. Any comments – did anything you see not make sense to you?
3. Assume you have a study registered on the system. Use the system to view the data collected

   Probe:

   a. Any comments – did anything you see not make sense to you?
4. Assume you have a study and need to track the pain scores for your participants. See if you can register this study on the system
5. See if you can reset your password and change your account type (role)

Appendix 10: The usability testing session guide

Checklist for the session:

⇒ 2 copies of list of tasks separated

⇒ 2 pens

⇒ Screenshots of the design to take notes

⇒ Observation sheet

⇒ Consent form and information sheet

⇒ Laptop +iPad + charger and lightning cable

⇒ Pre –questionnaire + SUS +interview questions

⇒ Open the thinking aloud demo video

⇒ Charger

⇒ Check internet availability

⇒ Book room if needed

Session guide

- Thank the participant and ensure he/she does not have any question about the study procedure.
    - **Script**: Thank you for coming in today and for helping us with this research study. My name is Asma a PhD researcher at University of Leeds. Have you read the information sheet? Do you have any questions about the session today and your participation before we start?
    - If necessary, go through the information sheet and provide a brief introduction to the study and the objectives.
        - **Script**: One of the barriers to effective pain management is that cancer pain is not routinely monitored or measured. **The purpose** of the study is to develop a pain recording system for adult cancer patients to support better pain management and to provide a secure means for collecting pain data for research purposes. The system consists of three main components: app used for the patients' use, database, and web application for the Healthcare Professionals' (HCPs') and researchers' use.
- Ensure consent obtained

- Ask to complete the pre-test questionnaire
- Set up the computer and the recorder and connect the iPad to the computer
- Provide an explanation on how the test will run and overview of the think aloud protocol
    - **Script**: Today I would like you to try out **an app/web application** prototype and give me feedback about what you think works well and how you think it could be improved. This will help us to tailor the system to make sure it works well and is acceptable to its intended users.
    - **Script:** I am going to ask you to try out the application prototype through a number of written activities that I will be handing to you one at a time. This study is interested in what you think while you are browsing and using the application. This means speaking out loud everything you are thinking as you are going through the application. You don't need to worry about speaking in sentences, or explaining your thoughts, I just want you to say out loud whatever thoughts you might have. I know this is quite an unusual thing to do, so if you go quiet I will remind you to continue to think aloud. Please try to speak clearly and keep talking right up until you have finished trying out the application.
    - **Script:** Because constantly speaking out loud might be something you haven't tried before while using **a computer/your smart device** I thought of showing you an example of that, so I will show a thinking aloud demo video–Show the video https://www.nngroup.com/articles/thinking-aloud-demo-video/
    - **Script:: Also** we could try a warm up exercise before I introduce you to the application
        - So, I would like you to try thinking aloud while using the **iPad/computer**. On the **iPad/computer** I would like you to use the Internet to search information on the weather or any product.
    - **Script:** Thank you, I think you have got the idea. Now, I would like you to try out the application but I would like to remind you about few things:

  - Please ask me to stop at any point if you need to for any reason.
  - Please remember it is not a fully functional app it is only a prototype. For example, you will not be able to type in anything but I would like you to imagine that you do so where you think it is needed and tell me that please.
  - Since I'll be observing, I won't be saying much **but I might probe into some design interfaces.**
  - Remember, I am evaluating the design, not you...
  - Your feedback, both good and bad, will help me learn and improve the application
  - While you are trying out the app tell me what you are thinking, what you are doing, whether you expect something, are surprised...
  - Some activities might be very short and some may be longer. I may skip some or add some new ones.
- Tell the user that you will **start recording** (screen and audio)
- Hand in the actual tasks one by one asking the user to read them aloud – **script**: Can I ask you to read the activity aloud?
- Ask to answer the rate question (ESQ) after each task
- Take note for the usability metrics – Observation sheet
- After finishing all the tasks, stop and save the recording and ask to complete the SUS questionnaire
- Set up the recorder and remind the user that that you will record the interview
- Conduct the brief semi-structured interview
- Stop and save the recording and conclude the test and thank the user
- Ask if he/she would like to sign the section on the consent form regarding further communication and participation
- Write down any comments about the whole session after the participant leave

Appendix 11: The usability testing pre-test questionnaire

Patients' pre-test questionnaire

1. Are you
   a. Female b. Male c. Prefer not say/other

2. What is your age?
   a. 18-40 b. 41-65 c. Over 65 years

3. Do you own a smart device e.g. a smartphone, iPad, or tablet?
   a. Yes b. No

4. If you answered 'Yes' for question 3, please answer the following questions:
   A. How confident are you using your smart device?
      a. Very confident b. Confident
      c. Slightly confident d. Not at all

   B. What sort of purpose do you usually use your smart device for? (*you can select more than one)*
      a. To use Apps b. To make calls
      c. To send Emails d. To play games
      e. To listen to music or audible books f. To text
      g. To read e-books h. Other

   C. Have you tried any apps for pain? If yes, can you please write which apps had been tried?
      a. Yes,_____ b. No

   D. Have you tried any other health related apps? If yes, can you please write which apps had been tried?
      a. Yes,_____ b. No

E. In which device do you prefer to use the intended app for the pain recording system?
   a. Smartphone b. tablet/iPad

HCPs and researchers pre-test questionnaire

1. Are you
   a. Female b. Male c. Prefer not say/other

2. What is your age?
   a. 18-40 b. 41-65 c. Over 65 years

3. What is your role? Can you please write more about your speciality?
   a. Healthcare professional b. Researcher
   _____ _____
   c. Both
   _____

4. How many years of experience you have in your role?
   _____

5. Are you using any health related apps? If yes, can you please write which sort of apps?
   a. Yes,_____ b. No

6. How confident are you using computer and internet based applications in your work?
   a. Very confident b. Confident
   c. Slightly confident d. Not at all

Appendix 12: The usability testing observation sheet

Observation sheet

Task#	Completion time	Success (Circle 1)	Errors	Note of any UI and problem
1	Start: End:	0 unsuccessful completion 1 successful completion	0 no error committed 1 at least one error committed	
2				
3				

Appendix 13: The SUS scale

System Usability Scale

Plesae record your immediate response to each item below, rather than thinking about items for a long time.

	Strongly disagree				Strongly agree
1. I think that I would like to use this app frequently	1	2	3	4	5
2. I found the app unnecessarily complex	1	2	3	4	5
3. I thought the app was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this app	1	2	3	4	5
5. I found the various functions in this app were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this app	1	2	3	4	5
7. I would imagine that most people would learn to use this app very quickly	1	2	3	4	5
8. I found the app very awkward to use	1	2	3	4	5
9. I felt very confident using the app	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this app	1	2	3	4	5

Using SUS

The SU scale is generally used after the respondent has had an opportunity to use the system being evaluated, but before any debriefing or discussion takes place. Respondents should be asked to record their immediate response to each item, rather than thinking about items for a long time.

All items should be checked. If a respondent feels that they cannot respond to a particular item, they should mark the centre point of the scale.

Scoring SUS

SUS yields a single number representing a composite measure of the overall usability of the system being studied. Note that scores for individual items are not meaningful on their own.

To calculate the SUS score, first sum the score contributions from each item. Each item's score contribution will range from 0 to 4. For items 1,3,5,7,and 9 the score contribution is the scale position minus 1. For items 2,4,6,8 and 10, the contribution is 5 minus the scale position. Multiply the sum of the scores by 2.5 to obtain the overall value of SU.

SUS scores have a range of 0 to 100.

Appendix 14: The interview topic guide (usability testing study)

Brief semi-structured interview topic guide

Patients

1. When you tried out the app, what features did you like and you dislike?
2. In your opinion, do you think the app would help in monitoring and managing cancer pain better? Do you think the app would support pain self-management? Why?
3. In your opinion, what can be put into the app to help in better understanding pain and how to monitor it? Is there anything would you like to see in the app?
4. What could motivate or prevent from using the app on regular basis?

HCPs

1. When you tried out the web application, what features did you like and you dislike?
2. In your opinion, do you think the system will help in monitoring and managing cancer pain better?
3. In your opinion, what can be put into the app or the web application to help in better pain management? Is there anything would you like to see in the app or the web application?

Researchers

1. When you tried out the web application, what features did you like and you dislike?
2. In your opinion, do you think the system will help in monitoring cancer pain better and will be beneficial for you as a researcher?
3. In your opinion, what can be put into the app or the web application to help in better pain monitoring? Is there anything would you like to see in the app or the web application?

Appendix 15: The uMARS Scale

Instructions for use:

Raters should:

1. Use the app and trial it thoroughly for at least 10 minutes;
2. Determine how easy it is to use, how well it functions and does it do what it purports to do;
3. Review app settings, developer information, external links, security features, etc.

Scoring

A: Engagement Mean Score = _____

B: Functionality Mean Score = _____

C: Aesthetics Mean Score = _____

D: Information Mean Score* = _____

* Exclude questions rated as "N/A" from the mean score calculation.

App quality mean score _____ = A + B + C + D / 4

The *App subjective quality* scale can be reported as individual items or as a mean score, depending on the aims of the research.

The *Perceived impact* items can be adjusted and used to obtain information on the perceived impact of the app on the user's knowledge, attitudes and intentions related to the target health behaviour.

Mobile Application Rating Scale: user version (uMARS)

App Name: _____

Circle the number that most accurately represents the quality of the app you are rating. All items are rated on a 5-point scale from "1.Inadequate" to "5.Excellent". Select N/A if the app component is irrelevant.

App Quality Ratings

SECTION A

Engagement – fun, interesting, customisable, interactive, has prompts (e.g. sends alerts, messages, reminders, feedback, enables sharing)

1. **Entertainment: Is the app fun/entertaining to use? Does it have components that make it more fun than other similar apps?**
   1 Dull, not fun or entertaining at all
   2 Mostly boring
   3 OK, fun enough to entertain user for a brief time (< 5 minutes)
   4 Moderately fun and entertaining, would entertain user for some time (5-10 minutes total)
   5 Highly entertaining and fun, would stimulate repeat use

2. **Interest: Is the app interesting to use? Does it present its information in an interesting way compared to other similar apps?**
   1 Not interesting at all
   2 Mostly uninteresting
   3 OK, neither interesting nor uninteresting; would engage user for a brief time (< 5 minutes)
   4 Moderately interesting; would engage user for some time (5-10 minutes total)
   5 Very interesting, would engage user in repeat use

3. **Customisation: Does it allow you to customise the settings and preferences that you would like to (e.g. sound, content and notifications)?**
   1 Does not allow any customisation or requires setting to be input every time
   2 Allows little customisation and that limits app's functions
   3 Basic customisation to function adequately
   4 Allows numerous options for customisation
   5 Allows complete tailoring the user's characteristics/preferences, remembers all settings

4. **Interactivity: Does it allow user input, provide feedback, contain prompts (reminders, sharing options, notifications, etc.)?**
   1 No interactive features and/or no response to user input
   2 Some, but not enough interactive features which limits app's functions
   3 Basic interactive features to function adequately
   4 Offers a variety of interactive features, feedback and user input options
   5 Very high level of responsiveness through interactive features, feedback and user input options

5. **Target group: Is the app content (visuals, language, design) appropriate for the target audience?**

   1 Completely inappropriate, unclear or confusing
   2 Mostly inappropriate, unclear or confusing
   3 Acceptable but not specifically designed for the target audience. May be inappropriate/ unclear/confusing at times
   4 Designed for the target audience, with minor issues
   5 Designed specifically for the target audience, no issues found

SECTION B

Functionality – app functioning, easy to learn, navigation, flow logic, and gestural design of app

6. **Performance: How accurately/fast do the app features (functions) and components (buttons/menus) work?**

   1 App is broken; no/insufficient/inaccurate response (e.g. crashes/bugs/broken features, etc.)
   2 Some functions work, but lagging or contains major technical problems
   3 App works overall. Some technical problems need fixing, or is slow at times
   4 Mostly functional with minor/negligible problems
   5 Perfect/timely response; no technical bugs found, or contains a 'loading time left' indicator (if relevant)

7. **Ease of use: How easy is it to learn how to use the app; how clear are the menu labels, icons and instructions?**

   1 No/limited instructions; menu labels, icons are confusing; complicated
   2 Takes a lot of time or effort
   3 Takes some time or effort
   4 Easy to learn (or has clear instructions)
   5 Able to use app immediately; intuitive; simple (no instructions needed)

8. **Navigation: Does moving between screens make sense; Does app have all necessary links between screens?**

   1 No logical connection between screens at all /navigation is difficult
   2 Understandable after a lot of time/effort
   3 Understandable after some time/effort
   4 Easy to understand/navigate
   5 Perfectly logical, easy, clear and intuitive screen flow throughout, and/or has shortcuts

9. **Gestural design: Do taps/swipes/pinches/scrolls make sense? Are they consistent across all components/screens?**

   1 Completely inconsistent/confusing
   2 Often inconsistent/confusing
   3 OK with some inconsistencies/confusing elements
   4 Mostly consistent/intuitive with negligible problems
   5 Perfectly consistent and intuitive

SECTION C

Aesthetics – graphic design, overall visual appeal, colour scheme, and stylistic consistency

10. **Layout: Is arrangement and size of buttons, icons, menus and content on the screen appropriate?**

    1 Very bad design, cluttered, some options impossible to select, locate, see or read
    2 Bad design, random, unclear, some options difficult to select/locate/see/read
    3 Satisfactory, few problems with selecting/locating/seeing/reading items
    4 Mostly clear, able to select/locate/see/read items
    5 Professional, simple, clear, orderly, logically organised

11. **Graphics: How high is the quality/resolution of graphics used for buttons, icons, menus and content?**

    1 Graphics appear amateur, very poor visual design - disproportionate, stylistically inconsistent
    2 Low quality/low resolution graphics; low quality visual design – disproportionate
    3 Moderate quality graphics and visual design (generally consistent in style)
    4 High quality/resolution graphics and visual design – mostly proportionate, consistent in style
    5 Very high quality/resolution graphics and visual design - proportionate, consistent in style throughout

12. **Visual appeal: How good does the app look?**

    1 Ugly, unpleasant to look at, poorly designed, clashing, mismatched colours
    2 Bad – poorly designed, bad use of colour, visually boring
    3 OK – average, neither pleasant, nor unpleasant
    4 Pleasant – seamless graphics – consistent and professionally designed
    5 Beautiful – very attractive, memorable, stands out; use of colour enhances app features/menus

SECTION D

Information – Contains high quality information (e.g. text, feedback, measures, references) from a credible source

13. **Quality of information: Is app content correct, well written, and relevant to the goal/topic of the app?**

    N/A There is no information within the app
    1 Irrelevant/inappropriate/incoherent/incorrect
    2 Poor. Barely relevant/appropriate/coherent/may be incorrect
    3 Moderately relevant/appropriate/coherent/and appears correct
    4 Relevant/appropriate/coherent/correct
    5 Highly relevant, appropriate, coherent, and correct

14. **Quantity of information: Is the information within the app comprehensive but concise?**

    N/A There is no information within the app
    1 Minimal or overwhelming
    2 Insufficient or possibly overwhelming
    3 OK but not comprehensive or concise
    4 Offers a broad range of information, has some gaps or unnecessary detail; or has no links to more information and resources
    5 Comprehensive and concise; contains links to more information and resources

15. **Visual information: Is visual explanation of concepts – through charts/graphs/images/videos, etc. – clear, logical, correct?**

N/A There is no visual information within the app (e.g. it only contains audio, or text)
1 Completely unclear/confusing/wrong or necessary but missing
2 Mostly unclear/confusing/wrong
3 OK but often unclear/confusing/wrong
4 Mostly clear/logical/correct with negligible issues
5 Perfectly clear/logical/correct

16. **Credibility of source: does the information within the app seem to come from a credible source?**

N/A There is no information within the app
1 Suspicious source
2 Lacks credibility
3 Not suspicious but legitimacy of source is unclear
4 Possibly comes from a legitimate source
5 Definitely comes from a legitimate/specialised source

App subjective quality

SECTION E

17. **Would you recommend this app to people who might benefit from it?**

1	Not at all	I would not recommend this app to anyone
2		There are very few people I would recommend this app to
3	Maybe	There are several people I would recommend this app to
4		There are many people I would recommend this app to
5	Definitely	I would recommend this app to everyone

18. **How many times do you think you would use this app in the next 12 months if it was relevant to you?**

1 None
2 1-2
3 3-10
4 10-50
5 >50

19. **Would you pay for this app?**

1 Definitely not
2
3
4
5 Definitely yes

20. **What is your overall (star) rating of the app?**

1	★	One of the worst apps I've used
2	★★	
3	★★★	Average
4	★★★★	
5	★★★★★	One of the best apps I've used

Perceived impact

SECTION F

1. **Awareness – This app has increased my awareness of the importance of addressing the health behaviour**

Strongly disagree				Strongly Agree
1	2	3	4	5

2. **Knowledge – This app has increased my knowledge/understanding of the health behaviour**

Strongly disagree				Strongly Agree
1	2	3	4	5

3. **Attitudes – The app has changed my attitudes toward improving this health behaviour**

Strongly disagree				Strongly Agree
1	2	3	4	5

4. **Intention to change – The app has increased my intentions/motivation to address this health behaviour**

Strongly disagree				Strongly Agree
1	2	3	4	5

5. **Help seeking – This app would encourage me to seek further help to address the health behaviour (if I needed it)**

Strongly disagree				Strongly Agree
1	2	3	4	5

6. **Behaviour change – Use of this app will increase/decrease the health behaviour**

Strongly disagree				Strongly Agree
1	2	3	4	5

Further comments about the app?

THANK YOU!

QUT Queensland University of Technology

YOUNGANDWELL

Appendix 16: The pain control strategies form

Please answer the following two questions regarding how did you try easing your pain during the past 24 hours.

Q1. Have you taken your medication as prescribed? (*Select one*)

☐ Yes most of the time
☐ Sometimes
☐ No
☐ No pain medication prescribed

Q2. Have you tried anything to reduce your pain? (*you can select more than one*)

☐ Some exercise (swimming, walking)
☐ Yoga, meditation or mindfulness
☐ Warm bath/shower
☐ Massage
☐ Spiritual or religious activities
☐ Talking with someone
☐ Distracting myself to take my mind off the pain (painting, baking)
☐ Acupuncture treatment
☐ Reflexology treatment
☐ Hypnotherapy
☐ Other
☐ Nothing

Appendix 17: The BPI-SF

1903

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : _____

Study Subject #: ☐☐☐☐

PLEASE USE BLACK INK PEN

Study Name: _____

Protocol #: _____

PI: _____

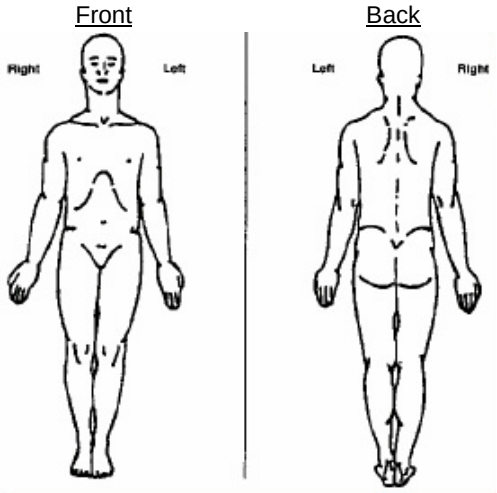
Revision: 07/01/05

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.



3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

No Pain — Pain As Bad As You Can Imagine

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1903

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : _____

Study Subject #: ☐☐☐☐

Study Name: _____

Protocol #: _____

PI: _____

Revision: 07/01/05

PLEASE USE
BLACK INK PEN

7. What treatments or medications are you receiving for your pain?

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐ No Relief	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐ Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

B. Mood

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

C. Walking ability

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

E. Relations with other people

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

F. Sleep

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

G. Enjoyment of life

☐0 Does Not Interfere ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10 Completely Interferes

Appendix 18: The feasibility study ethical approval letter

From: Rachel De Souza [Medicine]
Sent: 19 December 2019 11:28
To: Asma Abahussin [umaab] <umaab@leeds.ac.uk>
Cc: Medicine and Health Univ Ethics Review <FMHUniEthics@leeds.ac.uk>
Subject: Re: MREC 17-059 Amd 1 Oct 2019 Approval
Importance: High

Dear Asma

MREC 17-059 Amd 1 Oct 2019 - Designing and developing pain recording system for adult cancer pa ents

With many apologies from the co-Chair's for the delay, I am pleased to inform you that the amendment applica on listed above has been reviewed by the School of Medicine Research Ethics Commi ee (SoMREC) and following receipt of your response to the Commi ee's ini al comments, I can confirm a favourable ethical opinion with the study documenta on submi ed as at date of this email.

Please retain this email as evidence of approval in your study file.

Please no fy the commi ee if you intend to make any further amendments to the original research as submi ed and
approved to date. This includes recruitment methodology; all changes must receive ethical approval prior to implementa on. Please contact the Research Ethics & Governance Administrator for further informa on (FMHUniEthics@leeds.ac.uk)

Ethics approval does not infer you have the right of access to any member of staff or student or documents and the premises of the University of Leeds. Nor does it imply any right of access to the premises of any other organisa on, including clinical areas. The commi ee takes no responsibility for you gaining access to staff, students and/or premises prior to, during or following your research ac vi es.

Please note: You are expected to keep a record of all your approved documenta on, as well as documents such as sample consent forms, risk assessments and other documents rela ng to the study. This should be kept in your study file, which should be readily available for audit purposes. You will be given a two week no ce period if your project is to be audited.

It is our policy to remind everyone that it is your responsibility to comply with Health and Safety, Data Protec on and any other legal and/or professional guidelines there may be.

I hope the study con nues to go well.

Best wishes
Rachel

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Rachel de Souza, Research Ethics & Governance Administrator, The Secretariat, Room 9.29, Level 9, Worsley Building, Clarendon Way, University of Leeds, LS2 9NL, Tel: 0113 3431642, r.e.desouza@leeds.ac.uk
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Appendix 19: The University of Leeds IT department approval

Name of applicant	Asma Abahussin
Faculty/Service	Faculty of Medicine and Health
University Username	umaab
Email Address	umaab@leeds.ac.uk
Contact Number	113 343 4572
Application/Software being applied for	Hosting service

Identify the main reason for requesting the exemption

I have been developing a system for cancer pain management consisting of three parts: a mobile app, database, and a web application as a portal. I need a hosting service to pilot the system with a group of participants. Discussing with the IT team at the University to provide us with this service has come to the conclusion that using hosting service within the university is not feasible in the meantime. So, using a third-party provider is the only available alternative. A reliable service provider named OVH (https://www.ovh.co.uk/) located in the UK were suggested to the IT and was accepted by them for us to use.

Please describe what type data will be processed, shared or stored

For example unclassified, classified - confidential, classified highly confidential
Nature of Classified information – Personal data, Propriety, Sensitive/contentious research

There will be some numerical data and personal data. However, the participants will be asked to use fake personal information to create a user account. In other words, there will be no identifiable data held on the hosting service. The IT team clarify that the suggested platform above is only suitable under the GDPR with the classification of data that has been defined.

Faculty Sign Off

To be signed to confirm that the faculty or service will conform to the University data protection policy and take full responsibility for security of data and any subsequent loss of data that may be detrimental to the University

Name: Matthew Allsop	Signature:
Job Title: University Academic Fellow	Date: 02-12-2019

Information Security Sign Off

Name: Philip Hobley	Signature:
Job Title: IT Governance Manager	Date: 2 December 2019

Comments: No real identifiable information will be used during the project, only the fake information. This exemption is for the duration of this proof of concept phase for the development of the app. Should the need arise to use real data covered by GDPR this exemption needs to be revisited.

Note: This exemption will only remain valid for 12 months from the date of approval and will require review

Version 1.0

Page 1

Appendix 20: Recruitment sites

Recruitment sites approached for patient group in two batches:

	Site name	Website	Status
First batch (5 sites)	The Yorkshire Cancer Community Organisation	https://yorkshirecancercommunity.co.uk/	Agreed and advertised the study
	The patient and public group (PPG) of the Bowel Cancer Intelligence UK and Yorkshire Cancer Research Bowel Cancer Improvement Programme, University of Leeds	https://bci.leeds.ac.uk/get-involved/	Agreed and advertised the study
	Use MY Data movement	http://www.usemydata.org/index.php	Agreed and advertised the study
	The research advisory group (RAG) of the Patient Centred Outcomes Research (PCOR), University of Leeds	https://pcor.org.uk/research-advisory-group/	Agreed and advertised the study
	Bowel Cancer UK	https://www.bowelcanceruk.org.uk/	Agreed and advertised the study
Second batch (15 sites)	Calderdale and Huddersfield head and neck cancer support group	https://en-gb.facebook.com/pg/headandneckcancersupport/posts/	No response
	The Jayne Garforth Cancer Information Centre	https://www.macmillan.org.uk/in-your-area/local-dashboard/detail/Information%20and%20support%20centres/7223/The-Jayne-Garforth-Cancer-Information-Centre	No response
	Cancer Support Yorkshire	https://cancersupportyorkshire.org.uk/	No response
	Living Well	http://www.livingwell-cancer-	No response

		support.org.uk/resources.php	
	Bowel Cancer Support Group (Halifax and Huddersfield)	https://communitydirectory.kirklees.gov.uk/communityDirectory/organisationdetails.aspx?orgid=4042	No response
	Weston Park Cancer Charity	https://www.cancersupportcentre.co.uk/	No response
	Sheffield bowel cancer support group	https://www.bowelcancersupport.org/	No response
	Leukaemia Care	https://www.leukaemiacare.org.uk/support-and-information/support-for-you/find-a-support-group/sheffield-haematology-support-group/	No response
	Cavendish Cancer Care	https://cavcare.org.uk/	No response
	HUG Cancer Support Group	https://www.opa.org.uk/hug-cancer-support-group.html	Rejected to help
	Prostate Cancer UK	https://prostatecanceruk.org/get-support/find-local-support/prosper-prostate-cancer-support-group-harrogate	No response
	Harrogate & Ripon Centres for Voluntary Service	https://www.harcvs.org.uk/directory/organisation/5247	No response
	The Breast Cancer Haven centre in Leeds	https://www.breastcancerhaven.org.uk/	Agreed and advertised the study
	Leeds Maggie's Centre	https://www.maggies.org/our-centres/maggies-leeds/	Rejected to help
	The Sir Robert Ogden Macmillan Centre	https://www.leedsth.nhs.uk/a-z-of-services/leeds-cancer-centre/leeds-cancer-support/the-sir-robert-ogden-macmillan-centre/	No response

Appendix 21: The feasibility study recruitment documents

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Consent to take part in a study of testing pain recording system developed for adult cancer patients	Add your initials next to the statement if you agree
I confirm that I have read and understand the information sheet dated 17.10.2019 explaining the above research project and I have had the opportunity to ask questions.	
I understand that my participation is voluntary and that I am free to withdraw at any time before data analysis starts (3 days after taking part) without giving any reason and without there being any negative consequences. If I do not wish to answer/perform any particular question/task, I am free to decline. I understand it may not be possible to withdraw data that I have provided once data analysis starts.	
I agree that my interaction with the PainRecord app and the data I enter in it for two weeks will be saved in a secure server accessed only by the research team.	
I agree that the brief interview is audio recorded; and transcribed for the research purposes.	
I give permission for members of the research team to use, share and maintain the responses and information I provide as described in the information sheet dated 17.10.2019. I understand that I will not be identified or identifiable in any reports/publications result from the research.	
I give permission for direct quotes to be used in research reports and publications. All quotations will be anonymised.	
I agree to take part in the above research project.	

Please consider your decision for the following:	Sign next to the statement if you agree
I agree to be contacted again (if needed) for the purposes of this research to provide additional information or participate in a brief interview.	

Name of participant	Date (dd/mm/yyyy)	Signature of participant
Name of researcher	Date (dd/mm/yyyy)	Signature of researcher

Thank you for agreeing to take part in this study.
Your contribution is very much appreciated.

Research title	*Document type*	*Version #*	*Date*
Pain recording system design and development	Consent form (patient)	1	17/10/2019

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School of Medicine

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/

Participant Information Sheet

Testing pain recording system developed for adult cancer patients

Version (1) 17/10/2019

You are being invited to take part in a research study conducted at the University of Leeds as a part of a PhD project. Before you decide whether you would like to take part, we would like to explain why the research is being done and what it will involve. Please take the time to read the following information and 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.

What is the purpose of the study?

Pain is one of the most devastating symptoms for cancer patients. One-third of cancer patients who experience pain may not receive effective treatment. One of the barriers to effective pain management is that cancer pain is not routinely monitored or measured.

The purpose of the study is to develop a pain recording system for adult cancer patients to support better pain management and to provide a secure means for collecting pain data for research purposes. The system consists of three main components: a mobile app for the patients' use, database, and web application portal for the Healthcare Professionals' (HCPs') and researchers' use. The system now is developed and need to be tested by potential users to check its technical integrity along with its acceptability and usability.

Why have I been invited?

The main group of users of the intended system will be community cancer patients. Therefore, we would like input from this group to help us test the system. We would like to invite you to participate by testing the developed app "*PainRecord*" as a part of the system and providing feedback about what you think works well and how you think it could be improved. This will help us to improve the system and solve any technical problems before publishing it.

What do I have to do if I take part?

If you decide to participate, you will take part in 3 related research activities as follow:

- Attend an introductory session that will last approximately 30 minutes where a brief explanation about the nature of the participation and what expected to be achieved will be provided. Then, if you happy to proceed, you will be asked to do the following:
  - Sign the consent form
  - Complete a questionnaire that asks some basic information about yourself and your views on using a smartphone application for health promotion
  - Install the *PainRecord* app in your own smart device (iOS device) and set up an account using fake personal data with the help of the researcher

- Explore the app and complete one pain entry every day **over a period of two weeks** starting from the introductory session date. You do not need to have had any prior experience apart from the very basic skills of smart devices' use.
- After two weeks, you will receive by post an evaluation questionnaire for the app to complete. The researcher, then, will contact you to ensure that you received it and ask you to attend a brief interview where you can bring the completed questionnaire with you. The interview will last approximately 30 minutes and will be audio recorded. The aim of it is to elaborate more on your experience of using the app.

The introductory session and the interview will be held at a convenient place/time to you which may be at the University of Leeds premises, in any agreed quiet place or alternatively if you prefer at the venue where your cancer support group meets usually in Leeds.

Do I have to take part?

It is up to you to decide whether you would like to take part in the study as participation is voluntary. However, you will be offered a £20 Amazon voucher as a Thank you for your time. If you agree to take part, we will go through this information sheet with you again and ask you to sign a consent form. You can change your mind about taking part at any time, without giving a reason. If you do decide to not take part or withdraw after accepting or taking part, this will have no consequences in any way. In that case, any information held about you will be destroyed. However, you may not be able to withdraw information you have contributed once data analysis starts which will be 3 days after taking part.

What are the possible advantages and disadvantages of taking part?

You may realise the potential benefit from using the app that could reflect in your behaviour in managing pain. However, as the app is still in a testing phase it will run in your device for only a short period of time. When the app is ready for public use, you will be able to install it from the app store. Until that time comes, you will be advised of some available pain app that could help.
The information we collect from you will help us to improve the app and solve any technical problem before publishing the app, which is part of the pain recording system aiming to enhance pain management for cancer patients.

Will my taking part in the study be kept confidential?

Any information we have about you or from you will be kept confidential in accordance with the Data Protection Act 2018. The recorded audio, as well as the field notes, took during the interview will be transcribed. Your name and contact details will be kept separately from the transcript and any details that could be used to identify you will be removed from the transcript. We will use a code number to identify audio files, transcripts, and questionnaires belong to you. Aggregated and anonymised responses from you and from other participants will be shared through reports and publications derived from the study. We might use direct quotes from your responses to explain or interpret the findings but these will not be attributed to you and will be entirely anonymous. You will not be identified or identifiable in any reports/publications resulting from this study. At the end of the study and in line with the policies of the University of Leeds, the data captured through the study will be assessed for suitability for inclusion in the Leeds Data Repository for access by researchers to conduct secondary analysis on the anonymous dataset.

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All electronic data will be stored on a password-protected computer used within the University of Leeds servers. The data entered in the app will be stored in a secure server accessed only by the researcher and will not be identifiable. Any paper copies will be kept in a locked filing cabinet within a locked office in a secure building at the university. We will keep information relating to the study according to the University of Leeds's data protection policies.

What will happen to the results of the study?
The findings will be written at the end of the project within a PhD thesis. You may, if you wish, have a summary of the findings to read for yourself once the study is complete. We will publish our findings in academic journals and conferences throughout the project. You will not be personally identified in any report or publication.

Who is organizing and funding the research?
The study is supported by a governmental scholarship for PhD studies at the University of Leeds.

Who has reviewed the study?
This study has been reviewed by the School of Medicine Research Ethics Committee at University of Leeds on 19th December 2019 and given a favourable opinion [SoMREC project number MREC 17-059 Amd 1].

Who can I contact for further information?

If you have any questions or concerns regarding this study or would like additional information to assist you in reaching a decision about participation, please contact me, the principal investigator, Asma Abahussin at +44 113 343 4572 or by email at umaab@leeds.ac.uk.

Institution:
School of medicine / Leeds Institute of Health sciences
University of Leeds

Worsley Building, Level 10
Clarendon Way
Leeds LS2 9NL, UK

Also, you can contact my supervisor Dr Matthew Allsop at +44 113 343 4185 or email m.j.allsop@leeds.ac.uk.

Thank you for taking the time to read this information sheet and consider this study. If you are willing to take part in this research project, please contact me on my contact details above.

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Consent to take part in a study of testing pain recording system developed for adult cancer patients	Add your initials next to the statement if you agree
I confirm that I have read and understand the information sheet dated 17.10.2019 explaining the above research project and I have had the opportunity to ask questions.	
I understand that my participation is voluntary and that I am free to withdraw at any time before data analysis starts (3 days after taking part) without giving any reason and without there being any negative consequences. If I do not wish to answer/perform any particular question/task, I am free to decline. I understand it may not be possible to withdraw data that I have provided once data analysis starts.	
I agree that my interaction with the Pain Recording System and the data I enter in it will be saved in a secure server accessed only by the research team.	
I agree that my answers to the online surveys will be saved in a secure server accessed only by the research team.	
I agree that the brief interview is audio recorded; and transcribed for the research purposes.	
I give permission for members of the research team to use, share and maintain the responses and information I provide as described in the information sheet dated 17.10.2019. I understand that I will not be identified or identifiable in any reports/publications result from the research.	
I give permission for direct quotes to be used in research reports and publications. All quotations will be anonymised.	
I agree to take part in the above research project.	

Please consider your decision for the following:	Sign next to the statement if you agree
I agree to be contacted again (if needed) for the purposes of this research to provide additional information or participate in a brief interview.	

Name of participant	Date (dd/mm/yyyy)	Signature of participant
Name of researcher	Date (dd/mm/yyyy)	Signature of researcher

Thank you for agreeing to take part in this study.
Your contribution is very much appreciated.

Research title	*Document type*	*Version #*	*Date*
Pain recording system design and development	Consent form (Professionals)	1	17/10/2019

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Participant Information Sheet

Testing pain recording system developed for adult cancer patients

Version (1) 17/10/2019

You are being invited to take part in a research study conducted at the University of Leeds as a part of a PhD project. Before you decide whether you would like to take part, we would like to explain why the research is being done and what it will involve. Please take the time to read the following information and 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.

What is the purpose of the study?

Pain is one of the most devastating symptoms for cancer patients. One-third of cancer patients who experience pain may not receive effective treatment. One of the barriers to effective pain management is that cancer pain is not routinely monitored or measured.

The purpose of the study is to develop a pain recording system for adult cancer patients to support better pain management and to provide a secure means for collecting pain data for research purposes. The system consists of three main components: a mobile app for the patients' use, database, and web application portal for the Healthcare Professionals' (HCPs') and researchers' use. The system now is developed and need to be tested by potential users to check its technical integrity along with its acceptability and usability.

Why have I been invited?

One of the user groups of the intended system will be HCPs and researchers. Therefore, we would like input from this group to help us test the system. We would like to invite you to participate by testing the developed system "*Pain Recording System*" and providing feedback about what you think works well and how you think it could be improved. This will help us to improve the system and solve any technical problems before publishing it.

What do I have to do if I take part?

If you decide to participate, you will take part in 4 related research activities that need to be completed online and should not take more than 30 minutes. You will receive, by email, the instruction for these activities which include:

- Sign the consent form and send it back to the researcher by email.
- Complete an online survey that asks some basic information about yourself and your role.
- Access the developed *Pain Recording System* via a link provided and explore it by completing some given tasks.
- Evaluate the system by completing an online survey.

Then, if your time permit, the researcher will contact you to ask whether you are happy to participate in 30-minute interview to discuss your experience of using the system and your feedback. The interview will be

audio-recorded and will be held at a place most convenient to you which may be a quiet room at your workplace.

Do I have to take part?
It is up to you to decide whether you would like to take part in the study as participation is voluntary. If you agree to take part, we will ask you to sign a consent form. You can change your mind about taking part at any time, without giving a reason. If you do decide to not take part or withdraw after accepting or taking part, this will have no consequences in any way. In that case, any information held about you will be destroyed. However, you may not be able to withdraw information you have contributed once data analysis starts which will be 3 days after taking part.

What are the possible advantages and disadvantages of taking part?
There will be no immediate benefits for you, but the information we collect from you will help us to improve the system and solve any technical problem before making it available for professional use. The study will not involve any type of payments or incentives. Participation is voluntary and the time spent in this study will not be compensated.

Will my taking part in the study be kept confidential?
Any information we have about you or from you will be kept confidential in accordance with the Data Protection Act 2018. The recorded audio clips, as well as the field notes, took during the interview will be transcribed. Your name and contact details will be kept separately from the transcript and any details that could be used to identify you will be removed from the transcript. We will use a code number to identify audio files, transcripts, and questionnaires belong to you. Only aggregated and anonymised responses from you and from other participants will be shared through reports and publications derived from the study. We might use direct quotes from your responses to explain or interpret the findings but these will not be attributed to you and will be entirely anonymous. You will not be identified or identifiable in any reports/publications resulting from this study. At the end of the study and in line with the policies of the University of Leeds, the data captured through the study will be assessed for suitability for inclusion in the Leeds Data Repository for access by researchers to conduct secondary analysis on the anonymous dataset. All electronic data will be stored on a password-protected computer used within the University of Leeds servers. The data entered in the system or in the online surveys will be stored in secure servers accessed only by the researcher and will not be identifiable. Any paper copies will be kept in a locked filing cabinet within a locked office in a secure building at the university. We will keep information relating to the study according to the University of Leeds's data protection policies.

What will happen to the results of the study?
The findings will be written at the end of the project within a PhD thesis. You may, if you wish, have a summary of the findings to read for yourself once the study is complete. We will publish our findings in academic journals and conferences throughout the project. You will not be personally identified in any report or publication.

Who is organizing and funding the research?
The study is supported by a governmental scholarship for PhD studies at the University of Leeds.

Research title	*Document type*	*Version #*	*Date*
Pain recording system design and development	Information sheet for professional group	1	17/10/19

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Who has reviewed the study?
This study has been reviewed by the School of Medicine Research Ethics Committee at the University of Leeds on 19th December 2019 and given a favourable opinion [SoMREC project number MREC 17-059 Amd 1].

Who can I contact for further information?

If you have any questions or concerns regarding this study or would like additional information to assist you in reaching a decision about participation, please contact me, the principal investigator, Asma Abahussin at +44 113 343 4572 or by email at umaab@leeds.ac.uk.

Institution:
School of medicine / Leeds Institute of Health sciences
University of Leeds

Worsley Building, Level 10
Clarendon Way
Leeds LS2 9NL, UK

Also, you can contact my supervisor Dr Matthew Allsop at +44 113 343 4185 or email m.j.allsop@leeds.ac.uk.

Thank you for taking the time to read this information sheet and consider this study. If you are willing to take part in this research project, please contact me on my contact details above.

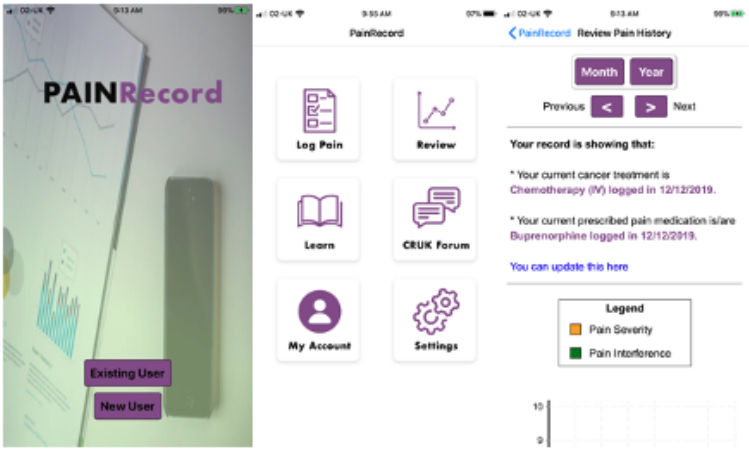
Research title	*Document type*	*Version #*	*Date*
Pain recording system design and development	Information sheet for professional group	1	17/10/19

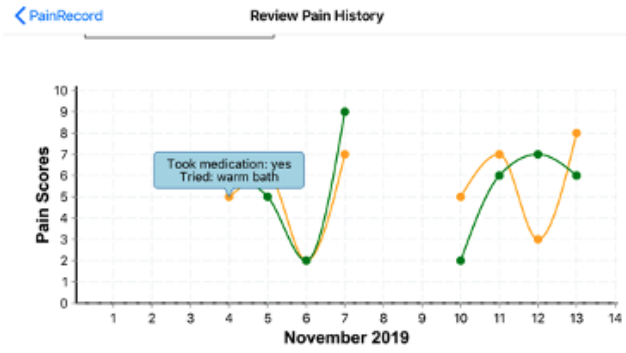
Appendix 22: The feasibility study recruitment materials

Invitation post:

Testing PainRecord mobile app

Pain is one of the most devastating symptoms for cancer patients. One of the barriers to effective pain management is that cancer pain is not routinely monitored or measured. PainRecord mobile app has been developed as a part of a system that aims to facilitate regular pain recording and support better pain management for cancer patients. The app itself has been designed with the potential to support pain self-management if it is used on a regular basis. It could help the user monitor pain and reflect on what could help on easing or triggering pain. We would like a group of potential users to test the app and provide feedback for further improvement before publishing it. The participants need to be cancer patients who have experienced at least one episode of pain within the last six months and own an iOS smart device (iPad or iPhone) to be able to access and use the mobile app. Participants will be offered a £20 Amazon voucher as a Thank you for their time. This is a part of PhD project at the University of Leeds. If you are interested in participating and would like to get more details about this, please contact Asma Abahussin on umaab@leeds.ac.uk .





Invitation poster:

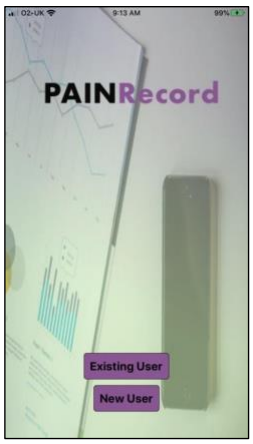
Would you like to test a new mobile phone application for cancer pain management?

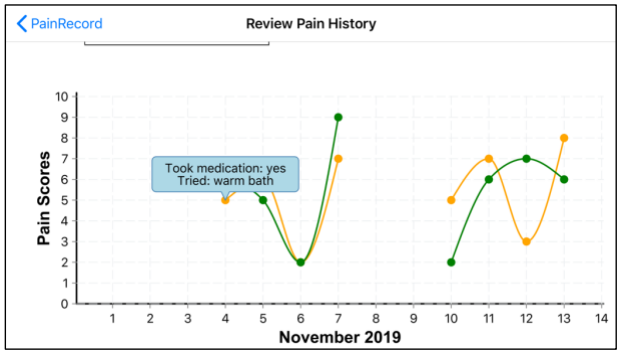
Pain can occur for patients with cancer. One of most common barriers to effective pain management is that cancer pain is not routinely monitored or measured. *PainRecord*, a new mobile phone app, has been developed as a part of a system that aims to support regular pain recording and support better pain management for cancer patients.

PainRecord itself has been designed with the potential to support pain self-management if it is used on a regular basis. It could help people to monitor pain and reflect on what could help to ease pain or to avoid triggering pain. We have provided examples of how the app looks, below.

We would like people to test the app and provide feedback to make sure it meets the needs of patients with cancer. We are looking to recruit people who have cancer and may have experienced one or more episodes of pain in the last six months. To download the app you will need a device made by Apple, such as an iPhone or iPad. If you take part in the study you will be offered a £20 Amazon voucher as a thankyou for your time.

This research is part of a PhD project at the University of Leeds. If you are interested in taking part and would like more information, please contact Asma Abahussin on umaab@leeds.ac.uk





Appendix 23: Questionnaires used for patients

Administrative data sheet (Patients group)

Name _____

Email address *(if you have one)*:_____

Mobile phone no: _____

Home address: _____

Post code _____

Patients' questionnaire used in the introductory session

5. Are you

   d. Female e. Male f. Prefer not say/other

6. What is your age?

   d. 18-40 e. 41-65 f. Over 65 years

7. What is the type of the smart (iOS) device that you have?

   c. iPhone d. iPad e. Both

5. How confident are you using your smart device?

   e. Very confident f. Confident
   g. Slightly confident h. Not at all

6. What sort of purpose do you usually use your smart device for? (*you can select more than one)*

   i. To use Apps j. To make calls
   k. To send Emails l. To play games
   m. To listen to music or audible books n. To text
   o. To read e-books p. Other

7. Have you tried any apps for pain before? If yes, can you please write which apps had been tried?

c. Yes,_____ d. No

8. Have you tried any other health related apps before? If yes, can you please write which apps had been tried?

c. Yes,_____ d. No

9. In which device will you use the *PainRecord* app?

c. Smartphone d. iPad

Appendix 24: The MAUQ Questionnaire

University of Pittsburgh

School of Health and Rehabilitation Sciences
Department of Health Information Management

6021 Forbes Tower
Pittsburgh, Pennsylvania 15260
Phone: 412-383-6653
Fax: 412-383-6655
HIM: http://www.shrs.pitt.edu/him
SHRS: http://www.shrs.pitt.edu

mHealth App Usability Questionnaire (MAUQ)
for Interactive mHealth Apps Used by Patients

#	Statements	N/A		1	2	3	4	5	6	7	
1.	The app was easy to use.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
2.	It was easy for me to learn to use the app.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
3.	I like the interface of the app.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
4.	The information in the app was well organized, so I could easily find the information I needed	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
5.	I feel comfortable using this app in social settings.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
6.	The amount of time involved in using this app has been fitting for me.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
7.	I would use this app again.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
8.	Overall, I am satisfied with this app.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
9.	Whenever I made a mistake using the app, I could recover easily and quickly.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
10.	This mHealth app provides an acceptable way to receive healthcare services.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
11.	The app adequately acknowledged and provided information to let me know the progress of my action.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
12.	The navigation was consistent when moving between screens.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE
13.	The interface of the app allowed me to use all the functions (such as entering information, responding to reminders, viewing information) offered by the app.	☐	DISAGREE	☐	☐	☐	☐	☐	☐	☐	AGREE

14.	This app has all the functions and capabilities I expected it to have.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
15.	The app would be useful for my health and well-being.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
16.	The app improved my access to healthcare services.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
17.	The app helped me manage my health effectively.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
18.	The app made it convenient for me to communicate with my healthcare provider.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
19.	Using the app, I had many more opportunities to interact with my healthcare provider.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
20.	I felt confident that any information I sent to my provider using the app would be received.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE
21.	I felt comfortable communicating with my healthcare provider using the app.	☐	DISAGREE ☐ ☐ ☐ ☐ ☐ ☐ ☐ AGREE

In this questionnaire, 1 - strongly disagree, 2 – disagree, 3 – somewhat disagree, 4 – neither agree nor disagree, 5 – somewhat agree, 6 – agree, 7 – strongly agree

To determine the usability of an app, calculate the total and determine the average of the responses to all statements. The higher the overall average, the higher the usability of the app.

Please cite: Zhou L, Bao J, Setiawan A, Saptono A, Parmanto B, (2019), "The mHealth App Usability Questionnaire (MAUQ): Development and Validation Study", *JMIR mHealth and uHealth*, 7(4):e11500. DOI: 10.2196/11500. PMID: 30973342

Appendix 25: The patients interview topic guide (feasibility study)

Brief interview topic guide for patient group

1. What was your experience of using the PainRecord app?
2. During the period of trying out the PainRecord app, did you face any challenges with using the app? If yes, can you please explain them?
3. Were there any features that you disliked?
4. Were there any features that you liked?
5. Was there anything additional that you would you like to see in the app or you think would be useful in this app?
6. How did the app make you feel about your pain? Did you use your pain scores on the app? Did you do anything different when using the app?
7. To what extent do you think the app would be useful for reporting your pain for longer periods of time?

Appendix 26: The participation email

Participation email

Dear …,

Thank you for signing the consent form.

Your reference number is 103, you will need to quote this in your online responses.

Please follow the three steps below in order to test the system and provide your feedback:

1. Complete the online survey that asks some basic information here: https://leeds.onlinesurveys.ac.uk/the-pain-recording-system-evaluation-basic-info

2. Using a computer, please visit and explore the portal designed for the Pain Recording System here: https://painrecordingsystem.co.uk/portal/. Use the attached sheet to help you explore the portal functionalities.

3. Complete the online evaluation form for the system here: https://leeds.onlinesurveys.ac.uk/the-pain-recording-system-evaluation-new

Please let me know if you encounter any problem completing these steps.

Many thanks,

Asma

Appendix 27: The questionnaires used for professionals

Professionals' pre-test online questionnaire

7. Please enter your reference number in the box. Your reference number was included in the email with details of how to access the portal.

   _____

8. Are you

   d. Female e. Male f. Prefer not say/other

9. What is your age?

   d. 18-40 e. 41-65 f. Over 65 years

4. What is your role? Can you please write more about your speciality?

   d. Health care professional _____

   e. Researcher _____

   f. Both _____

5. How many years of experience you have in your role?

   _____

Brief online questionnaires used along with the validated usability questionnaires

For Professionals

1. What was your overall perception of the Pain Recording System? Please provide any comments in the box, below.
2. Did you face any difficulties or technical problems while exploring the system? If yes, could you please briefly explain them?
3. Were there any features that you liked or disliked? Please can you explain why you liked or disliked them?
4. Are there any additional features or content you would like to be included alongside the existing content?

5. To what extent do you think the system would be useful in the management of patients with cancer pain?
6. Where do you think the system could be aligned to the existing pain management pathways for cancer patients?
7. To what extent do you think the system would be useful in collecting pain data and supporting research on pain in patients with cancer?

Appendix 28: Testing the Pain Recording System portal support sheet

Testing the Pain Recording System portal support sheet

Important notes:

- There are three types of user that the system has been designed for; healthcare professionals (HCPs), researchers, and a joint clinician-researchers. You can log in to examples of the three different user profiles, by using the following email addresses:
    - HCP account with email: test_hcp@hotmail.com
    - Researcher account with email: test_researcher@hotmail.com
    - Account with both mentioned roles with email: test_both@hotmail.com

  All of the accounts have 123456 as a password.

- Dummy patient accounts have been created using mock pain data to demonstrate how data captured via a patient mobile app would be displayed. This is to simulate the working system and provide you as a HCP or a researcher with a better representation of the way that the system can display patient/participant data.

- Registered HCPs can view the pain history of any patient registered in the system through the mobile app by searching for a patient record using a patient's system ID or their date of birth. A HCP can add the patient to their monitoring list if they need to follow a patient's progress.

- Registered researchers can register a study in the system and provide study participants with a study ID. When participants use a linked mobile app, data entered by the participant will be displayed in the researcher portal and can be identified using the assigned study ID.

Tasks to explore the portal functionalities:

- After logging in as a HCP or clinician-research, using the details above:
    - Search for patients with the following details:
        - ID: 138
        - Date of birth: 31/12/1984
        - ID: 149
    - When you are in the patient page with the ID 138, please do the following:
        - Explore the displayed patient data
        - Explore the patterns of pain displayed
        - Hover over different point
        - Interact with the graph to view pain reports of months and years
        - Add this patient to your monitoring list
    - View your patients monitoring list and do the following, please:
        - Explore the displayed patient data

        - Try to use the actions available for you
    - Log out
- After logging in as a researcher or clinician-research using the details above:
    - Find your studies list and view any selected study using the ‘View’ action, and do the following please:
        - Explore the displayed study and participant data
        - Download the participant data table and the raw pain data
    - Register a study with fake information, try the ‘Edit’ and then the ‘Delete’ actions on your created study.
    - Log out
- Create an account for yourself using fake information and please do the following:
    - Log in to your new account
    - View your profile and make any changes
    - Log out

Appendix 29: Student communications

allpg-bounces@lists.leeds.ac.uk on behalf of
Student Communications <StudentCommunica
tions@leeds.ac.uk>
Tue 17/03/2020 16:05
To: allmasters@lists.leeds.ac.uk; allug@lists.leeds.ac.uk; allpg@lists.leeds.ac.uk

ATT00001.txt
451 bytes

Dear students and postgraduate researchers,

The Government announced last night a new phase of its efforts to prevent the spread of the coronavirus (COVID-19).

Although it is seeking to effect a large degree of 'social distancing', the Government is recommending that 'all educational settings' remain open. The focus of its strategy is on avoiding 'non-essential' contact and travel.

The University has therefore agreed the measures set out below. We appreciate that some of them will raise questions – both of interpretation and on implementation – and we will provide further information as quickly as we can. But we thought it best to share with you now the essence of the approach being taken to the unprecedented challenges which the University is facing. We also wanted to share with you now important new student education arrangements (see 5 below and the download of the online document regarding student education arrangements)

1. For the rest of this term, and **with effect from 6pm tomorrow (Wednesday 18 March)**, all physical lectures and classes (including seminars) for taught undergraduate and postgraduate programmes will be cancelled. This includes laboratory and other practical classes. So far as possible, teaching will be delivered online.

2. After tomorrow, all open days, conferences and other major events scheduled before Monday 27 April will be cancelled or postponed to a later date.

3. Over the rest of the week – that is by 6pm on Friday 20 March – we will make an orderly transition to a point at which only essential services and activities will be delivered on campus, observing the principle of 'social distancing', with as many staff and students as possible enabled to work remotely.

4. We are systematically thinking through a complex range of issues so that we can define what is meant by 'essential services and activities', but the list will certainly include:
    a) protecting the health and safety of those staff and students who have to be on campus;
    b) providing appropriate support to students in halls of residence and on campus, and the online delivery of academic material and other support to all of our students, wherever they are;
    c) maintaining the vital infrastructure of the campus – including security, communications and information technology, and utilities;
    d) ensuring that we can continue to pay our staff and suppliers and to meet other financial obligations;
    e) recruiting and eventually admitting the next cohort of students;
    f) some essential research and associated support activities, including research on COVID-19.
    g) (We expect that some of these essential functions and activities can be delivered remotely, but all will require at least some staff presence on campus.)

5. We have agreed a new approach to examination and assessment in the summer term, as explained on the coronavirus website. The new arrangements mean that your academic progress

will be protected if your studies and assessments have to be carried out remotely. We have also established a central and dedicated helpdesk for all staff and students with questions about online learning and teaching. Please email digitaleducation@leeds.ac.ukand we will get back to you as quickly as possible.

6. The University will continue to keep the position under careful and regular review in these very difficult and fast-moving times, and will ensure that clear guidance on the arrangements for next term (due to begin on Monday 27 April) will be sent to all staff and all students by e-mail (and announced on our website) by Friday 17 April.

If you are a Tier 4 student, you may now return home to continue studying online. This will not affect your Tier 4 visa. You do not need to let us know if you are leaving unless you intend to withdraw permanently from your programme of study.

Other students may also leave campus now.

These are extraordinarily challenging times for staff, students and our friends and families. The University's approach over the next few difficult months will be shaped by four principles:

1. **Trust** – we are confident that staff will continue to work diligently when they are off campus, and that students will continue to focus on their learning;
2. **Care** – we will do everything we can to support staff and students – wherever they are – and we will be fully understanding of the position of staff and students who may be unwell themselves or who are caring for loved ones;
3. **Support** – all staff will be paid in accordance with current contractual arrangements and the Student Hardship Fund remains available under the usual arrangements;
4. **Respect** – in these unprecedented times, it is important that everyone is treated with respect and professionalism;

As indicated above, further details will be announced as soon as possible (which in practice is likely to be tomorrow).

We are in the process of updating the website to reflect this new guidance. Thank you for your patience while we update the pages.

With best wishes,

Roger Gair
University Secretary
University of Leeds

Lesley Jowsey
Thu 19/03/2020 08:39

Faculty of Medicine and Hea...
3 MB

Email circulated to All LIHS & LIME Staff & PGR Students on behalf of Professor Laura Stroud

Dear all LIHS/LIME staff and students

Hopefully you will be up to date with the University latest coronavirus guidancehttps://coronavirus.leeds.ac.uk/. I'd like to outline what this means for staff and students in LIHS and LIME.

Building closure and working from home

The University has asked that by the end of the week, **6pm on Friday 20 March** as many staff (and postgraduate researchers) are enabled to work from home.

As a result the Worsley Building will close at 6pm on Friday and you will not be allowed access after this time. We don't know how long the closure will last but it could be for a considerable period of time.

Please can you:

1. Ensure, where possible, that you are enabled to work remotely.
   - The University does not have many citrix licences so you are unlikely to have access to the N drive. This will have an impact on our ability to deliver some areas of business. Being mindful of sensitive information and GDPR, please consider transferring your files to OneDrive where you can.
   - Please consider the working from home health and safety guidance attached.
2. Ensure that your line manager or supervisor has agreed a mechanism for keeping in regular contact with you. This is a fast moving situation and we do not have clarity on many aspects so we will need to keep lines of communication open.
3. Keep up to date with the University guidance and follow the recommendations: (https://coronavirus.leeds.ac.uk/

Research Activity

Please see the email below, received on Wednesday morning. There is an expectation that any research activity that cannot be done remotely should be suspended. Given the applied nature of our research portfolio, this definition is extended to include research sites which may be physically outside our premises, including recruitment and fieldwork undertaken with external partner organisations (e.g. NHS, Social Care, Voluntary sector).

You will see that all research requiring physical access to university premises or research sites must be brought to a stop in an orderly manner as soon as possible. I ask that this happens completely **by 5pm Friday, 20 March 2020**.

If you really feel there is need for an exception, please make your case to your head of division and, if they support the case, they will then seek my approval as the director (I would then need approval of the dean). Please do not make a request lightly. It is expected that most requests will be declined.

Your cooperation with immediate effect will be greatly appreciated.

Research work done remotely should continue; we are still employed, working or studying. Therefore, please agree plans with your line-manager or supervisor for the research work you will do during this time and how you will keep in touch with your supervisor and team.

This is of course a difficult time, my thoughts are with you.

With best wishes

Professor Laura Stroud
Director, Leeds Institute of Health Sciences
Associate Dean (Student Education)
School of Medicine
University of Leeds
101 Clarendon Road
Leeds
LS2 9LJ

PLEASE ENSURE THIS MESSAGE IS CASCADED TO YOUR FACULTY RESEARCH COMMUNITY AS SOON AS POSSIBLE*

Dear colleagues

Further to previous communications about the University's approach to the fast-changing COVID-19 situation, I am writing to confirm our position with respect to our research activities.

As you know, the University's overall approach is to make an orderly transition over the rest of this week to a point at which only essential services and activities will be delivered on campus, observing the principle of 'social distancing', with as many staff and students as possible enabled to work remotely.

We have said that we will continue some essential research and associated support activities, but otherwise we must move to a pause in research activities – including postgraduate research projects – which require physical access to University research facilities, laboratories and buildings. However, we recognise that exceptionally a number of projects and activities will need to continue (for example, essential COVID-19 research, clinical trials, essential maintenance of equipment/facilities/animals/ samples) and that there may be essential projects that cannot be paused immediately.

Such exceptional cases should be agreed by your Executive Dean and subsequently forwarded for agreement by the Deputy Vice-Chancellor (Research and Innovation) ASAP. In order to request such an exception, please submit a brief outline that covers the following:

1. Explain why the research activity or project is essential to continue
2. Explain what labs or facilities you need access to and for how long
3. Explain who will need access
4. Explain what supporting services you will require (eg technical support, wash up facilities etc)
5. Attach a risk assessment that includes consideration of social distancing

We understand that the UK response to these unprecedented circumstances will be potentially disruptive to the people and talent which underpin the UK's research base, but we must prioritise the wellbeing of our staff and students. To reassure you all, our staff and students will have the full support of the University during and after this pandemic. The University (through the Russell Group) is communicating with senior colleagues in UKRI to ask for clarity on, and compensation for, any impacts on funded projects and programmes. Please bear with us as these discussions take place; we will communicate further on this once we receive more information.

If there are any questions, please discuss initially with your Executive Dean who can then forward any queries to me.

Many thanks for your understanding and cooperation.

Best wishes,

Lisa

Professor Lisa Roberts, Deputy Vice-Chancellor: Research & Innovation, University of Leeds
Marjorie and Arnold Ziff Building | LS2 9JT | Telephone: 0113 343 9739 | Email:dvc.res@leeds.ac.uk
PA: Sarah Foster | Telephone: 0113 343 9739 | Email: s.foster@adm.leeds.ac.uk

Appendix 30: Apple first review response

Reply Delete Junk Block ···

App Store Connect: Your app "PainRecord APP" (Apple ID: 1485152863 Version: 1.0 Build: 1) has one or more issues

App Store Connect <no_reply@email.apple.com>
Wed 04/11/2020 20:28
To: You

App Store Connect

Dear Developer,

We identified one or more issues with a recent delivery for your app, "PainRecord APP" 1.0 (correct the following issues, then upload again.

ITMS-90809: Deprecated API Usage - New apps that use UIWebView are no longer accept use WKWebView for improved security and reliability. Learn more (https://developer.apple.com/documentation/uikit/uiwebview).

Though you are not required to fix the following issues, we wanted to make you aware of the

ITMS-90683: Missing Purpose String in Info.plist - Your app's code references one or mor access sensitive user data. The app's Info.plist file should contain a NSLocationAlwaysUsag key with a user-facing purpose string explaining clearly and completely why your app needs Starting Spring 2019, all apps submitted to the App Store that access user data are required purpose string. If you're using external libraries or SDKs, they may reference APIs that requi string. While your app might not use these APIs, a purpose string is still required. You can co developer of the library or SDK and request they release a version of their code that doesn't APIs. Learn more (https://developer.apple.com/documentation/uikit/core_app/protecting_the_user_s_privacy).

ITMS-90683: Missing Purpose String in Info.plist - Your app's code references one or mor access sensitive user data. The app's Info.plist file should contain a NSLocationWhenInUseUsageDescription key with a user-facing purpose string explaining cl completely why your app needs the data. Starting Spring 2019, all apps submitted to the App access user data are required to include a purpose string. If you're using external libraries or may reference APIs that require a purpose string. While your app might not use these APIs, string is still required. You can contact the developer of the library or SDK and request they r version of their code that doesn't contain the APIs. Learn more (https://developer.apple.com/documentation/uikit/core_app/protecting_the_user_s_privacy).

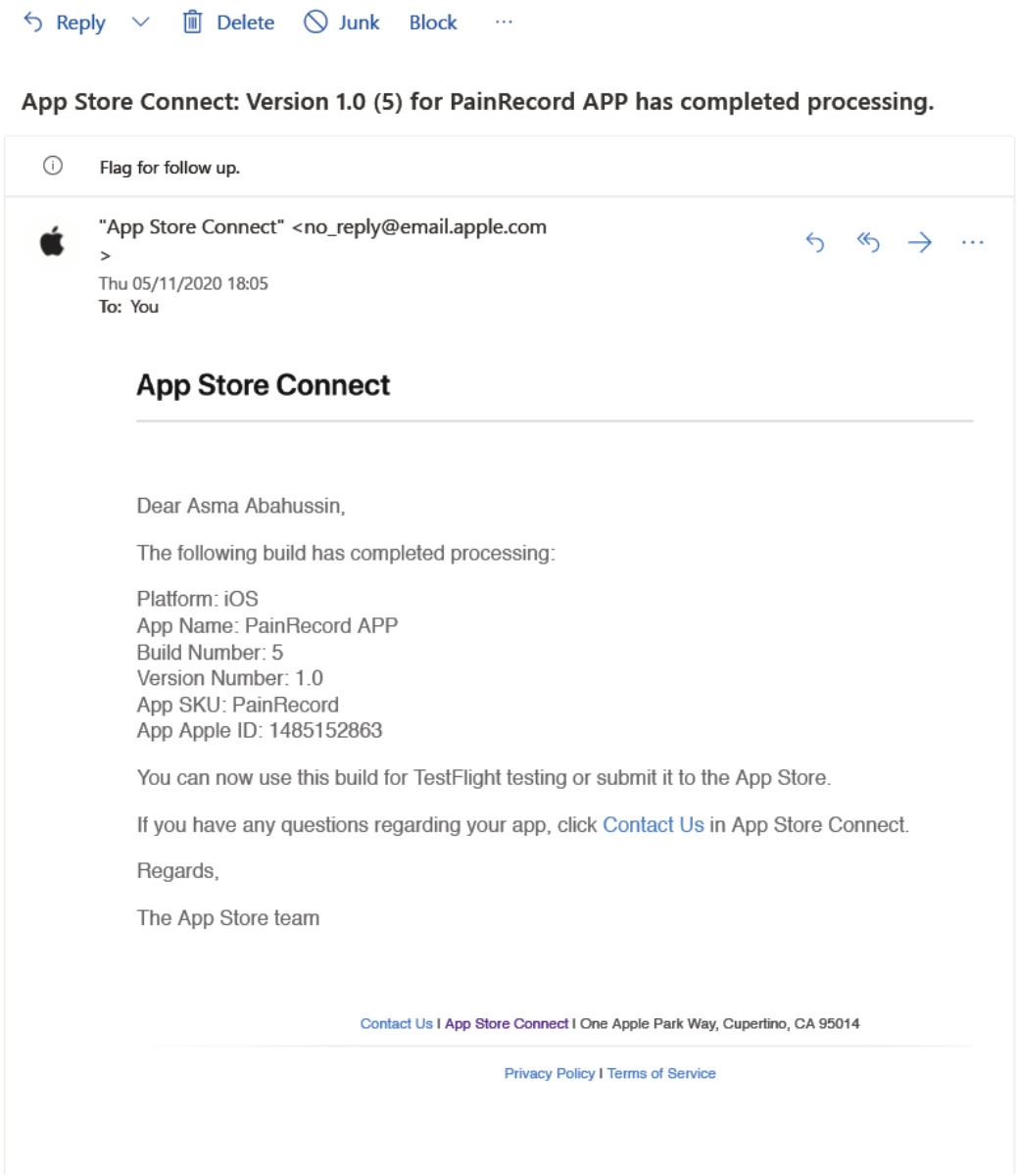
Best regards,

The App Store Team

Contact Us | App Store Connect | One Apple Park Way, Cupertino, CA 95014

Privacy Policy | Terms of Service

Appendix 31: Apple approval after first review



Reply Delete Junk Block ···

App Store Connect: Version 1.0 (5) for PainRecord APP has completed processing.

Flag for follow up.

"App Store Connect" <no_reply@email.apple.com
>
Thu 05/11/2020 18:05
To: You

App Store Connect

Dear Asma Abahussin,

The following build has completed processing:

Platform: iOS
App Name: PainRecord APP
Build Number: 5
Version Number: 1.0
App SKU: PainRecord
App Apple ID: 1485152863

You can now use this build for TestFlight testing or submit it to the App Store.

If you have any questions regarding your app, click Contact Us in App Store Connect.

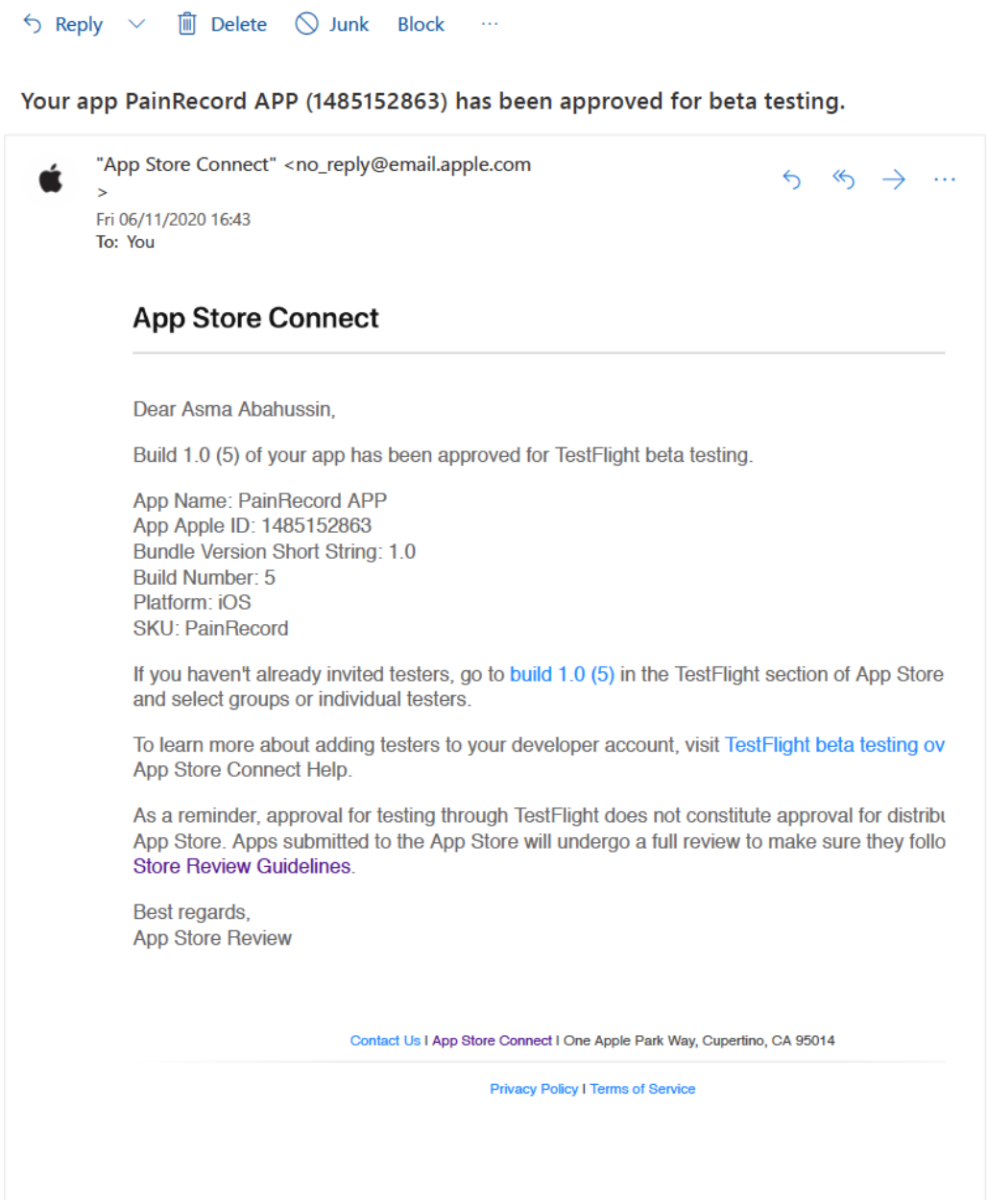
Regards,

The App Store team

Contact Us I App Store Connect I One Apple Park Way, Cupertino, CA 95014

Privacy Policy I Terms of Service

Appendix 32: Apple approval after second review



Reply Delete Junk Block ···

Your app PainRecord APP (1485152863) has been approved for beta testing.

"App Store Connect" <no_reply@email.apple.com
>
Fri 06/11/2020 16:43
To: You

App Store Connect

Dear Asma Abahussin,

Build 1.0 (5) of your app has been approved for TestFlight beta testing.

App Name: PainRecord APP
App Apple ID: 1485152863
Bundle Version Short String: 1.0
Build Number: 5
Platform: iOS
SKU: PainRecord

If you haven't already invited testers, go to build 1.0 (5) in the TestFlight section of App Store and select groups or individual testers.

To learn more about adding testers to your developer account, visit TestFlight beta testing ov App Store Connect Help.

As a reminder, approval for testing through TestFlight does not constitute approval for distribu App Store. Apps submitted to the App Store will undergo a full review to make sure they follo Store Review Guidelines.

Best regards,
App Store Review

Contact Us I App Store Connect I One Apple Park Way, Cupertino, CA 95014

Privacy Policy I Terms of Service

Appendix 33: The Covid-19 impact on the Ethics Committee

From: Lynn Auty <L.M.Auty@leeds.ac.uk>
Sent: 28 April 2020 15:59
Subject: FW: FOR CIRCULATION: School of Medicine Research Ethics Committee (SoMREC) Operation Update during Pandemic

Circulated to all LIHS Staff and PGR Students with apologies for cross-posting.

Sent on behalf of Rachel de Souza, Lead Research Ethics & Governance Administrator

SoMREC – Operation Update during COVID-19 Pandemic

The SoMREC is working with a reduced capacity but is currently closed to the review of new applications. However, new applications will be logged and issued with a study reference number but will not be sent to the committee for review until we are in a position to do so. This was instigated on Friday 20th March 2020 in line with University guidelines around research. Applications that are already in the system, including those received up to 20th March will be reviewed.

Any approved applications that require changes due to the Covid-19 pandemic-related restrictions will be scrutinised via amendments. Any Covid-19 related changes for studies pending approval should be made prior to approval being issued where possible, otherwise an amendment must be submitted prior to the study commencing.

Ethics applications related to the Covid-19 pandemic have priority. Where a Covid-19 related application will also require HRA approval, prior to being accepted for SoMREC review permission for the study to be delivered will be sought in line with the agreed Faculty process. Once the research has permission to go ahead, SoMREC will prioritise these applications.

Any research that involves any NHS staff (including clerical staff), NHS premises, resources or any other burden to the NHS is paused. Taught postgraduate students and research postgraduate students are being asked to consider their plans with their supervisors in line with the guidelines from the University.

Kind regards,

Yasmin Hafiz (she/her)

PA to Professor Mark Kearney, Dean of Medicine

School of Medicine, 7.08 Worsley Building, Clarendon Way, LS2 9NL

Email: Y.Hafiz@leeds.ac.uk

Phone: 0113 34 38040