A Realist Study of Self-management Apps to help People living with Chronic Low Back Pain

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A Realist Study of Self-management Apps to help People living with Chronic Low Back Pain

By

Rebecca Jane HUNTER

This thesis is submitted in partial fulfilment of the requirements of the University of Highlands and Islands for the degree of Doctor of Philosophy

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June 2023
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This thesis exists thanks to so many people. Firstly, I would like to express my gratitude to the Inverness and Highland City-Region Deal programme for funding my studentship. I am also extremely grateful to my colleagues in the NHS Highland Pain Service for their support.

My heartfelt thanks go to all the stakeholders and study participants who gave me their time. This thesis would not be possible without their contribution. In particular to those people living with persistent pain who shared their experiences, good and bad. I am incredibly grateful and privileged to hear their stories. I hope I have done them justice.

I was extremely lucky to have Professor Trish Gorely, Dr Michelle Beattie and Dr Ania Zubala as my supervisory team. The thesis you are reading is testament to their amazing support, mentorship, and guidance. It was never my intention to leave my clinical world and pursue a PhD. However, under their direction and with a lot of patience, they have helped me to become the clinical academic I now am. There are not enough words to express my gratitude.

I have had the tremendous good fortune to thoroughly enjoy every moment of my PhD. This is in no small part to the friends I have made along the way. Thank you to my fellow PhD students. Navigating this journey was less intimidating with you alongside.

My particular thanks go to Dr Ronie Walters and Dr Anna Melvin. To Ronie, the first person I met on this PhD adventure. I could not have done this without you. Thank you for your generous friendship, for the countless hours spent listening to my rants; for helping me to celebrate the wins and for propping me up after the knocks. To Anna, my fellow
realist nerd. You have been my invaluable sounding board throughout this process. Thank you for your encouraging words, your sage advice, and the weekly restorative chats. I can’t wait for us to meet again in person.

Finally, I would like to thank my friends and family. To Professor Simon Kirby who helped keep my imposter syndrome in check by never doubting for a moment that I could do this. To Oreo, and the reason my study door now has a cat flap. Thank you for your comfort and company in the short time you were with us. To my Mum and Dad, my most vocal cheerleaders. Thank you for the food parcels, the last-minute childcare and for the million things you still do for me.

Lastly, and most importantly, to my husband David and my son, Sam. David, there are not enough golf balls in the world to thank you for the love and unwavering support you have given me. This work has been a true partnership and I am so grateful that I could share it with you. To Sam, you were three when I started this journey and now you are about to turn nine. You have been amazing at putting up with mum working at the weekends and missing swimming trips. Thank you for our bathtime chats and bedtime stories which are always the best part about my day. This thesis is for you both.
Abstract

Background

For the majority of people with chronic low back pain (CLBP), there is no cure. Instead, clinical guidelines recommend supporting people to self-manage CLBP. Mobile health applications could help with this. However, studies to date do not explain why self-management apps may work for some people with CLBP, and not for others. The aim of this research was to understand what it is about a self-management app for CLBP that works, who it works for, why and under what circumstances.

Method

This research was conducted within the paradigm of scientific realism which uses a generative understanding of causation to explain programme outcomes. These causal explanations are expressed as programme theories. The research was designed in two parts, a realist synthesis followed by a realist evaluation.

Realist Synthesis

Six databases and several non-academic sources were searched. Sources were selected and appraised for relevancy, richness, and rigour. Nineteen realist interviews were conducted with stakeholders and also included in the review. Data was coded with analytical memos making retroductive inferences. Causal explanations were presented in context-mechanism-outcome configurations to form three programme theories under the themes of empowerment, self-management burden and timing. These were tested further in a realist evaluation.
Realist Evaluation

Nine people living with CLBP were recruited and used a commercially available self-management app for chronic pain (Curable) for twelve weeks. Afterwards, realist telephone interviews were conducted to test the CMOCs from the realist synthesis. Data was coded using abductive and retroductive logic to create 20 CMOCs. These propositions supported the initial three programme theories around empowerment, self-management burden and timing.

Conclusion

Three programme theories were created that identify how, why and in what circumstances a self-management app might support a person living with CLBP. Programme theory one suggests that, if introduced as adjunct to care, an app could be an empowering tool to self-manage CLBP. Programme theory two proposes that a mobile app can help reduce some of the self-management burden by providing people with CLBP a means of recording data that, with healthcare professional’s buy-in, could facilitate consultations. Finally, programme theory three identifies that a person with CLBP must feel believed and have accepted their condition before they are likely to use a self-management app.
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<tbody>
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<td>AI</td>
<td>Artificial intelligence</td>
</tr>
<tr>
<td>App</td>
<td>Application</td>
</tr>
<tr>
<td>CDSMP</td>
<td>Chronic Disease Self-management Programme</td>
</tr>
<tr>
<td>CCM</td>
<td>Chronic care model</td>
</tr>
<tr>
<td>CFS</td>
<td>Chronic fatigue syndrome</td>
</tr>
<tr>
<td>CLBP</td>
<td>Chronic low back pain</td>
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<tr>
<td>CMOC</td>
<td>Context, mechanism, outcome configuration</td>
</tr>
<tr>
<td>eHealth</td>
<td>Electronic health</td>
</tr>
<tr>
<td>FM</td>
<td>Fibromyalgia</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HCP</td>
<td>Healthcare professional</td>
</tr>
<tr>
<td>IASP</td>
<td>International Association for the Study of Pain</td>
</tr>
<tr>
<td>IBD</td>
<td>Irritable bowel disorder</td>
</tr>
<tr>
<td>IBS</td>
<td>Irritable bowel syndrome</td>
</tr>
<tr>
<td>IRPT</td>
<td>Initial rough programme theory</td>
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<tr>
<td>mHealth</td>
<td>Mobile health</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>MRT</td>
<td>Middle range theory</td>
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<tr>
<td>NOSRES</td>
<td>North of Scotland Research Ethics Committee</td>
</tr>
<tr>
<td>PC</td>
<td>Personalised computer</td>
</tr>
<tr>
<td>PIS</td>
<td>Participant Information Sheet</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>SMP</td>
<td>Self-management programme</td>
</tr>
<tr>
<td>ToC</td>
<td>Theory of Change</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>YLD</td>
<td>Years lived with disability</td>
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<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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<tr>
<td>Term</td>
<td>Definition</td>
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<tr>
<td>Abduction</td>
<td>Taking an observation or set of observations and making logical assumptions to explain them. Could be considered a form of ‘reading between the lines’.</td>
</tr>
<tr>
<td>Axiology</td>
<td>A concept within a research paradigm that questions the values of the research and the motivations of the researcher. Axiological considerations focus on why the research is regarded as worthwhile.</td>
</tr>
<tr>
<td>Context</td>
<td>The influential force that determines whether a mechanism is activated or not. There are many different types of contexts (e.g., social, economic, psychological); and they can operate at different levels (e.g., personal or institutional).</td>
</tr>
<tr>
<td>CMO configuration (CMOC)</td>
<td>Stands for context-mechanism-outcome configuration and is a heuristic to remind researchers of the realist way of explaining things: e.g., this particular context, generates this mechanism, which produces this outcome. It can be used at the beginning of the research project to help make predictions of how a programme might work in certain circumstances and/or at the end as a framework to structure the analysis</td>
</tr>
<tr>
<td>Critical realism</td>
<td>A philosophy of science concerned with exploring the unobservable levels of reality to explain observable</td>
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<table>
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<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>social phenomenon.</td>
<td>Whilst trying to minimise researcher bias, critical realism recognises knowledge is socially constructed. Critical realism has a distinct axiological position in that it aims to be emancipatory and challenges social norms.</td>
</tr>
<tr>
<td>Deduction</td>
<td>Creating ideas on how behaviour/events might work and testing these ideas in the real world to see if they are true. Could be considered a top-down approach to reasoning.</td>
</tr>
<tr>
<td>Epistemology</td>
<td>A concept within a research paradigm that considers how and to what extent reality can be known.</td>
</tr>
<tr>
<td>Generative Causation</td>
<td>The idea that forces which cause something to happen are triggered in particular contexts and may not always be observable.</td>
</tr>
<tr>
<td>Induction</td>
<td>Making sense of things by observing behaviour or events. Could be considered a bottom-up approach to reasoning.</td>
</tr>
<tr>
<td>Initial Rough Programme Theory (IRPT)</td>
<td>Ideas created at the beginning of a realist study that attempt to explain how and why the programme(s) of interest is thought to work by describing the context, mechanism, and outcomes at play.</td>
</tr>
<tr>
<td>Interpretivism</td>
<td>A research paradigm that assumes humans construct their own realities based on their experiences and</td>
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<td>Term</td>
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<tr>
<td>beliefs about the world and considers knowledge to be subjective.</td>
<td></td>
</tr>
<tr>
<td>Mechanism</td>
<td>The real but invisible forces that make programmes work (or not). A mechanism is not a particular component of the programme but rather, they are the reactions the participants have to the resources the programme offers (e.g., increased reassurance [reaction] as a result of a mHealth chatbot [resource]).</td>
</tr>
<tr>
<td>Middle Range Theory (MRT)</td>
<td>Theories about the context(s) and mechanism(s) that bring about particular programme outcome(s). MRTs are more general than programme theories which means they can be used to guide the implementation of a similar programme in a different setting.</td>
</tr>
<tr>
<td>Mind Independent Reality</td>
<td>A central premise of realist ontology that there is an independent reality that exists outside of our ability to conceive of it. Furthermore, this reality has an intrinsic nature that exists irrespective of our ability to conceptualise or articulate it.</td>
</tr>
<tr>
<td>Objectivism</td>
<td>The assumption there is a single, external reality which researchers should observe and measure in an impartial manner and without influence so as to be able to understand the truth of things.</td>
</tr>
<tr>
<td>Ontology</td>
<td>A concept within a research paradigm that considers the nature of reality and what is out there to be known.</td>
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<td>Definition</td>
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<tr>
<td>Outcome</td>
<td>The intended or unintended consequences of a programme.</td>
</tr>
<tr>
<td>Paradigm</td>
<td>A set of beliefs or world view that influences how researchers think about and study the world.</td>
</tr>
<tr>
<td>Positivism</td>
<td>A research paradigm that assumes there is a single, observable reality that can be objectively measured.</td>
</tr>
<tr>
<td>Post-positivism</td>
<td>A research paradigm that assumes there is a single, observable reality but our understanding of it will never be perfect since our means of creating knowledge is subject to inherent flaws.</td>
</tr>
<tr>
<td>Realist review</td>
<td>A type of literature review that seeks to explain why programmes work the way they do, who they work for and in what circumstances they work. It is characterised by its theory-led approach and its generative understanding of causation.</td>
</tr>
<tr>
<td>Realist evaluation</td>
<td>A theory-led approach to evaluation that uses primary data to explain why programmes work the way they do, who they work for and in what circumstances they work. As with a realist synthesis, the evaluation is underpinned by realist principles of generative causation.</td>
</tr>
<tr>
<td>Realist studies</td>
<td>A term used in this research to refer to realist synthesis and realist evaluation collectively.</td>
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<tr>
<td>Term</td>
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<tr>
<td>Retroduction</td>
<td>A way of making sense of things by identifying hidden causal forces to explain why observable patterns in behaviour/events come about.</td>
</tr>
<tr>
<td>Refined Programme Theory (RPT)</td>
<td>Ideas produced after the initial rough programme theories have been tested either with secondary data (realist synthesis) or with primary data (realist evaluation).</td>
</tr>
<tr>
<td>Richness</td>
<td>A term used in realist research to describe useful pieces of evidence that give detailed descriptions of programme conditions or make clear the thoughts and assumptions underlying the programme’s creation and outcomes.</td>
</tr>
<tr>
<td>Scientific realism</td>
<td>A term used in this research to describe the paradigm created by Pawson and Tilley(^1). Scientific realism assumes a mind-independent reality (reality exists whether we know it or not) and has a generative understanding of causation. Although it shares a number of assumptions with critical realism, scientific realism does not aim to be emancipatory or normative in its research. Scientific realism is a theory-led approach to research that seeks to understand why, how, for whom and under what circumstances social programmes work (or not). These theories are built from observing programme outcomes and seeking the causal mechanisms responsible and the contextual factors that activated them. Whilst aspiring to create knowledge that is an accurate reflection of reality,</td>
</tr>
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<td>Term</td>
<td>Definition</td>
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</tr>
<tr>
<td>scientific realism</td>
<td>recognises this knowledge, created through human interpretation, is fallible.</td>
</tr>
<tr>
<td>Subjectivism</td>
<td>The assumption that social reality is constructed by people’s beliefs, experiences, and cultures. Researchers look to understand the idiosyncratic nature of these different realities to make sense of social phenomena.</td>
</tr>
<tr>
<td>Substantive Theory</td>
<td>Theories that have been well-established in a particular field that help to explain certain behaviours or outcomes. Examples of substantive theory in Health and Social Care research would be Social Cognitive Theory; Self-Determination Theory; Normalisation Process Theory.</td>
</tr>
<tr>
<td>Theory</td>
<td>A way of connecting concepts or organising facts (proven or hypothetical) into a coherent explanation of a phenomenon. Theories vary in their level of abstraction (e.g., some can be specific and singular; others may be grand and all encompassing). Different types of theory have been used throughout this research and have been described in this glossary.</td>
</tr>
</tbody>
</table>
Declaration

I declare that this thesis has been composed solely by myself and that it has not been submitted, in whole or in part, in any previous application for a degree. Except where stated otherwise by reference or acknowledgment, the work presented is entirely my own.

Signature: [Signature]

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Publications and Presentations

Publications


Presentations


Hunter, R., Beattie, M. & Gorely, T (2022, February 8th). I’ve found the swamp, now what? Introduction to realist review methodology. [Webinar]. Nottingham University. https://mediaspace.nottingham.ac.uk/media/Nottingham+Realism+Group+_I%27ve+found+the+swamp%2C+now+what_Becky+Hunter+Tuesday+8th+February+2022/1_ojno6hpi
Chapter 1: Introduction

1.1 Overview
Chronic low back pain (CLBP) has been described as a “wicked problem”\(^2\). It is multifactorial, socially complex and lacks a definitive solution. Low back pain is the leading cause of global disability\(^3\) and costs the worldwide economy billions\(^4\). At a personal level, CLBP is associated with significant emotional distress and functional disability\(^5\). The prevalence of CLBP increases with age and so, with our globally ageing populations, this burden is set to increase.

International guidelines recommend supporting people to self-manage CLBP\(^6-8\). Within this guidance, patient empowerment has been identified as a key mechanism underpinning self-management\(^9\). However, there is tension in the self-management agenda between the rhetoric of patient empowerment and the reality faced by many people living with long term pain\(^10\). Whilst self-management does not mean ‘going it alone’ many chronic pain patients feel abandoned by the health care service when they are discharged to self-manage\(^11\). This was keenly felt in the early stages of the Covid-19 pandemic when NHS pain services were suspended\(^12\). In the aftermath, there were calls within the healthcare sector for a rethink in how pain management services were delivered and a push towards the use of digital technology\(^13\).

\(^*\) Parts of this chapter have been published in PEC innovation (Hunter R, Beattie M, O’Malley C, Gorely T. Mobile apps to self-manage chronic low back pain: A realist synthesis exploring what works, for whom and in what circumstances. PEC Innovation. 2023 Jun 16:100175.) and are reproduced here with their permission under the creative commons attribution licence CC BY 4.0 [online]. 2021. Available from: https://creativecommons.org/licenses/by/4.0/.
There is some evidence that self-management programmes delivered via mobile apps are effective in reducing pain and disability for people with CLBP\textsuperscript{14-16}. However, little is known about who might benefit from a mobile app and why, as to date, systematic reviews have focused on the effectiveness of mobile apps for CLBP\textsuperscript{17}. Although useful, the focus on effectiveness does not help us get inside the black box of the programme itself to understand the mechanisms that make it work. As such, there is still much to learn regarding target populations, intervention components and contextual factors to fully understand the potential mobile apps might have. Furthermore, there is little research exploring whether a self-management app is something a person with CLBP would want to use. The aim of this study is to explore how and why a mobile app might help a person self-manage CLBP. Since people living with CLBP are experts in their own condition and are the intended users of self-management apps, it was considered essential to include their voices within the research.

1.2 What is Chronic low back pain?
Low back pain can be defined as pain that manifests in the lower back between the lower rib margins and buttock creases\textsuperscript{18}. It can be accompanied by pain in one or both legs and may also come with neurological symptoms such as paraesthesia\textsuperscript{4}. Chronic low back pain describes pain that has lasted for more than three months\textsuperscript{19}. It has also been described as pain that lasts longer than the expected healing time\textsuperscript{20}. For the vast majority of people who present with CLBP no identifiable pathological cause can be found to explain their ongoing pain\textsuperscript{21}. MRI or X-ray imaging are poor diagnostic tools for CLBP since signs of spinal abnormality such as intervertebral disc or lumbar facet joint degeneration can also be found in subjects who report no back pain\textsuperscript{22}. When no specific nociceptive source can be found people are classified as having ‘non-specific low back pain’\textsuperscript{4}. 
CLBP is difficult to define because it lies outwith the two traditional pain descriptors. Non-specific CLBP is neither nociceptive in nature—i.e., associated with real or threatened tissue injury or neuropathic i.e., a disease or lesion affecting the peripheral or central nervous system. Reports estimate that 90% of patients presenting in primary care with back pain will have non-specific LBP\textsuperscript{23}. Non-specific LBP is not the only condition where the classifications of nociceptive or neuropathic pain do not apply. Fibromyalgia for example, which is estimated to affect around 2.5 million people in the UK\textsuperscript{24}, also falls under the umbrella of ‘non-specific’ pain. These figures demonstrate that, under the traditional definitions, a large group of people are left without a valid pathophysiological descriptor for their pain experience\textsuperscript{25}. To address this concern, the International Association for the Study of Pain (IASP) proposed adding the term ‘nociplastic’ as a third mechanistic descriptor of pain\textsuperscript{25}. Nociplastic pain describes a state of chronic pain in which there are clinical and psychophysical findings to suggest altered nociceptive function despite a lack of clear evidence of actual or threatened tissue damage that might activate nociceptors or neuropathic sensors\textsuperscript{25}. These three pain mechanisms are not distinct entities. In CLBP there may be a mixed pain presentation with nociceptive, neuropathic and nociplastic components forming a chronic pain continuum\textsuperscript{26}.

Despite their propensity to overlap, there are two important reasons to recognise and distinguish between the different pain mechanisms. Firstly, treatment focused on addressing the underlying pain mechanisms has been shown to be more beneficial than an approach that focuses on treating the disease or specific symptoms\textsuperscript{27}. For example, people with nociplastic pain typically respond better to centrally targeted treatments rather than peripheral ones\textsuperscript{25}. Secondly, the term nociplastic pain can help validate a person’s pain experience and aid communication between patients and health care practitioners.
Before the term nociplastic was adopted, people whose pain did not conform to the definitions of nociceptive or neuropathic pain were given descriptors such as ‘dysfunctional’, medically unexplained, ‘psychogenic’, or ‘pathological pain’. These terms carried with them an inherent stigma that the pain was not ‘real’ or that the person was making it up.

However, focusing on underlying pain mechanisms is insufficient when discussing the nature of pain. Pain is much more than a reaction to a noxious stimulant or a result of tissue damage, it is an unpleasant emotional experience brought about by a complex interplay between a person’s environment, thoughts and experience. In recognition of this the IASP of pain revised its definition of pain in 2020 to: “An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage.”

The updated definition acknowledges the all-encompassing effect pain can have on a person. As the number of people living with CLBP is increasing, further burden is placed on both the individual and society at large to manage the condition.

1.3 The impact of CLBP

1.3.1 Personal impact of CLBP

CLBP is associated with significant emotional distress (such as anxiety, anger, frustration, or depressed mood) and functional disability (interference in daily life activities and reduced participation in social roles). However, the personal impact of CLBP extends far beyond the physical suffering and emotional distress of living with persistent pain. It is well established that people living with CLBP encounter stigmatisation, social isolation, and a loss of their social role.

Struggling with CLBP can have a profound impact on a person’s sense of identity both at home and in the workplace. Many people with CLBP
are unable to work. For those who remain employed there is considerable stress brought on by trying to do their job whilst struggling with CLBP. This stress can come from many directions such as not being able to perform their tasks, hostility from work colleagues, fear of having to take time off or losing their job all of which adversely impacts on their working experience. CLBP can also negatively affect a person’s role within the family potentially restricting their ability to participate in parenting, sexual relationships and leisure activities. Role reversal, dependency and activity restriction can place tremendous strain on a person living with CLBP and their loved ones. Given the physical, psychological and social impact of CLBP it is not surprising that anxiety and depression are common in people with CLBP as well as an increased risk of suicide.

1.3.2 Socioeconomic impact of CLBP
Studies on the prevalence of low back pain tend to report ‘point prevalence’ that is, the proportion of the population affected by back pain at a given point in time. The data typically does not make clear if the figures reflect the same people with back pain or different people and if the episode is a first occurrence, a repeat episode or ongoing back pain. For this reason, the socioeconomic impact of LBP is discussed in the following sections rather than CLBP per se.

In 2019, there were 568.4 million prevalent cases of LBP worldwide and LBP remains the leading cause of years lived with disability worldwide. Exact figures on the prevalence of CLBP in the UK population are difficult to find but it has been reported that 2.5 million people in the UK have back pain every day of the year. These figures carry with them substantial socioeconomic burdens in terms of direct costs (i.e healthcare utilisation) and indirect costs such as reduced work productivity, workforce absenteeism, and social welfare costs. The economic impact of CLBP will vary from country to country depending
on the culture and social systems in place\textsuperscript{4} and not all studies include indirect costs in their calculations which makes it hard to draw comparisons\textsuperscript{4}. Regardless, it has been suggested that the true economic impact of LBP is likely to be underestimated since most studies do not consider the hidden healthcare costs of LBP such as transport to appointments etc\textsuperscript{4}.

Although the reported figures are estimations, it is clear that LBP places a considerable burden on world economies. Low back pain accounts for 12.5\% of all work absence in the UK\textsuperscript{52}. In 2016, close to 31 million workdays were lost in the UK due to musculoskeletal problems including back pain\textsuperscript{53}. In Europe, back pain is the most common reason for sick leave and early retirement\textsuperscript{4}. In a number of European studies, the cost of low back pain was estimated to vary between 1.4\% – 2.3\% of a country’s Gross Domestic Product\textsuperscript{54-56}. In the UK back pain was estimated to cost £12.3 billion\textsuperscript{57} and in the United states neck and back pain cost approximately $134.5 billion annually\textsuperscript{58}. In the European Union over €12 billion per year was spent on back pain\textsuperscript{52} and in Australia back pain was calculated to cost the economy $2.8 billion Australian dollars, representing 2.4\% of the country’s total health expenditure\textsuperscript{59}. The likelihood of developing disabling LBP increases with age\textsuperscript{3} and so, as the world’s population gets older, we can expect LBP to be a growing global concern.

\textbf{1.4 Addressing the global concern of CLBP}

In recognition of the growing burden chronic diseases are placing on both individuals and healthcare systems there have been calls made by institutions like the World Health Organisation (WHO) to move away from the acute episodic model of care towards a more organised long-term approach to managing illnesses\textsuperscript{50}. 
1.4.1 Acute vs Chronic model of care

The Chronic Care Model (CCM) developed by Wagner and colleagues in the 1990s was one way of delivering this new approach to managing chronic conditions. The CCM was created to facilitate a paradigm shift from acute, compliance-orientated care to a more appropriate long-term management of chronic illnesses\(^{61, 62}\). The model comprises six interacting components necessary for effective chronic care: delivery system design; decision support; self-management support, clinical information systems; community resources; and health care organisation\(^{61, 62}\). Together these six elements were intended to act as a ‘roadmap’ to help HCPs improve their practise and care of the chronically ill\(^{63}\). The CCM has demonstrated statistically significant improvements in outcomes from self-management support interventions across several long-term conditions\(^{64}\) and is considered particularly applicable to low back pain\(^{65}\). The CCM has influenced chronic care policies in the United States\(^{66}\), Australia\(^{67}\), New Zealand\(^{68}\), Canada\(^{69}\) and Scotland\(^{70}\).

1.4.2 Biomedical model vs. Biopsychosocial model

In addition to changing the model of healthcare provision from acute to chronic care it was recognised that there needed to be a change in how chronic conditions were treated\(^{71}\). It was Descartes in the 17th century that suggested tissue damage was directly proportional to pain\(^{72}\). This linear relationship between pathology and pain became deeply embedded in the medical profession for centuries to follow and became known as the biomedical model\(^{73}\). Within this biomedical paradigm, the absence of objective, physiological evidence of tissue damage meant pain was presumed to be psychological in nature\(^{30}\). However, the American pathologist and psychiatrist, George Engel was concerned the biomedical approach to healthcare was dehumanising the patient by separating the body from the person\(^{74, 75}\). He argued that conceptualising illness in purely biological terms was reductionist and,
as a result, could not explain the complex nature of health conditions. In response, Engel proposed the ‘biopsychosocial model’. This new model was intended to provide a more comprehensive approach to understanding and treating ill health. The biopsychosocial model treated the whole person by considering the complex interplay between the biological, psychological, and social aspects of health. Although the biopsychosocial model has been criticised for fragmenting and compartmentalising healthcare assessments— with HCPs struggling to integrate each part of the model and tending to revert to the more familiar biomedical component—this is arguably a fault in its application rather than the model itself. Despite its limitations, the biopsychosocial model has been shown to be more effective in the multidisciplinary treatment of CLBP than biomedical approaches and a biopsychosocial approach to managing low back pain has been endorsed by international healthcare guidelines.

However, HCPs are struggling to translate these guidelines into their clinical practice with many still using biomedical approaches to manage chronic pain conditions. This is important for CLBP, because the way pain is explained shapes how people think about their back, how they behave and how they interact with the environment. Poor information can have a nocebic effect by generating, exacerbating, or maintaining a person’s pain. For instance, being told to ‘watch your back’ or your vertebral discs have ‘slipped’ can lead a person to believe that their back is fragile. This in turn can cause over-protective, fear avoidance behaviour which can inadvertently cause more pain and disability. Farin, Graman and Schmidt found good communication between HCPs and patients plays an important role in predicting positive outcomes after rehabilitation for people with CLBP in relation to pain, disability, quality of life and pain-related psychological impairment. Conversely, HCPs who adhere to a biomedical approach to care show poor adherence to treatment guidelines for low back
pain and their attitudes and beliefs have shown to negatively affect the outcomes of patients with low back pain.

Since physiotherapists are key healthcare professionals involved in helping a person to self-manage CLBP it is useful to know how they deliver this care. Research suggests that it has been difficult for the biopsychosocial model to become integrated into physiotherapy practise. The norms inherent in the biomedical model remain pervasive in the education and culture of the physiotherapy profession. As a result, many physiotherapists report a lack of confidence and training to deliver biopsychosocial interventions to treat musculoskeletal conditions like CLBP. This is significant since the competence and ability of a physiotherapist to deliver treatments with a psychological component has been shown to positively influence the outcome of treatment in people with neck and back pain.

1.5 Self-managing CLBP

In recognition that ‘complete well-being’ is an untenable goal for most and acknowledging the growing prevalence of people living with chronic conditions a new understanding of health was proposed in 2011, which emphasised one’s ‘ability to adapt and self-manage in the face of social, physical and emotional challenges’. In the new definition of health, the importance of self-management is clearly stated and underpins guideline recommendations for treating CLPB. In recognition that CLBP is a long term and reoccurring condition, international guidelines recommend that treatments focus on reducing the distress and disability associated with the CLBP and supporting self-management. However, confusion over what is meant by the term ‘self-management’ and how to operationalise it has made it difficult to integrate the concept into practise and to measure its effectiveness.
1.5.1 Defining Self-management

There is no definitive definition for self-management in relation to chronic conditions. As a result, it has been critiqued as an ambiguous concept\textsuperscript{102}. Many CLBP studies\textsuperscript{17, 103, 104} have used Barlow et al.’s\textsuperscript{105} definition of self-management, which is: ‘the individual’s ability to manage the symptoms, treatment, physical and psychological consequences and lifestyle changes inherent in living with a chronic condition’\textsuperscript{(p178)}. However, other definitions of self-management can be found in the literature. Ersek et al.’s\textsuperscript{106} definition is similar to Barlow et al. but they specifically state the goal of self-management is to increase function and decrease pain. Wilkinson and Whitehead’s\textsuperscript{107} definition mentions the role of family, community and HCPs have in facilitating an individual’s ability to manage their symptoms. They also note that, in addition to the physical and psychological impact of managing long term conditions, there are cultural and spiritual consequences also. Despite these slight variations, all three definitions identify the goals of self-management but fail to make explicit the behavioural changes expected to achieve them\textsuperscript{108}.

As the current project is situated within Scotland and NHS Scotland, it is useful to consider how the Scottish Government defines self-management. In their 2004 self-management strategy for long term conditions the Scottish Government defines self-management as: “A person-centred approach in which the individual is empowered and has ownership over the management of their life and conditions”\textsuperscript{(p12)}. Although the Scottish Government identified empowerment as a key component of self-management they failed to explain what they mean by the term ‘empowerment’ and, like the previous definitions on self-management, what behaviour changes to look for to determine if a person has become empowered to self-manage.
The difficulty in defining self-management is compounded by the literature which often uses self-management and self-care as synonymous terms\textsuperscript{109}. Although there are variations in how the concept of 'self-care' is defined\textsuperscript{9, 110, 111}, the important distinction between the self-management and self-care, is that self-care, for the most part, does not involve a healthcare professional whereas self-management does\textsuperscript{112}. Failing to recognise the essential role and influence healthcare and social support play in the self-management process has led to criticism being levelled at the word 'self' in self-management.

Some authors have described self-management as an oxymoronic phrase since it does not reflect the complexity of how long-term conditions are managed\textsuperscript{113}. Which is to say that 'self-management' was never intended to be something that people were expected to do alone\textsuperscript{8}. However, many patients report to feel abandoned when they are discharged from the healthcare service\textsuperscript{11}. Arguably the lack of clarity in what is meant by the term 'self-management' has made the concept vulnerable to misinterpretation and misappropriation\textsuperscript{114}. As governments are increasingly shifting healthcare responsibilities away from the state and on to the individual\textsuperscript{115} the idea that self-management is a collaborative effort and not a solo one may be getting lost.
Given the lack of clarity around the term self-management in relation to CLBP, it was considered important to provide a clear definition of how self-management was applied in this research. Drawing on the work of a number of key papers\textsuperscript{105, 107, 116-118} Figure 1.1 provides a definition of self-management as it has been applied to this work.

![Figure 1.1: Definition of Self-Management of CLBP](image)

1.5.2 Operationalising Self-management

A lack of clarity in how to define self-management in relation to chronic pain conditions has made it challenging to operationalise\textsuperscript{119} and evaluate\textsuperscript{108} self-management interventions. This difficulty is compounded because self-management can mean different things depending on the illness and the desired outcomes\textsuperscript{120}. Certain tasks and skills will be more significant depending on the condition needing to be self-managed\textsuperscript{121}. For instance, self-managing rheumatoid arthritis includes self-monitoring and tracking symptoms, medication adherence, lifestyle changes and collaborating with healthcare decisions\textsuperscript{122}. By contrast, self-managing asthma has more of an emphasis on controlling symptoms, preventing acute exacerbation, and improving lung function\textsuperscript{123}. In documenting the work of living with a
chronic disease, Corbin and Strauss\textsuperscript{124} were the first to identify the processes of self-management\textsuperscript{121} breaking it into 3 sets of tasks: medical management, behaviour management and emotional management.

Building on Corbin and Strauss’s model and combining it with their own research findings, Lorig et al’s\textsuperscript{125} Chronic Disease Self-Management Programme (CDSMP) emphasised three self-management skills: problem solving; decision making and resource utilisation. The CDSMP also stressed the importance of forming of a good patient/health care provider partnership and action planning. Although the CDSMP has been critiqued for lacking sufficient detail to replicate\textsuperscript{126} and failing to recognise the importance of family and social support\textsuperscript{127} it is one of the most widely used and researched self-management programmes\textsuperscript{63}. As such, the CDSMP has influenced how self-management has been operationalised in CLBP studies\textsuperscript{17, 128} including this research.

Self-efficacy is considered the central driver of behaviour change and improved patient outcomes in the CDSMP\textsuperscript{61, 116, 129}. Self-efficacy is a central theory in Bandura’s Social Cognitive Theory\textsuperscript{130, 131} and has been identified as a key behaviour change theory in the self-management of chronic conditions\textsuperscript{118, 132}. Self-efficacy is an individual’s belief in their ability to successfully learn and perform a specific behaviour to achieve a desired outcome\textsuperscript{130}. Self-efficacy is considered a key moderator and mediator of behaviour change in the self-management process\textsuperscript{111}. The theory is repeatedly used in the research on self-management interventions for chronic conditions as evidence by Miller et al’s\textsuperscript{133} study. In their concept analysis of chronic disease self-management interventions, 111 articles from a total of 226 included in the analysis specifically mentioned being guided or influenced by theoretical
frameworks. Of those 111, a little under half (n.54) used self-efficacy theory.

Although self-efficacy has been used extensively in the self-management literature —including mHealth research on low back pain\(^{134}\) —some have suggested self-efficacy is too individualistic in its focus and neglects the social context in which health behaviour takes place\(^{135}\). An alternative but related concept —which often appears in research alongside self-efficacy— is patient empowerment\(^{136-138}\). As previously noted, the Scottish Government identified empowerment as being integral in self-managing long term conditions. Aujoulat et al.\(^{139}\) described empowerment as “a process by which a person is able to act on a situation previously thought to be overwhelming or impossible to cope with”\(^{1230}\). An empowered patient has been described as someone who is “actively and autonomously involved in decision making related to his/her health”\(^{140}(p224)\). However, ‘empowerment’ can be interpreted differently amongst patients, HCPs and policy makers which can lead to tension between the groups\(^{10},\,141\). This is especially problematic when, as is the case with the Scottish Government’s self-management policy, there is a lack of clarity as to how empowerment is defined. Since these tensions are an important contextual factor in this research project, they are briefly discussed in the following section.

1.5.3 Tensions in the Self-Management Policy

In the 1960’s and 70’s a self-care social movement grew out of the discontent many felt at being marginalised and ignored by the medical profession when it came to managing their own healthcare\(^{142}\). Criticism

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* Parts of section 1.5.3 have been published as a blog post for the Physiotherapy Pain Association (Hunter, 2022. Available from https://ppa.csp.org.uk/news/2022-01-11-ppa-blog-patient-empowerment-part-neoliberal-agenda) and are reproduced here with their permission under the creative common’s attributions licence. CC BY 4.0 [online]. 2021 Available from: https://creativecommons.org/licenses/by/4.0/.
was levelled at healthcare professionals for their failure to recognise that people with chronic diseases had an expertise in regard to their own body. This expertise, derived from their lived experience, meant they should be considered equal partners in their healthcare with the right to choose their own treatment and management\textsuperscript{143}. This necessitated a paradigm shift in which the locus of control and agency over a person’s health moved away from the healthcare professional and onto to the person living with the condition\textsuperscript{144}. Central to this movement were the concepts of autonomy, personal responsibility and empowerment in the context of rejecting the traditional ‘doctors knows best’ culture\textsuperscript{142}. However, further discontent has arisen amongst some patients and health advocates who feel their right for autonomy and empowerment has been co-opted by the government as a way of cutting healthcare expenditure\textsuperscript{145}.

In the 1990s and early 2000s the UK Government capitalised on self-management as a means of reducing healthcare utilisation in the wake of growing numbers of people living with chronic conditions\textsuperscript{146}. In response to the sustainability crisis faced by the NHS, the Government sought to empower patients to take better care of their own health\textsuperscript{147}. In 2002, the Wanless report was commissioned to evaluate the financial resources needed to meet the rising demands being placed on the National Health Service. The report stated that promoting patient self-management had the potential to save the UK economy billions of pounds\textsuperscript{148}. It also noted that when people are not fully engaged in their own care, opportunities to reduce the healthcare burden are lost. This set the tone for healthcare policies in the years to come.

The language embedded in the Wanless report and subsequent polices has been interpreted by some with a neoliberal lens in which a social and moral obligation is placed on the citizen to ‘choose’ to become a fully activated and responsible participant in the management of their
own wellbeing\textsuperscript{145, 149, 150}. If a person ‘chooses’ to follow self-management programmes set out by government institutions, they are regarded by society as ‘good self-managers’. Conversely, if a person chooses not to be accountable for their own health they are ‘bad self-managers’: adding to society’s burdens rather than helping it\textsuperscript{151}. It has been argued that strategies which impose a moral responsibility on the individual for maintaining their own health care risk becoming exploitative rather than empowering\textsuperscript{152}.

Despite entitling their self-management policy ‘Gaun Yersel’ (Go on Yourself), the Scottish Government were keen to stress that self-management was not something a person was expected to do alone\textsuperscript{8}. Rather, self-management was a collaboration and partnership between the patient and HCP. However, there are inherent difficulties in reconciling a self-management policy that supports collaboration with a HCP, whilst at the same time claiming self-management is something that could reduce healthcare utilisation. This has created a dilemma for HCPs since no guidance has been offered on how to support both agendas.

A systematic review of patient-professional partnerships and chronic back pain self-management revealed most patients wanted quick and easy access to healthcare services, such as physiotherapy, with the availability of follow-up contact or review sessions\textsuperscript{153}. Throughout the literature people with CLBP repeatedly requested follow-up sessions to provide reassurance and to maintain motivation with self-management\textsuperscript{154-159}. This presents a challenge for physiotherapists to provide ongoing self-management support whilst being cognisant of the economic pressure within a healthcare system that employs them\textsuperscript{160}. In their search to understand what constituted a ‘good self-manager’ Ellis et al.\textsuperscript{151} found HCPs and healthcare commissioners used the term to describe individuals who were more autonomous and less dependent
Although reduced dependency may be considered a positive outcome in respect to a healthcare service trying to save money; failing to provide follow-up or ongoing support has led some people with CLBP to feel they have been abandoned to self-manage on their own.\textsuperscript{11}.

1.5.4 Efficacy of CLBP self-management programmes

In light of these tensions within the self-management policy it is worth considering whether self-management programmes are effective in helping people living with CLBP. Without an agreed definition for chronic pain self-management there has been a lack of standardisation in how self-management programmes for CLBP are delivered and evaluated. This heterogeneity makes it difficult to evaluate the effectiveness of self-management interventions on CLBP. That said, there have been two systematic reviews and meta-analysis that have evaluated self-management programmes for LBP.\textsuperscript{162, 163}

Olivera et al.’s\textsuperscript{162} systematic review and meta-analyses on self-management interventions for low back pain used the six core components of effective self-management outlined in the Australian Government’s Primary Health Care strategy:\textsuperscript{164} 1) knowledge of the condition and management options, 2) negotiation of a plan with HCPs, 3) participation in health-promoting activities, 4) self-monitoring and management of signs and symptoms, 5) management of psychological and physical impact of the condition, and 6) confidence in their ability to use support services. Olivera et al. identified 13 trials studies that met these criteria. Using the Grading of Recommendations, Assessment, Development and Evaluation approach (GRADE)\textsuperscript{165} to interpret the results, they found moderate quality evidence that, when compared to minimal interventions (e.g. waiting list, usual care, and written information), self-management interventions had a small (less than 6 on a 100 point scale) but statistically significant effect on pain.
and disability for people with low back pain. However, there was low quality evidence that showed self-management was equally or less effective than interventions such as massage, acupuncture, yoga and exercise. Based on these results Olivera et al. questioned whether a 6% decrease in pain and disability made self-management interventions a worthwhile investment for both the patient and the healthcare service compared with a minimal intervention.

In a later systematic review and meta-analysis. Du et al. focused on self-management interventions as a treatment ‘package’ which included six core components: problem solving; decision making; resource utilisation; forming a therapeutic relationship between HCP and patient, goal setting and action planning, and self-tailoring. Unlike Olivera et al.’s previous review, which included patients with low back pain of any duration, Du et al. specifically focused on CLBP, defining ‘chronic’ as pain that had lasted longer than 12 weeks. Their review included 13 randomised controlled trials (RCTs) comparing self-management programmes with usual care, waiting-list control, exercise programmes and occupational therapy sessions. From their analysis, Du et al. found self-management programmes had a moderate, significant effect in reducing pain intensity in the first year. They also found for disability, there was a moderate significant effect in improving symptoms immediately after treatment and at three months follow up; as well as small but significant effects in the intermediate and long term (within the first year).

Based on these results Du et al. concluded that self-management programmes could play a safe and positive role in helping people living with CLBP. However, because the focus of the review was on efficacy, Du et al.’s study does not offer an insight into who might find these programmes effective and why. Furthermore, whether self-management programmes are effective or not becomes a moot point if
people with CLBP are unable to access them. In their guidance on practice implications, Du et al. suggest that, in addition to face-to-face-treatment, internet-based approaches could be useful in delivering self-management programmes to make them more accessible and convenient to patients.

1.5.5 Access to self-management programmes for CLBP.

Timely access to pain self-management programmes is essential since increased waiting times have been shown to have a detrimental impact on a person’s pain, disability, mental health, and quality of life. However, waiting times to access physiotherapy and specialist pain services who deliver CLBP self-management programmes can be lengthy. This problem has been exacerbated by the Covid-19 pandemic. There are also issues over inadequate numbers of pain specialist staff to meet the rising demand of chronic pain patients. In addition, in countries where healthcare is not free at the point of use, concerns over costs or insurance coverage may prevent people with CLBP from accessing care. Other barriers include transport issues to access programmes. Against this backdrop self-management programmes delivered by mobile apps have the potential to provide people with CLBP timely, cost effective and equitable access to ongoing support.

Despite access to pain treatment being a fundamental human right, at the height of the global Covid-19 pandemic, pain services worldwide were categorised as non-essential and temporarily suspended. This enabled healthcare resources to be redirected to intensive care units, respiratory wards, and other Covid-19 related services. However, it also removed much needed support for people living with chronic pain. The Covid-19 pandemic has prompted a rethink in how pain management services are delivered with an emphasis being placed on
digital technology, to enable ongoing support when physical access to healthcare services is not possible\textsuperscript{13}.

The use of mobile health (mHealth) technology was already on the rise, but the global pandemic accelerated the trend. In 2021, there were over six billion smartphone subscriptions worldwide and this figure is forecasted to grow by several hundred million in the next few years\textsuperscript{175}. According to a report published in 2021 by the IQVIA Institute for Human Data Science there are over 350,000 health-related apps commercially available worldwide with over 90,000 health apps being added in 2020 alone\textsuperscript{176}. These figures point to the ubiquity of mHealth apps in people’s everyday lives and their increasing popularity.

\section*{1.6 mHealth}

\subsection*{1.6.1 Introduction to mHealth}

Electronic health or eHealth has been defined by the WHO “as the use of information and communications technologies to support health and health-related fields”\textsuperscript{177(n.p)}. Mobile health or mHealth is a sub-category of eHealth and describes health practises which are supported by mobile phones or other wireless communication devices\textsuperscript{178}. The key distinction between eHealth and mHealth as it relates to this research is that eHealth self-management interventions for CLBP are web-based programmes accessed by a laptop or personal computer (PC) whereas mHealth interventions are programmes typically accessed via a mobile application (app) that can be accessed whilst ‘on the move’ using a smartphone or tablet.

\footnote{Although Brew-Sam (2019, p.18) notes the distinction between eHealth and mHealth is getting increasingly blurred now that online content is available anywhere from either a mobile or static device.}
This research adopts Danaher et al.’s description of mHealth interventions as “typically behaviourally or cognitive-behaviourally-based treatments that have been operationalized and transformed for delivery via mobile devices”\(^{(p92)}\). As technology has advanced mobile phones have become ‘smarter’ and their functionality now extends beyond the simple text messages and calling features of earlier models. In addition to making telephone calls, smartphones now offer users the ability to access the internet, download apps, record, and send videos, listen to music and podcasts, video chatting and more. As smartphones have become more sophisticated, so too have mHealth apps prompting a keen interest amongst healthcare authorities in unlocking their potential.

1.6.2 The potential of mHealth

In March 2018, at the 71\(^{st}\) World Assembly, WHO recognised mHealth as an important resource for health service delivery due to their ease of use, broad reach and wide acceptance\(^{178}\). With the rapid improvement in technology infrastructure, digital literacy, and growth in global cellular networks even people in low-middle income countries who hitherto have been excluded from these advantages have much to gain from mHealth technology\(^{180}\). It has been suggested that mHealth can be a particularly efficient way of delivering healthcare services to low-income patient populations\(^{181}\), to those living in inaccessible areas\(^{182}\) as well as vulnerable and marginalised groups\(^{183}\).

In comparison to internet programmes delivered on a PC or laptop, a mobile app can be taken with the individual anywhere allowing for more frequent interactions\(^{179}\). With more frequent data inputs the app has the potential to build up a picture of the user which in turn gives the opportunity to tailor the intervention to the user’s fluctuating psychophysical state and environmental context\(^{184}\). It has been suggested that digital therapeutic care delivered via mHealth apps can help people pro-actively self-manage their low back pain by providing explanatory educational material; physical and mindfulness exercises
as well as providing encouragement in the form of tailored feedback messages, push notifications and data driven activity recommendations\textsuperscript{185}. Furthermore, mHealth can provide the ongoing support promised in self-management policies but often found lacking in current pain services. mHealth can also provide standardised, evidence-based information thus reducing variation of pain treatment delivered between clinicians and health care services\textsuperscript{186}.

1.7 mHealth apps to self-manage CLBP

1.7.1 Current evidence

In their review of eHealth (web based and mobile based) self-management programmes for low back pain, Du et al.\textsuperscript{187} conducted a subgroup meta-analysis to see if there was a difference between delivering a web-based self-management program on a PC or a mobile based one delivered via an app. Although this analysis consisted of only 3 studies\textsuperscript{16, 134, 188}, the researchers found mHealth had a superior effect in terms of decreasing pain and disability in comparison to web-based self-management programmes\textsuperscript{187}. A more recent scoping review also found promising evidence that people with CLBP would benefit from self-management mHealth apps alongside traditional care\textsuperscript{189}. However, in both studies, the research question asked whether these mHealth interventions were effective and there was no focus on how and why these effects came about. As a result, mHealth apps for CLBP remain opaque ‘black boxes’ without much understanding as to how, why and for whom these interventions might benefit.

1.7.2 Research gaps and justification for this research

Chib et al\textsuperscript{190} created a model with which to categorise mHealth studies. This model placed mHealth studies into three categories: inputs, mechanisms, and outputs. Input studies focused on accessibility, usability, usage, and data quality. Output studies looked at clinical outcomes (e.g. pain and disability) whereas mechanism studies were
interested in behaviour change (e.g. adherence, motivation). The author applied Chibb et al.’s tripartite model to Rintala et al.’s 2022 scoping review on mHealth apps for low back pain self-management to get an idea as to the kind of mHealth studies that have been conducted to date. Of the seven studies included in the review, four could be categorised as output studies\textsuperscript{16, 191, 192, 193}, one as an ‘input study’\textsuperscript{194} and one\textsuperscript{195} had both an input and an output focus. Only Irvine et al.’s study\textsuperscript{134} covered all three categories by using theory to help identify underlying explanatory behavioural mechanisms like adoption and self-efficacy as well as reporting on physical outcomes (output) and process outcomes (input). Interestingly, the Irvine et al. study, published in 2015, was the oldest of the seven studies. With the more recent studies in Rintala et al’s scoping review focusing on outputs it suggests this has become the current direction of focus in mHealth research on self-management apps for CLBP.

This lack of mechanism-focused research in studies identified by Rintala et al. is consistent with another study undertaken by Chib et al.\textsuperscript{196} which evaluated the theoretical advancements of mobile apps. Only 16 studies (19\%) of the 85 articles included in their review were ‘mechanism’ studies. Of these sixteen, a little over half (n.9) studied the adherence mechanism (i.e. why users continue to engage with an app and if they follow instructions). The remaining studies used theories such as the technology acceptance model to explore adoption mechanisms and others used behavioural change theories such as COM-B theory and the transtheoretical behaviour change model to explore motivation mechanisms. None of the apps in the 85 articles included in Chib et al’s review addressed CLBP and although there were apps designed to facilitate self-management (for weight loss and falls prevention for example) no theory of empowerment was used to explore mechanisms. To our knowledge there have been no published studies to date that have explored a theory of empowerment in self-
management apps for CLBP despite the Scottish Government identifying empowerment as a key component to self-managing long term conditions.

Without theory-led research into mechanisms, we are left not knowing who an intervention might work for, why and in what circumstances. Furthermore, not knowing why an intervention works makes it difficult to replicate the intended effects. Theories can help to identify the behavioural mechanisms and contexts likely to bring about a desired outcome and in so doing potentially increase the effectiveness of both the intervention and its implementation\textsuperscript{184}. Recognising the value in theory-led research, the Medical Research Council (MRC) recommends that an evaluation of a complex intervention begin with theory development around how the intervention is thought to bring about a change\textsuperscript{197}. The MRC considers an intervention complex if it involves a number of interacting components; targets a range of behaviours; requires expertise and skills from those delivering and receiving the intervention; has a number of outcome measures and permits a degree of flexibility or tailoring of the intervention and or its components\textsuperscript{198, 199}. By this definition, a mobile app delivering a self-management programme to help people with CLBP can be considered a complex intervention. The lack of mechanism studies in mHealth research on self-management apps for CLBP and the MRC’s recommendation to use theory when evaluating complex behaviour change interventions guided the decision to undertake a theory-led study into mobile apps to self-manage CLBP.
1.8 Chapter 1 Summary

Figure 1.2: Chapter 1 Summary

1. Chronic low back pain (CLBP) is important because it affects a lot of people globally and the numbers are increasing.

2. Addressing the issue of CLBP requires a shift in how healthcare services are delivered and how care is administered to people living with chronic conditions.

3. International guidelines recommend people with CLBP should be treated with self-management support but this concept is poorly defined.

4. This lack of clarity as to what self-management means has made it hard to operationalise and assess its effectiveness.

5. There are also tensions underlying the self-management agenda which threaten to undermine it, such as lack of ongoing support.

6. mHealth could help mitigate some of these issues by providing timely, cost effective and equitable access to ongoing self-management support.

7. Current research into the effectiveness of mHealth has mainly focused on inputs and outputs and not mechanisms.

8. More theory based research is needed to know why, how and for whom mHealth apps could be beneficial for people self-managing CLBP.
Chapter 2: Methodology*

2.1 Introduction
Having established the need for more theory-led research in the field of mHealth and noting the declining trend in mechanism focused studies of self-management apps for CLBP, this chapter introduces scientific realism, the theory-led approach adopted in this research project. It begins by introducing three common paradigms in health and social science research: positivism, post-positivism and interpretivism. This is followed by an explanation of scientific realism and how it is situated amongst these paradigms. This explanation involves a discussion of how elements of critical realism have shaped scientific realism but how the latter is a distinct paradigm in its own right and why scientific realism and not critical realism was adopted. Since this research is a theory-led design, a short introduction on approaches to theory development follows before introducing the principles of Pawson and Tilley’s realist methodology and how it has been applied in this research to meet the work’s aims and objectives.

In explaining how scientific realism has been used in this research, definitions of mechanisms and context have been outlined for clarity. In addition, since the application of the CMO heuristic can differ between realist research, an explanation of how context-mechanism-outcome configurations (CMOCs) have been used in this work has been made explicit with a worked example. Finally, because scientific realism is

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not the only form of theory-led evaluation, the chapter concludes with a brief comparison of Theory of Change evaluation and their use of logic models. This comparison serves to strengthen the justification for choosing scientific realism in this research.

2.2 Research philosophies and paradigms in healthcare

According to Kuhn200, a scientific paradigm is a set of common assumptions and beliefs that influence how scientists think about and address problems. Kuhn cautioned that scientists operating within different paradigms may lack the ability to communicate and collaborate effectively with each other due to fundamental differences in their methodologies and definitions of reality201. This is because a researcher's paradigm will influence what they consider to be reality (their ontology); how they understand that reality (their epistemology); and the value judgements they make (their axiology). Collectively these positions affect their methodological decisions. It is therefore important that researchers be clear as to the paradigm they operate in and the impact this has on their ontological, epistemological, and axiological positions so that others, who may not share this worldview, can understand their approach202. Each research philosophy comes with its own set of assumptions based on its ontological, epistemological, and axiological position. These philosophies lie on a continuum between two opposing extremes: objectivism on one end and subjectivism on the other. These philosophical assumptions are applied to research via paradigms203. Each paradigm has a different worldview or set of beliefs that determines what counts as knowledge and evidence. This in turn, influences the purpose of scientific research and how it is conducted204. For instance, positivism and post-positivism research seeks to predict, constructivism seeks to understand whereas critical realism seeks to emancipate205.
As illustrated in Figure 2.1, there are many different research paradigms in social and behavioural research and a full discussion of them is out with the scope of this work. Within the field of health and social care, in which this research is situated, two paradigms: positivism and interpretivism are often used as reference points to discuss different research philosophies since they sit on either end of the objectivist-subjectivist continuum. Sitting between these poles are the paradigms of post-positivism and critical realism. Although arguments have been made that paradigms are incommensurable, scientific realism adopts a pragmatic approach to research and features of both post-positivism and critical realism can be found within it. The following section gives a brief outline of these three paradigms and is considered a prelude before explicating where scientific realism sits on the research philosophy continuum.
Figure 2.1: The Multidimensional Model of Research Methodology

2.2.1 Objectivism and subjectivism

To appreciate the differences between positivist, post-positivism, and interpretivism, it is useful to discuss the objectivist-subjectivist continuum on which they sit. Objectivism assumes there is a single, external reality which is experienced by all social actors. Objectivists consider social entities to have an enduring character that exist out with of our interpretation or experience of them. As such, these social entities can be studied in much the same way as physical entities would be in the natural world. Guba and Lincoln have likened this objectivist stance to a researcher standing behind a one-way mirror observing and objectively recording natural phenomena without influencing it. Relating this approach to the field of medicine, an objectivist would consider there to be recognisable and objective facts about the human body and what is considered normal functioning to maintain good health. From this perspective, the human body can be studied in an objective way for signs of malfunction to identify disease.

Epistemologically, objectivists study the social world through impartial collection of observable data, in the pursuit of universal laws or absolute norms to explain phenomena. This process involves trying to remove or control for extraneous causal factors that may impact their study. From an axiological position, objectivism aspires to be as free from bias, prejudice and interpretative judgements as possible.

At the other end of the spectrum, subjectivism asserts that social reality is created by the perceptions and actions of the social actors within

* Murphy (2008) notes this view of objectivism would nowadays be termed ‘naturalism’. Whilst recognising the substantial body of literature around objectivism/naturalism and the normative values placed on what is considered to be good or bad health, the general point being made in this context remains the same whether it is termed objectivism or naturalism.
it. In other words, it is people who build their unique reality based on their own beliefs and experiences. For subjectivists, there are multiple social realities which are in a constant state of flux due to the nature of the social interactions on which they are built. The epistemological approach to subjectivist research is to collect different narratives, opinions, and experiences from social actors to build an understanding of how they perceive their reality. Rather than control for extraneous causal factors, subjectivists would assert that these factors are the key to reaching a deeper understanding of people’s social reality.

2.2.2 Positivism and post-positivism

Positivism sits at the objectivist end of the aforementioned continuum. Ontologically, the positivist paradigm assumes there is an independent, singular, reality that exists untouched by human influences and can be observed and measured. In much the same way as the natural world is governed by immutable laws, positivists assert that social phenomena are ruled by social laws. These laws are constructed from the repeated and systematic gathering of empirical data that demonstrate cause and effect relationships (in Humean terms known as constant conjunctions) which, once established can be used to explain reality.

Epistemologically, objectivism underpins the positivist paradigm and was long considered to be the gold standard approach in healthcare research to support evidence based medicine. Only observations of phenomena that could be measured and that were free of external influence (bias) were considered credible and meaningful data with which to build human knowledge. To meet this criteria positivists hold a dualist and objective approach to investigation, believing it is possible for the researcher and research subject to be separate entities, neither one influencing the other. By separating themselves in this way
positivists believe the knowledge they create can be considered to be true of reality. Methodologically positivism research follows a hypothetico-deductive model. This is a cyclical process that begins with a hypothesis which is then tested in an environment that has been carefully controlled to minimise (as far as possible) any confounding variables. The results are used to confirm or refute the original hypothesis. The goal of positivist research is to produce findings that could be used to explain and predict phenomena so as to be able to create universal laws.

Whilst post-positivism shares a common understanding that there is a single, tangible and objective reality it departs from positivism in the assumption that this reality can ever be truly ‘known’. Post-positivism, whilst striving for objectivity, acknowledges that humans are fallible and subject to external influences which will inevitably affect the nature of their study and the knowledge they create. As a result, observations and measurements will be imperfect and so too, our understanding of reality. This means, whilst the truth is out there, our understanding of it will always be partial, incomplete and flawed. For this reason, post-positivism adopts a falsification approach to scientific enquiry. Unlike, positivism that assumes a theory can be proven correct, post-positivism set out to falsify theory. To use Popper’s well-known example (see Figure 2.2), millions of white swans may be observed over thousands of years leading to the generalisation that all swans are white. However, it only takes one black swan to prove this generalisation false. In other words, it is impossible to observe all
swans to be certain of the theory that ‘all swans are white’ and thus post-positivists argue a theory can never be considered ‘true’.

However, it is possible to prove a theory false and in this way, through continual theory refinement science progresses. In sum, post-positivism sits towards the objectivism end of the continuum in its assumption that there is an external reality which researchers strive to study objectively but moves towards the subjectivist end of the spectrum in its recognition that research is influenced by human nature and therefore the best we can hope to achieve is an approximation of the ‘truth’. 
2.2.3 Interpretivism

Interpretivism is situated on the opposite end of the objectivist-subjective continuum. There are many strands to interpretivist research including constructionism, constructivism, postmodernism, poststructuralism, and ethnomethodology and others. For the sake of this general discussion, interpretivism has been used as an umbrella term that encompasses these different approaches which share common philosophical assumptions. Ontologically interpretivism assumes there are multiple realities, and truth is subjective. Interpretivism rejects the positivist notion that life’s complexity can be reduced to universal social laws. Different people, from different times and cultures will create their own idiosyncratic realities\(^{210}\). From an epistemological position, interpretivism assumes the researcher and the research object are inextricably and interactively linked\(^{211}\). As a result the knowledge created is a social co-construction between the researcher and the research subjects which will be mutually influenced by their experiences, history, culture and goals\(^{221}\). The goal of interpretivist research is to understand the lived experience from the perspective of those who live it.

2.3 Outlining the paradigm of Scientific Realism

The research in this thesis was undertaken within the paradigm of scientific realism\(^*\), specifically the approach developed by Pawson and Tilley\(^{1, 222, 223}\). Like positivist and post-positivism, scientific realism adheres to a mind-independent reality. This is the premise that reality has an independent and intrinsic nature that exists outside of our ability to conceive of it\(^{224}\). However, the paradigms differ in the empirical

\(^*\) Pawson and Tilley (1997) use the term scientific realism to describe their approach, but this was later debated by Pawson (2006, 2013) who was unable to settle on a term. Despite the lack of nomenclature, the principles underlying the paradigm remain consistent throughout Pawson’s work and in the absence of an alternative shall be referred to as scientific realism in this research.
assumption that reality can be seen and observed. Ontologically, scientific realism aligns with Bhaskar\textsuperscript{225} and the philosophy of critical realism. This approach is underpinned by the ontological assumption that reality is stratified into three overlapping layers: the empirical, the actual, and the real. The empirical domain is the level at which phenomena can be observed and measured; in the actual domain, phenomena exist and have real effects on outcomes but are not directly observable and in the domain of the real, phenomena are unobservable with latent potential that, when the context is right, can become activated. It is because of their position that reality is stratified that scientific realism places an emphasis on obtaining ‘ontological depth’.

Ontological depth describes the process of going ‘below’ the empirical level to build an explanation of a phenomenon by theorising about what is happening at different layers of reality. Jagosh\textsuperscript{226} used the metaphor of an iceberg to depict the concept of ontological depth (see Figure 2.3: Realist concept of ontological depth adapted from Jagosh\textsuperscript{226}.)
2.3). The empirical layer was envisaged as the tip of the iceberg that could be seen sticking out of the water and, as one sinks below the water (a reference to ontological depth) we begin to take in the domain of the actual and then, deeper still, the domain of the real. A central premise in realist ontology is the assumption that although things cannot be seen they are no less real and, furthermore, even if they cannot be seen they can still have an effect on reality. This view of reality is reflected in the notion of generative causality. Put at its simplest, generative causation is the idea that what is happening under the surface, unseen, generates something to happen at the top which we can see.

In scientific realism, these unobservable, causal phenomena, are referred to as mechanisms. When studying a social programme,
those resources. Exploring how mechanisms work within a particular context is central to realist research. This generative model of causation (see Figure 2.4) proposes that in order to understand how X and Y brought about a respective outcome, one must appreciate what the underlying mechanism(s) might be and show an appreciation for how context influences the way the relationship plays out. Pawson and Tilley created the CMO heuristic to help explain this retroductive causation of how and why things work.

The epistemological position of scientific realism aligns with a constructivist (interpretivist) paradigm. In realist research, knowledge is subjectively constructed using abductive and retroductive logic. Retroduction describes a process of thinking in which one observes an outcome or experiences a phenomena and then attempts to reason backwards to theorise what underlying mechanisms were responsible. Retroduction can involve both inductive and deductive theorising; the former using evidence to create new causal insights and the latter using evidence to test the causal insights from initial theories. Since causal mechanisms are invisible, retroduction uses abduction to imagine what may be happening in the unobservable layers of reality (i.e., the actual and the real). Jagosh described abduction as the creative inference required to imagine underlying causal mechanisms. He also described it as a form of reasoning which examines evidence and makes causal inferences based on ‘educated guess work’ and ‘informed hunches’. It is for this reason realist research has been described as being evidence informed rather than evidence based. Anti-realists may criticise the use of abductive logic as simply ‘guess work’ but advocates would counter by arguing that abduction is the only way to introduce new ideas into the scientific evidence base.
CMO configurations are theories about the relationship between mechanisms and context that bring about a particular outcome. To unpack this further, in a particular situation which has its own unique, dynamic, and emergent features\textsuperscript{232} (context), a resource is introduced which then evokes a reaction in the mind and/or social system (mechanism) that leads to an outcome (outcome). Context is a central force within realist review and realist approaches. As supported by Greenhalgh and Manzano\textsuperscript{232} context is not a single, static, and abstract component; instead, it is a ‘force and relates to the psychological, organisational, economic and technical relationships that influence each other\textsuperscript{[88]} to continually drive our explanations. Context, in essence, shapes the way mechanisms and outcomes present themselves and it is omnipresent throughout the whole CMO process. The process of creating CMOCs helps to explain the deeper and hidden processes of causality to not just understand ‘is this effective’ but ‘why, how and for whom is it effective’\textsuperscript{233}.

2.3.1 Scientific realism not critical realism

Although they share some philosophical assumptions, scientific realism does not sit within the paradigm of critical realism as some have claimed\textsuperscript{234, 235}. Scientific realism is a separate paradigm. Indeed, there has been much debate between Pawson and Porter in which the difference between the two have been described at length\textsuperscript{236-241}. Without wishing to recreate the esoteric discussion in this research, understanding why and at what point the two approaches differ facilitates a better understanding of scientific realism. Porter’s main criticisms appear to lie in Pawson (and Tilley’s) axiological position, i.e. their value-neutral approach as well as the apparent confusion around their conceptualisation of mechanism and context.

Critical realism aims to understand and change the world\textsuperscript{242}. In particular critical realists try to identify factors that may be constraining
individual actions with the aim of liberating them from such constraints to promote justice and equality\textsuperscript{243}. Pawson, however, pushes back against the normative and emancipatory approach of critical realism and attempts to avoid such judgements\textsuperscript{223}. Although Pawson did not disagree with the notion that research could or should be devoid of values, he emphasised the need for the scientific accumulation of evidence to produce research findings based on data rather than values. Pawson advocates the ‘critical’ approach in scientific realism should align itself with Campbell’s notion of ‘post-positivist critical realism\textsuperscript{244}’ in which the scientific community scrutinises, disputes, tests and monitors each other’s findings in an attempt to keep research honest and through this critical process get closer to the ‘truth’ of matters\textsuperscript{223}. Although not explicitly stated, the axiological position of scientific realism can be inferred from the value it places on developing theories based on generative causation to further an understanding of why and how programmes work, for whom, and in what context. In so doing scientific realism values theory-based research that will help guide policy-makers and programme implementation\textsuperscript{222, 245}.

The other point of contention highlighted by Porter\textsuperscript{240, 241} and others\textsuperscript{234, 242} focuses on the CMO configurations used within scientific realism as a heuristic to create causal explanations. Hinds and Dickson\textsuperscript{234} argue CMO configurations fail to adequately separate the different levels of reality (the empirical, actual and real) which reduces a researcher’s ability to apply the retroductive and abductive theorising required to make inferences at and between each level. In a similar vein, Porter\textsuperscript{240, 241} argues that Pawson and Tilley’s\textsuperscript{1} conceptualisation of ‘mechanism’ conflates structure and agency and in so doing fails to tease out the interplay between human actions and the social structures governing those actions. Porter also takes issue with the inconsistency in Pawson and Tilley’s\textsuperscript{1} conceptualisation of context. Porter\textsuperscript{241} claims at times context aligns with the critical realism approach that context has causal
powers but in other instances context is a mere description of background conditions.

Pawson refutes Porter’s criticisms, claiming that scientific realism makes clear that context includes social structures and has causal powers and that mechanisms are focused on agency. Despite this ‘clarity’ however there are many researchers who have reported on the difficulty in applying the CMO heuristic and the confusion in differentiating between context and mechanism in scientific realism\(^\text{230, 246-250}\). Greenhalgh and Manzano\(^\text{232}\) also noted that context has been conceptualised in many realist studies as a static backdrop to a programme’s intervention (echoing Porter’s critique) instead of the dynamic influential force Pawson and Tilley intended it to be. Whereas the difference between critical realism and scientific realism is nuanced and, at times, arguably difficult to navigate, the debate is a useful guide for researchers. The academic discourse between Porter and Pawson explicates the concepts of mechanisms and context whilst also helping researchers to remain cognisant of the purpose of scientific realism.

### 2.4 Choosing scientific realism

As a chronic pain specialist physiotherapist, working in the NHS, the author was interested in the power dynamics within healthcare, particularly, at the individual level between a person with CLBP and HCPs. Given this interest, it would seem that critical realism would have been an appropriate research approach. Critical realists examine how social power is enacted within groups and individuals and explores ways in which this power can be an emancipatory force\(^\text{242}\). In this research, critical realist orientations can be found within the critique of self-management policies and in the discussions around the ambiguous conceptualisation of self-management and empowerment. However, critical realism does not have a methodology and its focus tends to remain at the theoretical and philosophical level\(^\text{242}\). Williams\(^\text{251}\)
suggested scientific realism provides a bridge between the philosophy of critical realism and its practical application. Despite the propensity to lean towards critical realism, scientific realism was chosen for this research due to its practical application as well as its ability to create and communicate research results that are meaningful to key stakeholders. Key stakeholders in this research were people living with CLBP, healthcare professionals, academics, app developers and healthcare policy makers. As the author of this research is a HCP, creating meaningful research results with the potential to influence clinical practice and patient care made scientific realism particularly appealing.

In creating scientific realism, Pawson and Tilley set out to address the gap between academics in their ivory towers and politicians in their government chambers. Pawson argues that realist research was purposely designed so as to be able to ‘talk the talk’ of policy makers. By that he meant the results of realist research should be presented in such a way so as to identify how a programme could be implemented in a policymaker’s particular ‘patch’ and identify potential pitfalls to look out for. Tricco et al. found that a lack of relevancy and context as well as poor presentation and confusing statistical reporting made it difficult for policy makers and HCPs to practically apply the findings from systematic reviews. Fox supports this argument, claiming that findings published in a large proportion of systematic reviews are, for the most part, irrelevant to policy makers and practitioners. In response to this critique, there have been calls for closer collaboration between the research community and policy makers with the latter taking more of an active role in setting the research priorities.

Pawson and Tilley wanted to address how the lengthy process of research could work with the time sensitive nature of policy making. Pawson noted that by the time research evaluations have been
completed, policy interests are likely to have changed and priorities shifted\textsuperscript{257}. As a result, he argued, ‘real time’ evaluations have minimal impact on policy making\textsuperscript{258}. Whilst Pawson and Tilley do not claim that realist research can keep pace with policy cycles, they believe ‘short termism’ can be overcome by the realist approach. For instance, they argue that by including data from a range of different disciplines, times, topics, and methodologies realist evaluations can glean information that goes beyond the traditional shelf-life of a typical systematic review or meta-analysis\textsuperscript{259}.

### 2.5 Principles of realist methodology

Having discussed scientific realism and justified its choice for this research, what follows is a discussion of how scientific realism informs the principles of realist methodology. Although there is no a rigid or pre-defined methodology that realist research must follow, there are general principles and steps that guide the process\textsuperscript{260, 261} (see Figure 2.5). Realist research begins by creating theories as to how a programme or intervention is thought to work. These nascent theories guide the research design. Evidence is collected and examined with a view to understanding the various contexts and underlying mechanisms that bring about outcomes. In the process, the initial theories are tested, refuted, or revised. The end result of realist research is refined theory that can be used to inform programme implementation, guide policy makers and as a starting point for further study\textsuperscript{222, 223}. 


In the following sections, key methodological principles are discussed in relation to each of the five steps in the realist research process. In describing the initial theorising stage, the role of substantive theory is emphasised, and reference is made to the specific substantive theories that guided this research. In step two, research design, a brief description of the similarities and differences between a realist synthesis and realist evaluation are outlined. In step three, the concepts of relevance, richness and rigour are introduced in relation to data selection and appraisal. In step four, a comparison is made between systematic reviews and realist syntheses so as to make clear what constitutes ‘good’ evidence in relation to realist research. Finally,
in step five, the term ‘middle range theory’ is introduced referring to the level of abstraction needed to ensure refined theory is able to ‘travel’.

2.5.1 Initial theorising
In realist enquiry, the unit of analysis is the programme theory – the idea or assumptions as to how the programme or intervention is thought to work\textsuperscript{223}. There are many different ways to create initial programme theories. Researchers can review published literature, policy documents, interview content experts and programme users as well as draw on their own experiences and hunches\textsuperscript{262}. Substantive theories can also help with theory development. Substantive theories are theories that have been well-established in a particular field that help to explain certain behaviours or outcomes\textsuperscript{263} (e.g. Social Cognitive Theory). Substantive theories can help throughout the research process. In the beginning, they can provide a ‘lens’ to conceptualise the research. Particularly when dealing with complex interventions that offer many ways of addressing the problem, a substantive theory can help researchers focus their research. Taking mHealth interventions to self-management CLBP as an example, feminist theories might look at gender differences in how self-management is presented whereas economic theory might focus on cost implications.

Throughout the research process ‘thinking with theory’ can help guide the researcher to view the same data differently and in so doing, potentially fill the gaps in our understanding of phenomena\textsuperscript{264}. Substantive theories help researchers identify to researchers what parts of the program are important to look at, which elements interact, what the nature of those interactions might be, what rules might guide them, and what contextual factors might affect these interactions\textsuperscript{265}. In so doing, a substantive theory can help to identify hidden mechanisms and contribute to programme theory building. The advice on finding substantive theories in the literature is to read widely in the initial
mapping phase of the research\textsuperscript{223}. When examining complex social programmes, researchers may decide to use more than one theory to help guide their research. Using a framework of three or four theories can help initial programme theory development at multiple levels of the social system e.g., interpersonal, institutional, infrastructural and cultural\textsuperscript{265, 266}.

Bandura’s Social Cognitive theory, specifically the concept of ‘self-efficacy’ was well known to the researcher from her undergraduate physiotherapy training. Although self-efficacy theory was considered relevant for this research, criticism has been levelled at research teams who revert to using theories that are well known to them\textsuperscript{267}. To not fall foul of such critique, a purposeful search for alternative theories to inform this work was conducted (outlined in Chapter 3, section 3.3.2). The conceptual framework in the research design as well as the Scottish Government’s use of the word ‘empowerment’ in their self-management strategy for long term conditions\textsuperscript{8} directed the research focus towards theories on empowerment. In reading around the concept of empowerment in the health literature the researcher was sensitized to the concepts of ‘power’ and ‘resistance’ by papers that drew on the work of Foucault\textsuperscript{151, 268-273}. However, it was May et al.’s Burden of Treatment theory\textsuperscript{274} and Lee and Koh’s model of empowerment\textsuperscript{275} that proved most useful as these were less abstract making them easier to apply to theory development at the individual and interpersonal level.

Burden of Treatment Theory considers not only what it means for a person to live with the physical and emotional demands of a chronic condition but draws attention to the work involved, for both the patient and their relational network in having to manage a chronic condition. May et al\textsuperscript{274}, argue this work has been increasing over decades as political drivers encourage patients to assume responsibility for
managing their own care using terms such as ‘self-care’, ‘self-empowerment’ and self-actualisation. Drawing on Normalisation Process theory\textsuperscript{276} as well as Shippe et al.’s\textsuperscript{277} Cumulative Complexity Model and the works of Roger et al.\textsuperscript{146, 278-280} on demand, self-care and social networks, May et al. created a structural model entitled Burden of Treatment theory to better understand what resources patients draw upon to manage both the burden of illness and the burden of treatment.

The appeal of Burden of Treatment theory in relation to this research was its cognisance of the complexity in trying to understand the various interactions between healthcare systems and patient behaviours in relation to managing a chronic condition. In addition, Burden of Treatment theory focuses on generative mechanisms and contextual factors that affect the extent to which a patient and their relational network are able to manage the work involved in living with a chronic condition. For instance, they identified agency, relationality, control, and opportunity as central components of ‘capacity’ which, in turn, was considered to be a key contextual factor in managing the burden of treatment. Finally, May et al.’s Burden of Treatment theory understood the benefit of presenting their theory at the middle range of abstraction so as to make their assumptions more generalisable and presented them at different levels (societal, system and granular) to assist in their applicability.

Burden of Treatment theory helped to develop theories in this research relating to the structural, institutional, and professional dynamics at play in using a mobile app to self-managing CLBP. However, although Burden of Treatment alluded to the power dynamics between patients, HCPs and healthcare services, the concept of empowerment was not explicitly considered. For this reason, theories around empowerment were also considered. This initially involved reading Foucault’s discourses on power\textsuperscript{281-283} which helped sensitise the author to the
power dynamics inherent in the healthcare service between policy makers, practitioners, and patients. However, it was Lee and Koh’s conceptual definition of empowerment that ultimately helped to guide theory development because it was easier to apply than the grand theories of Foucault.

Reviewing the literature on empowerment, Lee and Koh saw two different aspects being presented. One they called the ‘behaviour’ aspect which understood empowerment as the behaviour of a supervisor to empower their subordinate. This ‘behaviour aspect’ of empowerment was attributed to the work of Boren, Harari and Rothstein. The other, which Lee and Koh termed the ‘perception’ aspect draws on the work of Conger and Kanungo, Thomas and Velthouse and Spreizer and focused on the psychological state of the subordinate as result of being empowered by their supervisor. Lee and Koh argued that a proper definition of empowerment should merge both aspects of behaviour and perception and went on to define empowerment as: the psychological state of a subordinate perceiving four dimensions of meaningfulness, competence, self-determination and impact, which is affected by empowering behaviours of the supervisor. Lee and Koh go on to apply their definition to the four dimensions of empowerment identified by Thomas and Velthouse: meaningfulness, competence, self-determination, and impact (see Figure 2.6).
What Lee & Koh make explicit within Thomas and Velthouse’s framework is the effect the person in authority has on the four dimensions. Although Lee and Koh were concerned with human resource management, their model of empowerment was useful to this research. It was easy to see how their definition of empowerment could apply to the healthcare setting if the term ‘subordinate’ was replaced by ‘patient’ and ‘supervisor’ by ‘health care professional’. Indeed, Shulz and Nakamoto have already translated this framework into the healthcare setting in relation to health literacy and patient empowerment in health communication. In terms of this research, Lee and Koh’s model of empowerment provided a lens that guided where to look for data and identified important features within it. In addition, the model incorporated other theories deemed important to this work (e.g., self-efficacy theory and self-determination theory) whilst making it apparent that these elements in isolation were insufficient to explain the concept of empowerment.
Using Westhorpe’s\textsuperscript{265} approach of ‘layering’ substantive theory both Lee and Koh’s empowerment model and Burden of Treatment theory were used to theorise events at different levels of reality (the empirical, actual and real). Being explicit with the substantive theories that have influenced this work is a form of transparency. It makes the reader aware of the perspective that has been applied to the research (i.e., how it has been framed) thus making it more explicit as to why the data has been viewed in the way it has. Throughout the research there was a constant blend of programme theories with substantive theories to assist with the creation, testing and refining of the programme theories. This blending of theory is thought to be particularly helpful in identifying inaccuracies in programme theories and highlighting relevant contextual factors\textsuperscript{260}.

2.5.2 Designing realist enquiry

The initial programme theories determine the subsequent research design i.e. what data needs to be collected and how in order to test the initial theories\textsuperscript{291}. Realist studies can take the form of a realist synthesis (also known as a realist review) or a realist evaluation. Both approaches seek to understand social programmes and initiatives. The aim of scientific realism is to go beyond empirical inquiry that focuses solely on ‘what works’. Realist studies seek to advance an understanding of how a programme works, who it works for, why and in what context.

Realist synthesis is a form of literature review that synthesises existing research and secondary sources, looking for underlying causal forces that might explain why programmes work in one context and not in another. Since this detail is likely to have been removed from empirical literature that privileges RCT data, a realist synthesis consults a variety of literature sources for ideas with which to build and test programme theories. Piecing this array of literature together helps the researcher
create a tacit understanding of underlying mechanisms, whilst recognising how the various features of context influence them. In contrast, a realist evaluation uses primary data to evaluate a programme or intervention. Scientific realism is a ‘methods neutral’ approach to research and usually involves both quantitative and qualitative data to provide a range of evidence with which to develop and test theory\textsuperscript{222}. This broad and inclusive research design impacts on how data is collected and appraised.

2.5.3 Data collection
Since the purpose of realist research is to develop explanatory theory, the criteria for where to collect data and what to include in a realist synthesis differs from other evidence syntheses\textsuperscript{292}. The inclusion criteria for realist research is fundamentally guided by the data’s ability to contribute to theory building and testing\textsuperscript{292}. These decisions are guided by considering whether the data is rich in explanatory detail, rigorous, and relevant to the research aim and objectives. Published realist research has differed in how these terms have been applied, particularly in relation to rigour. This variation has led to confusion and, for clarity this research applied the appraisal and reporting suggestions for relevance, richness and rigour outlined by Dada et al\textsuperscript{292}. Figure 2.7 has been taken from this paper. It summarises how to assess for relevance, richness and rigour and demonstrates the process that has been followed in this research. Not wishing to duplicate the paper further it is worth, however, spending some time discussing the concept of rigour in scientific realism since it differs from the way rigour is judged in other evidence syntheses\textsuperscript{293}.

Rigour is defined and applied differently depending on the research paradigm. The RAMESES quality standards for realist reviews defined rigour as ‘whether the method used to generate that particular piece of data is credible and trustworthy’\textsuperscript{294(p6)}. Pawson et al.\textsuperscript{295} suggest sample
size, data collection techniques, analysis methods and research claims should be considered when assessing rigour. Quality guidelines and checklists have been created to help researchers make these judgements. However, these tools become redundant when Pawson\textsuperscript{296} claims that ‘nuggets’ of wisdom can be found in methodologically weak studies. Furthermore, most non-academic sources do not have quality checklists that can be applied. An assessment of rigour in realist studies therefore, is less about judgements on sample size etc. and more about the trustworthiness of the data\textsuperscript{297}. To assess data’s trustworthiness, it is necessary to establish its provenance. If data has come from less credible sources, such as opinion pieces, this can be redressed by adding supporting data from multiple sources with higher trustworthiness\textsuperscript{297}. 
Figure 2.7: Proposed considerations for applying relevance, richness, and rigour appraisals in realist review

(Reproduced from Dada S, Dalkin S, Gilmore B, Hunter R, Mukumbang FC. Applying and reporting relevance, richness, and rigour in realist evidence appraisals: Advancing key concepts in realist reviews. Research synthesis methods. 2023, Mar 5.p. 509. With permission from John Wiley & Sons Ltd.)
However, assessing rigour in a realist review is a two-fold process. Judgements of rigour in realist studies must extend beyond assessments of data. Wong\textsuperscript{298} argues that an assessment of rigour in a realist review should be at both the data level and at the level of programme theory. Since the aim of a realist research is to develop explanatory programme theories it is essential that these theories are themselves rigorously developed. This is arguably even more important considering these theories are derived from the unseen processes of retroductive and abductive reasoning. The rigour of a programme theory, relies on judgements about explanatory coherence\textsuperscript{299, 300}. Evaluating the coherence, or explanatory power of a theory can be done by judging whether it has made an ‘inference to the best explanation’. In other words, whether it offers a better explanation of the available data than its rivals\textsuperscript{301}. Three criteria determine a theory’s explanatory coherence: consilience, simplicity, and analogy\textsuperscript{299}

![Diagram of Explanatory Coherence](image)

Figure 2.8: Definitions of the three determinates of explanatory coherence (Thagard 1988)
(see Figure 2.8). Of the three, consilience, or explanatory breath, is considered the most important for choosing the best explanation.

2.5.4 Testing theories with evidence
Once theories have been judged as having good explanatory coherence they are tested with evidence. As with data collection, what evidence is used and where it is found is guided by realist principles that do not adhere to a hierarchy of evidence. To explain this further it is worth comparing how judgements of evidence in a realist synthesis differ from a more traditional systematic review.

In the early 1990’s, ‘evidence-based medicine’ was introduced in an attempt to rid the medical profession of clinical decision-making being based on unsystematic rationale and expert-opinion. There were calls within the medical community for strict methodological protocols to be put in place that would ensure robust scientific evidence was the basis for decision making. In response, the Cochrane Collaboration was established in 1993 to ensure medical research was based on high quality data. From this Collaboration came a hierarchy of evidence that placed the randomised controlled trial (RCT) at the top. However, in social research there is much criticism of the RCT for its failure to deal with the complexity of social programmes and its inability to explore inside the ‘black box’ of programme implementation.

In an attempt to be reproducible and get closer to the ‘truth’ of how things are, RCTs have a strict experimental design. To be confident with their claims that X plus Y equals Z, RCTs attempt to control, where possible, for all extraneous causal factors. However, from the perspective of scientific realism these confounding variables cannot and should not be controlled when evaluating social programmes. Pawson argues that human agency is the reason an intervention either works or fails. To try and control for this or strip it from the trial
produces results which do not explain how and why an intervention works and makes it unlikely that an intervention will be successful when implemented outside of the experimental setting in the real world.

Scientific realism acknowledges that programmes are introduced into complex open social systems in which there are likely to be multiple causal mechanisms operating at different levels and in different contexts\(^\text{305}\) – none of which can be controlled for the purpose of evaluation. Just as one can never stand in the same river twice, realist research acknowledges that a social intervention has to be embedded into a pre-existing social system where it will adapt and change as it goes through the many stages of the implementation chain and when it is transferred elsewhere\(^\text{223}\). Since RCT data has been stripped of context and human agency, realist research looks for other sources of evidence, that may not have the scientific pedigree of the RCT but may provide more useful information in explaining how and why an intervention works and for whom.

**2.5.5 Refined theory**

Using evidence to test programme theories helps to refine them. The aim of realist research is to develop refined, transferable theories to inform programme implementation in different settings\(^\text{248}\). Drawing on the work of Merton\(^\text{306}\), Pawson and Tilley\(^\text{1}\) describe these transferable theories as ‘middle range theories’. Merton divided theory into three levels: low level, middle range, and grand theory\(^\text{307}\). Although the lines between each level can blur Merton described middle range theory as

> “…sitting between the minor but necessary working hypothesis that evolve in abundance during day-to-day research and the all-inclusive systematic effort to develop a unified theory that will explain all observed uniformities of social behaviour, social organisation and social change.”\(^{\text{448}}\)
Middle range theories have been described as 'bridges' in that they provide explanatory links between one programme and another. This in turn, helps enhance our overall understanding of how programmes, interventions or practices that share similar characteristics (also referred to as ‘family of programmes’) operate. Although the precise details and contexts of an intervention may change over different domains, lessons learnt from one study can be used as a starting point for evaluating similar programmes which negates the need to start a review from scratch and, by extension, stops the ‘constant reinvention of the wheel’. Pawson describes this accumulated knowledge as ‘reusable conceptual platforms’ or ‘mechanism libraries’ which can be used as launch pads for further discovery. The key for Pawson and Tilley was the ability of middle range theory to ‘travel’. By sitting at a level of abstraction elevated above simply commenting on the specifics of a particular programme, middle range theories enable the researcher to develop more portable programme theories that can be transferred or pattern-matched into different contexts and policy domains.

2.6 Scientific realism applied in this research

Having thus outlined the principles of realist methodology the following section describes how these principles have been applied in this research. Scientific realism was designed to evaluate social programmes. It has an explanatory focus in that it seeks to explain why a programme works, for whom, and in what context. In this research the principles of scientific realism were used to explore the mechanisms and contexts that might explain why a mobile self-management app may work for some people with CLBP and not for others.
2.6.1 Research aims and questions

Research aim
The aim of this research was to develop a transferable framework of propositions to suggest how mobile apps could support people to self-manage chronic low back pain – specifically addressing what it is about a self-management app that works, for whom, why and under what circumstances.

Research Questions

- What theories help to explain why, how, for whom and in what context a self-management app may benefit people living with CLBP?

- What are the mechanisms that might explain why, how and for whom a self-management app for CLBP may work?

- How does a change in context help or hinder these generative mechanisms?
Objectives

1. Critically evaluate the assumptions underlying the program strategy for self-management apps for chronic conditions like chronic low back pain.

2. Undertake a realist synthesis of the evidence to develop theories on how and why a mobile app might help a person self-manage chronic low back pain.

3. Undertake a series of interviews with key stakeholders in the field of chronic pain, including those with lived experience, to develop, test and refine theories on how and why a mobile app might help a person self-manage chronic low back pain.

4. Combine the results of objectives 1, 2, and 3 to develop a theoretical framework that suggests how mobile apps could support people to self-manage chronic low back pain.

5. Conduct a realist evaluation of a self-management app with a sample of participants living with chronic low back pain to test and refine this theoretical framework.

2.6.2 Research Design

The research was designed in two parts. The first addressed objectives 1-4 and was a realist synthesis to develop, test and refine programme theories relating to self-management apps for people living with CLBP. The second part of the research satisfied objective 5 and was a realist evaluation of a self-management app for people living with CLBP, undertaken to test the theories developed from the realist synthesis and refine them further.
2.6.3 Realist Synthesis

Academic and non-academic sources were synthesised to create, test and refine programme theories that explained what it is about a self-management app for CLBP that might work, who it might work for, why and in what context. In addition, transcripts from realist interviews with key stakeholders, namely people with lived experience, HCPs, policy makers and an NHS technology consultant were included. By incorporating stakeholder interviews within the realist synthesis, the research borrowed techniques used in realist evaluation which required additional steps explained further in section 3.3. This extra work extended an already lengthy process but added credibility to the research process and its findings. Furthermore, incorporating stakeholder data in this way aligned with the goals of the research design and added to the validity of the results.

2.6.4 Realist Evaluation

The programme theories developed in the realist synthesis underwent further testing in a realist evaluation. People living with CLBP used a commercially available app called Curable for 12 weeks and were interviewed afterwards to test the programme theories from the realist synthesis against their experience. In keeping with the nature of realist evaluation, the study was not evaluating if the app worked or not but rather, the aim was to test if the programme theories developed in the realist synthesis held up under empirical scrutiny.

The final output of the research was twenty CMOCs arranged under three connected and refined programme theories that explained how, why, for whom and in what context a self-management app for people with CLBP might work. These theories were presented as middle range theories and used to develop recommendations for key stakeholders namely: people living with CLBP, policy makers, healthcare professionals, app developers, and researchers.
2.6.5 Transparency in the research

Due to the flexible and iterative nature of realist research and the reliance on retroduction and abduction to create programme theories it was essential that the research was undertaken and reported transparently. Being transparent in how the research has been designed and how theories have been developed, tested, and refined, allows others to assess the rigour of the work and the credibility of the findings. Several methods were adopted in this research to enhance its transparency.

A reflective journal was kept throughout the research process to record and think through decisions. An extract from this journal detailing the researcher’s thought processes in addressing the issue of rigour has been published in a co-authored methodology paper (See Appendix A). Transparency in the research was also aided by Robert Horn’s concept of knowledge mapping and visual language to facilitate an understanding of how to navigate complex processes. Much of the data analysis and theory development took the form of mind maps and causal diagrams both to help the researcher make sense of the data and to aid the reader in following the researcher’s logic. Finally, Maxwell’s interactive model was used to be transparent about each component of the research design (see Figure 2.9). It is an interactive model because each component is connected to several others in a reciprocal and influential relationship via a continual back and forth. Maxwell argues this model reflects a realist approach to research design since it recognises that the way in which a researcher assigns meaning to social phenomena will have a causal impact on the way the research is conceptualised and conducted. Rather than trying to control for this influence it is essential to recognise and make transparent these thoughts and how they influence the research design.
Figure 2.9: Interactive research design adapted from Maxwell [311]
As alluded to earlier (section 2.3.1) there has been some confusion in how mechanism and context have been conceptualised in realist research. For this reason, it was considered important to be explicit in how these terms have been defined and applied in this work. The concept of context in this research aligns with Greenhalgh and Manzano's\textsuperscript{232} definition. Context is not a single or static component of the programme theory, it is a causal force which influences whether or not a mechanism is generated. To illustrate how context has been applied in this research, a CMOC from the realist synthesis (Box 1) has been used an example.

By providing support as well as a means by which to contact a HCP if needed (C) a self-management app provides users with the reassurance of a ‘safety net’ should they feel they need additional support (M) thereby mitigating feelings of abandonment (O).

This CMOC provides a causal explanation as to why someone with CLBP may feel less abandoned if they used a self-management app. The context in this CMOC is not static. The concept of support (which has both psychological and structural components) can vary and fluctuate. This affects whether the mechanism (a feeling of reassurance) is activated and determines the strength of the activation (i.e. how strong the feeling of reassurance is). Whether the mechanism is activated or not and the strength of this activation, subsequently affects the strength of the outcome (a mitigated feeling of abandonment). There are also two temporal components to context in this CMOC. The first component relates to ‘when’ a mechanism is
likely to be generated and the second component resides in the description of the support as ‘ongoing’.

This example also serves to illustrate how the term mechanism has been used in this research. In the CMOC reassurance has been identified as a mechanism. Reassurance is not a component of the self-management app’s programme, rather it is a reaction by the app user to the resource the app provided (a safety net). Furthermore, reassurance is not an observable entity, nor is it present in all circumstances – it is reliant on the context before it manifests itself.

2.6.7 CMO configurations in this research
As well as variations in how mechanism and context is applied in realist research there are also differences in how the CMO heuristic is used. Pawson and Tilley created the CMO configuration as a heuristic to help researchers create programme theories from their data with a specific focus on expressing causal relationships. Some researchers, however, have added other explanatory elements to their CMO configurations to help them develop realist causal explanations. In their review of realist configurations, De Weger et al. identify a number of permutations including Context-Intervention-Mechanism-Outcome (CIMO); Strategy/Intervention-Context Mechanism-Outcome (S/ICMO); and Intervention-Context-Actor-Mechanism-Outcome (ICAMO). Although De Weger et al. suggest additional explanatory factors can help realist studies that have a specific focus (e.g. Mukumbang et al.’s use of the ICAMO configuration to explore the same intervention on different actors) they caution that adding explanatory factors could, obfuscate rather than enhance causal explanations. They conclude by advising researchers to be clear as to why they have chosen their particular realist configuration and for what explanatory purpose.
Pawson and Manzano-Santaella\textsuperscript{314} argue that disaggregating CMO configurations into constituent components, typically presented in a matrix of C’s, M’s, and O’s breaks the connection between the elements and thus loses causal insight. Cognisant of this pitfall the CMO configurations in this research were kept in their original format (C-M-O). The author felt that adding additional explanatory factors or to split mechanisms into ‘reasoning’ and ‘resource’ as others have done\textsuperscript{315}, could hinder rather than help theory building. Furthermore, De Weger et al.\textsuperscript{291} noted when they used the original CMO configuration in their research, it enabled them to gather and analyse research data at a personal and granular level. This level of focus aligned with the aims of this research and further supported the use of the CMO configuration in its original format.

\textbf{2.6.8 CMOCs vs. logic models}

Although the CMOC is unique to scientific realism, other forms of theory-led evaluation use similar heuristics. In a final argument to support the use of scientific realism for this research, a brief discussion of theory of change (ToC) and its use of logic models concludes this chapter.

Scientific realism belongs to the family of theory driven evaluation – a methodological approach that came about in response to the uninformative policy and programme evaluation that was outcome driven and methods-focused\textsuperscript{316, 317}. Theory driven evaluation is a form of ‘hybrid evaluation’\textsuperscript{318} which assesses the implementation and effectiveness of an intervention as well as the underlying causal mechanisms and contextual factors that brought about change. To fully explicate why scientific realism was chosen from this family of theory driven evaluation it is useful to compare it to another form of theory driven methodology, the theory of change (ToC). According to Scriven\textsuperscript{319}, theory of change is the idea about how a program works to
bring about its effect. ToC is concerned with the inner workings of a programme and the connections between the component parts whereas realist evaluation focuses on the behavioural change the programme brings about and the motivational and psychological forces behind these changes\(^3\). 

Blamey and McKenzie\(^3\) argue the difference between realist evaluation and ToC can be seen by comparing the level of theory development each approach is primarily interested in. ToC develops theory at the implementation level to further an understanding of how programme outcomes come about, how they can be improved and monitored. In contrast, realist evaluation develops theory at the program level to understand why a programme works or not. This slightly different theoretical focus effects the tools each method uses in the research process. ToC are built on logic models\(^4\) whereas realist evaluation uses the CMO configurations. Logic models are visual representations or narrative explanations of how an intervention is thought to bring about an outcome. Logic models typically include activities, outputs, outcomes, and overall impact\(^4\). Although ToC extends logic models to include causal links that explain which element caused or resulted in another element, Dhillon and Vaca\(^4\) argue that ToC do not usually extend to explore the underlying causal mechanisms. To bring in the realist notion of a stratified reality, ToC does not venture into the realm of the ‘real’. This would reflect the focus of ToC being at a higher, implementation level of theory development. Returning to the research question and aims, realist research as opposed to ToC was chosen because of its focus on

\(^1\) Dhillon and Vaca (1998) maintain that a strong ToC should include underlying causal mechanisms but acknowledge mechanisms are not commonly identified in ToC logic models.
understanding the underlying mechanisms that bring about behavioural change at a programme level.

2.7 Chapter 2 Summary

Figure 2.10: Chapter 2 Summary
3.1 Introduction

In the introduction to this research, it was noted that mHealth technology has the potential to help the rising number of people living with CLBP self-manage their condition. However, gaps remain in our understanding of how self-management apps might help, who they could help, why and in what context. Furthermore, there are those who stress caution when it comes to ‘techno-optimism’. In particular, criticism has been levelled at the over-inflated promise that mHealth technology is an empowering tool to assist people self-manage their long-term conditions. In light of this critique, there have been calls made in the literature for a closer examination of the rhetoric behind policy makers’ advocation of mHealth technology and self-management programmes.

The introduction chapter also highlighted tensions in the concept of self-management and empowerment amongst key stakeholders namely, people living with CLBP, HCPs and healthcare policy makers. Exploring this underlying tension could be integral to understanding the mechanisms that determine whether self-management apps for CLBP work or not. It could also help to explain how introducing a self-management app to people living with CLBP could lead to unintended consequences. What this tension highlights, from the outset, is the

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importance of including stakeholders throughout the research process so theories which are produced align with stakeholders’ understanding of key concepts and, in so doing, are meaningful to them. These four factors: 1) lack of theory based mHealth research into self-management apps for CLBP; 2) potentially over inflated promises of mHealth; 3) tensions in the terms self-management and empowerment; and, 4) the importance of hearing from key stakeholders, formed the rationale (see Figure 3.1) for undertaking a realist synthesis of published sources relating to self-management apps for people living with CLBP.

Figure 3.1: Research rationale
Accepting Pawson’s premise that a programme will work for some people some of the time\textsuperscript{223}, the aim of this realist synthesis was to develop a theoretical framework to explain why, how, for whom and in what context a self-management app may benefit people living with CLBP. The following were identified as key objectives in meeting this aim:

1. Evaluate a wide range of sources (academic and non-academic) to identify initial programme theories underpinning self-management apps for CLBP.

2. Interview key stakeholders in the field of CLBP to create, test and refine these programme theories

3.2 The realist synthesis overview

Unlike traditional systematic reviews which are primarily focused on exploring the effectiveness of an intervention, a realist synthesis is concerned with the inner workings of an intervention that might explain why, for whom and in what context an intervention might work. A realist synthesis is guided by stakeholder input throughout the process\textsuperscript{323} to ensure the research findings are credible and meaningful\textsuperscript{295}. Involving stakeholders in the research was a key component of the design of this project. This consideration was also the reason for including stakeholder transcripts from realist interviews as primary data in the synthesis. Although this approach is unusual — since a realist synthesis typically relies on secondary sources — it is not without precedence\textsuperscript{324}. Including transcripts in this way was considered essential due to the lack of representation from people living with CLBP in the secondary sources.

Ensuring that a wide variety of relevant voices were represented in this synthesis was also the reason for choosing a diverse range of
published sources. These included social media posts, artwork, newspaper articles, policy papers as well as more traditional sources such as academic studies. In this way, it was envisaged that the views of people who may not be typically represented in empirical research would find expression in this work. Including a broad range of sources in a realist synthesis is in keeping with realist research methods. Since the aim of a realist synthesis is to look beyond observable outcomes and explore the inner workings of a programme it is understood that the synthesis will include varied data sources spanning different paradigms\textsuperscript{325}. Wong\textsuperscript{297} encourages realist researchers to be imaginative and inclusive about where relevant data might be found.

3.3 Method

![Diagram: Eight iterative stages in realist synthesis](image)

Figure 3.2: Eight iterative stages in realist synthesis

Realist research is not a prescriptive method\textsuperscript{230} which means the steps involved in a realist synthesis can vary between studies. For instance, Maidment et al.\textsuperscript{326} identified 5 steps in their realist synthesis whereas
Rycroft-Malone et al.\textsuperscript{323} had only four. This synthesis followed eight iterative stages (see Figure 3.2) which are outlined in the following sections. Given the iterative and flexible nature of a realist synthesis it is important that readers of the research are able to clearly identify the steps taken and be satisfied of its methodological rigour\textsuperscript{295}. To that end, this review has been transparently reported with reference to the RAMESES quality standards for realist synthesis\textsuperscript{327} [see Appendix B].

3.3.1 Stage 1: Background mapping
Informal discussions and email correspondence were conducted by the author within her professional network (i.e., NHS Scotland and third sector) to help identify salient issues in the research area and direct the author to relevant information. Abrams et al.\textsuperscript{328} have critiqued realist reviews for failing to be specific in how stakeholder input informed and impacted on the synthesis. In this instance, discussions within ALLIANCE’s Discover Digital Oversight Group meant the author was informed that the Scottish Government’s Digital Health Care Strategy was being updated and was emailed the latest version when it was released in May 2021. This step aligns to what Manzano\textsuperscript{329} has described as theory gleaning in which key stakeholders are consulted in the initial stages of the research to help identify contextual factors that may be influencing behaviours and outcomes.

In addition to consulting with stakeholders, published studies involving self-management apps for long-term health conditions were reviewed to sensitise the research team to the area. Key policies around self-management and digital health technology from UK Government websites and national pain charities were also consulted. To widen the research perspective, newspapers, blogs, artwork, social media, and book chapters were included to gain insights from a broad range of viewpoints and experiences. Finally, key terms such as ‘self-management’ and ‘empowerment’ were explored in a process called
The search strategies for identifying blogs, book chapters and artwork followed a snowballing method. For instance, whilst searching a UK pain charity website for relevant reports the author was directed to links relating to a person’s blog or an art project of interest. The media search strategies were less opportunistic, and a short description of both methods are outlined here.

**Newspaper search strategy**

The Publishers Audience Measurement Company (PAMCo) is the governing body overseeing audience measurement for the published media industry in the United Kingdom. Data released by PAMCo was used to identify the top six UK newspapers (The Sun, The Mirror, The Daily Mail, The Metro, The Independent and The Guardian) based on 2020 yearly figures for Total Brand Reach. A global news monitoring and search engine (FACTIVA) was then used to access articles in these six newspapers. The FACTIVA database required specific dates to perform its search and so, to limit the results due to project time constraints, a two-year period was selected counting back from the date of the initial search (3rd April 2020 – 3rd April 2018). Three separate searches were conducted firstly under “back pain”, then “self-
management” and finally "ehealth Or mhealth OR digital health OR telemedicine OR health app” (see Figure 3.3). A total of 924 articles were collected after duplicates were removed and were read in full by the author. A simple screening criteria was applied based on whether the article contributed to programme theory development (yes include, no exclude). After a full text screen of 924 articles, 20 were taken through to be included in the synthesis.

**Twitter search strategy**

Over a seven-month period (February – October 2022) six twitter accounts were followed by the author. The twitter accounts belonged to large, registered pain organisations in the UK. Tweets relating to areas of interest e.g ‘back pain’, ‘self-management’, ‘empowerment’ and ‘mobile apps’ were bookmarked and amalgamated into a ‘Twitter moment’ 331. At the end of the seventh month period the Twitter moment was downloaded into a Microsoft Word document and all identifiable user information removed. A bespoke data extraction template was created (see Appendix C.1 for a completed example) and relevant exerts were highlighted and annotated. These annotations were then extracted and placed into a coding journal (see Appendix D for an example extract). As this was a novel approach to capturing and using data from Twitter in a realist synthesis, the author sought advice from an experienced realist researcher to discuss the rigour and credibility of using Twitter as a ‘stakeholder’ 332. The outcome of the correspondence assured the author that due consideration had been given to the rigour of the process.
3.3.2 Stage 2: Create Initial rough programme theories

Substantive theories were purposively selected to help create initial rough programme theories (IRPTs). As discussed in section 2.5.1, substantive theories can help researchers consider what part of an intervention might be important. Guided by the processes outlined in Booth and Carroll, a purposive search was conducted to find substantive theories relating to self-management and back pain. A search of Google Scholar was conducted by the author on 19th May 2021, for articles related to the research area that might mention relevant theory (see Figure 3.4 for search terms). Google Scholar was chosen on the advice of Booth because the terms ‘theory’ or ‘logic model’ do not often appear in title and abstract searches which can make it difficult to find useful papers in journal databases. The initial search (Google Scholar search V1) yielded 298 results which, due to research time constraints, was considered too large a number to screen. The original search was therefore repeated (Google Scholar search V2) with the addition of the term ‘app’. This second search

![Diagram showing the search process]

Figure 3.4: Google search for substantive theories
resulted in 48 articles which were read in full by the author. Whilst reviewing the articles any reference to theory, models, or frameworks (collectively termed as substantive theories by the author) was recorded in a separate Microsoft Excel spreadsheet for consideration. Fourteen substantive theories were identified in this process (see Figure 3.4) and May et al's Burden of Treatment theory was used to inform programme theory development.

There was no mention of empowerment theory in the 48 articles reviewed. Empowerment was considered an important critical lens to apply to this research since it had been mentioned in the policy literature relating to mHealth and self-management. For this reason, an additional Google Scholar search was conducted using the following search string: “self-management” AND “patient empowerment” AND “app”. This identified Brew-Sam’s published work on app use and patient empowerment in diabetes self-management. Brew-Sam’s research led the author to Lee and Koh’s conceptual definition of empowerment which was used to inform programme theory development.

By the end of the mapping exercise and informal literature search sixteen IRPTs in the form of ‘if/then’ statements were created (See Table 3.1). Six of these IRPTs were selected at random and presented at a Realist Methodology training conference (CARES 2020 Realist Methodology Training Conference, Aug 3-12th 2022) to ensure they adhered to realist principles and for peer review. Feedback from the conference supported the method used to develop the IRPTs and no

Further details of Burden of Treatment theory and Lee and Koh’s conceptual definition of empowerment along with a justification for choosing both can be found in Chapter 2, section 2.5.1.
revisions were suggested. The sixteen IRPTs were subsequently taken to stakeholders for comment.

Table 3.1: Sixteen IRPTs taken to first stakeholder consultation

<table>
<thead>
<tr>
<th>Number</th>
<th>Programme theory</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>If a mobile app can give patients the knowledge to self-manage their condition and the confidence to handle all the tasks this entails, then they will not require ongoing input from the healthcare service or access to secondary level of care.</td>
</tr>
<tr>
<td>2</td>
<td>If people with chronic low back pain are not given a specific diagnosis that validates their condition, then trust in the HCP breaks down and a patient may fail to accept the need to self-manage.</td>
</tr>
<tr>
<td>3</td>
<td>If people with CLBP prefer the more traditional relationship with HCPs i.e., ‘the doctor knows best’ then a self-management app is unlikely to be successful because patients have failed to ‘buy in’ to the idea of empowerment and prefer the role of the passive patient.</td>
</tr>
<tr>
<td>4</td>
<td>If HCPs are unable to see the utility of a self-management app or see it as a threat to their position, then it is unlikely to be accepted and supported because HCPs and patients prefer to be seen face to face, and an app cannot replicate the benefit that comes from a face-to-face appointment.</td>
</tr>
<tr>
<td>5</td>
<td>If HCPs and patients consider a self-management app as a means by which the government can save money on recruiting more healthcare practitioners, then a digital self-</td>
</tr>
</tbody>
</table>
management programme is unlikely to be successfully implemented.

6 If there is confusion in the term ‘self-management’ between policy makers believing it is an adjunct to ongoing healthcare treatment, HCPs who regard it as a successful outcome of treatment with the patient unlikely to return and patients seeing self-management as a means by which they are ‘fobbed off’ then this confusion undermines the self-management agenda because no one is really clear as to what the outcome is supposed to be.

7 If a self-management app was offered after a patient had been seen face to face by a HCP and discharged to self-manage, then it may be accepted more by patients because they have had the reassurance that comes from a face-to-face contact and have been provided with a resource (an app) that gives them ongoing support at home.

8 If patients and HCPs lack the resources to engage with mHealth technology then it is unlikely to be adopted and they will continue with the old, more familiar ways of healthcare.

9 If a self-management app meant that patients with CLBP did not have to travel to see a HCP and could access advice in a time and place of their choosing then it is likely that it will be seen as positive tool.
<table>
<thead>
<tr>
<th>Number</th>
<th>Programme theory</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>If the government does not specify exactly how they envisage health technology can be developed and implemented or provide the leadership to support this implementation, then it is unlikely that a self-management app for CLBP will make it into the healthcare service.</td>
</tr>
<tr>
<td>11</td>
<td>If people with CLBP are not given a specific diagnosis that validates their condition and reassures them that the medical profession ‘knows’ what is wrong with them then they will struggle to accept the need for long-term self-management. Instead, patients will continue to search for a diagnosis and ‘cure’.</td>
</tr>
<tr>
<td>12</td>
<td>If a self-management app was able to reassure a person with CLBP and reduce their fears, then the app will have more utility and meaning for the user and therefore it will be more likely to be accepted.</td>
</tr>
<tr>
<td>13</td>
<td>If a person with CLBP uses a self-management app to monitor their progress, then they will not develop the intrinsic motivation to sustain long term behavioural change and will continue to rely on external prompts to engage with self-management.</td>
</tr>
<tr>
<td>14</td>
<td>If a person with CLBP is not able to use the technology required to engage with a self-management app either due to the lack of IT infrastructure, or resources such as money or digital literacy then this might exacerbate health inequalities.</td>
</tr>
</tbody>
</table>
15 If people with CLBP are given a mobile app to help them self-manage their condition and believe they are no longer entitled to ongoing care or think there is some alternative agenda at play (like a means of getting rid of a nuisance patient, or it is a cost saving exercise) then an unintended consequence could be a feeling of resentment amongst this patient group and a failure to engage with the self-management app.

16 If people with CLBP have become accustomed to physically distancing from other people due to the Covid 19 pandemic and are used to having more of their everyday interactions online, then a self-management app may become more acceptable and a preferred way of managing one’s own health.

3.3.3 Stage 3: First Stakeholder consultations

Sampling strategy
Unlike other qualitative methods (those underpinned by grounded theory for example) calculating the number of interviews to conduct in realist research is based less on concepts of data completeness and theoretical saturation and more on judgements of relevance, richness and rigour. As a result, in realist research more attention is given to purposively selecting stakeholders who can help contribute to theory

*A full explanation of how these terms have been defined and applied in this research can be found in Chapter 2, section 2.5.3.*
building, testing and refining and there is less concern over how many interviews may be considered an acceptable amount.

**Stakeholder characteristics**

Twelve stakeholders were purposively selected for their experience in dealing with long-term pain (see Table 3.2). Stakeholders were divided into two groups. Experiential stakeholders were adults who had been diagnosed with CLBP (or a condition that resulted in CLBP). Professional stakeholders were either healthcare workers treating people with CLBP; senior NHS staff responsible for implementing healthcare policy, members of charity groups supporting people living in pain; or people working in the field of health technology.

<table>
<thead>
<tr>
<th>Role</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persons living with long term pain</td>
<td>4</td>
</tr>
<tr>
<td>Pain specialist Health Care Professionals</td>
<td>3</td>
</tr>
<tr>
<td>NHS Senior management and Board members</td>
<td>2</td>
</tr>
<tr>
<td>Third Sector Pain Charity Directors</td>
<td>2</td>
</tr>
<tr>
<td>NHS technology redesign (consultant)</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12</strong></td>
</tr>
</tbody>
</table>

Table 3.2: Stakeholder characteristics in first consultation

**Stakeholder recruitment**

Experiential stakeholders were recruited through an advertisement placed on a twitter account that had been created for the study (see Appendix E). Professional stakeholders were recruited via healthcare connections and networking events and contacted by the author via email. NHS ethical approval for the study was obtained from the West of Scotland Research Ethics Committee (Reference number: 20/WS/0041).
Stakeholder interviews
Informed written consent was obtained prior to conducting a sixty-minute recorded telephone interview with each stakeholder. During the interview 8-10 IRPTs were selected for comment depending on the relevance that potential programme theory had to the stakeholder’s experience. Realist interviews are designed to confirm, refute, and refine programme theory and can add to the theoretical awareness and trustworthiness of the realist research process.

Data Collection Methods
To ensure qualitative research is undertaken to a high standard there must be evidence of congruency between the researcher’s methodology and their methods. For this reason, it was decided to conduct semi-structured realist interviews. This interview style was chosen because, unlike other qualitative interviews that explore participant’s view and experiences, realist interviews use the participant’s experience to create, refine, refute, and dispute theories about how programmes may work. This realist approach to qualitative interviewing marries with the aims of the study and aligns with the ontological and epistemological position of realist research.

Realist interviews are based on a teacher-learner cycle which is a distinct characteristic of realist evaluations. In the teacher-learner relationship the interviewer presents a theory about the programme under review for the interviewee to consider. The interviewee in turn confirms, refutes, falsifies, or affirms the theory based on their lived experience. In this way, a cyclical relationship is established between the interviewer and interviewee, the former starting in the teacher role then becoming the learner. As a result, the interviewee is more than a simple source of information but becomes an integral part of the meaning-making process.
Following the advice outlined by the RAMESES II project on conducting realist interviews, multiple and contradictory theories about the programme were presented and discussed with the participants so as not to be accused of leading the interview. In addition, as the interviews progressed, the researcher informed the interviewees of alternate views and opinions that had arisen in other participant interviews. This was a deliberate attempt to elicit more detailed responses and to encourage interviewees to think about the programme from alternate perspectives out with their own experience (See Appendix F for Interview script).

**Data coding and analysis**

Interviews were transcribed and coded by the author. The coding strategy followed the principles outlined in the Centre for Advancement in Realist Evaluation and Synthesis training programme (see Appendix G for coding criteria). Extracts of the transcripts were highlighted and inferences from the data were made using abductive and retroductive logic. These inferences were extracted and recorded in a series of analytical memos in a coding journal. The memos were subsequently mind-mapped into a series of causal loops using a whiteboard and then Xmind software (Version 22.10). Using analytical memos in this way was informed by Gilmore et al.’s review and the mind-mapping exercise was influenced by Robert Horn’s work on knowledge mapping for complex social messes and drew on the causal loop diagrams from Mukumbang et al.’s work (See Appendix H for an illustration). At the end of this process the sixteen IRPTs had been reduced to six (Table 3.3). These six were deemed to be the most meaningful and relevant to the stakeholders and helped to narrow the scope of the research.
Table 3.3: Six initial rough programme theories taken for testing

<table>
<thead>
<tr>
<th>Number</th>
<th>Programme theory</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <em>Face to face vs. virtual</em></td>
<td>Being assessed face-to-face gives both HCPs and people with CLBP the reassurance they have been 'assessed properly', and that 'nothing has been missed'. In addition, for many people with CLBP, a face-to-face assessment gives them further reassurance, that their symptoms - although not visible - have been taken seriously and they are not being 'fobbed off' (their words) <em>(Context)</em>. If a mobile app can provide the empathy, reassurance, validation, and trust <em>(Mechanism)</em> that they get from a face-to-face therapeutic encounter with an HCP then they will find a mobile self-management app beneficial <em>(Outcome)</em>.</td>
</tr>
<tr>
<td>2. <em>Timing</em></td>
<td>A person with CLBP needs to have a face-to-face assessment with a HCP before introducing a self-management app <em>(Context)</em> so they are reassured <em>(Mechanism)</em> and can trust the app <em>(Outcome)</em>.</td>
</tr>
<tr>
<td>3. <em>Patient journey</em></td>
<td>Having a persistent pain condition that is not visible to the outside world makes some people with CLBP feel as if their symptoms are not 'real' or that they have not been believed when they try to explain the impact pain is having on their life. Furthermore, some patients find it hard to accept a diagnosis that has no known anatomical pathological cause <em>(Context)</em>. If a patient invests their energies on pursuing different treatment options and seeking second opinions from</td>
</tr>
</tbody>
</table>
a multitude of HCPs in order to gain the reassurance that their condition is 'real' and that it is not 'all in their head' **(Mechanism)** then it is unlikely that they are ready to engage with a mobile self-management app **(Outcome)**.

### 4. Covid

Although digital healthcare appointments were being used in the NHS before the Covid-19 pandemic, the number of healthcare services going ‘virtual’ has significantly increased because of the social distancing measures introduced to stop the spread of the virus. As a result, both HCPs and patients, are becoming more accustomed to delivering and receiving digital healthcare **(Context)**. If digital health becomes a ubiquitous form of healthcare delivery, then, patients will be more familiar with using mHealth **(Mechanism)**, may trust it more **(Mechanism)** and, as a result, find mobile apps to be more acceptable **(Outcome)**.

### 5. Self-efficacy

In the UK there are insufficient HCPs to treat the growing number of patients living with CLBP. As a result, there are lengthy waiting times to access pain services. In addition, people living in geographically remote areas, may have to travel long distances to attend pain clinics. **(Context)** If a mobile self-management app could expedite patient access to pain education, advice and reassurance thus giving them the confidence to manage their condition on their own **(Mechanism)** then it may serve to reduce
waiting times to access pain clinics and negate the need to travel long distances (Outcome)

6. Control

<table>
<thead>
<tr>
<th>Context</th>
<th>If a person with CLBP were able to access a mobile self-management app when they wanted and from a location of their choosing (Context) then the app could restore a sense of control (Mechanism), in that they no longer have to wait for an appointment to see a HCP to get the treatment and advice they are looking for to help them self-manage (Outcome)</th>
</tr>
</thead>
</table>

3.3.4 Stage 4: Search empirical databases.

The literature search strategy was prepared by the author in consultation with a subject librarian and their thesis supervisors. The search strategy used a combination of keywords and MeSH terms, and an example of a full database search is included in Appendix I. The informal literature search undertaken as part of the mapping exercise in stage 1 revealed a paucity of empirical literature on mHealth apps for CLBP. This was not surprising given mHealth is a relatively new field. In the absence of research directly related to the programme under review, realist researchers are encouraged to review and learn from studies of similar programmes. For this reason, research on mobile apps for chronic pain, fibromyalgia, irritable bowel disease and chronic fatigue syndrome were included in the search strategy. These conditions were purposely chosen because they come under an umbrella of conditions with medically unexplained symptoms. Medically unexplained symptoms are symptoms for which no pathological cause can be identified or the origin remains unclear. It was reasoned that people suffering with these conditions may share similar feelings of not being believed or feeling like they have been told
their symptoms are 'all in their head'. They may also share a desire to obtain a specific diagnosis for their symptoms.

For the database search, the research question was broken down into key conceptual components: back pain; irritable bowel syndrome, chronic pain, chronic fatigue syndrome, fibromyalgia / self-management / mobile apps/ chronic. Search terms were piloted in MEDLINE and key papers from stage 1 were used to test the sensitivity of the search. The literature search was run over two days (11th and 12th May 2021) and included the following databases: CINAHL; MEDLINE; EMBASE; PsycINFO, Scopus, ACM Digital. Search results were limited to English language studies and no start or end dates were specified.

Selection and appraisal
The database search resulted in 662 articles. Duplicates were removed via the reference management software (Zotero version 6.0.10) leaving 433 articles for screening. See Figure.3.5 for a flow diagram of article selection and inclusion.
Figure 3.5: Flow diagram of article section and inclusion
Results were imported into Rayyan — a web and mobile app for systematic reviews\textsuperscript{348}. The selection and appraisal stage was a two-step process similar to the steps taken in the Maidment et al.\textsuperscript{326} realist review. The decision to include or exclude a study was based on relevancy. Relevancy was determined by how the study contributed to programme theory development. There were two relevancy screens. The first was a title and abstract screen piloted and applied to all papers by the author. Papers were scored on a five-point scale from highly relevant (1) to likely irrelevant (5) (See Appendix J). Reasons for exclusion were recorded and 20\% of the results were checked by thesis supervisors for consistency. Articles categorised as ‘less relevant’ (4) or ‘likely irrelevant’ (5) were kept to one side, leaving 35 articles to be taken through for a second screen.

Two articles could not be obtained leaving the full texts of 33 articles to be screened a second time for relevancy as well as rigour, and richness (See Appendix K). Rigour was assessed in terms of the trustworthiness of the data and richness in terms of how much explanatory detail it offered. The conceptualisation and application of rigour, relevance and richness followed the research brief published by Dada et al.\textsuperscript{292}. Articles were scored for relevance and rigour using a 4-point scale from high to none. Judgements were made based on how the article could contribute to programme theory development and were ranked by the author in discussion with the research team. A total of thirteen articles rated high (\(n.7\)) or moderate (\(n.6\)) were included in the synthesis (see Table 3.4)
Table 3.4: Thirteen articles from database search

<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Title</th>
<th>Authors</th>
<th>Year</th>
<th>Country</th>
<th>Study</th>
<th>Condition</th>
<th>CMOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doc ID</td>
<td>Title</td>
<td>Authors</td>
<td>Year</td>
<td>Country</td>
<td>Study</td>
<td>Condition</td>
<td>CMOC</td>
</tr>
<tr>
<td>--------</td>
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<td>-------</td>
<td>-----------</td>
<td>------</td>
</tr>
<tr>
<td>LIT15</td>
<td>Evaluation of Self-Management Support Functions in Apps for People With Persistent Pain: Systematic Review.</td>
<td>Devan H, Farmery D, Peebles L, Grainger R</td>
<td>2019</td>
<td>New Zealand</td>
<td>SR</td>
<td>CP</td>
<td>1, 3</td>
</tr>
<tr>
<td>LIT21</td>
<td>A Smartphone-Based Health Care Chatbot to Promote Self-Management of Chronic Pain (SELMA): Pilot Randomized Controlled Trial.</td>
<td>Hauser-Ulrich S, Künzli H, Meier-Peterhans D, Kowatsch T. A</td>
<td>2020</td>
<td>Switzerland</td>
<td>RCT</td>
<td>CP</td>
<td>2</td>
</tr>
<tr>
<td>Doc ID</td>
<td>Title</td>
<td>Authors</td>
<td>Year</td>
<td>Country</td>
<td>Study</td>
<td>Condition</td>
<td>CMOC</td>
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<td>------</td>
</tr>
<tr>
<td>LIT23</td>
<td>Smartphone Applications Designed to Improve Older People's Chronic Pain Management: An Integrated Systematic Review.</td>
<td>Dunham M, Bonacaro A, Schofield P, Bacon L, Spyridonis F, Mehrpouya H.</td>
<td>2021</td>
<td>UK</td>
<td>SR</td>
<td>CP</td>
<td>1, 5, 9</td>
</tr>
<tr>
<td>Doc ID</td>
<td>Title</td>
<td>Authors</td>
<td>Year</td>
<td>Country</td>
<td>Study</td>
<td>Condition</td>
<td>CMOCS</td>
</tr>
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<td>-------</td>
</tr>
<tr>
<td>LIT30</td>
<td>Designing a mobile-based solution for self-management of chronic pain</td>
<td>Meawad F, Yang SY, Loy FL, Chang EJ,</td>
<td>2018</td>
<td>Singapore</td>
<td>EV</td>
<td>CP</td>
<td>1,7</td>
</tr>
<tr>
<td>LIT33</td>
<td>Digital Health Apps in the Clinical Care of Inflammatory Bowel Disease: Scoping Review</td>
<td>Yin AL, Hachuel D, Pollak JP, Scherl EJ, Estrin D.</td>
<td>2019</td>
<td>USA</td>
<td>ScP</td>
<td>IBS</td>
<td>2, 8, 9, 10</td>
</tr>
</tbody>
</table>

Legend: **Studies** CR: Critical Review; CT: Clinical trial; EV: Evaluation Study; MA: Meta-analysis; Pilot: Pilot study; ScP: Scoping review; SR: Systematic review; RCT: Randomised Controlled Trial; Qual: Qualitative study. **Conditions** CLBP: Chronic low back pain; CP: Chronic pain; IBS: Irritable bowel syndrome; LBP: Low back pain
3.3.5 Stage 5: Extract and organise data

A bespoke data extraction form was created (see Appendix C.7) and study characteristics, methodological rigour, and articles of interest in the reference list were recorded. Analytical memos and inferences were created and extracted into a coding journal. The included academic literature was predominately quantitative in nature. As a result, the data was beneficial in identifying relevant contexts and outcomes but did not help the research team identify causal mechanisms that would explain why mobile apps may or may not work for people self-managing CLBP. To supplement the literature, evidence was brought in from other sources identified in stage 1 (see Table 3.5). This aligns with Booth et al.’s pick and place search strategy. The context-mechanism-outcome framework was used to pick data from the background search undertaken in stage 1 and place it within the realist synthesis to help with theory development. Due to the varied nature of the data sources, each required bespoke data extraction forms to be created. Completed examples of these forms can be found in Appendix C. Data was extracted and coded using the CARES coding framework (see Appendix G).
Table 3.5: Supplementary literature from stage 1

<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Supplementary evidence</th>
<th>Search strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>PP02</td>
<td>TEC: Digital Citizen Delivery Plan (2021/22)</td>
<td>Government Website</td>
</tr>
<tr>
<td>PP05</td>
<td>National Advisory Committee for Chronic Pain: Minutes of Meetings(2018-2021)</td>
<td>Government website</td>
</tr>
<tr>
<td>PP07</td>
<td>Enabling, Connecting and Empowering: Care in the Digital Age (2021)</td>
<td>Government website</td>
</tr>
<tr>
<td>Thsec02</td>
<td>10 Years of Scotland’s Self-Management Fund (2019)</td>
<td>Charity website</td>
</tr>
<tr>
<td>Thsec03</td>
<td>Discovering Digital Self-Management (The ALLIANCE) report (2019)</td>
<td>Charity website</td>
</tr>
<tr>
<td>Art01</td>
<td>Wings by Paula Knight, Translating Pain Art project (2018/19)</td>
<td>Snowballing</td>
</tr>
<tr>
<td>Doc ID</td>
<td>Supplementary evidence</td>
<td>Search strategy</td>
</tr>
<tr>
<td>--------</td>
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<td>-----------------</td>
</tr>
<tr>
<td>Art02</td>
<td>The medical record swallows the story by Sara Wasson, Translating Pain Art project (2018/19)</td>
<td>Snowballing (seed charity website)</td>
</tr>
<tr>
<td>Art03</td>
<td>Partners in my care by Anon, Translating Pain Art project (2018/19)</td>
<td>Snowballing (seed charity website)</td>
</tr>
<tr>
<td>News01</td>
<td>What can doctors do for your back pain? Not as much as you can (Guardian, February 2020)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News02</td>
<td>Stuck on painkillers, but we’re not addicts. (The Guardian, February 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News03</td>
<td><em>Get personal for back pain</em> (The Daily Mirror, October 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News04</td>
<td>Jobcentre Plus advisors have told people looking for work to avoid words that sound worse than they are (The Guardian, October 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News05</td>
<td>Government forced into U-turn over disability benefits for chronically ill (The Guardian, October 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News06</td>
<td>The safer painkillers experts fear are as risky as opioids (The Daily Mail, September 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News07</td>
<td>Britons keep quiet about pain to avoid annoying others (The Independent, September 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News08</td>
<td>Could you get hooked on the pills your doctor prescribes? (The Daily Mirror, September 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>Doc ID</td>
<td>Supplementary evidence</td>
<td>Search strategy</td>
</tr>
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</tr>
<tr>
<td>News09</td>
<td><em>Under the weather</em> (The Daily Mail, September 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News10</td>
<td><em>Grandad Junkie</em> (The Sun, September, 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News11</td>
<td>Why don’t doctors trust women? (The Guardian, September 2019)</td>
<td>Factiva search</td>
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<tr>
<td>News12</td>
<td>Alexa, how can Amazon make even more untaxed millions in profit? (The Sun, July 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News13</td>
<td>Until recently chronic pain was dismissed as psychological (The Daily Mail, September 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News14</td>
<td>Why prescribing playlists for people with dementia is on the money (The Guardian, November 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News15</td>
<td>Back pain: how to live with the world’s biggest health problems (The Guardian, June 2018)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News16</td>
<td>Gloomy weather makes chronic health conditions more painful study suggests (The Independent, June 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News17</td>
<td>Call for poor and disabled to be given NHS fitness trackers (The Guardian, May 2019)</td>
<td>Factiva search</td>
</tr>
<tr>
<td>News18</td>
<td>Painkillers may make your agony worse (The Daily Mail, January 2019)</td>
<td>Factiva search</td>
</tr>
</tbody>
</table>
3.3.6 Stage 6: Refine programme theories

During stage 6 the six IRPTs were refined to create seven rough programme theory ‘areas’ (see Appendix L). Each area was a pattern code\textsuperscript{361} that identified a ‘big picture’ with constituent codes attached. These constituent codes guided the realist interviews in the second consultation with stakeholders.

3.3.7 Stage 7: Second consultation with stakeholders

The seven programme theories were discussed with the stakeholders in what Manzano\textsuperscript{329} would describe as a process of theory refining and consolidation. The second consultation replicated the first (section 3.3.3)
and involved seven new stakeholders all of whom were living with CLBP. They were recruited via an additional advertisement placed on the study’s Twitter page. In a similar process to the first consultation, the stakeholder transcripts were coded by the author using analytical memos but, in this instance, both deductive and inductive-retroduction was applied.

Causal insights from the stakeholders were used to test and refine the seven theory areas (deductive) whilst at the same time data from the transcripts was used to create new causal insights (inductive). These memos were added to the coding journal.

3.3.8 Stage 8: Synthesise findings and draw conclusions.

![Figure 3.6: Steps in data analysis and synthesis](image)

The evidence was synthesised via a process of mind mapping (see Appendix M for an illustration). Although it is listed as 'stage 8', data synthesis was an ongoing and iterative process that took place throughout the review. It involved going over the coding journal, transcripts, and articles repeatedly and applying retroductive and abductive logic to create chains of inferences eventually becoming 16 refined CMO configurations.
Lee and Koh’s\textsuperscript{275} conceptual definition of empowerment and May et al’s\textsuperscript{274} burden of treatment theory were brought back into the synthesis as substantive theories to help with theory development. The analysis process was facilitated throughout by discussions with the research team and by presenting preliminary findings and nascent theories at realist training events and conferences. The final CMO configurations were presented and discussed with one of the experiential stakeholders in a sense checking and validation exercise.
3.4 Findings

3.4.1 Introduction

The following chapter is a summary of the research findings which is a synthesis of thirteen published studies (see Table 3.4), twenty-five non-academic sources (see Table 3.5) and nineteen stakeholder interviews. From this data, 16 CMOCs were created to produce three refined programme theories on how self-management apps may work for people with CLBP (see Table 3.6). In the following section, each programme theory is discussed in turn with an summary figure that illustrates how the programme theory addresses the question of what works, for whom, why and in what context when it comes to self-management apps for CLBP. All quotes used to support the CMOCs are written verbatim.

Table 3.6: Sixteen CMOCs creating 3 refined programme theories

<table>
<thead>
<tr>
<th>No.</th>
<th>CMOC</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Traditional NHS-led self-management programmes for CLBP provide participants with little choice in how, when and where they are delivered (C). A self-management app for CLBP can be accessed at a time and location that is convenient to the user (M) which</td>
<td>PP6; PP7; PS03; PS06; PS07; ES02; ES11; ThSec2; ThSec3; LIT08;</td>
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</tbody>
</table>
restores a person’s sense of control and autonomy (O).

<table>
<thead>
<tr>
<th>No.</th>
<th>CMOC</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Many people with CLBP rely on HCPs for support because they do not know how to manage their symptoms (C). By providing the user with knowledge, advice and strategies to self-manage CLBP a mobile app enables the user to gain confidence and agency (M) to manage their condition on their own (O).</td>
<td>PP1; LIT21; LIT30; LIT33; PS01; ES01; ES09; ES11; ES12</td>
</tr>
<tr>
<td>2</td>
<td>A person with CLBP needs to be able to recognise themselves in the advice and information the app provides (C) so that they can trust what they are being told (M) otherwise they are unlikely to engage with the app because they do not consider it as being relevant to their situation (O).</td>
<td>LIT09; LIT11; LIT14; LIT15; ES01; ES05; ES09</td>
</tr>
<tr>
<td>3</td>
<td>If a mobile app fails to provide the user with options that have not been tried before (C) then the initial hope they may have felt at being offered something that might alleviate News20; News 02; News3; PP5; PS12; PS02;</td>
<td></td>
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<tr>
<td>No.</td>
<td>CMOC</td>
<td>Sources</td>
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<td>-----</td>
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</tr>
<tr>
<td></td>
<td>their pain (M) can turn to bitterness, disappointment and sometimes anger (O).</td>
<td>RS14; BK1; E008; ES09; LIT14</td>
</tr>
<tr>
<td>5</td>
<td>If a self-management app was used as an adjunct to care and not a replacement (C) then HCPs are likely to welcome the tool as it helps them to deliver ongoing support remotely (M) thereby enabling them to treat more patients in their limited clinic time (O).</td>
<td>PS01; PS02; PS03; PS04; PS06; ES04; LIT23</td>
</tr>
</tbody>
</table>

**Programme theory two: Self -Management Burden**

If people with CLBP have the capacity to engage with a mobile app then it can reduce the burden of having to self-manage CLBP by providing ongoing support, facilitating communication with HCPs, and mitigating feelings of abandonment. (CMOCs 6-11)

<table>
<thead>
<tr>
<th>Number</th>
<th>CMOC</th>
<th>Sources</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>Introducing an app to a person with CLBP who lacks the internal and or external resources to engage with it (C) can cause further stress and frustration (M) which adds to their burden of having to manage long term back pain (O).</td>
<td>BK1; LIT 09; LIT24; PP01; PS02; BLOG01</td>
</tr>
<tr>
<td>No.</td>
<td>CMOC</td>
<td>Sources</td>
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<td>--------------------</td>
</tr>
<tr>
<td>7</td>
<td>Monitoring their progress with a mobile app and sharing this data with a HCP (C) can help a person with CLBP convey more of a ‘complete picture’ of how they are managing their condition (M) and thereby improve the communication and quality of a healthcare consultation (O).</td>
<td>LIT08; LIT09; LIT25; LIT30; Art2; ES03; ES04; ES05; ES06; ES09; ES12; PS04</td>
</tr>
<tr>
<td>8</td>
<td>Using an app to record and share their data with an HCP (either before or during the appointment) (C) can maximise the effectiveness and efficiency of the healthcare appointment (M) thereby reducing the frustration felt by patients when valuable consultation time is wasted bringing HCPs ‘up to speed’ (O).</td>
<td>PS01; ES02; ES03; ES08; ES09; PP4; ART2; LIT33; LIT08; Twitt02</td>
</tr>
<tr>
<td>9</td>
<td>By providing ongoing support as well as a means by which to contact a HCP if needed (C) a self-management app provides users with the reassurance of a ‘safety net’ should they feel they need additional support (M) thereby mitigating feelings of abandonment (O).</td>
<td>PP1; Twit05; Blog1; BK1; ThSec2; ES04; ES03; ES09; PS01; PS04; PS05; LIT11; LIT23; LIT33</td>
</tr>
</tbody>
</table>
A self-management app that enabled a person with CLBP to maintain contact with a HCP (C) can provide a reassuring ‘safety net’ (M) leaving them more confident to be discharged from the healthcare service (O).

In the absence of supportive ‘real life’ relationships (C) a self-management app with a chat bot feature that has been designed to communicate in a human-like way to offer comfort and reassurance (M) can help someone with CLBP feel less alone (O).

Programme theory three: Timing
A person with CLBP is likely to benefit from a self-management app early on in their patient journey but not before they feel believed and reassured by HCPs and have accepted their condition cannot be cured. (CMOCs 12-16)

If a person with CLBP remains steadfast in their search to find a cure for their back pain (C) and are unwilling to accept an active role in self-managing their condition (M) then they are likely to be disappointed with a self-
<table>
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<tr>
<th>No.</th>
<th>CMOC</th>
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<tbody>
<tr>
<td>12</td>
<td>management app because it does not rid them of their pain (O).</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Before a person with CLBP can accept the need to self-manage their condition they need to feel that HCPs believe them (C). Feeling believed triggers a sense of reassurance that they have been taken seriously (M) which makes them trust the HCP (O).</td>
<td>ES01; ES02; ES04; ES05; ES06; ES08 PS08; News04; News13; News 11; News19; Book01; Blog01</td>
</tr>
<tr>
<td>14</td>
<td>When a person with CLBP trusts a HCP (C) then they are likely to be more receptive (M) to HCP’s recommendation of a self-management app (O).</td>
<td>ES01; ES02; ES04; ES05; ES06; ES08 PS08; News04; News13; News 11; News19</td>
</tr>
<tr>
<td>15</td>
<td>When a person has been reassured that there is no serious spinal pathology, and they are not likely to do any harm to their backs (C) they become less fearful of movement (M)</td>
<td>News01; News15; Twitt01;</td>
</tr>
</tbody>
</table>
and are more likely to engage with the strategies offered by a self-management app (O).

16

Introducing a self-management app early on in a patient’s journey —whilst medical management and investigations are ongoing— (C) can provide reassurance and advice to help a person with CLBP return to everyday activities (M) and thereby reduce the risk of maladaptive behaviours developing (O).

<table>
<thead>
<tr>
<th>No.</th>
<th>CMOC</th>
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<tbody>
<tr>
<td>16</td>
<td>Introducing a self-management app early on in a patient’s journey —whilst medical management and investigations are ongoing— can provide reassurance and advice to help a person with CLBP return to everyday activities and thereby reduce the risk of maladaptive behaviours developing.</td>
</tr>
</tbody>
</table>

3.4.2 Programme theory 1: Empowerment

Given the importance of empowerment in healthcare policies relating to self-management, the research team purposely drew on Lee and Koh’s conceptual definition of empowerment to develop this programme theory (introduced in section 2.5.1).

Convenience, Accessibility and Choice

According to the Scottish Government (2021) [PP07] convenience, accessibility, and choice lead to patient empowerment. However, the inflexibility of the National Health Service (NHS) makes it difficult to offer a self-management programme that meets this criterion. Back pain self-management programmes delivered by the National Health Service (NHS) are typically conducted in-person, in a group-setting, usually in a hospital or medical venue, with a Health Care Professional (HCP) leading the
programme. The healthcare infrastructure in terms of room availability and space, clinic diaries, and staffing levels determine when, where, how many can attend and how long the self-management programme will be. As a result, there is little flexibility in how the programme is delivered and a person with CLBP has no choice in most of these decisions. These issues were recognised by the professional stakeholders (PS03; PS06; PS07), two of whom (PS06; PS07) had experience of running group self-management programmes for CLBP. PS07 commented:

“...we found that logistically the patients may not be able to commit themselves to a set day a week for six consecutive weeks as it’s going to be.” [PS07, lines 339-442]

Compounding this lack of choice and inconvenience is the distance most participants usually must travel to attend a CLBP self-management programme. Many in the review findings reported this journey exacerbated their pain and disincentivised them from attending.

“...if it meant that I didn’t have to go through the ordeal of having to travel the distance, you know, it’s all quite... and as I say if I do have to travel through to Aberdeen it does have a knock-on effect. I’m in pain, a lot more pain for at least two or three days after that.” [ES02, lines 98-100]

Furthermore, the dynamic created by an HCP leading the self-management group can also feel like a restriction of patient choice: participants with CLBP can be left with a sense that they are being told what to do. To address this, non-directive language was purposively chosen by Geraghty et al.\textsuperscript{350} [LIT11]) for their internet-based self-
management programme (SupportBack) to promote internalisation amongst the users. Geraghty et al. argued this approach would make participants feel they were the ones making an informed choice about whether to engage in suggested behaviours rather than because they had been instructed to do so.

Using digital health technology to provide equitable access to healthcare in a way that empowered patients was a key theme in the Scottish Government policy papers [PP06, PP07] and in the reports published by the Health and Social Care Alliance Scotland (The Alliance) [Thsec2; Thsec3]. More specifically, the literature on self-management apps argued that apps can deliver the convenience, choice and accessibility in a way that traditional self-management programmes cannot [LIT08, LIT09, LIT15, LIT18, LIT23, LIT30, LIT34].

A self-management app was seen as a means by which a person with CLBP could get the knowledge, support and answers they were looking for without having to travel miles to attend a self-management programme. Furthermore, the information in the app could be accessed whenever it suited the user thus negating the need to take time off work, sort out childcare arrangements, organise lifts with friends etc. In addition, users could look at the content they wanted to, for as long as they needed and revisit it as many times as they liked. These claims were supported in Svendsen et al.’s [LIT09] review on digital interventions for the self-management of low back pain: “the flexibility made it mine” p.10 and in the stakeholder consultations:
“If the information’s there 24/7, you can tap in and tap out as and when you can, when you’re available to do it.” [ES11, lines 102-104]

**CMOC – 1**

Traditional NHS-led self-management programmes for CLBP provide participants with little choice in how, when and where they are delivered (C). A self-management app for CLBP can be accessed at a time and location that is convenient to the user (M) which restores a person’s sense of control and autonomy (O).

*Sources: PP6; PP7; PS03; PS06; PS07; ES02; ES11; ThSec2; ThSec3; LIT08; LIT09; LIT15; LIT18; LIT23; LIT30; LIT34; News08*

**Knowledge and self-reliance**

The Scottish Government [PP01] stress that a key mechanism by which a person with long term health conditions, such as CLBP can self-manage is by becoming empowered to take ownership and control of their own health. How exactly they go about becoming empowered is less clear. What the policy paper does mention as being important in the empowerment process, is for HCPs and patients to become partners in care, with shared decision making and to move away from the traditional ‘doctor-knows-best’ approach. However, the findings from this review indicate that many patients with CLBP do not feel empowered [Art03; Twit03; News11; Blog01 PS03; ES08].

A lack of knowledge about the human body and back pain specifically creates a power differential between the HCP who knows more about the condition and how to manage it than the person with CLBP. In this
instance, there needs to be a transfer of power (in the form of knowledge) from the HCP to the person with CLBP for the latter to feel empowered. This point was stressed throughout the consultation with PS01.

“But I don’t know anything about my back, so I am actually naturally disadvantaged so I’m almost already compromised because you [HCP] have knowledge I don’t have and I don’t know how much of it you’re giving to me. If I was better informed, there wouldn’t need to be so much of a shift in power….” [PS01, lines 164-167]

Whereas some sources in the review saw the imbalance of power deriving from the HCP/patient relationship (PS01), others believed it was pain itself that strips people of their power (ES12). However, regardless of what or who took their power, most sources agreed, the means of restoring it was to learn more about back pain.

“when you start on your journey, you are stripped of every ounce of power that you’ve ever had…. [you are] thrust into this world of intense pain constantly, you can’t do anything else and you don’t have control over anything else, everyone has to help you. You are completely powerless. But then when you start to learn about your condition and learn about methods of coping with it you are reclaiming that power and it is a wonderful feeling to then have, well its power at your fingertips, where the more you learn the better you get at coping”. [ES12, lines 425-431]

If a person knew more about their body and how to manage back pain, they would not need to rely as much on others for help. Two stakeholders
spoke [ES01; ES09] of the benefits an app could bring if it provided them with the information and reassurance, they were looking for, so they did not have to visit a HCP. Most studies included in the synthesis alluded to the pressure primary care physicians were under in dealing with the rising numbers of people living in chronic pain and the need to push self-management skills as a way of alleviating the demand. However, the correlation between increased knowledge and self-management skills delivered by an app and a decrease in healthcare utilisation was not explicitly supported in the literature included in this review. One of the objectives Meawad et al\textsuperscript{357} [LIT30] had in designing a self-management app for chronic pain was that it may allow patients to reduce their dependence on healthcare professionals, but they had yet to test this proposition. Yin et al’s\textsuperscript{358} [LIT33] was the only study that looked at healthcare utilisation in their review of digital apps for irritable bowel syndrome. Their findings showed a general decrease in the number of hospitalisations and outpatient visits made by app users but there were mixed results when it came to the number of telephone calls made to HCPs.

**CMOC - 2**

Many people with CLBP rely on HCPs for support because they do not know how to manage their symptoms (C). By providing the user with knowledge, advice and strategies to self-manage CLBP a mobile app enables the user to gain confidence and agency (M) to manage their condition on their own (O).

*Sources: PP1; LIT21; LIT30; LIT33; PS01; ES01; ES09; ES11; ES12*
Personalisation

Knowledge can only be considered empowering if the person feels that the information they are being given relates to them. When back pain persists for longer than three months, regardless of its origin (i.e., because of arthritic changes in the spine, disc bulges or for no known reason) the recommended treatment approach is the same: chronic back pain needs to be self-managed [LIT08; LIT09; LIT11; LIT14; LIT15; LIT21; LIT30]. However, this realisation is lost on many people with CLBP. Experiential stakeholders in this review expressed reservations about using a self-management app for their CLBP believing that the information would be too generic.

“…. Does the Bot know me? Has the Bot seen me first? Possibly along the lines of again ‘how personal is this? ’Is this the standard generic responses that everyone is getting?’ Because I am not going to be the only one that’s having a bad day and so is that just going to be the standard response that everyone’s getting?” [ES05, lines 412-415]

Although experiential stakeholders recognised the self-management information was generally helpful, the usefulness of it was limited if they were unable to recognise their own personal presentation of back pain in the advice and strategies offered. The more personalised the information, the more relevant and trustworthy it was considered to be. This finding was repeated in the literature sources [LIT09; LIT11; LIT14; LIT15]. Devan et al [LIT15] extended this argument to include tailoring the information so that it was culturally relevant to the user.
CMOC - 3

A person with CLBP needs to be able to recognise themselves in the advice and information the app provides (C) so that they can trust what they are being told (M) otherwise they are unlikely to engage with the app because they do not consider it as being relevant to their situation (O).

Sources: LIT09; LIT11; LIT14; LIT15; ES01; ES05; ES09

Hope

The sources in this synthesis indicated that many GP's feel rushed and pressurised to give patients something that will help alleviate their pain [News18]. GPs struggle to treat patients with CLBP who do not respond well to pain medication because they feel they have no other treatment options available to them [News14; News08]. This can result in patients being given painkillers that are ineffective and unwanted. People with CLBP are looking for something new that will help them cope with their pain and have become frustrated with being offered painkillers.

“Many of us take painkillers for years because we are still in pain. We are not addicts. We are treating a debilitating condition when no other option is offered.” [News02]

This frustration can motivate people with CLBP to try alternate modalities, like an app, in the hope that it will help them manage their condition more effectively. However, the findings of this review suggest that if the self-management app does not provide information, advice or strategies that the patient has not heard or tried before then this sense of hope can quickly give way to frustration, despair and even bitterness [LIT14].
CMOC – 4

If a mobile app fails to provide the user with options that have not been tried before (C) then the initial hope they may have felt at being offered something that might alleviate their pain (M) can turn to bitterness, disappointment and sometimes anger (O).

Sources: News20; News 02; News3; PP5; PS12; PS02; RS14; BK1; E008; ES09; LIT14

Adjunct to care

The concept of empowerment was explored from the patient and the HCP’s perspective. An initial rough programme theory developed early in the mapping stage hypothesised that HCPs would feel threatened by a self-management app. The theory being that the app would remove the valuable therapeutic relationship that develops between the HCP and patient and therefore would not be as effective at helping a person self-manage their back pain. However, the findings from HCP stakeholder consultations, refuted this IRPT*. If the self-management app did not replace HCP care but rather supplemented it, then HCP stakeholders considered the app as a way of spreading limited healthcare resources further. As one professional stakeholder commented, the app could be seen as a way to “work smarter, not harder” [PS01].

In this context, a self-management app could be seen as an empowering tool, enabling HCPs to work more effectively and efficiently. For example, instead of reviewing a patient every four weeks, the HCP could extend this period to six weeks, knowing that the self-management app could provide

* See Appendix N for a worked example of how IRPT 4 was refined to become CMOC 5.
ongoing support in the interim. With the number of people living with CLBP outstripping the number of HCPs available to treat them, Dunham et al.\textsuperscript{354} [LIT23] supported the idea that an app could be a valuable way by which treatment could be supplemented – particularly in times, such as the COVID-19 pandemic when access to regular care was severely limited.

**CMOC – 5**

If a self-management app was used as an adjunct to care and not a replacement (C) then HCPs are likely to welcome the tool as it helps them to deliver ongoing support remotely (M) thereby enabling them to treat more patients in their limited clinic time (O).

*Sources: PS01; PS02; PS03; PS04; PS06; PS08; ES04; LIT23*

However, it is unlikely that all HCPs will embrace self-management apps. Svendsen et al.\textsuperscript{349} [RS09], noted that digital health interventions (DHIs) were less likely to be embraced by HCPs who preferred ‘hands-on’ treatment. Furthermore, there were concerns that, in their limited consultation time, HCPs might forget to mention the digital health intervention as an option or have insufficient time to demonstrate how it worked or provide sufficient information on its utility.
Having discussed the five CMOCs that underpin programme theory one, Figure 3.7 applies this theory to the research question: what works, for whom, why and in what context when it comes to a self-management app for CLBP.

**Programme theory one: Empowerment**

People with CLBP can feel empowered by a self-management app if the app is personal and relevant to their situation, can be accessed when and where they need it and is presented as an adjunct to ongoing care.

**WHAT WORKS**

A self-management app for CLBP that is accessible whenever and wherever the user likes. An app that provides the user with knowledge about their CLBP they can relate to and offers new, personalised pain management strategies.

**FOR WHOM**

For people living with CLBP who are seeking more agency over managing their condition. For people who are unable/unwilling to attend in-person self-management programmes.

**WHY**

The app user is given the choice, autonomy and convenience in how they access and engage with personalised self-management support for CLBP – triggering a sense of control, agency and empowerment.

**IN WHAT CONTEXT**

If the self-management app is used as an adjunct to care and not a replacement. If the app meets or exceeds the user’s expectations.

Figure 3.7: Programme theory one – what works, for whom, why and in what context?

### 3.4.3 Programme theory 2: Self-management burden

The following CMO configurations centre around the challenges inherent in self-managing CLBP and the role a mobile app can have to help or hinder these efforts.
Burden of treatment/care

Although delivered in different ways, the reviewed literature maintains that the underlying premise of self-management apps is to provide users with education, advice, and strategies to help them manage their condition. [LIT08; LIT09; LIT11; LIT15; LIT18; LIT21; LIT 23; LIT 24; LIT 25; LIT30; LIT 34]. In so doing, it presupposes that a person living with a long-term condition, such as CLBP, has the capacity to engage and utilise these resources. A person’s ability to self-manage their CLBP is influenced congruently by their internal resources (e.g., confidence, competence, motivation, energy etc) and external resources (e.g., time, financial security, positive home environment, sufficient food/heating etc) [PP01].

Expecting a person to self-manage their CLBP and engage with a self-management app without considering a person’s internal and external resources is likely to produce failed results and add to a person’s burden of care [BK01]. Svendsen et al. [LIT09] noted that the use of DHIs was constrained by physical and psychological factors and facilitated by social support. In Hunt et al.’s [LIT 24] trial of ‘Zemedy’, a mobile app designed to help people self-manage Irritable Bowel Syndrome (IBS), the researchers noted that participants who dropped out of the trial had higher rates of visceral anxiety and fear of food at baseline. Hunt et al. concluded that, for this population, in-person therapy may be more appropriate. A similar finding was reported by a professional stakeholder working in the NHS Pain Service. They commented that those with complex needs, such as mental health issues in addition to long term pain, did not cope well when the COIVD-19 restrictions meant consultations were delivered remotely (either by telephone or by video consultation).
“… our kind of patient population is, sometimes quite challenging in many ways and many of them have very significant mental health issues in addition to their chronic pain issues. And it’s very clear having spoken to hundreds of patients now that they have not coped very well with the whole lockdown situation. … So, it’s been very difficult. So, it became clear to us very quickly that there were some patients you could manage over the phone or by VC [video consultation] and they were very happy with that and there were a lot of patients that you had to see face to face.” [PS02, lines 318-329]

The findings make it clear that expecting a person to self-manage their CLBP and engage with an app without considering these factors is likely to produce failed results. Policy documents highlighted the need for the digital infrastructure to be in a place to support mobile apps alongside initiatives to improve digital literacy [PP01]. At a personal level, the sources indicated that for people in crisis (both physical or mental) a mobile app would have the unintended consequence of adding to the stress and burden they are already under.

**CMOC - 6**

Introducing an app to a person with CLBP who lacks the internal and or external resources to engage with it (C) can cause further stress and frustration (M) which adds to their burden of having to manage long term back pain (O).

*Sources: BK1; LIT 09; LIT24; PP01; PS02; BLOG01*
Ongoing support/monitoring

It takes a considerable amount of energy and motivation to continually engage with self-management strategies. Many stakeholders spoke of the benefit they would find in having a HCP ‘checking-in’ to monitor their progress and keep them motivated [ES03; ES04; ES05; PS08]. The Scottish Government’s National Advisory Committee for Chronic Pain noted that people who have attended pain services need ongoing support when they are discharged from care [PP05]. For the most part, experiential stakeholders felt it was important that this follow up be with a HCP because a ‘real person’ could make an assessment and judgement on their progress in a way that a self-management app could not.

“Because I think that’s the thing as well, pain-management programs are seen as the end of the road for a lot of people. And after them, you’re on your own in the cold. To know that in six months, I’m gonna get a lovely phone call from that great physiotherapist that I spoke to or that great psychologist. And they’re gonna ask me if I’m okay. That goes a hell of a long way”. [ES04, lines 664-667]

However, the time between review appointments (if offered) can be lengthy. Having follow-ups spaced six months apart for instance, would fail to give the HCP a complete picture of the person’s pain experience. Long-term pain is volatile, on top of base-line levels of pain there can be frequent ‘flare-ups’ of acute pain. In a biannual review, a HCP would only be seeing a person in one moment, on one particular day. This presentation may not be indicative of how a person with CLBP is managing on a daily basis. One stakeholder [ES12] spoke of their frustration at attending their long-awaited consultation with an Orthopaedic
surgeon only to be told when they entered the clinic room that they appeared to be ‘walking a bit better’ and was discharged. Had the surgeon seen them a few days earlier, ES12 claimed the picture would have been very different.

In their review of digital interventions for the self-management of low back pain, Svendsen et al.\textsuperscript{349} [LIT09] found daily monitoring could keep a person motivated to work towards their goals and self-managements tasks. In addition, they reported that users valued follow up and being able to use the data they had collected so they, and others, could evaluate their progress. In their trial of the ‘Manage My Pain’ app, Bhatia et al.\textsuperscript{356} [LIT25] reported users had a clinically significant reduction in pain-related anxiety and pain catastrophising. They suggested that the reason for this may lie within the app’s self-monitoring features, such as the diary of the patient’s lived experienced. These daily reflections were thought to help “attenuate the psychological correlates of chronic pain”\textsuperscript{356(p12)} a concept that aligns with acceptance and commitment therapy principles. Furthermore, having the ability to share these reflections with HCPs either remotely (through the app portal) or via reports that could be taken to appointments was thought to empower patients by improving their ability to communicate with HCP. Both the patient and the HCP could see a ‘complete picture’ rather than a ‘snapshot’ enabling them to make a more objective assessment of the person’s progress between review appointments.
CMOC - 7

Monitoring their progress with a mobile app and sharing this data with a HCP (C) can help a person with CLBP convey more of a ‘complete picture’ of how they are managing their condition (M) and thereby improve the communication and quality of a healthcare consultation (O).

Sources: LIT08; LIT 09; LIT25; LIT 30; Art2; ES03; ES04; ES05; ES06; ES09; ES12; PS04

Meaningful consultations

Staff shortages mean there are not enough HCPs to help the rising number of people living with CLBP [PS01]. In the UK, particularly in remote locations, there is a heavy reliance on locum doctors [ES02; ES03]. Although it is recognised that there is value in maintaining continuity of care from the same healthcare professional [PP04] the reality for many patients is that they rarely see the same GP in successive appointments.

“...my doctor that I saw originally, he left so I get a random doctor who doesn’t know my past and doesn’t seem to read my records” [ES05, lines 225-226]

What is more, a person with CLBP is likely to see a number of different HCPs (e.g., physiotherapists, surgeons, rheumatologists, neurologists, psychologists) throughout their medical management. Stakeholders complained of the exhaustion they experienced having to go over their medical history repeatedly and their frustration that valuable consultation time was being wasted getting a new HCP ‘up to speed’.
“Nowadays we don’t get continuity with our GPs and when you go into a new GP, to try and explain all of this, you can’t get it all out with your 10min appointment”. [ES08, lines 202-203]

Stakeholders also expressed disappointment at the amount of time spent by the HCP during the consultation gathering information that was not as meaningful to them and which took time away from matters they preferred to discuss. To stakeholders, it seemed HCPs were not interested in getting to know them and their story, but instead were more focused on objective measures such as the amount of pain medication they were taking.

“I don’t know what records are stored so every time I speak to a doctor its, “so yeah, I see you’ve had these tablets for this long” but is it recorded how bad the pain is? Is it recorded that that person can’t walk?.....It just seems to be now the only point of phoning a doctor is just to get more tablets. There is no other benefit of speaking to a doctor because its never gotten me anywhere.” [ES09, lines 96-100]
This drawing (Figure 3.8) [ART2]—submitted to the ‘Translating Chronic Pain’ creative project funded by the UK Arts and Humanities Research Council (2017)—seems to echo ES09’s sentiments.

![Figure 3.8: The medical record swallows the story by Sara Wasson](image)


The cartoon depicts the patient conversing with their GP, but the story gets swallowed and lost in the medical database. The review findings suggest that this feeling resonated with patients living with other painful long-term conditions. In their review of digital apps for patients with Irritable Bowel Disorder (IBD), Yin et al.[358] [LIT 33] reported that many IBD patients felt their quality of life was not discussed in healthcare visits.

By providing a record of objective measurements Du et al.[17] [LIT08] noted that eHealth (which includes mobile apps) could help HCPs and patients track the changes in their CLBP over time and facilitate the communication between the HCP and patient. However, they failed to elaborate on, how exactly this communication could be ‘facilitated’. Supplementary data
provided by artwork and stakeholders suggested that communication was facilitated by the app’s data because it freed up time. By allowing HCPs to view the objective measures they were interested in immediately or before the appointment, allows more time to get to know the patient and discuss their concerns.

CMOC - 8

Using an app to record and share their data with an HCP (either before or during the appointment) (C) can maximise the effectiveness and efficiency of the healthcare appointment (M) thereby reducing the frustration felt by patients when valuable consultation time is wasted bringing HCPs ‘up to speed’ (O).

Sources: PS01; ES02; ES03; ES08; ES09; PP4; ART2; LIT33; LIT08; Twitt02

Abandonment/Safety net

The Scottish Government’s policy on managing long term conditions was keen to stress that self-management is not about the patient being left on their own without support [PP1].

“Self-management is the responsibility of the individual. However, this does not mean people doing it alone” [PP1 p.8]

However, many people living with chronic pain feel abandoned by the NHS [Twitt05; Blog01]. The word ‘self’ in ‘self-management’ can imply the responsibility for ongoing healthcare management lies with the individual and not, as it was meant to be, an ongoing collaboration between patient and HCP [Bk1]. To address this misnomer, there has been a notable shift in the official narrative towards the term ‘supported self-management’
Changing the terminology to ‘supported self-management’ is mere semantics however if it does not reflect actual practise. Stakeholders in the review felt they were discharged too soon under the guise of ‘self-management’ and felt ill-equipped to manage their back pain on their own [ES04; ES03; ES09; PS04].

By providing ongoing support in the form of advice, reassurance, education, and self-management strategies—a mobile app could mitigate these feelings of abandonment. Stakeholders spoke of the app as a form of ‘safety net’ [PS01; PS05; ES03] in that it was a resource they could use to help with self-management strategies but also a means by which they could maintain contact with a HCP if and when they felt they needed it (e.g. by text message or interactive communication portal). A number of papers included in the review noted the benefits of having the ‘best of both worlds’ – a digital intervention with the ability to contact a HCP if needed [LIT11; LIT23; LIT33].

**CMOC - 9**

By providing ongoing support as well as a means by which to contact a HCP if needed (C) a self-management app provides users with the reassurance of a ‘safety net’ should they feel they need additional support (M) thereby mitigating feelings of abandonment (O).

Sources: PP1; Twit5; Blog1; BK1; ThSec2; ES04; ES03; ES09; PS01; PS04; PS05; LIT11; LIT23; LIT33
Dependency

Some professional stakeholders expressed concerns that the burden on healthcare services would be exacerbated if patients expected ongoing support [PS06; PS07]

“...I think patients do have quite a lot of positive things if you keep in regular contact and they feel supported and – like you say – they don't feel abandoned, but I suppose it does in a way, it does, promote a little bit of dependency and because of such a massive number of patients in XXXX that could potentially involve, whether that's practical? At the moment we only have three members of staff.” [PS06, lines 210-214]

However, this was contradicted by several professional stakeholders [PS01; PS05; ES03] who claimed that—in their experience—offering a way for discharged patients to quickly access support should they need it, resulted in less healthcare contacts in the long term. In their experience, the comfort and reassurance of having a ‘safety net’ meant patients rarely needed to use it.

“...you actually found the waiting list did go down, people didn’t knock at the door so much, because they knew you were there, you were there whenever they needed you” [ES03, lines 221-223]

As mentioned earlier, most of the studies on self-management apps included in this review did not measure healthcare utilisation. Notably, the one that did [LIT 33] concluded that there were mixed results when it came to the number of telephone contacts app users made to HCPs. This finding offers a degree of support to PS06’s concerns that app users may
burden the service with text enquiries and instant chat messages. However, this form of support — delivered via a mobile app —maybe less burdensome than a re-referral back into the healthcare service.

**CMOC - 10**

A self-management app that enabled a person with CLBP to maintain contact with a HCP (C) can provide a reassuring ‘safety net’ (M) leaving them more confident to be discharged from the healthcare service (O).

**Sources:** PS01; PS05; PS06; ES03; LIT33

**Social isolation**

The results of the review indicate that many people with CLBP become socially isolated. People living with chronic pain report that it becomes too painful to leave the house, too difficult to focus on tasks, and too tiring to have a conversation.
In the drawing ‘Wings’ by Paula Knight [Art01, Figure 3.9] the figure is depicted as bedridden, held captive by their pain which has manifested itself as wings torn from their back. The feelings expressed in this drawing echoed sentiments made by ES08, a person in their early 60s who had suffered with back pain for years. ES08’s story typified many people’s experiences in the review findings. Living in a small community, ES08 felt that everyone knew their business and liked to gossip behind their back,
particularly after they had had issues with their mental health. This increased their desire for privacy and led ES08 to withdraw from social interactions.

“I am a very private person and I know what the people up here are like now and they just stab you in the back. I don’t trust people since I had my nervous breakdown” [ES08, lines 500-501]

ES08 also spoke of feeling ashamed for not being strong enough to cope with their ongoing back pain which made them reluctant to share their feelings with others.

“I don’t like talking about myself and how I feel in front of people because it makes me feel ashamed that I am not able to ‘fight it’ and be ‘hardy’ – you know what I mean?” [ES08, lines 266-268]

Because ES08’s back pain is invisible, they felt judged by onlookers that there was nothing wrong with them. Against this backdrop, when ES08 was presented with the idea of conversing with a computerised conversational agent (a.k.a a chat bot) within a self-management app, they became moved and excited by the thought:

“No, no – that actually gave me goose bumps because I feel like - this sounds rubbish - I’d feel there was somebody there that is listening to me but not actually, judging me”. [ES08, lines 285-286]

ES08’s feelings of distrust, shame and judgement and their desire for anonymity made the thought of a chat-bot appealing. They likened it to the
relationship they had already developed with ‘Alexa’, Amazon’s virtual assistant technology.

“But then I’ve got an Alexa in the corner here and I speak to her! And I think, sometimes it’s so silly because I’ll say thank you to her and she’ll say thank you back and she’ll give me bits of information in the daytime that I ask her and I don’t feel ashamed about talking to her but, yeah I’d feel that that would be really useful because its somebody in that corner that isn’t going to judge me.” [ES08, lines 517-521]

The results from Hauser-Ulrich et al.\textsuperscript{353} study [LIT21] on IBS suggests that a mobile app with a chatbot that communicates in an empathetic, human-like style, could help people self-manage their chronic illness as well provide meaningful ongoing support. Their findings indicated that participants wanted to interact with the chatbot in the same way they would with a human. The results also suggested people may divulge more when conversing with a chatbot because it provides a safe space for a cathartic release of emotions. This suggestion was supported by one of the stakeholders:

“So you could scream and yell at the app as much as you want and call it all of the names under the sun and this, that and the other – and you are never going to offend anyone...” [ES11, lines 195-197]

The app could also provide company and reassurance at any time of day, even at unsociable hours when many people in pain are awake at night with no-one to talk to [ES04; ES11].
However, a parasocial relationship with an app's chatbot was considered, by other stakeholders, as a poor proxy for the ‘real thing’. When ES10 was at the beginning of their struggle with CLBP they thought a chat-bot function within a self-management app could have provided them with the company they were seeking in a way that would not have taxed their limited energy.

“I withdrew, I isolated myself, purely because people sucked what limited energy I had out of me. So if I had the ability to interact with someone, something that wasn’t an actual person, that wasn’t reducing you know, increasing my fatigue and I could interact with it at any time – it would have been perfect.” [ES10, lines 284-287]

However, in the next few lines ES10 stressed that this anthropomorphic relationship with an app could never provide the comfort and support they found from interacting with real people who were in a similar situation to them.

“I think its limited. You’re only every going to achieve so much with it because ultimately, you’re still isolated and you’re missing that social contact. And certainly, the social contact has been invaluable for the group- I’ve seen it. Even with Covid kicking in, there’s a few of them that definitely took a step back within that first year and when we couldn’t meet up for lunches and they were, they really did, their pain levels went through the roof, they went backwards. Just because they couldn’t take part in those monthly meetings, they were missing the peer support. Even though the peer support was there through the chat and being
able to phone and you know, communicate – the real person interaction wasn’t there." [ES10, lines 289-296]

As artificial intelligence (AI) and healthcare technology advances, there is a need to consider the ethical implications of relying on digital technology to provide empathy and emotional support in lieu of human interaction [Thsec1]. However, the findings of this review indicates that for some people who feel socially isolated or who lack the energy or inclination to interact with people, mobile apps with a chatbot feature, can provide a meaningful relationship to the user.

CMOC – 11

In the absence of supportive ‘real life’ relationships (C) a self-management app with a chatbot feature that has been designed to communicate in a human-like way to offer comfort and reassurance (M) can help someone with CLBP feel less alone (O).

Sources: ES08; ES10; ES11; LIT21; LIT24; News07; Thsec1; Art1
Based on the six CMOCs that go to create programme theory two, Figure 3.10 identifies who might find a mobile app beneficial in relieving the self-management burden that comes with CLBP and in what circumstances. Importantly, it also exposes the app’s ‘black box’ by revealing what is about an app that helps reduce the self-management burden and why.

Figure 3.10: Programme theory two – What works, for whom, why and in what context?
3.4.4 Programme theory 3: Timing

This final theory area introduces CMO configurations that consider when to introduce a self-management app and what needs to happen before a person with CLBP is likely to engage with a self-management app.

Acceptance

It takes time for a person living with CLBP to come to terms with the fact they may never be completely free of pain. With this realisation comes the understanding that HCP’s and the treatment they can offer in the form of medication, injections or surgery is limited and unlikely to cure their back pain [News01]. However, as more treatment options are tried and found wanting, this realisation, for some, begins to take hold. With this acceptance, a person transitions their efforts from seeking a cure for their back pain to finding ways to manage it. At this point, they may become more receptive to using alternative modalities such as a self-management app.

However, the findings of this review suggest that if a person fails to accept their long-term back pain and remains fixated on becoming completely pain-free, they are unlikely to fully engage with a self-management app. Self-management apps are designed to offer a person with CLBP advice and support to help them live well with pain [LIT08; LIT11], but they do not offer a cure [LIT21]. For those who are looking to be pain-free, then, a self-management app will not provide what they are looking for and therefore they are unlikely to find it useful.

“….in order to use the website in an effective and helpful way, individuals must be aware that no medical authority, no miraculous
drug, or other passive therapy might cure the illness, and have to accept becoming actively involved in their care” [LIT14, p.32].

This finding was also supported by Svendson et al.[LIT09] who noted that people who did not want or accept the need to take an active role in their healthcare failed to engage with digital interventions to manage their back pain.

**CMOC - 12**

If a person with CLBP remains steadfast in their search to find a cure for their back pain (C) and are unwilling to accept an active role in self-managing their condition (M) then they are likely to be disappointed with a self-management app because it does not rid them of their pain (O).

*Sources: News01; LIT09; LIT14*

**Believed**

Aligned to the CMOC acceptance is the need for people with CLBP to feel believed. An initial rough programme theory (IRPT) hypothesised that a person with CLBP would need a medical diagnosis to explain their ongoing pain before they could accept their condition and engage with self-management. A diagnosis helps people with CLBP communicate and explain to others why their back pain has persisted for so long.

“Patients certainly like a label and I can appreciate why because sometimes it’s so that they can help friends, family members who are questioning why they still have a problem, and they need to put a name to it, or you know, if they’ve got issues with employment, it sounds, being able to give their employer, a diagnosis of I don’t know, a spondylolisthesis, even if it’s only a
grade one, sounds far more justifiable to be able to be off work” [PS07, lines 179-183]

However, as the review progressed, it became apparent that it was not the 'label' people with CLBP sought rather it was a feeling that they had been believed by others and their experiences were considered real.

“When I finally did get my diagnosis, it was a huge relief to have a name for what I was experiencing. However, that relief was tempered when I soon began to realise that many people do not consider fibromyalgia to be a real illness. If a condition does not have a medical test to confirm it, then that condition does not exist, they believe.” [News19]

People with CLBP feel that others, particularly HCPs do not believe the pain they are in. This sentiment was repeated throughout the review findings [ES01; ES02; ES04; ES05; ES06; ES08 PS08; News13; News19]. As a result, many people with CLBP focus their energies on seeking validation for their pain experience. Feeling believed can help a person with CLBP trust a HCP and move towards accepting their long-term condition and redirect their efforts into strategies to help them self-manage CLBP.

“I came to realise, and it took me a long time to do it, that actually what I wanted was somebody just to say ‘you are telling me you’ve got back pain, I believe you’. That’s what I needed, that’s what I needed somebody to do, to say ‘okay’ just so that you know that

* Appendix O illustrates how this IRPT 2 was refined to become CMOC 13 and CMOC 14
you’re, that it’s not an exaggeration and that you are not making it up and that you are not going mad it’s just somebody saying, giving you the confidence, again this is a precursor to self-motivation and self-reliance somebody give you the confidence that they don’t understand what you’ve got but they accept fully what you are saying. So, moving away from a ‘diagnosis’ and moving it back towards a confirmation that they, the practitioner, accepts that you’ve got a problem” [ES01, lines 255 – 263].

Although stakeholders in the review considered it important to feel believed before they could move on with self-management; it was interesting to note that none of the formal literature included in the review (government papers; third sector reports and academic literature) recognised this as an important causal mechanism.

**CMOC– 13**

Before a person with CLBP can accept the need to self-manage their condition they need to feel that HCPs believe them (C). Feeling believed triggers a sense of reassurance that they have been taken seriously (M) which makes them trust the HCP (O).

*Sources: ES01; ES02; ES04; ES05; ES06; ES08 PS08; News04; News13; News 11; News19; Book01; Blog01*
When a person with CLBP trusts a HCP (C) then they are likely to be more receptive (M) to HCP’s recommendation of a self-management app (O)

Sources: ES01; ES02; ES04; ES05; ES06; ES08 PS08; News04; News13; News11; News19;

Fear/Reassurance
Back pain generates a powerful, instinctive, fear response: “…I was terrified to move…” [News15]. A twitter thread [Twitt01] discussed possible reasons for this reaction. They suggested it is the fear of paralysis that makes the back such an emotive body part in comparison to peripheral joints. The back is central to human activity (both physically and mentally) and regardless of how remote the possibility of paralysis or damage might be, humans have a visceral desire to protect the back.

“we're scared of back pain because it’s inherently more intimidating/disabling than other common problems.” [Twitt 01, 8]

“Unlike other peripheral injuries, some back injuries can indeed leave you quadriplegic or paraplegic” [Twitt 01, 20]

Understandably therefore, a patient with CLBP wants to feel they have been ‘properly’ assessed to be reassured there is no underlying sinister pathology causing their back pain and nothing has been missed. Once these investigations are completed and their fears alleviated, they are
more likely to engage with the strategies offered by a self-management app.

“…maybe if it was something like, you saw a physio of whatever for a couple of sessions? Something like that? And then went on to the self-management point you know? I think initially people would feel it’s, it’s may be a more valuable treatment if they see someone initially” [PS04, lines 231-233]

In addition to this, people with CLBP need reassurance that engaging with self-management strategies will not make their back pain worse. Through the language HCPs have used, and well-meaning people might have said, people with CLBP develop a sense that their back is fragile and needs protecting. For example, discs are described as “crumbling”; cartilage has been “worn away”; joints are “bone on bone” and there is “wear and tear” throughout the spine. As a result, friends and family might encourage people with CLBP to ‘take care’ and ‘watch your back’. Unsurprisingly, this language evokes a strong protective response and people with CLBP become fearful of movement.

People don’t understand their physical, human biology, therefore they are frightened about what they might do to themselves if they do it wrong, So that’s a fundamental thing. ..“Have I done too much?” “Should I be doing that?” “It doesn’t feel right, oh my goodness!” [PS01, lines 267-269]

ES08 spoke of the reassurance she would get from an app that showed her the correct way to do her exercises, reminding her of the proper
technique so she wouldn’t do anything ‘wrong’ and providing feedback on what to expect and what was ‘normal’.

I don’t know how to explain it – I feel that you’d be doing it properly because I think I’ve been to physios, years and years for my back pain. And you come home and you think ‘god that hurts’ but then they’re always drumming it into you ‘just tiny a little bit at a time’ and then the tiny little bit, you think that’s not doing anything, so you tend to over do it and then, but if you’ve got that [app] to sort of guide you” [ES08, lines 55-59]

A similar sentiment was expressed by a participant in Geraghty et al.’s [LIT11] study when they spoke of the reassurance they gained from the internet support which resulted in less fear around engaging in activity to manage their back pain.

CMOC - 15

When a person has been reassured that there is no serious spinal pathology, and they are not likely to do any harm to their backs (C) they become less fearful of movement (M) and are more likely to engage with the strategies offered by a self-management app (O).

Sources: News01; News15; Twitt01; PS03; PS04; ES08; LIT11

Timing of introduction

Self-management was described in the findings as an ‘end of road’ treatment; a strategy which is introduced to manage long term pain conditions when other options (like medication) have failed [PP4; ES04].
However, delaying the introduction of a self-management programme can have a detrimental impact on a person’s quality of life. The longer a person lives with CLBP the more likely maladaptive health behaviours (such as fear avoidance, learned helplessness or an over reliance on pain medication) will become embedded in their pain response. Many stakeholders wished they had been introduced to self-management sooner than they had been [ES04; PS04; ES10; ES11].

“...I do believe the sooner the better, absolutely the sooner the better. If I had had access to this 22 years ago....I should've had access... ideally right at the start would have been perfect.” [ES10 lines 159-163]

However, a person with CLBP may not see the utility of a self-management app if it is introduced too soon i.e., before a person with CLBP has accepted the long-term nature of their condition (CMOC12), before they trust they have been believed (CMOC13; CMOC14) or before they have had investigations and treatments (CMOC15). The findings of this review, suggest a beneficial ‘middle road’ could be found. Bhatia et al's [LIT25] found that those assigned to use their ‘Manage My Pain’ app —whilst also receiving standard care in pain clinics— saw a decrease in anxiety and pain catastrophising when compared to the control group. Introducing a self-management app earlier on in a person’s treatment, alongside investigations and medical management, starts the process of learning to
live well with back pain. If it later transpires that no resolution to their pain can be offered in the form of surgery and/or medication, no time has been lost in developing skills to help manage their CLBP in the long term. As ES04 commented:

“So, while patients are going through the process of trying to find out what’s wrong with them, they can learn to manage their pain from the beginning.” [ES04, lines 280-281]

**CMOC - 16**

Introducing a self-management app early on in a patient’s journey — whilst medical management and investigations are ongoing— (C) can provide reassurance and advice to help a person with CLBP return to everyday activities (M) and thereby reduce the risk of maladaptive behaviours developing (O).

*Sources: PP4; ES04; PS04; ES10; ES11; LIT25*
Figure 3.11 highlights the importance of timing when considering what works, for whom, why and in what context in relation to a self-management app for CLBP. Although the findings suggest that it would be beneficial to introduce a self-management app early on in a person’s journey with CLBP, feeling believed, being reassured, and reaching acceptance are important prerequisites.

3.5 Discussion and Conclusion

3.5.1 Discussion

Despite political assurances to the contrary many studies, including this one, report that people with CLBP often feel abandoned to self-manage their condition on their own. Lack of ongoing support due to resource
constraints in the healthcare service has been described as ‘care left undone’. There is also debate in the literature as to whether self-management under the guise of ‘empowerment’ places an onerous moral obligation on the patient. Considering the scepticism and confusion around the term ‘self-management’ this study highlights the importance of using a mobile app as an adjunct to ongoing care and not as a replacement. This finding is in line with Vo et al.’s meta-ethnographic review of patient’s perceptions of mHealth apps. Whilst they acknowledged apps helped users become more engaged with self-management, patients in the review were keen to stress that apps should be a complementary tool and not a replacement for HCP input. However, Vo et al. offer no further explanation as to why patient’s felt this way. This research — in keeping with its realist nature— looked for causal mechanisms to explain why people with CLBP wanted an app as an adjunct to care. This study found that if people with CLBP are discharged with only a mobile app for support they are likely to feel abandoned rather than empowered. Not knowing why an outcome occurs makes it difficult to replicate desired results, or in this instance, avoid unintended consequences.

Recent surveys evaluating remote consultations make it clear that some clinicians and patients prefer in-person care. However, it is well recognised that patients with CLBP often feel their pain is not taken seriously by HCPs. This study supports the literature that people with CLBP need to feel believed by a HCP. This has implications on user engagement with a self-management app for CLBP. Introducing an app before a person with CLBP feels they have been believed or taken seriously may be interpreted as further evidence that they have been ‘fobbed off’ by the healthcare profession. This feeling of not being taken
seriously is compounded by the fact that many HCPs often lack the time and training\textsuperscript{369, 370} to deliver good quality pain management. As a result, many people with CLBP are left disappointed and frustrated by their medical consultations. In this context, a mobile app may be preferable for some, if it meant avoiding healthcare appointments. A mobile app could provide, quick, reliable, and reassuring answers to a person’s query about their back pain. However, the information provided by the app must be personalised if users are to consider it trustworthy and relevant. Similar concerns over the generic nature of an app’s information have been found in the literature with users expressing a desire for the app to be both specific to their particular complaint and to their user preferences\textsuperscript{371, 372}. A counter argument, however, is that HCPs consultations need to be improved with better pain education and a departure from the biomedical model of treating CLBP\textsuperscript{373}. Although this research does not refute the need for HCPs to deliver better pain management it suggests that for some, the face-to-face encounter with a medical professional is not always the superior experience many assume it to be.

For some people with CLBP, communicating with a mobile app via a chatbot may provide a non-judgemental and comforting relationship many find lacking in 'real person' interactions. These findings are consistent with Baptisa et al’s\textsuperscript{374} study which reported users of the self-management app felt the embodied conversational agent (a.k.a chatbot) provided them with ongoing, non-judgemental, emotional support and reduced diabetes-related stigma. Whilst not all stakeholders in this study agreed, some did support the growing body of evidence that suggests people can develop meaningful relationships with computerised agents which can reduce feelings of social isolation\textsuperscript{375, 376} and support self-management of long-term conditions\textsuperscript{372}. 

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3.5.2 Strengths/Limitations

This realist review was guided by the RAMESES quality standards for realist synthesis and metanarrative reviews\(^{294}\) to ensure the research was conducted systematically and transparently. However, there are some limitations which should be noted. Due to its iterative nature, this research followed early advice on realist reviews to avoid pre-publication\(^{295}\). As a result, the protocol for this review was not publicly registered.

Many of the sources in the synthesis could be described as opinion pieces or commentaries leading to questions of the trustworthiness of the findings. A process of triangulation\(^{298}\), crystallisation\(^{377}\) and purposively looking for the ‘disconfirming case’\(^{378}\) was employed to add credibility and plausibility to the CMOCs and programme theory. The integrity and rigour of the findings was further enhanced by regular stakeholder input, research team discussions and peer review.

Since managing CLBP is a global concern, academic research from across the world was included in the review. However, the Government policy documents, third sector reports and stakeholders mainly come from Scotland (the study location). That said, many of the findings resonate with the policy directions across the UK and beyond.

3.5.3 Innovation

To my knowledge this is first realist review that seeks to address why, for whom and in what circumstances a mobile app might help someone to self-manage CLBP. Furthermore, it uses a novel approach to realist synthesis by conducting realist interviews with key stakeholders and including them as primary data in the synthesis. Using stakeholder input in this way helped to identify significant contextual factors and hidden
generative mechanisms likely to bring about the success or failure of using a mobile app to self-manage CLBP. Furthermore, it increased the likelihood that the research findings would be meaningful to people living with CLBP.

The importance of patient empowerment in the use of self-management apps has been explored in research around diabetes but to my knowledge, this is the first review to apply a conceptual definition of empowerment to mobile app use in self-managing CLBP. In addition, the research drew on substantive theories which enhances the transferability of the findings.

Finally, this study has important implications for clinical practice. It highlights the need for people with CLBP to feel believed and taken seriously by a HCP before introducing a self-management app. This requires good communication skills, up to date knowledge on chronic pain and a biopsychosocial approach to pain management. A summary of the findings and the impact they may have for key stakeholders is presented in Figure 3.12.

3.5.1 Conclusion

With growing numbers of people living with CLBP and limited access to pain self-management programmes it is essential that innovative ways are found to deliver this care. The Covid-19 pandemic highlighted the utility of using digital healthcare technology. However, if self-management apps are to be most effective, they should be introduced as an adjunct to care and not as a replacement. In this way, mobile apps can help to reframe the term self-management, so it no longer feels like abandonment. If a self-management app can be introduced early in a patient's journey and
delivered in a personal way that offers choice and does not add to a person’s burden of care, then the term ‘patient empowerment’ can be a meaningful promise for people self-managing CLBP. Together these three programme theories: empowerment, self-management burden and timing provide a better understanding of how mobile apps can fulfil the promise of digital health technology for people self-managing CLBP.

Having developed these three programme theories this research sought to develop them further by testing them in a realist evaluation. Combining realist studies within the same project in this way is not uncommon. A follow-up realist evaluation was considered particularly important since the theory of being believed as an antecedent to accepting a self-management app had not been mentioned in the academic literature or policy papers included in the review despite it being an important contextual factor to many of the interviewed stakeholders. The premise that an increase in knowledge provided by a self-management would lead to less healthcare utilisation also seemed to be an untested assumption worth further exploration.
Impact for Key Stakeholders

PEOPLE LIVING WITH CHRONIC BACK PAIN
Mobile apps can help people with CLBP stay motivated with self-management. Recording data via a mobile app can help to enhance communications with HCP. In addition, ongoing support offered by an app can help to mitigate feelings of abandonment.

HEALTHCARE PROFESSIONALS
Patients need to feel believed and that their pain has been taken seriously before introducing a self-management app. Furthermore, a mobile app should be used as an adjunct to care and not a replacement.

HEALTHCARE POLICY MAKERS
Policies aimed at promoting the use of mobile apps should ensure there is access to the latest wireless technology and should be rolled out alongside initiatives to improve digital health literacy.

MHEALTH APP DEVELOPERS
Recognise the need for the information to be personalised to the user. Consider having interactive communication portals or text messaging functions in the app to enable users to keep in touch with HCPs. Including Chatbots into the app design may provide users with empathy and support.

RESEARCHERS
Further research is needed to see if mobile app self-management reduces the burden on healthcare services.

Figure 3.12: Impact for Key Stakeholders
3.6 Chapter Summary

Figure 3.13: Chapter three summary

1. A realist synthesis was undertaken with the aim of better understanding what it is about a self-management app that works, who it works for, why and in what context.

2. There were eight steps in the realist synthesis which included two rounds of realist interviews with stakeholders to help refute and refine the programme theories.

3. Academic literature in the form of journal articles were included in the review as well as 'non academic' sources such as artwork, blogs, social media and newspapers.

4. Data was coded using analytical memos. Retrospective and abductive logic was used to to create inferences about context, mechanisms and outcomes.

5. These analytical memos were turned into CMO configurations using mind mapping exercises.

6. In an iterative, back and forth process of analysis and synthesis, 16 IRPTS became 3 programme theories with 16 refined CMOCs.

7. These 3 programme theories centred around empowerment, self-management burden and timing.

8. The next step next in the research project is to test and refine these programme theories further in a realist evaluation of a self-management app for people living with CLBP.
Chapter 4: Realist Evaluation of a Self-Management App for Chronic Low Back Pain

4.1 Introduction

The realist synthesis discussed in the previous chapter (Chapter 3) produced three refined programme theories with sixteen CMO configurations. Programme theory one focused on the concept of empowerment. It proposed that if people living with CLBP had a self-management app presented as an adjunct to ongoing care, which was relevant and adaptable to their personal needs and which they could access whenever and wherever they liked, then a self-management app could be an empowering tool. Programme theory two considered the balance required to ensure a self-management app was a beneficial tool and not an unintended burden. The theory suggested a self-management app could help alleviate some of the self-management burden, particularly feelings of abandonment, by providing ongoing support and by facilitating communication with HCPs with the caveat that the person with CLBP needs to have the capacity (both internal and external) to engage with the app. The final theory, programme theory three, was concerned with timing. It recommended that a self-management app be introduced to someone living with CLBP early on in their patient journey but not before they had been reassured, felt believed and had accepted their condition could not be cured. This chapter presents the rationale, method and findings of a realist evaluation that was subsequently undertaken to test and develop these programme theories further.

Unlike a realist synthesis which primarily uses secondary sources to test and create programme theories, a realist evaluation tests theories using
primary data. A realist evaluation is a systematic approach to studying how people respond to social programmes delivered in ‘real-life’ complex environments and how this influences programme outcomes. In this instance, a realist evaluation was used to test whether the theories from the realist synthesis held up to scrutiny after people living with CLBP had used a self-management app to help them manage their condition. Like a realist synthesis, a realist evaluation uses the same realist logic which starts with the premise that an intervention is likely to work for someone some of the time with different people responding in different ways depending on their personal, social, historical and cultural context. The key to a realist evaluation is to identify who those people might be, why they respond to the programme in the way that they do and what circumstances influence this response.

Realist evaluations are increasingly used in healthcare research and several realist evaluations have been published recently relating to mHealth interventions from around the world. For example, a quick literature search using the term ‘realist evaluation’ reveals a Canadian realist evaluation into an app to help self-manage diabetes, a South African evaluation of an app to deliver ante-natal and post-natal care, an Australian evaluation of a web-based programme to prevent cardiovascular disease; and a Nigerian study of a disease surveillance app to identify suspected cases of Acute Flaccid paralysis (an indicator of wild poliovirus) in armed conflict areas. Despite their disparity, these studies share a similarity in that they are all evaluating complex interventions being implemented in messy, real-world situations. For this reason, choosing to conduct a realist evaluation that embraces social complexity rather than trying to control it, makes sense. Since realist evaluation is a theory-led research approach it complies with the...
recommendation made by The Medical Research Council (MRC)\textsuperscript{199} which encourages a theory-based approach to evaluation when reviewing complex interventions.

The aim of this realist evaluation was to test and develop the programme theories from the realist synthesis with regards to self-management apps for CLBP, namely answering who they would or would not work for, why and in what circumstances. The intended result was to create a transferable theoretical framework that could inform future app development in this area and guide programme implementation. To meet this aim, a sample of people living CLBP were recruited to use a self-management app for three months. Afterwards, the programme theories were tested and refined based on their experiences.

4.2 Method
The study adhered to the RAMESES II quality and reporting standards for realist evaluation\textsuperscript{261} (see Appendix P). This framework ensured the research was conducted systematically, transparently and with rigour.

4.2.1 Ethics
The research was sponsored by The University of Highlands and Islands (UHI) and was guided by the UHI’s Research Ethics Framework (2020). The protocol received ethical approval from the UHI Research Ethics Committee (ETH2122-0819).

So that each participant was suitably informed about the study and the nature of the Curable app (detailed later in section 4.2.4), participant information sheets were created and written in layperson’s language to ensure they were accessible (see Appendix Q). Each participant was
given a 72 hour ‘cooling off’ period before two forms of written consent were obtained: One consent form allowed the Curable app to collect personal data from the users (thus ensuring the study met UK GDPR Regulations) and the second, gained consent for individuals to participate in the 12-week study of the app and recorded interview (see Appendix R).

The research team gained confirmation from the Organisation for the Review of Care and Health Applications (ORCHA) and the North of Scotland Research Ethics Service (NOSRES) that the self-management app chosen for the study (‘Curable’) was not considered a ‘medical device’ as per the Medicines and Healthcare products Regulatory Agency (MHRA) regulations nor were the study participants considered patients (See Appendix S). Consequently, NHS ethical approval was not required for this study. NOSRES also confirmed their approval in the steps the research team had made to ensure the data collection methods of the Curable app was transparent to the study participants. All data was managed in accordance with the Data Protection Act (2018) and UHI’s Research Data Management Policy and Guidelines (2018). All interviews were recorded with an encrypted digital voice recorder and access to the study data was restricted to the research team.

4.2.2 Study design
The study was carried out remotely in Scotland with nine participants living with CLBP. Participants were asked to use the Curable app for twelve weeks to help them self-manage their condition. They were purposely given no instructions as to how many times they needed to access the app over the course of the study and they could engage with the app in any way they chose. At the end of twelve weeks, the study participants took part in a one to one, semi-structured realist interview. The sixteen CMOCs
from the previous realist synthesis (section 3.4.1, Table 3.6) were used as an interview guide.

4.2.3 Study Participants
The sampling strategy was informed by theoretical considerations (i.e. testing theories with people who have CLBP) and practical constraints of the research project (e.g. timing and resources). The decision to invite some stakeholders from the realist synthesis to participate in the evaluation enabled the research team to revisit theories the stakeholders had put forth in the realist synthesis and test these theories after they had used a self-management app.

4.2.4 Intervention
At the time this study was undertaken there were no commercially available apps specifically aimed at self-managing CLBP. Consequently, a generic pain self-management app was chosen for the study. The Curable app was developed by a US-based company (Curable Inc.). The app can be used on both iOS and android platforms and was created to help people with chronic pain to self-manage their condition. The advice and education offered by the app is underpinned by pain neuroscience which focuses on how emotions, past experiences, and traumatic life events can affect the brain and central nervous system, perpetuating the pain response. The app’s content was developed in consultation with pain psychologists, clinical specialist doctors, and physiotherapists. In a systematic review of nineteen mobile apps designed to help people self-manage chronic pain, Curable was rated amongst the top three, meeting the largest number of items to support skills in the self-management of pain. The Curable app was the only app in the review that provided pain education in its self-management programme. Since education is a
fundamental component of any programme designed to help people self-manage a chronic health condition\textsuperscript{116} the Curable app was felt to be appropriate for this study.

Pawson and Tilley maintain ‘programmes are theories’ – in that they are the thoughts, ideas, and assumptions in the minds of the developers as to how and why a programme is thought to work (mechanisms) \textsuperscript{1}. For this reason, it was decided that the study should begin by interviewing one of the co-founders of the Curable app. An email with a study information sheet was sent to Curable Inc and one of the co-founders consented to a recorded interview. This interview identified the assumptions underpinning the Curable app with regards to the mechanisms thought to explain how the app worked (e.g. reducing fear) and the contextual factors considered important for a favourable outcome (e.g. knowledge of the condition). Although no new programme theories were added, the interview was a useful sense-checking and validation exercise as many of the points raised by the app’s co-founder were already part of the 16 CMOCs put forth for testing.

\textbf{4.2.5 Data collection methods}\n
Data collection was via semi-structured realist interviews and the 16 CMOCs from the realist synthesis were used as an interview guide (see Appendix T for the realist evaluation interview script). The rationale and methods were the same as those outlined for the stakeholder interviews conducted in the realist synthesis (section 3.3.3). The decision to conduct individual semi-structured interviews by telephone was largely determined by the social distancing measures in place at the time due to the Covid-19 pandemic. However, there were advantages to conducting telephone interviews in comparison to in-person interviews. It has been suggested
that the anonymity of telephone interview reduces responder bias and can lead to more accurate and truthful data collection\textsuperscript{387}. Furthermore, there is no evidence to suggest that telephone interviews produce lower quality data than face to face interviews\textsuperscript{388}.

4.2.6 Recruitment

The study used three concurrent recruitment streams. In stream one, stakeholders involved in the realist synthesis who had consented to being approached regarding future studies were contacted. In the second stream, an invitation to participate was posted on a private Twitter account (@RealBackstory) developed specifically for the project and shared amongst relevant interest groups. Finally, in stream 3, several pain charities and third sector groups agreed to post the research invitation directly on their websites and social medial platforms. Those interested in participating in the study contacted the researcher by email. A diagram detailing the participants journey through the study is provided in Figure 4.1.
4.2.7 Inclusion/exclusion criteria

The inclusion criteria were kept purposively broad because HCPs see a wide spectrum of patients with CLBP. However, a sample of participants who had been identified by a third sector charity as self-reporting to have had good experiences with self-managing CLBP were deliberately chosen to evaluate juxtaposing views and open up the opportunity to explore rival theories; thereby enhancing the trustworthiness of our findings.

Inclusion criteria

- Any gender or sexual orientation
- Aged 18 or older
- Self-managing chronic back pain (defined as pain in the back lasting > 3 months)
• Have seen a medical practitioner about their back pain prior to being involved in this study
• Not currently undergoing medical treatment in the form of surgery, physiotherapy, scans, or other medical investigations for their back pain.
• May still be taking analgesic medication prescribed by their GP for their back pain
• Have a smartphone capable of running the Curable app
• Able to participate in a telephone interview

Exclusion criteria
• Lacking capacity to provide informed consent
• Chronic pain condition that does not include back pain
• Unable to commit to 12-week study

4.2.8 Data Analysis
Interviews were conducted and recorded by the author and transcribed by a third party. Transcripts were analysed and coded following the principles outlined in the Centre for Advancement in Realist Evaluation and Synthesis training programme. This involved repeated rounds of direct, indirect, and holistic coding to identify key causal mechanisms and contextual factors. The initial sixteen CMOCs from the realist synthesis was used as a coding framework. Inferences were made from the data using abductive and retroductive logic and recorded in a series of analytical memos in a coding journal (see Appendix U for an extract of the coding journal).

To ensure the research findings were credible, a form of triangulation was used in which disconfirming cases, rivalry and counterfactuals were
deliberately sought out and placed alongside each other for analysis. This helped identify aspects of context considered important and ensured the complexity within the data was preserved and not flattened out to create uniform themes. The rigour of the final theories were judged using the principles of explanatory coherence (as discussed in section 2.5.3) For example, the theory that people with CLBP will be disappointed by an app that does not align with their understanding of pain was considered more consilient than the initial theory that people would be frustrated if the app did not provide them with new information. This judgement was made on the basis that it explained more of the data coming from the participant interviews than the initial theory. This analytical process was enhanced by regular participant input, research team discussions and peer review.
4.3 Realist Evaluation Findings

Nine participants, aged between 35 and 70 and all living with CLBP for over three years participated in the study. Three were female and six were male. After testing the sixteen CMOCs from the realist synthesis, twenty CMOCs were created from the realist evaluation forming three refined programme theories. Eight of the initial sixteen CMOCs from the realist synthesis were refined; three were split to create six new CMOCs; two CMOCs were well supported from the findings and remained unchanged; two CMOCs were merged into one new CMOC; two new CMO’s were created from disconfirming cases; and one CMOC could not be tested directly but a new theory was created in relation to the original theory (see Figure 4.2).

![Figure 4.2 Twenty CMOCs created from the Realist Evaluation](image)

The results of the realist evaluation supported the three programme theories from the realist synthesis: programme theory one empowerment;
programme theory two self-management burden and programme theory three timing. The refinement in these theories came from the twenty CMOCs created to support them. Data from the realist evaluation enhanced an understanding of why, how, for whom and in what context an app may help a person with CLBP self-manage their condition. In programme theory one the concept of empowerment is unpacked further, for instance it was identified that HCP buy-in is an important contextual factor if a person with CLBP is to feel empowered by using an app in their healthcare consultations. Within the self-management burden theory (programme theory two) there was overriding agreement with the findings from the realist synthesis that an app should be an adjunct to care and people with CLBP valued follow up contacts with HCPs. However, the evaluation revealed new insights as to the role chatbots could potentially offer in reducing feelings of social isolation and how an app might still provide support in times of acute flares of CLBP. Finally, the need to feel believed before a person with CLBP can move on and accept self-management (and by extension, self-management apps) remained a central theme in the realist evaluation. However, whereas the realist synthesis focused on the importance of others believing a person’s back pain was real, in the realist evaluation it became apparent that it was equally important for people with CLBP to believe their own symptoms were real.

In the following sections, each programme theory is discussed in turn with supporting statements from the study participants. All quotes are reproduced verbatim, and participants have been identified with a coding system CUR01-09. Initial CMOCs deriving from the realist synthesis are identified in the text with the prefix ‘RS’ (e.g., ‘RS 1’ indicates CMOC1 from the realist synthesis). Illustrations have been created for each CMOC to
show how the initial CMOCs taken from the realist synthesis evolved in the realist evaluation. However, a table of the twenty CMOCs can also be found in Appendix V.

4.3.1 Programme theory one: Empowerment

The refined programme theory one entitled ‘Empowerment’ (see Figure 4.3) is created from seven CMOCs that came from study findings.
CMOC 1: Choice and flexibility

Figure 4.4: CMOC 1 Choice & flexibility

Original CMOC (RS 1)

- Traditional NHS-led self-management programmes for CLBP provide participants with little choice in how, when and where they are delivered (C)
- A self-management app for CLBP can be accessed at a time and location that is convenient to the user which restores a person's sense of control and autonomy (M)
- This in turn leads to greater engagement with self-management of CLBP and a sense of ownership over the programme (O)

Refined CMOC #1

- Each person with CLBP is likely to engage with the app's content differently (C)
- The app must adapt to a user's preferences so they feel they have agency, choice, and control over their self-management programme (M)
- which can lead to greater engagement with the app (O).
There was general agreement amongst participants that the Curable app offered a degree of flexibility that NHS self-management programmes were unable to — allowing them to revisit material whenever and wherever they wanted. This supported the initial CMOC (RS 1). However, participants felt the flexibility of the Curable app did not go far enough and expressed disappointment at the lack of choice in the way the content was delivered. CUR05, would have preferred to have watched the content as a video as opposed to just listening to it:

“...it just didn’t suit me and my lifestyle. I’m not one for listening to podcasts and things so to have to focus on just a voice. So used to them being video…”

CUR05, lines 54-59

CUR07 liked to combine listening to the app whilst they went for a walk but found that some of the content and accompanying tasks were not conducive to being on the move.

“...having time to go out for a walk and listen to it was quite useful. But some of the content wasn’t that great when you’re actually on the move.

CUR07, lines13-15

The refined CMOC (CMOC 1, Figure 4.4) expands the notion of ‘convenience’. It is not simply a matter of being able to access the app at a time and location of their choosing; it is about the app being flexible enough to meet a user’s needs at any given moment. Only then does the app give a person with CLBP a sense of control and agency in how they access their self-management programme.
CMOC 2 and CMOC 3: Knowledge

Figure 4.5: CMOC 2 & 3 Knowledge
The initial CMOC (RS 2) from the realist synthesis concerning knowledge and self-management focused on the power imbalance between the HCPs and the patient. The former having more power since they know more about CLBP as a medical condition. After analysing the data from the realist evaluation, the original theory was divided into two refined CMOCs (Figure 4.5): CMOC 2: Knowledge is empowering and CMOC 3: Knowledge reduces fear.

The findings support the initial theory (RS 2) that people with CLBP look to HCPs for support and guidance to manage their condition. However, the initial theory did not recognise the disappointment and frustration many felt towards HCPs at the lack of answers they were given. One reason for this is that not all practitioners have the same amount of expertise when it comes to chronic pain. As a result, not all people with CLBP have access to up-to-date, information to manage their CLBP.

“…not one practitioner’s going to know every method out there obviously, but like you say it’s much easier for an AI to have sort of a wealth of information at its fingertips so to speak.”

CUR02, lines 229-231

The app could make up for a shortfall in HCP knowledge and also keep itself up to date in a way that HCPs, with their time constraints, may find difficult to do. Sophisticated algorithms could mean a user had access to the latest research, guidelines, and treatments from across the world, the moment they were released on the internet. For CUR03 a sense of empowerment came from having the ability to keep abreast of the latest developments in the field of CLBP. Using the app, CUR03 could find their...
own solutions which made them less disappointed with their GP for not providing the answers they had been looking for.

“…time and time again through my long, long life, I've gone to them [GPs] looking for solutions and come away with nothing so I'm disappointed, whereas when I find out about it myself, I could understand it more. I suppose looking at it very basically was, I had all the hours god sends to understand it rather than a 10-minute appointment…”

CUR03, lines 396-400

CUR09 believed if their GP had given them a resource like the Curable app they would have been able to learn more about their condition and find solutions themselves, without having to continually return to their GP for advice and reassurance.

“…if my GP said alright there's an app here you can go on, you can put stuff into it and it'll come back with solutions. Yes because you can ask it questions and it comes up with certain solutions, try different ideas. Because you can't always keep going to GP, because they're tied up.”

CUR09, lines 118-121

CUR04 spoke in similar empowering terms as CUR03. By taking back control over how to help themselves, an app like Curable could help to restore a sense of agency over their condition and how to manage it.
“…ultimately you just lose complete control over managing you as a person, everything becomes associated around the pain and the illness, and regaining that control is extremely vital, and pain management helps that, and I think an app can really help you with that...Because you’re actually doing something about it, you’re taking a step to actually do something about it, you’re absorbing knowledge and trying to come up with a plan, a routine, and finding out what you can do yourself to change the outcome”

CUR04, lines 220-224

CMOC 2 is, for the most part, an unchanged version of the initial CMOC (RS 2). However, the refined version introduces control into the configuration as another element of empowerment which is activated when users are provided with knowledge to manage their CLBP without having to rely on HCPs. The refined CMOC also acknowledges how an app can help mitigate feelings of disappointment by giving people with CLBP solutions their GPs were not able to provide.

CMOC 3: Knowledge reduces fear
What the initial CMOC (RS 2) failed to capture however, was the role knowledge had in reducing a person’s fear of back pain. For this reason, a new CMOC was created (CMOC 3).

According to the co-founder of Curable, a key programme theory underpinning the app centred around increasing a person’s knowledge of their condition and thereby reducing their fear of it. The theory being, once a person knows more about their back pain (e.g., movement is helpful) they become less fearful of doing harm. Once fear is removed or
reduced, then people can move on and start to embrace self-management strategies. When a person establishes a different relationship with chronic pain, one that does not evoke fear, then, according to Curable, that person becomes ‘cured’ of feeling powerless.

For CUR04 managing the fear response in relation to their CLBP was critical in moving on with pain management.

“...that's exactly how pain management has helped me over the last eight years, managing that fear response, realising that it's not going to kill me...in the past that would have triggered a fear response which would have made things a hundred times worse and more awful...managing that fear is absolutely critical to pain management itself, and an app can help with that, without a doubt”.

CUR04, lines 486-489…512-516

Here again the idea of control is linked to knowledge and empowerment but in the new CMOC (3) the focus is on what this does at an individual level. In CMOC 3, confidence and agency are outcomes as a result of the reduction in fear that has been triggered by an increase in a person’s knowledge about their CLBP.
CMOC 4 Personalisation

Personalising the app’s content to the user as well as developing idiosyncratic responses based on the user’s input were considered important to the participants in this study. There was a consensus that the Curable app was not personal enough for people to make a connection with it. CUR05 struggled to relate to what was being said because it was...
delivered with an American accent using American idioms. Although they recognised that this was their own personal bias, the cultural differences presented an additional barrier to accepting the information being presented.

“…If it was presented in a different way that related to our context in Scotland and Britain, wherever, but it was just too Americanised for me, not just the accent but what they said and how they said it.”

CUR05, lines 216-217

Both CUR06 and CUR07 specifically mention the reference made in the app to the link between adverse childhood experiences and the increased risk of developing chronic pain. This immediately alienated them from continuing with the app. They found the suggestion that their pain could be linked to events in their childhood to be both repugnant and irrelevant.

“It was like what happen to me as a child that’s given me a bad back, as chronic pain. I wasn’t abused…. I felt it was sometimes saying, what happened to you – maybe about your upbringing or what happened to you in your past life, it was almost that they were trying to put something in your head, that this is what happened.”

CUR06, lines 125-126…129-131

What made the experience more frustrating to CUR07 was that the app did not learn from their responses and change direction.
“...but there was one thing, that said something about childhood emotional response. I was like, I'm pretty sure that my back doesn't have anything to do with that. I was like, okay, alright, I'll listen to it and hear them out. So, I listened to it and then it said, does any of this resonate with you, I actually pressed the thing that said, no, none of this resonates with me. Then the next thing is when you were a child, what was your relationship with your parents like? It has nothing to do with that.”

CUR07, lines 341-344

When the app asked CUR07 if the information they were receiving was relevant, CUR07 inferred that the app would learn from their responses and tailor the information accordingly. When this did not happen it became frustrating and reinforced the feeling that an app — which relies on algorithms — is no equal to human interactions that can alternate suggestions or advice in response to what has been said. This lack of personal responsiveness quickly undermined the app’s utility.

“It's not necessarily a trust thing. It's almost like a usefulness thing. I'm not going to turn it on often because I've started to hear more stuff that doesn't mean anything to me. It doesn't resonate with me. I don't believe it. I just don't find it helpful or useful or relevant. That's the issue and to be fair, that's exactly why I haven't used it for a while”

CUR07, lines 378-385
Personalisation is linked to the idea of validation. Treating everyone with CLBP in the same way is, for many sufferers, tantamount to feeling as if their pain is not being taken seriously or they are not believed.

“...everybody’s back pain is different. So, what they said in one of the speaking things to me is, you know, is that going to be the same for someone else? Because yes, I might have lower back pain, but somebody might have upper back pain...she’s going to get told the same thing so you know how is that any different to not being believed or helped or you know?

CUR01, Lines 104-106...155-156

The app needed to present the information in a way that considered each user’s unique medical history and packaged the advice accordingly. This point was acknowledged by the app’s co-founder who noticed that app users would hear testimonials from other back pain suffers who look and sound like them and have the same life experiences, but consider their back pain to be uniquely different because it originates at a different level of the spine.

This need for personalisation to create a bespoke user experience was identified in the realist synthesis and was well supported from the findings of the evaluation. As a result, the initial CMOC (RS 3) remained unchanged (Figure 4.6).
CMOC 5: Biomedical mindset

Figure 4.7: CMOC 5 Biomedical mindset

If a mobile app fails to provide the user with options that have not been tried before (C), then the initial hope they may have felt at being offered something that might alleviate their pain (M) may lead to frustration, annoyance, and disappointment for people with a biomedical mindset (M) as the hope they had for meaningful solution to their back pain is not realised (O).

A self-management app that presents an alternate way of understanding and managing CLBP (C) can turn to bitterness, disappointment and sometimes anger (O).

Original CMOC (RS 4)

Refined CMOC #5
The objection to treating all people with CLBP in the same way and the need for the app to deliver, personalised, idiosyncratic care appeared to resonate more strongly with those participants who were described in the study as having a ‘biomedical mindset’. Participants with a biomedical mindset still held the belief that their back pain was a result of an underlying pathological cause. These participants were disappointed with Curable’s approach because they did not accept the mind-body connection. For participants with a biomedical mindset, the app’s psychological explanation for chronic pain was tantamount to telling them their pain was ‘all in their head’.

“Pain is pain- The pain is not in my head; I have a diagnosis, it’s not in my head. Maybe people do have pain that, that do have mental issues and I think maybe it was more down the line of people with mental health [issues], in my personal opinion.”

CUR06, lines 135-137

Curable’s approach to pain self-management was not new to most participants but for the ones who were more biomedically minded [CUR06; CUR05], hearing information they were already familiar with was a disappointment because their hopes for a new solution to their pain had not been realised.

“In fact, I gave up on it because I was just thought this is just ridiculous. I just felt that it wasn’t teaching me anything that I didn’t I already know. It wasn't helping me.”

CUR06, lines 13-15
For others, [CUR01; CUR03; CUR04] the app served as a confirmation that they were ‘on the right track’ and it was a positive reinforcement of what they already knew.

“…for me it reaffirmed a lot of the knowledge, but I’ve got such a good routine in place, I know how to deal with anything that comes up, that yes it wasn’t disappointing, it was interesting.”

CUR04, lines 40-42

Participants who got on well with the Curable app had either already embraced a reconceptualization of pain or were willing to do so. As a result, the messages and strategies offered by the Curable app aligned to their way of thinking about pain.

Juxtaposing participants’ reactions to the education being offered by the Curable app allowed for deeper insights to be made about the initial ‘lack of novelty’ CMOC (RS 4). In the refined CMOC (5) it is clear that the context was not simply that the advice and education the app was offering was not new. It was rather that the app was presenting a way of thinking about pain and managing that did not align with the user’s biomedical mindset. This in turn caused the users to react with feelings of frustration, anger, and disappointment at an approach to managing CLBP they were not willing to accept.
CMOC 6: HCP buy-in needed

Original CMOC (RS 7)

- Monitoring their progress with a self-management app and sharing this data with a HCP
- and thereby improve the communication and quality of the healthcare consultation (O)

Refined CMOC #6

- can help a person with CLBP convey more of a 'complete picture' of how they are managing their condition (M)
- If a HCP does not see the value in the app's recorded data or dismisses its utility (C)
- then this disempowers the person with CLBP by devaluing their contribution to the consultation (M)
- which can adversely affect the therapeutic relationship (O).

Figure 4.8: CMOC 6 HCP buy-in needed
Although the users were not able to record their symptoms with the Curable app, CUR01 had used a different app in the past to assist with their healthcare consultation. Recalling this experience, CUR01 was able to test the initial theory (RS 7) that sharing data with a HCP would improve the consultation. When CUR01 presented data they had collected between their review appointments to their HCP, they reported that it wasn’t taken seriously and was dismissed. As a result, it had a detrimental impact on both the consultation and her relationship with the HCP.

“When I took that to my neurologist he just went “but how do I know that that is genuinely like the right information?” because I could be like oh well how was your headache that day? Well it was a 10 and he says but really was it a 10? Was it just because you were putting that in [the app]?”

CUR01, lines 400-403

In this instance, sharing data recorded via an app had the unintended consequence of making the consultation worse and disempowering the patient. CUR01’s experience offered a valuable contextual insight, that HCP buy-in was needed to realise the empowering potential of an app (Figure 4.8).
CMOC 7: Reduce HCP workload

Figure 4.9: CMOC 7 Reduce HCP workload
As no HCPs were included in the study, it was also not possible to test the CMOC (RS 5) that suggested HCPs would welcome a self-management app if it maximised their clinical time. However, several participants commented on the potential ways a self-management app for CLBP could reduce HCPs workload.

CUR08 felt the Curable app was beneficial in bridging the gap between appointment times. CUR08 believed that having an app to support people with CLBP at home, could extend the period between review appointments.

“…it helps until they maybe get to an appointment or whatever it may be. Something in the meantime until they maybe go and have a once over with a professional or a doctor. Absolutely, great.”

CUR08, lines 439-442

Similarly, if the app could notify users when there was a new development in CLBP treatment CUR09 reasoned GP appointment times wouldn’t be wasted by people looking for new options when none were available – they would only contact their GP when something new had been discovered.

“I would hope to think that Clara [Curable chatbot] could say “by the way those new tablets that came out, it might help you, make an appointment for GP”

CUR09, lines 440-442

In the original CMOC (RS 5) it was suggested that the app could be an empowering tool for HCPs by helping them to deliver ongoing support
remotely, thereby helping them treat more patients in their limited time. The revised theory (CMOC 7, Figure 4.9) adds further explanation as to what resources the app provides that enables people with CLBP to go longer between review appointments. Being able to get timely access from the app to the support and answers they need, gives people with CLBP more confidence to manage on their own between review appointments.

4.3.2 Programme theory two: Self-management burden

Figure 4.10: Programme theory two: Self-management burden

The six original CMOCs under programme theory two from the realist synthesis became nine CMOCs after the results for the realist evaluation had been synthesised. These nine CMOCs created the refined programme theory two: self-management burden (Figure 4.10).
CMOC 8 & 9 Cognitive Burden

Figure 4.11: CMOC 8 & 9 Cognitive burden
The initial CMOC (RS 6) suggested that a person’s ability to engage with a self-management app depended on their internal and external resources. However, when testing this theory with study participants, external resources received little attention with only occasional references made to poor internet connections, digital literacy, and the affordability of smartphones. Most of the participant discussion in relation to the Curable app focused on internal resources, particularly when engaging with the app during a flare up of pain. As a result, the initial CMOC (RS 6) was revised to create two new CMOCs (8 & 9, Figure 4.11). Both CMOCs related to alleviating the cognitive burden of utilising a self-management app during flare-ups.

The Curable App offered users information they could read or listen to but failed to appreciate that during times of acute pain and fatigue people may not have the internal capacity to absorb this information let alone transfer it into a helpful behavioural change.

“…because it’s all very well absorbing information when you’re in a logical state of mind. It’s obviously easier, but when you’re in an irrational state of mind trying to sit and absorb scientific information and trying to follow this precise programme…”

CUR02, lines 103-106

The Curable app was fine for times when a user had their pain well-controlled but mustering the energy to find their mobile phone, open the app and search for help was reported to be beyond a person’s capacity when their pain was acute. However, voice activation was suggested as a potential solution to this (CMOC 8).
“Voice activation is probably the only chance you’ve got because sometimes the pain is so unbearable. Sometimes when I’m on all fours I can’t even get my palm of my hand off the floor to even go reach for my phone. So, the only way I could actually unlock it would be voice activation”.

CUR07, lines 503-505

Another suggestion was for the app to be more assertive (CMOC 9). Rather than wait for the user to activate the app, CUR02 wanted the app to make its presence known and prompt them to engage with it.

“It’s expecting me to go into my phone, open the app and then find a programme, read through it and engage with the audio. Whereas I think that, you know, if this thing was saying, “Hey,” like a notification that pops us on your screen like you would with any other messaging service or kind of if it was more in the line of Siri or Alexa, that kind of thing, where I could talk to it, I didn’t have to even open my eyes to engage with it, I think that could be a beneficial thing”.

CUR02, lines 340-344

It was also suggested that, if the Curable app’s chat bot (Clara) got to know the user well, it could suggest things that might help. In this way, the app would take away the cognitive load of having to make a choice.

“…at times when you’re in so much pain, you just can’t be bothered with anybody, you just want some sort of reassurance or
someone to come up with an idea, because you can't think of anything for yourself. Like you say, Clara I'm having a really bad time, what do you suggest? She will probably come back with all the different things. Yes, give them a try, if it works brilliant, if it doesn't work, say I will try another Clara, what else do you suggest? But it's building that relationship between you and Clara.”

CUR09, lines 241-250

Although the participants recognised that it was difficult to engage with an app when their pain was acute, they stressed that this was true for all activities, including engaging with HCPs for support. As a result, most participants agreed that in times of acute pain nothing and no-one could help, causing them to socially withdraw until their pain had settled to a more tolerable level. Interestingly however, these two new CMOCs (8 & 9) suggest ways in which an app’s features could be adapted to suit people’s needs, even in acute pain.
CMOC 10: Consultations

Using an app to record and share their data with an HCP (either before or during the appointment) (C)

and thereby reduce the frustration felt by patients’ when valuable consultation time is wasted bringing HCPs ‘up to speed’ (O).

can maximise limited consultation time (M)

Original CMOC (RS 8)

Using an app to record and share data with an HCP (C)

can reduce the frustration felt when valuable consultation time is wasted bringing HCPs ‘up to speed’ (M)

can be brought ‘up to speed’ thereby maximising the effectiveness and efficiency of the consultation leading to a more satisfactory appointment (O).

Revised CMOC #10

Figure 4.12: CMOC 10 Consultations
Although it was not possible on the Curable app to record their symptoms and share this data with their HCP, many participants spoke of this as being a beneficial feature of a self-management app. Participants felt it would be helpful if they could record meaningful data on the app and share it with their HCP ahead of their appointment [CUR04; CUR05; CUR06; CUR07; CUR09]. The theory being that, if the HCP had access to pertinent information beforehand it would save time during the consultation and maximise what could be accomplished in the short appointment time.

“…when you go and see him [the GP], he’s got the information there …so I think there’s an opportunity for the GPs to use it and save them a lot of time, a lot of work.”

CUR09, lines 321-323

“I think if there was something like that, that I could then send to the surgery and the nurse practitioner can go through it and then if she thinks there was anything, then pass it on to the GP concerned. I think that would be amazing. I think the NHS will take that on board and run with it.”

CUR06, lines 494-497

These findings supported the initial CMOC (RS 8) that an app could reduce the frustration felt at wasting consultation time bringing HCP’s up to speed. However, in the refined CMOC (see Figure 4.12) ‘reduced frustration’ was understood to be a reaction to the resource the app provided and, as a result, was more of a mechanism driving the outcome.
CMOC 11 & 12: Monitoring

Figure 4.13: CMOC 11 & 12 Monitoring

CMOC 11 & 12: Monitoring

Original CMOC (RS 7)

- Monitoring their progress with a mobile app and sharing this data with a HCP (C)
- And thereby improve the communication and quality of a healthcare consultation (O).
- Can help a person with CLBP convey more of a 'complete picture' of how they are managing their condition (M)
- Can help to reduce the stress and pressure felt by people with CLBP at having to 'look ill' as well as having to recall details about how they have been managing (M)
- Using an app to record and share data with an HCP (C)
- Which improves the communication and quality of the healthcare consultation (O).

However

Revised CMOC #11

- Repeated prompts by an app to record symptoms (C)
- Adds additional burden to self-managing CLBP and serves as a constant reminder of their ill health (M)
- Which can worsen the pain experience (O).

CMOC 12

- Using an app to record and share data with an HCP (C)
- Which improves the communication and quality of the healthcare consultation (O).

New CMOC #12

- Plus
- Context
- Mechanism
- Outcome
In the realist synthesis it was theorised that monitoring a person’s progress with a mobile app and being able to share this data with a HCP would help a person with CLBP convey more of a ‘complete picture’ of how they had been managing (RS 7). CUR04 experience supported this original theory. CUR04 spoke of the difficulty they found in trying to summarise how they had been coping between appointments. CUR04 liked the idea of having access to ‘real-time’ data recorded on the app which meant they did not have to rely on their recall.

“…because they’re only seeing a snapshot of time when you go and see them, you’ve got maybe 20 minutes to tell them what you’ve done in six months or a year,…..because you’re able to be entirely honest with an app and you’re not relying on memory because it's done every day, or continually through the day, …memory is a big problem as well when you’re absolutely exhausted....I think going forward being able to do that and have the doctor have access to the details would be amazing, it really would.”

CUR04, lines 304-307…316-326

CUR04 also described medical consultations as stressful because the pain made it difficult to express themselves and to process what was being said.

“…your ability to communicate properly when you are so exhausted and have such high levels of pain, just isn’t there, it disappears, or rather it’s a skill you have to learn to be able to do that, and you don’t have it, it’s not a natural skill to have to be able
to store these things in your head, run them over before you go to your GP and then articulate them out well, with stress and exhaustion and things, that’s definitely a skill, and it’s one that takes a long time to practise.”

CUR04, lines 367-373

In this context, an app was considered a useful tool in facilitating communication with the HCP. App users could refer to notes they had made or data they had recorded to aid their memory and help to express themselves or pass on important information they may be struggling to articulate.

“…. getting it across you have to make them believe you, and it creates so much stress in that interaction, and if you were doing that on an app then you’re taking that stress out of it”

CUR04, lines 351-357

Finally, the ability for the app to provide objective data in medical appointments, could alleviate some of the pressure people with CLBP feel about ‘looking the part’ of the sick person. Study participants were concerned they would be judged as being ‘fine’ if they appeared in clinic seemingly pain-free. Objective data to support their claims could help to counter subjective assumptions made by HCPs and offer more of a complete picture.

“I think an app would be good for that, because if you’ve got history of that over a week before you have a consultation with a
GP, then you can access it and see exactly how you’re struggling, how you’ve noted you’re struggling, and it takes away some of the visual cues that you would need in order to make a judgement.”

CUR04, lines 404-408

The data from the evaluation enabled a further unpacking of the concept of ‘help’ (RS 7). In the refined CMOC (11) help is manifested by the app lifting some of the stress and pressure felt during a medical consultation (Figure 4.13). However, not all participants felt using an app to monitor their symptoms and share their data was helpful. Two new CMOCs were created from disconfirming cases. One of these CMOCs (CMOC 6, relating to the need for HCP buy-in) has already been discussed under programme theory one as it concerns the app’s role in empowering the user (see section 6.1.6). The other CMOC (12) is presented below as it relates to the unintended consequence of an app making the pain experience worse and, in so doing, adding to the burden of self-managing CLBP.

CMOC 12: Monitoring makes pain worse
Although participants could not use the Curable app to record their symptoms, two participants [CUR03, CUR05] recalled their experience of using different health apps to do this. Both CUR03 and CUR05 found the continual prompts to monitor and record their symptoms made their overall pain experience worse. CUR03 had multiple co-morbidities and became frustrated with the number of prompts they received to record their data.
“...because I have so many different things wrong with me, I have to check my sugars and all that, I have testosterone, sleep apnoea, measure my breathing and all this, how much, and you just find you go round and round and round, and that's all that's in your life, is your health, you don't have time for any pleasure because you're monitoring yourself all the time, so for me that submission can get tedious and you really think, Really?”

CUR03, lines 209-214

Whilst CUR05 found monitoring her symptoms via a pain diary meant she was focusing on her pain all the time which made her pain worse

“...I found it [keeping a symptom diary] very, very difficult to do and it actually felt like it made the pain worse because I was focusing on it.”

CUR05, lines 168-171

In both instances, continually monitoring their symptoms had the unintended consequence of adding to the self-management burden by making their pain experience worse (CMOC 12, Figure 4.13).
CMOC 13: Ongoing Support

Figure 4.14: CMOC 13 Ongoing support

CMOC 13: Ongoing support

Original CMOC (RS 6)
- By providing support as well as a means by which a user could contact a HCP if needed (C)
- A self-management app that enabled a person with CLBP to maintain contact with a HCP (C)
- thereby mitigating feelings of abandonment (O)
- can provide a reassuring ‘safety net’ (M)
- leaving them feeling more confident to be discharged from the healthcare service (O)

Original CMOC (RS 9)
- a self-management app provides users with the reassurance of a safety net should they feel they need additional support (M)

Original CMOC (RS 10)
- Could not be tested

Refined CMOC #13
- After discharge, a person with CLBP needs occasional reviews from a HCP in addition to a self-management app (C)
- to reassure them that they have not been left to manage their condition on their own (M)
- and prevent feelings of abandonment (O).

Figure 4.14: CMOC 13 Ongoing support
The Curable app did not offer a means by which users could keep in contact with their HCP. As a result, RS 9 and RS 10 relating to this form of ongoing support, could not be tested. However, the theory that the app provided a form of safety net which could reduce feelings of abandonment did resonate with participants and the two initial CMOCs (RS 9 & RS 10) were merged into one refined version CMOC 13 (Figure 4.14). The findings highlight that an app alone was insufficient in being able to provide long term self-management support and ongoing input from an HCP was valued.

Many study participants reported to feel abandoned by the NHS when they were discharged from the service, echoing the results from the realist synthesis.

“No, there is no ongoing support once you’re discharged and stuff, that’s it, you don’t hear from anybody, there is nothing, apart from unless you go back to your doctor again and start the process again, pretty much.”

CUR08, lines 107-109

For participants who felt abandoned in this way, the Curable app was seen as a safety net, in that it provided a measure of ongoing support and reassurance. However, most participants reported that the Curable app on its own would not be enough to feel they were being supported. Participants wanted to be reviewed by a HCP every so often, so as not to feel like they had been ‘tossed aside’ [CUR 08, Line 457].
“It is really having a safety net. I think with a lot of people, you can turn people away with [a] safety net, they get on a lot better within themselves. But if you turn to them and say well, we've done everything for you, we don't know what's up with you, we can't find nothing. They go away and they feel let down, disappointed. But if they say look, we've gone as far as we can, but we will give you this app, you build up a relationship with Clara and then say if there's any red flags, the GP will dial into every now and then, every six months and if there's anything reoccurring, what maybe needs more investigation, they will look into it”

CUR09, lines 373-379

“A follow-up with a real live person is always a good idea in my book, just to see how they're getting on, I wouldn't just want them to be given the app and say, “There you are, bye bye.”

CUR03, lines 56-59

When pressed to explain why CUR03 thought it necessary that this ongoing contact must be from a ‘real live person’ and not an app, CUR03 suggested:

“I think reassurance that they're not just a number, that someone does care as to how they're getting on, is interested in them. Again, it goes back to this abandonment and isolation, they feel part of a community.”

CUR03, lines 61-63
CMOC 14 & 15: Chatbots

Original CMOC (RS 11)

- In the absence of supportive ‘real life’ relationships (C)
- can help someone with CLBP feel less alone (O).
- a self-management app with a chatbot feature that has been designed to communicate in a human-like way to offer comfort and reassurance (M)
- can be less tiring for people with CLBP and can reduce sensations of shame, guilt and loneliness (M)
- and mitigate feelings of social isolation (O).

For some people with CLBP, an app’s chatbot cannot convey the warmth and empathy they get from supportive conversations with humans (C)

Refined CMOC #14

- however

New CMOC #15

- resulting in an interaction that is fake, cold, and devoid of meaning (M)
- and making a chatbot a poor proxy for human support (O).

Figure 4.15: CMOCs 14 & 15 Chatbots
The findings of the evaluation divided the initial CMOC (RS 11) into two: one refined (CMOC 14) and one new (CMOC15) (see Figure 4.15). The initial CMOC (RS 11) which suggested a chatbot could be a supportive entity for people self-managing CLBP was supported and refined by some of the findings. The data revealed important contextual factors that helped to explain why people with CLBP may lack supportive ‘real life’ relationships (e.g., criticism and judgement from others leading to social isolation). Understanding this context better, enabled a deeper exploration of the resources the chatbot feature provided (e.g., a less tiring and critical experience). These findings provided more explanatory detail to create a refined CMOC (14).

When asked about the theory behind the chatbot ‘Clara’ that guides the user through the Curable app, the co-founder of Curable stated that it was purposively designed so that people had an empathetic character they could build a relationship with. Several participants, including those who were advocates of an in-person, group, self-management programme (and therefore assumed to be more predisposed to ‘human contact’) felt a self-management app with a conversational agent had the potential to reduce social isolation.

“…because if you’ve been isolated for so long then the very act of meeting someone, getting to know them, taking emotion and all that into it, can be quite intimidating, whereas I suppose something you know is not quite real would be easier in some regards…”

CUR03, lines 98-101
Pain made participants feel short-tempered and irritable thus, rather than risk offending friends by being abrupt or rude they tended to withdraw from social contact. Participants spoke of the exhaustion of having to observe the social niceties when conversing with others. In this context, the app could provide people with CLBP access to support without having to go to the effort and stress of engaging with other people.

“I think that’s where the app also has a significant advantage, because I know myself in the early days, and from talking to all the people, we all went through self-isolation, where people just take too much out of you, you haven’t got the energy to cope, you’re overwhelmed with pain and lack of sleep, and when you isolate yourself like that, an app would be ideal because that’s a way in to that bridge, without any excess use of energy...”

CUR04, lines 122-125

A chat bot was seen as a non-judgemental entity and therefore could be spoken to without fear of criticism.

“I think actually having someone there that’s non-judgemental, someone there that is knowledgeable, someone you’ve built a relationship with, even virtually”

CUR07, lines 563-564

However, the data also provided evidence that refutes the initial CMOC (RS 11). For some [CUR06; CUR08] a chatbot would always be considered a poor proxy for a real human relationship. Communicating
with a chat bot, regardless of how sophisticated its responses, was seen as fake and lacking the warmth of a human relationship.

“The AI thing, again it's all very, I don't know, false I suppose. Again, it's not the personal- It's the personal thing, that’s the difference…. There’s no substance to [it]…. it’s not real, you’re not seeing facial expressions of somebody, how they react with you. The AI it’s robotic basically…. It's cold, put it that way.”

CUR08, Lines 333-362

The Curable app’s chatbot, Clara, was unable to recreate the natural back and forth responsive style of a human conversation. Furthermore, some participants felt that all chatbots would lack the warmth and empathy conveyed in the non-verbal responses embedded in a human interaction (e.g., micro expressions and body language). In the absence of this, some participants felt that the relationship with an app’s chatbot would always be empty, cold and devoid of meaning (CMOC 15).
4.3.3 Programme theory three: Timing

Programme theory three: Timing (Figure 4.16) took the initial five CMOCs from the realist synthesis and refined them. After synthesising the results of the evaluation, timing was closely related to a feeling of acceptance. Timing and acceptance played an interacting role in affecting a person’s willingness to engage with an app to self-manage CLBP. Interestingly, the role acceptance played in each CMOC was not the same. In different CMOCs acceptance was considered to be either be an important context, mechanism or outcome.

Figure 4.16: Programme theory three: Timing

Programme theory three: Timing is likely to benefit from a self-management app early on in their patient journey but not before they feel believed and reassured by HCPs and have accepted their condition cannot be cured.
CMOC 16: Expectations of a cure

If a person with CLBP remains steadfast in their search to find a cure for their back pain (C), then they are likely to be disappointed with a self-management app because it does not rid them of their pain (O).

and are unwilling to accept an active role in self-managing their condition (M).

People with CLBP who retain the cultural expectation that the healthcare service can and should cure their pain and struggle to accept otherwise (C), will be disappointed by an app that fails to meet these expectations (M), resulting in a lack of engagement (O).

Figure 4.17: CMOC 16 Expectations of a cure
The difficulty in accepting long term self-management of CLBP was attributed by study participants to the culture and expectations created by the NHS. Many people still expect the healthcare service to cure their illnesses. Participants who had accepted their back pain was a long-term condition felt that others, who were looking for immediate ‘fixes’ had not reached a level of acceptance needed to successfully self-manage CLBP.

“…I think it’s a problem with our culture in that we’re so enamoured with this immediacy, you know?”

CUR02, lines 268-270

Furthermore, self-managing a long-term condition like CLBP is hard and can take a long time to make the necessary behaviour changes. Some participants felt, in a culture that expected quick ‘fixes’, such a long-term health commitment was difficult to accept.

I think it’s maybe too much for them, they just can’t do it. Are they too – this is really controversial – are they too lazy to work it out for themselves, do they just want to be spoon fed? Again, it goes back to this, ‘well I’m going to the doctor so I expect a purple pill, and all will be well, I don’t have to think about it myself.’

CUR03, lines 166-169

It was only when CUR03 had accepted there was no cure for their ongoing back pain that they were able to move on and learn to live with it.
“…that’s when I started coping better, when I realised there isn’t a
cure there wasn’t just something in me, they could switch off. I
think acceptance of that, then you start recovering in a way, you
start to be able to live with it”

CUR03, lines 162-165

CUR03 thought those people who had yet to reach the level of acceptance
that he had, were unlikely to see the utility in a self-management app for
CLBP. CUR09 describes the process towards acceptance as a journey.

“As soon as you accept that you’ve got a chronic pain issue with
your back or any part of your body and it’s there long term. Once
you accept it and adjust your lifestyle around it and work with it not
against it, any sort of information you can gather through the app
or going to meetings about that. It’s all a learning curve for
everyone and everyone is on a different journey at a different
point. But it’s acceptance. A lot of people won't accept that they’ve
got a long-term issue.”

CUR09, lines 39-44

Although the study findings supported the initial CMOC (RS 12), in the
refined CMOC (16, Figure 4.17), contextual factors are explored further.
The reason some people find it hard to accept the need to self-manage
CLBP is because they still adhere to the cultural expectation that the
healthcare service will provide them with a cure. Time in CMOC 16 relates
to the idea that acceptance is a journey that starts with letting go of an
expectation for a cure to CLBP.
CMOC 17: A proper diagnosis

**CMOC 17: A proper diagnosis**

Original CMOC (RS 13)

- Before a person with CLBP can accept the need to self-manage their condition they need to feel that HCPs believe them (C)
- Feeling believed triggers a sense of reassurance that they have been taken seriously (M)
- Which makes them trust their HCP (O)

Refined CMOC #17

- A person with CLBP needs a diagnosis that adequately explains their ongoing pain (C).
- This validates their pain experience to themselves and others helping them to accept their condition (M)
- and making them more likely to engage with a self-management app (O).

Figure 4.18: CMOC 17 A proper diagnosis
For some study participants, acceptance only came when they had been given a definitive diagnosis. Having a medical explanation for their ongoing back pain, even if it was not accompanied by a cure, enabled CUR01 to move on and embrace self-management. CUR01 felt this was the reason they got on well with the Curable app and why others, who lacked this explanation, would not.

“I think if someone had no real reason and no real answers I think that would be a bit more different because like I’ve got the answers, I’ve you know had it, I’ve accepted it so I think that’s different for me rather than someone who doesn’t have.”

CUR01, Lines 370-372

The theory from the realist synthesis (RS 13) that people with CLBP need to feel believed remained an important factor in the realist evaluation. However, when testing this theory with study participants, feeling believed became a mechanism along with acceptance, that was triggered when participants felt they had been given a ‘proper’ diagnosis to explain their back pain. In keeping with the cyclical nature of realist research, this need for a diagnosis brought parts of the original IRPT (#2) back into theory development. A ‘proper diagnosis’ in this context was a medically recognised term like ‘spondylosis’ and not a vague descriptor like ‘non-specific’ back pain that could imply they were making their pain up.

“…I have a diagnosis, its not in my head.”

CUR06, Lines 135
“...at long last I had somebody who gave me an honest diagnosis and that was hugely relieving to hear that it was something physical, that I wasn’t going daft.... That’s where your discs have gone so that’s why you’re in pain.” So I got a proper diagnosis.”

CUR05, lines 259-261; 264-265

In the initial CMOC (RS 13) the focus was on the HCP believing a person’s CLBP was real. In the refined CMOC (17, Figure 4.18) it was equally important that a person with CLBP believed their pain was real. This belief came from being given a diagnosis which enabled them to accept their CLBP and embrace tools, like an app, to help them self-manage it. In relation to timing, it was clear that for many participants, introducing them to a self-management app needed to come after they had had a ‘proper diagnosis’.
CMOC 18: Trust the messenger

Original CMOC (RS 14)

When a person with CLBP trusts a HCP (C)

then they are more likely to be receptive (M)

to HCPs recommendation of a self-management app (O)

Refined CMOC #18

A person with CLBP needs to trust the person recommending a self-management app (C)

to reassure them that the app is credible (M)

before they are willing to give it a try (O).

Figure 4.19: CMOC 18 Trust the messenger
It was assumed in the initial CMOC (RS 14) that a person needed to trust a HCP before they would accept a self-management app for their CLBP. Although this was not refuted in the results of the evaluation, the assumption that the trusted individual would be a HCP needed to be revised. The co-founder of the Curable app was introduced to pain neuroscience by a friend they respected and trusted. This made them more receptive to what they were being told and willing to keep an open mind. Drawing from their own experience, the co-founder felt it was important that the advice and education contained in the Curable app was supported by respected pain science professionals and based on up-to-date, trustworthy evidence. This theory of ‘trusting the messenger’ resonated with participants in the study [CUR01; CUR03; CUR04]. Trust was enhanced if the Curable app was recommended by an NHS professional.

“…if it’s being recommended by health professionals, then people know it’s not just a sales gimmick, I think that’s an important thing maybe, that rather than just looking at it commercially, this is being recommended by the NHS…”

CUR03, lines 182-185

For one participant however [CUR05] the trust in the NHS had broken down to such an extent that it adversely impacted on the app’s credibility.

“When you’ve been written off effectively by the NHS and effectively abandoned by them you’re sceptical and maybe that’s held me back from really benefitting from the app potentially.”
The co-founder's introduction to pain neuroscience by a trusted friend and CUR04's experience with the NHS led to the initial theory (RS 14) being revised. Although trust remained a key contextual factor in whether a person with CLBP felt the app was credible, the new CMOC (18, Figure 4.19) recognised the trusted individual may not be a HCP.
CMO 19: Reassurance

**CMOC 19: Reassurance**

When a person has been reassured that there is no serious spinal pathology, and they are not likely to do any harm to their backs (C), they become less fearful of movement (M) and are more likely to engage with the strategies offered by a self-management app (O).

A person with CLBP needs an assessment from an HCP (C) to provide trust and reassurance that nothing sinister has been missed (M) before they use an app to self-manage their CLBP (O).

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Figure 4.20: CMOC 19 Reassurance
The study suggested that reassurance was an important mechanism in accepting a self-management app. Participants needed to know there was nothing to worry about in relation to their CLBP. For many participants [CUR01; CUR03; CUR05; CUR07; CUR08] this reassurance came from an assessment by a HCP and medical investigations (e.g. blood tests, X-rays or MRIs). Importantly, it was felt the app was not able to provide them with sufficient reassurance. As CUR08 put it:

“…an app can’t actually see what’s going on inside your body. So if there is something else causing something, you maybe need to go for that scan or the X-ray or whatever it may be. Have somebody physically looking at you. I think there’s a time and a place for it and probably later on down the path.”

CUR08, lines 135-139

For CUR07 even though the tests could not provide a definitive diagnosis, knowing the investigations had not revealed any significant health issue provided reassurance and enabled them to move on with managing their CLBP.

“It just gave me a total comfort, that there was no more guesswork, it was based on the evidence, that the evidence here was physical evidence. That was so strong for me. ... I’m not sure that I still wouldn’t want medical diagnosis, the medical imaging to be done. Because I had blood tests and everything else to prove there was nothing going on, there was no raised inflammatory marker nothing. So, all of that gave me and him total comfort that we knew exactly what was happening.”
In the refined CMOC (19, Figure 4.20) fear is less about moving in a way that might make their back pain worse and more about the fear that something sinister has been missed. Being assessed by a HCP is a key contextual factor that triggers reassurance and acceptance. Only after a person with CLBP has been assessed by a HCP and their fears addressed, are they likely to engage with a self-management app.
CMOC 20: Early in the journey

Figure 4.21: CMOC 20 Early in the journey

CMOC 20: Early in the journey

Original CMOC (RS 16)

★
Introducing a self-management app early on in a patient’s journey whilst medical management and investigations are still ongoing – (C)

and thereby reduce the risk of maladaptive behaviours (O)

can provide reassurance and advice to help a person with CLBP return to everyday activities (M)

Refined CMOC #20

★
Early introduction to a self-management app whilst medical management and investigation are ongoing (C)

gives a person with CLBP more time to embed self-management strategies into their life (M)

thus providing an opportunity to improve their quality of life sooner (O)

Figure 4.21: CMOC 20 Early in the journey
A key assumption underpinning the Curable app was the idea that if people with chronic pain were given access to advice and pain management strategies early on this would have a positive effect on their quality of life. This theory was supported by the experiences of many participants in this study. Several believed that if the NHS had introduced them to the information contained within the Curable app sooner, it would not have taken them so long to get a handle on managing their pain.

“…the sooner you start the journey the better. Without a doubt, managing chronic pain takes time, there’s a lot of knowledge you need to learn, there’s a lot of techniques you have to practise, and all these things don’t happen overnight, so the sooner you have access to information and start, the better, and I think it really has to be at 12 weeks, because I know the quality of life I’ve got now, and it’s been quite a journey over the last eight years, but if I’d had this quality of life, I could have had it 10 years earlier.”

CUR04, Lines 261-267

The initial CMOC (RS 16) that self-management needed to be introduced early on; whilst diagnostic tests were being conducted and treatment options were being explored was also well supported by study participants [CUR02; CUR03; CUR04; CUR06; CUR09].

“I think the way I would personally think to benefit from it most would be if someone said, “Okay, we’re starting the treatment. We’re going to do this, this and this. We are going to look at drug therapy, we are going to look at alternatives, but your homework
in the meantime is to try and make a tiny bit of progress by 
yourself with the help of this app.”

CUR02, lines 282-285

However, if an app was introduced too early, before tests and treatments 
were undertaken, there was a risk they would feel as if they had not been 
taken seriously and they were being fobbed off with a gimmick.

“I wouldn’t have used it. I would have probably been quite 
offended at it because it’s like well okay but so is that it? You’re 
just going to leave me with an App. You know for the rest of my 
life you’re just going to leave me with an app, that’s it?”

CUR01, lines 213-215

The results suggest the optimum time to introduce an app like Curable 
was in primary care, by a HCP. However, it is incumbent on HCPs to ‘sell’ 
a self-management app as part of a complete treatment package.

“…it depends if you sell it, if you like, I mean yes the tests are still 
absolutely vital and critical, but then if you were to sell it that, 
“What you’re going through is extremely stressful, and self-
management helps with managing your stress levels, the pain 
you’re going through isn’t just a physical thing, there are other 
factors taking place, and those other factors you can look at and 
learn to control,” I think it depends how you sell it to the person 
that’s coming through the door”.

CUR04, lines 245-250
The refined CMOC (20, Figure 4.21) builds on the initial CMOC (RS 16) by elaborating further on of the resources being offered by the app. If introduced early on, the app would give people with CLBP the opportunity to develop the skills needed to self-manage their condition sooner, without unnecessary delay. Thus, giving them the time needed to practise, hone, and embed these skills into their life. Although participants acknowledged that this would reduce maladaptive behaviours from developing (e.g., fear avoidance, social isolation, and a reliance on pain medication) a more general sense from the data was that timely introduction to a self-management app would improve participants quality of life sooner.

4.4 Discussion
Low back pain is one of the most common reasons for consulting a doctor\textsuperscript{20}. However, it is well recognised that low back pain continues to be poorly managed by HCPs worldwide\textsuperscript{369 84}. This is not surprising given the little —if any— pain education undergraduate physicians receive during their training\textsuperscript{391 392}. Being beholden on an HCP for answers and treatment creates a sense of powerlessness closely linked to the idea of learned helplessness\textsuperscript{393}. Learned helplessness describes the way a person behaves when they feel they have no resources within themselves to make an impact on their life and lack the ability to make self-determined decisions to pursue meaningful goals\textsuperscript{139}. Some argue that learned helplessness has arisen from the paternalistic style of healthcare which has created and perpetuated an unhealthy dependency on ‘the doctor knows best’ approach\textsuperscript{394}. Helplessness and fear avoidance behaviour is common in people with CLBP and are strong predictors of pain-related disability\textsuperscript{395}. 
The results from our study are consistent with Lim et al.'s findings that people with low back pain want education and advice to help them manage their condition. The findings of this evaluation suggest that by increasing a person’s knowledge of CLBP and how to manage it, an app can help reduce fear avoidance (CMOC 3). Furthermore, this increased knowledge made people with CLBP less reliant on HCPs for advice on how to manage their CLBP and in this way, helped to redress the power differential between the patient and HCP (CMOC 2).

Although the Curable app lacked the functionality to record and share data with the user’s physicians, participants in the study speculated that having this ability would make their consultations with HCPs more effective and efficient (CMOC 10) and less stressful (CMOC 11). Although these were speculative assumptions made by study participants there is research to support their ideas. Apps to record medical data and share with healthcare practitioners have already been shown to improve healthcare consultations in conditions such as irritable bowel syndrome, chronic pain, diabetes, and heart failure.

It should be noted however that recording and monitoring CLBP symptoms was not considered by all to be an empowering activity. For some participants, this activity added to their pain experience and overall burden of self-managing CLPB (CMOC 12). This finding supported other studies which found that continual monitoring of symptoms had a nocebo effect with greater symptom reporting, higher symptom severity and delayed recovery times. The results of this evaluation would suggest that monitoring is not always an empowering activity and should therefore be an optional feature of an app.
Furthermore, for a person to feel empowered they need to feel their input can influence and impact on decisions affecting them. One participant’s experience provided valuable insight as to the impact HCPs had on an app’s empowerment potential. In this instance the patient tried to exert some control over their consultation using data from the app to support them. However, their actions lacked impact because the physician refused to acknowledge the app’s data and the patient’s contribution. There is much debate as to whether empowerment is something that can be transferred from one individual to another. This encounter between the patient and physician supports Lee and Koh’s idea that empowerment is affected by the behaviour of the person in power. By refusing to relinquish their power over the consultation and value the patient’s contribution, the power differential remained in favour of the HCP. This incident further illustrates how the behaviour of some HCPs continues to contribute to a patient’s sense of learned helplessness. As a result, a new CMOC was created (CMOC 6) which stressed the need for HPC’s to value and acknowledge the data collected by a patient if they are to feel empowered by an app in their healthcare consultations.

Most study participants felt the Curable app was not personal enough for them (CMOC 4). It was felt that the app did not adapt its content to the user’s responses and preferences. Consequently, the app provided information participants considered irrelevant which had a detrimental impact on the app’s utility and user engagement. Two well established models in the field of technology adoption and implementation: Technology Acceptance Model and the Unified Theory of Acceptance and Use of Technology have perceived usefulness as one of the key mechanisms behind a person’s behavioural intention to use technology. High attrition rates are a common issue in mobile app usage. This could
be addressed if the app’s content was modified to the user. The more choice offered by a self-management app and the more tailored its advice is to the idiosyncratic presentation of the user’s back pain, the more likely it is that an app will be considered helpful and will sustain user engagement (CMOC 1).

For many, the difficulty in accepting the need to self-manage their CLBP was due to lack of diagnosis or definitive explanation as to the cause of their long-term back pain. Approximately 85% of patients with CLBP will not have an identifiable pathological cause to explain their ongoing symptoms. Participants in this study spoke of the relief in being given a diagnosis after receiving the results of their MRI despite it being well-established that imaging is a poor diagnostic tool for CLBP. This relief was in part due to the reassurance the MRI gave that there was no serious spinal pathology to be concerned with and also served as confirmation to them and others that their pain was real and not ‘in their head’. With regards to when to introduce a self-management app for CLBP, the results of this study suggested that for some participants getting a diagnosis helped them move towards accepting their condition and the need to self-manage it (CMOC17). This finding is supported by Van de Velde who observed that self-management was difficult if a person could not accept their condition or felt as if they had no control over their situation. This research also extends the findings of Stenner et al. who noted that for people with CLBP to live an active life with pain [their emphasis] required a change of mindset towards acceptance lest they be ‘stuck’ waiting for a cure that never comes (CMOC 16).

Those participants who were able to look beyond structural explanations for their continued back pain were more likely to find the mindfulness,
relaxation and meditation exercises offered by the Curable app to be beneficial in helping them manage their pain (CMOC 5). These participants found the resources helped them to accept living with and in pain. Research into acceptance of chronic pain, has found that those who adopt a realistic approach to pain, one that does not involve struggling against it or avoiding activities because of it; fare better in terms of pain related anxiety, depression and have less physical and psychosocial disability\textsuperscript{410}. However, participants in this study who found their current level of pain to be unacceptable and held out hope that the Curable app was going to provide them with significant pain relief were left disappointed (CMOC 16). This is a likely reflection of the biomedical model of healthcare that carries with it an expectation that all illnesses have an identifiable pathological cause and if they cannot be cured, they at least will be responsive to medical treatment.

The biomedical model of illness, on which the NHS was built, has instilled a cultural expectation that disease has a specific aetiology which, once diagnosed can be treated and resolved\textsuperscript{74}. Despite attempts to move away from this biomedical model, studies show that many people living with CLBP are still heavily influenced by this approach as evidenced by their steadfast search for a root cause to explain their ongoing pain\textsuperscript{396, 411-414}. One reason to explain this desire for a diagnosis (aside from ruling out sinister pathology) is that it provides legitimisation for their condition. In a culture that equates pain with an identifiable pathology, to have unexplained pain can lead to stigmatisation\textsuperscript{415} with people made to feel like malingerers\textsuperscript{416} or that they are making their pain up\textsuperscript{368}. A point neatly exemplified in a participants comment: “I have a diagnosis, it’s not in my head (CUR06, line 135).
With increasing numbers of people living with long-term health conditions, healthcare services worldwide have long been transitioning their model of care from acute episodic treatment to chronic care models. However, shifting expectations from 'curing' CLBP to 'managing' CLBP is challenging both for patients and clinicians. Participants in this study suggested that people who remained intent on finding a cure for their back pain were likely to be disappointed by a self-management app (CMOC 17). This resonated with the findings of Geurts et al’s systematic view which found patients with chronic non-cancer pain expected the healthcare service to provide a cure for their persistent pain and were disappointed when it failed to do so.

The results of this study showed that participants would have found a resource like the Curable app to have been beneficial earlier on in their pain journey. Many participants expressed regret that they had not been introduced to a resource like the Curable app earlier; believing that, had they have known more their back pain sooner, they would have been able to manage it better (CMOC 20). The current NICE guidelines for low back pain recommend self-management advice and information is offered by HCPs to patients at all steps of the treatment pathway. However, the decision as to when to introduce a self-management app is a challenging one. The results of this evaluation suggest that people with CLBP need to feel they have been given a ‘proper’ assessment from a ‘real’ healthcare professional before introducing a self-management app. Despite promising research into the effectiveness of remote/telerehabilitation assessments for people with low back pain, for most participants in this study, an app would not be able to provide the same level of reassurance they receive from an assessment by a HCP (CMOC 19). Although, two participants believed an app could do this in the future if the artificial intelligence
improved. Our findings suggest that a good time to introduce an app would be in primary care, whilst patients are undergoing treatment and investigation for their back pain. Aside from the realist synthesis that preceded this evaluation\textsuperscript{422}, we were unable to find any published studies into the optimal time to introduce a self-management app to manage low back pain which suggests this would be a fruitful area for further research.

It is well recognised in the literature that at times, the ability to engage in self-management may be beyond the capacity of some individuals\textsuperscript{423, 424, 274}. The variable nature of a person’s coping capacity speaks to a wider moral debate around self-management\textsuperscript{143}. There are some who argue, in our efforts to move away from medical paternalism and promote individual autonomy we place too great a burden on patient populations who are already vulnerable\textsuperscript{362}. This burden comes from the assumption that developing self-management skills will promote individual autonomy and less reliance on healthcare professionals. This premise belies the fact that individual autonomy exists on a continuum and will fluctuate over the course of a person illness\textsuperscript{425}. Given the variable nature of CLBP and a person’s ability to manage it, it is not surprising that even those participants in the study who had a favourable experience interacting with the self-management app, still wanted ongoing input from HCPs (CMOC 13).

This evaluation demonstrated that at times, asking a person to engage with a self-management app was too much of a burden. Having to read or listen to information contained within the app, process it and then translate it into meaningful action lay out with a person’ capacity, particularly in times of acute pain. Participants in the study reported that their pain made it difficult to focus on the information they were being given. At times,
even finding their mobile phone and opening the app was too much of a challenge. Although it is difficult to assess empirically there is evidence to suggest chronic pain adversely effects a person’s cognitive ability, particularly memory, attention, and processing speed. This suggests that at times of acute flares of CLBP people may lack the capacity to engage with self-management strategies, let alone a self-management app. Although there was general agreement with this conclusion a few participants suggested ways of improving a self-management app such as using voice-activation (CMOC 8) and having app-initiated choices (CMOC 9).

Participants were divided as to the role the Curable chatbot bot, Clara, played within the self-management app. Although ethically contentious there is research which suggests humans can develop meaningful emotional bonds with chatbots which can help to alleviate social isolation and loneliness and positively impact on a person’s wellbeing. Some participants felt that there was the potential to create such an empathetic and supportive relationship alliance with Curable’s chatbot Clara, had the programming been more sophisticated and her responses more intuitive (CMOC 14). Other participants did not agree and felt that a chatbot would be a poor approximation of the therapeutic relationship a person develops with their HCP, and which is an integral component of self-managing CLBP (CMOC 15). Regardless of whether the participants felt they could or could not develop a relationship with a self-management chatbot, the majority felt that the app alone was not sufficient in providing ongoing support when had been discharged from the healthcare service. Instead, participants believed the app could give them the confidence to go longer between healthcare appointments (CMOC 7) but ultimately a follow up with a HCP was needed. This finding is a consistent with the results of a
large cross-sectional online survey of mobile health usage\textsuperscript{430} that found more people favoured using apps as an adjunct to in-person doctor visits rather than as a substitute. It also echoes the concerns raised amongst older adults that mobile health technology might lead to less face-to-face contact\textsuperscript{431}.

4.5 Limitations

This study was guided by the RAMESES quality and reporting standards for realist evaluation\textsuperscript{381}. To our knowledge it is the first study that has looked beyond whether a self-management might work for people with CLBP to evaluate who it might work for, why and in what context. In so doing it has identified several key mechanisms and contextual factors to help guide decision making. However, there are some limitations to be noted.

The Curable app did not have some of the functionality that was initially theorised to be beneficial (e.g. monitoring patient symptoms and maintaining contact with HCPs) which made it difficult to test this proposition. However, it did not prevent the research team from gaining useful insights from the participants as to how, in theory, using an app to monitor their symptoms would help or hinder self-management. Similarly, an initial CMOC proposed that HCPs would find a self-management app to be a beneficial adjunct to care. Since no HCP’s were invited to participate in the trial of the self-management app this theory could only be tested from a patient perspective.

Participation in the study was voluntary which introduces a risk of selection bias. To address this, purposive sampling was used to ensure a variety of views towards self-management were represented. In addition, the study
had a small number of participants and only evaluated the Curable app which limits the claims that can be made about how representative its findings are for other self-management apps. However, the results have been presented as middle-range theories\(^{223}\). That is, the theories are at a level of abstraction whereby readers can judge whether they might be transferable to their context. As is the nature of theory-based evaluation, this study provides a useful foundation for further research into self-management apps for people living with CLBP.

4.6 Conclusion

There is not a ‘one size fits all’ recommendation when it comes to self-managing CLBP with an app. Humans are social actors and as such their reactions and responses to the resources being offered by a self-management app will fluctuate and vary. However, this realist evaluation has identified some key contextual factors and causal mechanisms to determine who may benefit from a self-management app for CLPB and why. A summary of these findings broken down into what works, for whom, why and in what circumstances is presented in Figure 4.22 (section 4.7).

An app can be empowering and help mitigate feelings of helplessness, fear, and loss of control. An app has the potential to redress the power imbalance in the therapeutic relationship between people with CLBP and HCPs. It can also instil a sense of comfort and reassurance by providing ongoing support. However, important contextual factors must be considered. A sense of empowerment is contingent on whether there is HCP buy-in and whether a person has the resources to engage with the app. To promote and sustain engagement the app needs to modify its content so that it is personalised to the user and be flexible enough to adjust to the user’s fluctuating capacity. Moreover, a person with CLBP
needs to have reached a level of acceptance over their condition before they are likely to consider a self-management app beneficial. Finally, a self-management app alone is insufficient in alleviating feelings of abandonment and therefore needs to be used alongside ongoing input from HCPs.
4.7 Summary of findings

SUMMARY OF FINDINGS

WHAT WORKS?
- Improving a person’s knowledge of the nature of CLBP
- Giving a person flexibility and choice in how a self-management programme is delivered
- Offering an app alongside ongoing support from a HCP
- Providing personalised responses based on a user’s medical history and input

FOR WHOM?
- People with CLBP who have accepted that this is a condition for which there is unlikely to be a cure and needs to be self-managed.
- People with CLBP who have accepted a different way of conceptualising pain and have moved past the biomedical model of care
- People with CLBP who have the internal capacity to take on board the information and strategies the app is providing.
- People with CLBP who have been reassured that there is no sinister spinal pathology causing their pain.

WHY?
- Restoring a sense of agency and control which is empowering
- Providing a sense of ongoing support which is reassuring and comforting
- Improving a person’s confidence and self-efficacy in their ability to self-manage their condition

UNDER WHAT CIRCUMSTANCES?
- Early on in a patient’s journey whilst they are undergoing investigations and treatment.
- When people lack the energy or inclination to engage with the outside world
- In between review appointments to consolidate strategies and maintain motivation

Figure 4.22: Summary of findings from realist evaluation
4.8 Chapter Summary

Figure 4.23: Chapter four summary
Chapter 5: Discussion and Conclusion

The results of this research have produced three programme theories around the ideas of empowerment, self-management burden and timing. They are underpinned by 20 CMO configurations. Together these programme theories create a transferable framework of propositions to suggest how mobile apps could support people to self-manage CLBP – specifically addressing what it is about a self-management app that works, for whom, why and under what circumstances. In this final chapter each programme theory is discussed in relation to the wider literature. The chapter concludes with a visual depiction of the theoretical framework (Figure 5.1).

5.1 Programme theory One: Empowerment
In policy papers, empowerment has been cited as a key factor in successfully self-managing long term conditions. In the mHealth literature self-management apps have been heralded as the tools to deliver this empowerment. In light of these statements, evaluating the rhetoric and concept of empowerment as it relates to self-management apps for CLBP has been a focal point throughout this research. On the whole, programme theory one support the ideas that an app can be an empowering tool for people self-managing CLBP. Importantly what this programme theory gives policymakers and practitioners is the missing explanation as to why this might be the case.

In the healthcare literature, patient empowerment is often defined as a process of behaviour change in which a person learns more about their condition and how to manage it which results in increased self-efficacy.
Knowledge is considered a key component of empowerment, with the assumption that understanding more about their condition enables patients to make informed healthcare choices and decisions about how to live their lives\(^{432}\). Although this way of conceptualising empowerment has been critiqued as a professional construct\(^{270, 433}\), reflecting the priorities of HCPs rather than patients, our results support this interpretation of empowerment. Participants appreciated the Curable app giving them access to up-to-date and evidence-based information on chronic pain. Some participants felt that this information was empowering because it enabled them to be less reliant on HCPs for answers and strategies (CMOC 2). By helping them to understand more about their back the app helped them overcome their fear of doing themselves harm and their confidence in managing their condition increased (CMOC 3). This confidence and timely access to support meant participants felt they could go longer between follow-up healthcare appointments (CMOC 7). As a result, these findings suggest a self-management app could lead to less demand on the healthcare service. However, further research is needed to evaluate the impact mHealth apps have on healthcare utilisation.

Those in the study that got on well with the Curable app reported to like the up-to-date evidence around chronic pain conditions that was collected in one place and had been validated as reputable information. Not only did this take the stress and effort out of having to find the information themselves but it also gave them the 'upper hand' when considering their self-management options. Instead of having to rely on HCPs who may or may not be sufficiently trained in chronic pain, participants could find the information they needed on their own. This enabled them to make informed decisions. No longer were HCPs telling them about their backs and what they could do; they were accessing information of their own
choice and making their own decisions accordingly (CMOC 2). This aligns with the self-determination component of Thomas and Velthouse’s psychological empowerment model. The self-management app gave the users choice, not only in when and where they accessed their self-management programme but what information they wanted to engage with and what actions they would subsequently take (CMOC 1).

However, many participants felt the Curable app was not flexible or personal enough for their idiosyncratic preferences and needs. It can be difficult to offer flexibility and choice whilst at the same time trying to implement standardised care. Lucivero and Jongsma highlight concerns that some self-management apps might be encouraging uses to comply with predetermined (medical) strategies rather than empowering users to make their own choices. Mobile apps that are designed to nudge users towards certain behaviours have led some to question whether this is empowerment or another form of institutionalised paternalism.

Providing tailored information is considered essential in helping people to self-manage long-term conditions. When participants were asked to engage in a self-management app for this research, some reported to be frustrated that the information they received from the Curable app was generic and not tailored to the responses they provided. As a result, they failed to see what meaning the information had for their presentation of back pain and disengaged with the app. In Thomas and Velthouse’s psychological empowerment model, meaningfulness is an individual’s belief that what they do is worth investing in and their activities are relevant and have meaning to their life. This was reflected in the results of this research which demonstrated that a person with CLBP needed to recognise themselves in the information and advice the app was providing.
in order for them to feel as if the suggestions were relevant and meaningful to them (CMOC 4).

This idea of relevancy and personalisation were closely linked in this research with how people with CLBP viewed their back pain. Those with a biomedical mindset — a belief that there is an underlying pathological cause behind their CLBP — struggled to see the relevancy in an app that was promoting an alternative, biopsychosocial approach, to managing CLBP. The results of this research were consistent with both Toye and Barker and Snelgrove et al who found people with CLBP who maintained a biomedical mindset tended to reject a biopsychosocial approach to understanding and managing their condition. Participants in this study who remained intent on finding a satisfactory explanation for their back pain or who were unable to accept that there were no effective interventions (i.e., medication, injections, or surgery) were disappointed and frustrated by the self-management app (CMOC 5). For example, the psychological components of the self-management programme such as mindfulness, relaxation and breathing exercises that were offered by the Curable app were considered unhelpful and meaningless to some participants. People with this mindset failed to see how this approach applied to them, as one participant explained ‘it may help for people with psychological issues, but I know what my back pain is, I have a diagnosis’.

When it comes to exploring the concept of empowerment, Archibald argues there is a surprising lack of discussion around ‘power’. Although the argument was made in the context of adult education this critique could equally apply to the healthcare discourse. For Lee and Koh an essential element to empowerment is the transfer of power to a subordinate. In the context of CLBP this transfer of power could be
interpreted as the HCP sharing their decision-making role with the patient. If a HCP still adheres to the traditional ‘doctor knows best’ approach to healthcare, then a patient cannot be empowered as the authority remains with the HCP. In other words, for a person self-managing CLBP to be empowered they must feel they have the power to influence their healthcare relationships. In the main, this research suggested a self-management app could help towards redressing the power differential in the HCP-patient relationship. However, the findings were tempered by the experience of one participant. In this instance, a HCP failed to recognise the app’s data as credible and in so doing, invalidated the person’s contribution to the consultation to the detriment of the therapeutic relationship (CMOC 6). This is consistent with Toye et al. who argued that as soon as a person feels invalidated, they become disempowered.

Discussions on the ethical implications of empowerment make it clear mHealth apps will not provide the techno-utopia many policy makers and technology providers would have people believe. As Lucivero and Jongsma point out this techno-optimism needs to be carefully assessed to see if the promises are plausible. Poor digital and health literacy, lack of accessibility and concerns about data security are a few of the many issues that could potentially widen healthcare inequalities as a result of using mHealth technology. Although these issues were raised briefly in the research the main discussion around mHealth app and empowerment focused on the moral burden it placed on people with CLBP.

In discussing each CMOC that underpins programme theory one, this research highlights to policymakers and practitioners what it is about a mobile app for CLBP that could be considered empowering. Up-to-date and personalised information available whenever and wherever a person
chooses to access it were identified as key features of what it is about a self-management app for CLBP that works. However, within this theory, the power dynamic in healthcare consultations and the idea of relevancy are arguably more important factors when considering programme implementation. Both of these points, centre around whether the app is introduced in a biomedical context that traditionally has the doctor in the position of authority or a biopsychosocial approach that values shared knowledge and understanding between the HCP and the person with CLBP. If an app is introduced within a context that considers chronic pain from a biopsychosocial perspective over a biomedical one, the chances of the app being considered relevant and therefore useful, is likely to be increased. However, the empowering effect of a mobile app is contingent on whether a HCPs are willing to buy-in to the app and recognise the contribution an app can bring to the healthcare consultations.

5.2 Programme theory two: Self-management burden

Programme theory two identifies ways a self-management app can help to reduce the burden of self-managing CLBP. A key take-home message for policymakers and practitioners is that an app should be introduced as an adjunct to ongoing input from the healthcare service. As useful as an app may be, if it is introduced as a replacement for regular follow ups from HCPs, then it is likely that this implementation plan will not be well received by people with CLBP looking for ongoing support.

Throughout this research there was an underlying tension within the data sources and amongst stakeholders as to what it means to self-manage CLBP. Despite repeated attempts to define and clarify the concept in the literature, the results from this study suggest self-management remains an ambiguous concept. Underlying this tension was the
ambiguity as to where and with whom, the burden of self-managing CLBP should ultimately rest. This research found there were variations in the expectations and understandings of self-management between different levels of the healthcare system from patients and practitioners to policy makers. From a HCPs perspective, the concept of self-management, finds them struggling to reconcile the promise of ongoing support with the economic pressures of limited healthcare resources and the growing number of people with CLBP needing help. Amongst some of the HCPs interviewed in this study there was a concern that giving patients a safety net — i.e. an app which could allow patients to access HCP support whenever they needed to — would foster patient dependency on the healthcare service.

Several HCPs in this research, thought an ‘open return’ policy might exacerbate demand on a service that was already struggling to meet the numbers needing treatment. They are not alone with these concerns, an investigation by Richard’s et al into therapists views on using a web-based and mobile application (goAct) to deliver psychotherapy treatment found a common worry expressed by participants was if the clients contacted them too frequently and whether the app made them ‘too available’ to clients. One HCP in this study however, who had already trialled this type of service for patients with CLBP found providing a ‘safety net’ was sufficiently reassuring that discharged patients did not feel they needed to return. This is consistent with Braeuninger-Weimer et al’s study that found that people with LBP felt more reassured when they were given an ‘open door’ to access the healthcare service again should they feel they needed it. This is significant since providing reassurance has been shown to improve health outcomes and decrease healthcare costs.
Self-management for HCPs focuses on enabling people with long-term conditions like CLBP to take an active role in managing their pain with a view to them becoming less dependent on healthcare services. This approach reflects the healthcare agenda set out by government looking to reduce the financial burden of chronic illnesses. Technology advances in the 1980’s made it easier for people to start monitoring their own health. The research that followed, suggested self-monitoring and behaviour modification was an effective way of reducing the socio-economic impact of chronic diseases. By placing an onus on the individual to manage their own healthcare rather than the state, policy makers came to view self-management as a means of reducing the healthcare costs associated with chronic illnesses. Critics of this approach however, saw it as governments’ placing the burden of self-management on to the patient by turning what started as an emancipatory self-care movement that demanded individual choice, autonomy and more recognition of the expertise that comes from lived experiences, into a means by which healthcare services could save money.

Participants in this research repeated requests made in published studies for continued ongoing support from HCPs. They argued CLBP is a lifelong, burdensome, condition and independent self-management is difficult to sustain particularly with a condition that fluctuates. Furthermore, there was a feeling of entitlement to ongoing support since self-management had been characterised as a partnership between the HCP and the patient. Unsurprisingly therefore, in this study, failing to provide ongoing support was tantamount to abandonment. These sentiments are consistent with other published studies in which patients with CLBP reported feeling left ‘empty handed’ and ‘hung out to dry’ or ‘discouraged and dismissed’ when they left consultations without an
adequate explanation, effective treatment or follow up. A similar feeling of disappointment was noticeable throughout this research, as people with CLBP felt let down by the lack of ongoing support despite the promise that self-management was not something they were expected to do alone. Although participants felt a self-management app would go some way towards feeling they were being provided with ongoing support, they still valued additional reviews with a HCP so as to not feel abandoned.

The role of ongoing support within the concept of self-management was a central component in the self-management burden programme theory. The definition of ‘ongoing support’ was inferred from the data in this study to be the means by which a person with CLBP could continue to have input from a HCP (ideally one they had already seen) without having to re-enter the healthcare service as a new referral. Being seen as a ‘return patient’ and not a ‘new referral’ was advantageous since new referrals go to back of the waiting list and have to start their journey all over again. This interpretation of ongoing support is similar to what has been described in the literature as ‘continuity of care’. The concept of continuity of care aligns with the chronic care model of healthcare which recognises the episodic nature of acute care is not suited to the management of long-term conditions. Participants in this study reported that long waiting times to access HCPs (be that that GPs, Physiotherapy, or Pain clinics) made them reluctant to be discharged for fear that, when they had an exacerbation of symptoms, they would not be able to access timely care and support.

The issue around ongoing support was brought to the fore during the global Covid-19 pandemic. At the height of the crisis, health authorities
worldwide suspended pain services and redirected healthcare resources to emergency departments and other Covid-19 related services\textsuperscript{174}. This left many people with chronic pain conditions without much needed support\textsuperscript{447}. To fill this void, there were calls in the healthcare sector for innovative approaches to delivering chronic pain management specifically with the view to utilising digital health technology, including mHealth\textsuperscript{13, 174}. In their systematic review of mobile health to support the elderly during the Covid 19 outbreak, Abbaspur-Behbahani et al\textsuperscript{448} concluded that this technology kept elderly and healthcare providers safe, expedited health service provision, lowered service provision costs, and decreased the risk of morbidity and mortality. As global warming plays an increasingly significant role in challenging the health of the world’s population\textsuperscript{218, 449-451} it is unlikely that this will be the last pandemic the world will see\textsuperscript{452}. It is therefore essential that healthcare services are able to be resilient in the face of volatile and demanding circumstances to ensure ongoing healthcare support is provided to people in need. As evidenced by the Covid-19 pandemic, mHealth can play a key role in providing this ongoing support and reducing the self-management burden.

Although it was not considered by most to be an adequate replacement for HCP contact there was an over-riding sense in this research that an app would be able to provide a meaningful form of support. The app was seen as a reassuring tool that meant people with CLBP felt less alone when they had been discharged from the healthcare service (CMOC 13). The app provided reassurance that there was a resource they could turn to whenever they needed support. Whilst the app reviewed in this research did not offer a feature that enabled users to contact their HCPs, participants in the realist synthesis thought this would be an additional benefit (RS 9 & 10). They felt reassured if using an app could enable them
to retain a connection to their HCP and gave them the ability to contact them should they need to.

These findings extend the results Qudah and Luetsch’s narrative review which found that mHealth apps fostered a sense of emotional security and connectedness with their HCP which improved the therapeutic relationship. This is important since developing a positive relationship between HCPs and people with low back pain has been shown to improve outcomes.

It is not only the patient and their HCP that share the burden of self-managing CLBP. Individual and Family Self-Management theory highlights the integral role positive relationships with friends and family can have in helping people self-manage chronic conditions. However, not all relationships are helpful. Gallant et al argue that family and friends can both help, and hinder, a person’s ability to self-manage their chronic illness. Participants in this research reported to feel judged by others to be faking their pain or making out that it was worse than it really was. This form of stigmatisation has been found in several qualitative studies that explore peoples’ experiences of living with CLBP. Many people with CLBP often feel their pain is invalidated by friends, family, and work colleagues. The reason for this stigma is thought to derive from the fact that CLBP does not have a specific aetiology and thus deviates from the normative view that pain is a result of a specific felt injury or pathology. A series of studies by De Ruddere and colleagues reported that lay people and HCPs disliked and distrusted people who had non-specific pain over those who had a recognisable medical condition. They also found lay people had less sympathy and were less amenable to help individuals who had ongoing pain with no medical explanation.
In an attempt to avoid social judgement, many in this study reported to withdraw from social interaction. It is well recognised that social isolation and loneliness have a detrimental impact on people’s health. Olivera et al. found that people with LBP were more socially isolated and had greater levels of perceived disability than the general population. Kinney et al.’s review of low back pain patients found people with CLBP had higher rates of major depression, substance abuse and psychopathology in comparison to acute back pain patients and the general population. Participants in this research reported that at times it was too painful to leave the house and too exhausting to engage in the social niceties expected in conversing with others. Whilst some participants reported to get support from interacting with support groups and sharing experiences, others in the research found groups to be intimidating and tiring. In this context, when there is a lack of social support (either because it is absent or because it has a negative emotional impact) a self-management app with a chatbot feature may be able to fill the void for some (CMOC 14).

A chatbot is a software application designed to simulate human-interaction. With the advancements in artificial intelligence, including natural language processing and machine learning, chatbot interactions are more sophisticated than they use to be. This has improved the chatbot’s ability to communicate in a more realistic and human-like way. Reeves and Nass’s media equation theory suggests there is a willingness in human nature to treat media (such as computers and chatbots) as if they are real people. Social response theory also claims human’s evolutionary behaviour means people have a tendency to respond socially to anything that displays human-like characteristics. Ho et al. found that participants who conversed with a chatbot had equally effective emotional, relational, and psychological benefits as they did when
disclosing to a human being. A reason for this may be because chatbots are non-judgemental agents. De Gennaro et al. found that an empathetic chatbot was able to improve a user’s mood after they had experienced social exclusion. Although the chatbot in the Curable app was not advanced enough for people to feel an emotional connection to it, some participants were excited at the prospect of future technological advancements that would enable them to communicate with a non-judgemental chatbot.

With the world’s rapidly ageing population and the growing healthcare demands of managing chronic illness, interest in the use of chatbots to facilitate behaviour change within healthcare is rising. At time of writing, there was no published research specifically relating to chatbots and the self-management of CLBP found. However, promising results were shown in Hauser-Ulrich et al.’s 8-week trial of a pain self-management programme, based on cognitive behavioural therapy, delivered via a text-based chatbot named ‘SELMA’. Their results showed participants demonstrated a significant positive relation between the intention to change behaviour and pain-related impairment as well as pain intensity. Furthermore, participants found the working alliance they established with SELMA was comparable to the relationships they experienced with human coaches via internet guided therapy.

Although it might be assumed that older adults may not like interacting with mHealth technology there is evidence to suggest this is not the case. In their qualitative study of older adults (≥ 60 years of age) with chronic pain, Parker et al. found 85% of the 41 participants were interested and willing to try mHealth technology. Furthermore, research suggests that older adults may find communicating with speech-based chatbots easier
than using a computer or smartphone\textsuperscript{476, 477}. The ease of using voice to communicate with an app resonated with the findings in this research. In times of acute flares of back pain, participants reported that having to find their phone, open the app and text for support would be too much of a burden. In this instance they suggested interacting with an app via voice activation would be beneficial (CMOC 8).

Despite the potential that chatbot technology may have, opinions on whether it was a useful feature of a self-management app for CLBP were divided. Some participants were adamant that a chatbot could provide nothing more than an artificial interaction which would not be able to replicate the intimacy and depth of feeling that comes from interacting with real people (CMOC 15). Others, including those who enjoyed attending self-management support groups (and might be assumed, therefore, to prefer human interaction), felt chatbots did have the potential to provide a meaningful, human-like, relationship with the user but the technology was not sufficiently advanced as yet to do this.

Although the idea of ongoing support formed a large component of self-management burden programme theory, it was not the only contributing premise. This research identified that a self-management app could help to alleviate the burden of healthcare consultations for people with CLBP. Participants spoke of the frustration at having to repeat their pain history each time they saw a new HCP. This annoyance was exacerbated in GP practises with a high turnover of locum practitioners because it prevented people with CLBP from building a sustained therapeutic relationship with their doctor. Participants felt HCP consultations would be more efficient if the HCP had access to the data they had collected between review appointment ahead of time. This would mean, when they saw the HCP
face to face, the HCP would be all 'caught up', enabling the person with CLBP to spend more time on discussing issues that were meaningful to them. Using the app’s data in this way could alleviate some of the pressure of having to recall information or articulate how they were feeling (CMOC 10).

Some participants felt that being able to share data they had recorded in the self-management app with their HCP would remove a measure of subjectivity from the consultation, relieving them of the worry at having to ‘play the part’ of a person in pain and allowing them to tell their story (CMOC 11). This tension of needing to look ill to be taken seriously by people (particularly HCPs) whilst not appearing so sick as to be considered faking it, has been identified in other pain-related studies. By monitoring their symptoms using the app, a person with CLBP would be able to provide the HCP with an accurate reflection of how they had been managing their condition in between review appointments thus negating the need to rely on their recall or the HCP’s snapshot assessment taken at each appointment (CMOC 11). Studies suggest collecting and sharing real time data on pain symptoms is valued by HCPs and older adults and helps patient’s ability to tell their story. Enabling patients to tell their story is a key component of patient-centred care. Participants in this research reported that an app could help them show their HCP the complete ‘big picture’ helping them to chronicle how they were managing their CLBP.

Not all participants in this research liked the idea of continually monitoring their symptoms. Some feared having to record their data would mean they would be constantly thinking about their condition which would make them feel worse and add to their self-management burden. Others, with
multiple co-morbidities, felt it was too onerous to record all their symptoms (CMOC 12). There have also been ethical issues raised about patients monitoring their symptoms in this way. Morley and Floridi\textsuperscript{147} suggest using apps to monitor symptoms, goals and progress is a very performance-based and outcome centred approach to patient empowerment. They argue that this is a form of self-surveillance. Over time, the myriad of data being collected by the app becomes a digital version of the ‘self’. This ‘digital self’ can be objectively evaluated by the app user to decide whether they are living up to standards of a ‘good self-manager’ (as defined by normative medical and social values)\textsuperscript{151}.

The issue of self-monitoring becomes ethically problematic when one considers that it is usually those in positions of authority (i.e. the HCP or policy makers) who set the base-line standards for what is considered ‘good health’\textsuperscript{141} or in this case ‘good self-management’. By using app data to ensure they (i.e. the person with CLBP) adhere to what is considered by society to be ‘good health’ this technology could be viewed as another tool by which modern medicine enslaves rather than empowers the individual\textsuperscript{147}. Lupton\textsuperscript{484} cautions that mHealth technology may contribute to feelings of shame and guilt by users who choose not to comply with the app or lack the capacity to do so, adding further stress and burden to managing their condition. Devan et al.’s\textsuperscript{445} systematic review and meta-synthesis on what works and does not work in self-management interventions for people with chronic pain found some people felt guilty for not being able to adhere to self-management strategies which led to self-criticism and self-dislike. Rather than empowering an individual Owens and Cribb\textsuperscript{440} argue that mHealth technology could be setting standards that are unachievable for some and may result in victim blaming.
Most participants in this research believed that at times, having to self-manage CLBP with only an app for support was too much of a burden. Whether it was for reassurance, motivation, empathy or simply to be assured that the healthcare service had not forgotten about them, most participants needed some form of input from a HCP over and above what they felt the app could provide. Prolonged pain can rob a person of their ability to concentrate. The fatigue and ‘brain fog’ that often accompanies CLBP makes it difficult to process information that would enable a person to make a reasoned choice. Lupton argues at times like these it is a reasonable and rational choice for an individual to defer to an authoritative figure and allow them to take the lead in healthcare decisions. Although this may be considered a reversal back to the ‘passive patient’ Anderson et al. assert, under the principles of self-determination; it is an empowered individual who makes the choice to defer to HCPs. This authoritative figure need not always be a HCP. One participant in the research felt, at times of acute pain, it would be helpful if the app could proactively decide on the best self-management strategy for them based on the techniques they commonly used. In this way it would reduce the cognitive burden of having to decide what was best (CMOC 9).

Programme theory two highlights key contextual factors such as loneliness and fear of judgement that contribute to the burden of self-managing CLBP. It also identifies causal mechanisms like stress reduction and storytelling that can help to alleviate some of this burden. The CMOCs in programme theory two are generally consistent with the published literature in this field. However, in bringing this literature together in one middle range theory, this research helps policymakers and practitioners understand how to successfully introduce a self-management app to people with CLBP. Central to this theory and a key consideration in
programme implementation is the delicate balance between an app providing a feeling of ongoing support or abandonment. If an app is introduced as a means of reducing healthcare costs, in lieu of ongoing input, then it is likely to have the unintended consequence of contributing to a sense of abandonment, thereby adding to the burden of self-managing CLBP rather than alleviating it.

5.3 Programme theory three: Timing
Programme theory three identifies several aspects of timing for policymakers and practitioners should consider before introducing a self-management app for people with CLBP. CMOCs in this programme theory stress the need to consider whether a person with CLBP has accepted the long-term nature of their condition and what impact the healthcare service’s slow transition from a biomedical approach to biopsychosocial model has on this level of acceptance.

It can take generations before scientific norms are challenged and deep rooted cultures within healthcare undergo a paradigm shift\textsuperscript{432}. Although it has been well established that the biomedical model is ill equipped to explain the complexity inherent in conditions like CLBP\textsuperscript{95,487,488}, it remains a pervasive approach in CLBP care\textsuperscript{489-491}. The quantity and quality of education in chronic pain across healthcare disciplines such as nursing\textsuperscript{492}, physiotherapy\textsuperscript{493} and medicine\textsuperscript{391,494,495} remains questionable. This perpetuates the mismanagement of conditions like CLBP\textsuperscript{42,71}. Despite guidelines and policies advocating for a more holistic, biopsychosocial approach to managing CLBP this approach is not adopted by all HCPs\textsuperscript{42,71}. If HCPs are struggling to accept a different way to understand and treat chronic pain it is not surprising that people with CLBP also find it difficult.
Kleinman\(^{496}\) maintains that explanatory models within healthcare systems are culturally specific heuristics that help individuals to understand and treat illnesses. The medical model, according to Kleinman, is one such explanatory model in which a person’s sense of legitimacy is contingent on gaining a diagnosis and treatment\(^{496}\). Rhodes et al\(^{414}\) found diagnostic tests that married a person’s subjective experience with objective evidence were a powerful means of legitimising an individual’s CLBP experience even if the diagnosis did not come with a cure. Introducing the notion that chronic pain has a psychological component, when the pervading explanatory model is one that equates illness with an identifiable pathological cause, can leave people with CLBP feeling as if they have been told they are making their symptoms up. Many qualitative studies have found people with CLBP feel their pain is not believed or that their pain is ‘all in their head’\(^{36, 413, 414, 478, 497}\). Given the difficulty and lack of confidence HCPs report in delivering a biopsychosocial interpretation of chronic pain\(^{498}\), it is perhaps not surprising that some patients come away from a healthcare consultation thinking they have been told their pain is not ‘real’.

People have come to expect the healthcare service to provide them with a diagnosis and cure for their ailments\(^{74}\). Human nature struggles with uncertainty\(^{499}\), this is particularly the case when it comes to pain. Pain is considered a threat and instinctively evokes a protective survival response\(^{500}\). For this reason, participants in this study needed and assessment with a HCP to reassure them no sinister pathology had been missed before they would engage with a self-management app (CMOC 19). Our bodies are attuned to seeking relief; guarding against potential threats and avoiding activities that might make our pain worse\(^{501}\). Whilst these are effective strategies for acute pain, they become
counterproductive with chronic pain. However, asking a person with CLBP to accept that there is no certainty as to what is causing their ongoing pain, no cure and that none of the survival strategies they have instinctively resorted to will help — may be too much to ask of some. Our findings support McCracken’s argument that when people fail to get a clear explanation for their chronic pain and/or effective treatment they direct their energies into finding a cure, potentially missing out on more productive activities like, in this instance, self-management (CMOC 17).

The fear that accompanies diagnostic uncertainty has been linked to increased emergency department admissions in the US with individuals continuing to return until someone could tell them what exactly was wrong with them. Rothbaum et al. noted that people need to understand and derive meaning from uncontrollable, adverse events in order to move towards acceptance. In the case of CLBP this acceptance is more likely to come if they are given an explanation for their symptoms that aligns with their understanding of pain. The need for a diagnosis that adequately explained their CLBP resonated strongly in this research and is consistent with Lim et al.’s systematic review of the health information needs of people with low back pain. Participants in this study who lacked an adequate explanation for their ongoing back pain, struggled to understand or accept it. Others spoke of the relief they felt when they were assessed by a HCP and finally given a ‘proper’ diagnosis. The reason for this relief was twofold. Firstly, relief came from the reassurance that there was no serious spinal pathology (CMOC 19) and secondly there was relief because a diagnosis legitimised their pain experience (CMOC 17).

Participants who found a self-management app to be beneficial felt accepting they had CLBP for which there was no effective cure was an
essential prerequisite for self-management. The literature on acceptance in chronic pain is extensive and a full exploration of the concept is beyond the scope of this work. Acceptance of chronic pain, as applied in this research, has been defined as acknowledging that pain will continue; abandoning futile attempts to control, avoid, or deny it and instead committing efforts towards living well with pain\textsuperscript{410, 504}. Acceptance in this context is not resignation or helplessness but a resolve and willingness to live with pain\textsuperscript{504}. Acceptance has been closely linked to personal empowerment whereby an individual draws on their inner strength to learn to live well with chronic pain\textsuperscript{505}. Aujoulat et al\textsuperscript{506} argue empowerment is more than successfully managing their own treatment, rather an individual has ‘successfully’ become empowered when they have managed to come to terms with their threatened sense of security and identity. In this respect empowerment has been described as both an outcome and a process\textsuperscript{507}. This process was described in Toye et al.’s\textsuperscript{413} metaethnography as a ‘healing journey’ in which a person living with chronic pain understands more about their pain, and in so doing is no longer frightened or threatened by it and can begin to learn to live with it. However, acceptance is not a linear process or a static state\textsuperscript{438}. At times someone may be able to accept the need to self-manage their CLBP and at other times they may not. These temporal fluctuations in acceptance are likely to impact on participants engagement with a self-management app. This point returns us to the earlier discussion around self-management burden and ongoing support. At times when it is difficult to accept the long-term nature of CLBP a self-management app may not be able to provide the support required and a review with a HCP is needed (CMOC 13).
Timing in programme theory three also considers when it would be appropriate for a self-management app to be introduced to people with CLBP. Studies show that unhelpful beliefs and behaviours, such as catastrophizing and fear avoidance, are difficult to alter once low back pain has become chronic (i.e. if it has lasted longer than 3 months or longer than the expected tissue healing time)\textsuperscript{508, 509}. Fear avoidance behaviour has been linked to an increase in disability\textsuperscript{510, 511}. Timely interventions to address these unhelpful beliefs and behaviour can prevent further disability thereby reducing healthcare costs and accelerating recovery times\textsuperscript{512}. Many in this research wished they had been given access to a self-management programme and education around their CLBP sooner in their journey instead of being prescribed increasing quantities of pain medication. The desire for a non-pharmaceutical approach to managing CLBP supports Chou et al.’s\textsuperscript{513} scoping review of patients perceived needs for their non-specific low back pain. Of the thirteen studies that reported on the perceived need for pharmacological management only five studies claimed patients preferred using medication. Being introduced early on to a self-management app was identified in this research as a means by which a person with CLBP could work on strategies to improve their quality of life sooner (CMOC 20).

Despite back pain being one of the most common reasons for someone to access GP support\textsuperscript{514-516}, many primary care physicians feel they lack the time, training and resources to adhere to the latest guidelines for treating CLBP\textsuperscript{369, 370}. This may explain why patients with CLBP continue to be prescribed long term opioid medication by their doctors despite this running contrary to treatment guidelines\textsuperscript{84}. In light of these difficulties, a self-management app might give GP’s an alternative biopsychosocial treatment to offer CLBP patients. Healthcare providers are being
encouraged to integrate digital health technologies such as mHealth into their practise\textsuperscript{517}. Although there is still work to be done in overcoming GP’s ambivalence towards prescribing mHealth apps\textsuperscript{518-520}, emerging evidence suggests some GPs find mobile apps a useful adjunct to their care\textsuperscript{521}. However, careful consideration is needed as to when to introduce a self-management app for CLBP. Even participants who were favourable towards using a mobile app felt that, if it was introduced by a HCP too early, i.e., before medication had been trialled and before investigations had ruled out serious pathology, it would seem as if they had not been taken seriously and they had been fobbed off with a gimmick. However, if the app was introduced in primary care, as an adjunct to pain medication and whilst other investigations were being carried out then participants felt the app would be considered a more acceptable intervention (CMOC 20).

In addition to timing, this research suggests that it is also important for a self-management app to be introduced by someone with whom a person with CLBP had developed a trusting relationship with (CMOC 18). For some in the research, that person was a HCP. Being introduced to an app by a HCP was felt to give it credibility and reassured people they could trust it. However, an interesting finding from this study indicated the opposite might also be true. If the person with CLBP did not have a good therapeutic relationship with the HCP who suggested the app, or if the HCP themselves had not bought into the idea of using a self-management app, then the app would not be considered an acceptable tool.

The discussion around programme theory three emphasises to policymakers and and practitioners the need to carefully consider the issue of timing before introducing a self-management app to people with CLBP. If introduced early in a person’s experience of CLBP a self-
management app has the potential to introduce life-improving strategies before maladaptive behaviours develop. However, if a self-management app is introduced before a person with CLBP feels their pain has been believed; before they have accepted the long-term nature of their condition and before they have been physically assessed by a HCP then there is a risk the app will not be considered the empowering tool it was intended to be. Timing is also contingent on whether both the person with CLBP and the HCP treating them still adheres to a biomedical approach to managing chronic pain or has transitioned to biopsychosocial approach. This will likely determine whether a tool like a self-management app is considered beneficial or whether efforts will continue to be directed towards finding an adequate diagnosis and cure for CLBP.

5.4 Strengths and limitations
The strengths and limitations of both the realist synthesis (see section 3.5.2) and the realist evaluation (see section 4.5) have already been discussed. What follows, is a discussion of the strengths and limitations of this research as a whole.

Realist methodology enabled this research to move beyond empirical findings that suggested self-management apps for people with CLBP were effective. The realist framework facilitated an ontologically deep exploration to discover the generative mechanisms and conducive conditions that would make self-management apps work and for whom. In so doing, this research has been able to make a novel contribution to the existing mHealth literature. The flexible and iterative nature of realist research, being guided by realist principles rather than strict methods, enabled the research to make these explanatory insights. Realist research allowed for a level of creativity in its application, which is why it was felt
acceptable to borrow features of realist evaluation (e.g., the use of stakeholder transcripts as primary data) and incorporate it into a realist synthesis. This served to enrich the data and to realise the goals of the research design to include the voices and experiences of people with CLBP in the research process.

The scope of the PhD was limited by time and resources. As a result, there remain fruitful avenues for further study which have been highlighted but not explored in this research. For instance, the focus of this research lay mainly at the intrapersonal (people living with CLBP) and interpersonal level (the relationship people living with CLBP and HCPs). It would be beneficial for future research to explore the use of self-management apps for CLBP at a systems level, both within and outside of the Healthcare Service. Furthermore, this research was explicit in its use of empowerment theory and burden of treatment theory throughout the process. Although, these theories were useful in helping to develop causal explanations and to identify important contextual factors, it would be beneficial to apply other theories to mHealth studies on self-management apps for CLBP. For example, the importance of acceptance was a key element in the research findings and applying theories of acceptance may produce further insights and deeper explanations into the use of self-management apps for CLBP. Finally, the findings of this research would serve as a relevant starting point for future studies into self-management apps for other chronic pain conditions. Particularly those that share the stigma that comes from unseen and unexplained medical symptoms, conditions such as fibromyalgia, endometriosis, irritable bowel syndrome and chronic fatigue syndrome.
This research was undertaken from the perspective of someone who continues to work for the NHS and specialises in chronic pain. This could be seen as both a strength and a weakness. On the one hand, the researcher’s position provides insider knowledge into the practises, values, and norms of the research area. In practical terms, this knowledge provided a ‘head start’ as to where to look for data, how to frame questions and who to ask. Inevitably however, this experience brought with it both a personal and professional researcher bias. This may have affected the data that was chosen and the insights that came from it.

Maxwell argues it is impossible to eliminate the researcher’s theories, beliefs, and perceptual lens from the research process. He goes on to suggest various validity checks to apply so that the researcher’s influence on the study is more positive than negative. This research employed a number of these checks such as, sense-checking with stakeholders, deliberately looking for rival cases or disconfirming theories and collecting data from a diverse range of sources. In addition, a reflexive journal was kept throughout the research documenting when and why decisions were made. Furthermore, the research has been conducted and reported with transparency so others can judge the credibility and trustworthiness of the theories it produced.

No matter how transparent or rigorous the research process however, realist research, particularly realist reviews, are not reproducible or standardisable. Pawson et al. argue that it is impossible to transparently document the sheer number of decisions, judgements and intuitions made during the research process. As a result, no two realist reviews will be the same. Furthermore, from a philosophical standpoint they question whether standardisation produces objectivity in science. Whilst scientific realism acknowledges there may be an objective truth 'out
there’ they maintain that our understanding of it will always be subjective and flawed. Acknowledging this fallibility, it is important to recognise that the programme theories produced in this research are not presented as ‘the truth’. Rather, these theories serve as a transferable framework to be taken forward and tested by others in a continual process of exploration and refinement. In so doing, the mHealth knowledge base will continue to grow and we can get ever closer to a comprehensive understanding of who might benefit from self-management apps for CLBP, why and in what circumstances.

5.5 Conclusion

We are experiencing a time when the average life expectancy is higher than it has ever been. There are both benefits and costs to living longer. The likelihood of developing CLBP increases with age and back pain is a global concern. Healthcare services recognise the need to change the way healthcare is delivered so that it can better serve those with chronic conditions. However, paradigm changes such as these are difficult and take a long time. Traditional medical models of healthcare remain culturally embedded both within the healthcare system and in society as a whole. It is hard for HCPs to adjust their thinking that not all ailments have an identifiable pathological cause and accept a feeling of powerlessness that they may not be able to provide a cure or meaningful relief for people living with CLBP. It is arguably even harder for people with CLBP to accept that they have to manage their condition long term and that they may never be pain free.

Healthcare policy makers maintain that self-management empowers a person to take autonomous control over their own care. For many people with CLBP this empowerment can feel more like abandonment. After
assurances that self-management is a partnership between themselves and their HCPs many people with CLBP feel let down when they need to wait months to access care. At the same time, HCPs are left in the challenging position of trying to fulfil a promise of ongoing support whilst trying to address the ever-increasing numbers of people with CLBP in need of their help. In this context a self-manage app for CLBP could help to alleviate some of the pressure placed on the healthcare service.

A self-management app can provide people with CLBP, reassurance, education, ongoing support as well as timely and convenient access to strategies to help them manage their pain. For some, an app may also provide a supportive and comforting relationship relieving feelings of social isolation. However, in order to fully appreciate the potential self-management apps may have for people living with CLBP it is essential to look beyond the architecture of the programme. Instead, a close exploration of how people react to the resources the self-management app provides is needed so that we might understand what makes the programme work and what doesn’t. By undertaking this deep exploration this research has identified that for some with CLBP, a self-management apps provide reassurance, comfort, control, and convenience which empowers them to self-manage their condition. Arguably this is far more useful information for policymakers and practitioners to take forward into their implementation planning than a study which produces numbers with a statistically significant effect size but with no explanation.

However, these mechanisms do not always manifest in app users. They are contingent on how the app is introduced, when it is introduced, who introduces it and the level of acceptance a person has come to with their CLBP. Furthermore, these contexts and mechanisms are not static and
are likely to fluctuate over a course of a person’s lifetime as their personal and social circumstances change. Despite advances in mHealth technology and sophisticated human-like chatbots, it is unlikely that mobile apps could ever replace face to face human interactions. However, if used as an adjunct to traditional care, mHealth apps could enable limited healthcare resources to be stretched further. Rather than feel threatened by this technology many HCPs recognise the help it could provide them to address the overwhelming and ever-increasing demands on their services.

For instance, it is unlikely that pandemics such as Covid-19 are going to be the last health crisis we see as populations increase worldwide and global warming continues. The global pandemic demonstrated that mHealth technology has the resilience to deliver quality healthcare in volatile social and environmental situations. Mobile phone technology is ubiquitous and is no longer the purview of the wealthy and the young. To fully appreciate their potential, it is essential to involve key stakeholders such as people living with CLBP, healthcare policy makers, healthcare professionals and mHealth app developers in the design, implementation, and evaluation of this resource. Furthermore, we need to unpack and analyse the theories that underpin each of these stages so that we can challenge and test their assumptions. This is the basis of scientific enquiry.

This research project has met its intended aim of creating a set of propositions which, together, would create a transferable theoretical framework to understand how a mobile app could help people self-manage their CLBP (see figure 5.1). Specifically, the aim was to understand who an app might work for, why and in what context. The research process has involved looking at a wide range of disparate
sources from artwork and social media to policy documents and academic papers. It has involved the use of theory from conception to completion to sensitise the research to the unseen generative forces at work. Finally, it has required retroductive and abductive logic to help make sense of it all.

In the end, what has been produced is not a list of recommendations nor does this research claim to have identified any universal truths. Instead, this research has created a series of propositions to be considered when introducing self-management apps for people with CLBP. This research has explored the theories underpinning self-management and empowerment and evaluated whether they stand up to empirical scrutiny. In so doing, the self-management app’s black box has been unpacked to expose what works (and does not work), for whom and why. In this way the theoretical framework points policy makers and healthcare practitioners towards successful implementation paths and highlights pitfalls to avoid.

That said, all realist researchers accept their work lacks a true end point. It is understood that the completion of one research project forms the starting point for the next. Whether the theoretical framework that has been created in this work can be considered credible or valid is a judgement that ultimately rests with the next set of researchers, healthcare professionals or policymakers who take the theories forward and tests them in their own setting. However, what makes this author confident in their findings is the knowledge that this process has been guided by key stakeholders throughout.

This research started from the ruminations of an NHS HCP who queried whether a mobile app could be the empowering tool policy and academic
papers reported it to be when their clinical experience of supporting people to self-manage CLBP suggested otherwise. Unsurprisingly, when evaluating a complex condition and a complex intervention, the answer is not simple but nuanced. Whilst mobile apps are not the panacea for self-managing CLBP, neither are they a gimmick to be dismissed. If introduced early on as an adjunct to care; when a person with CLBP feels their pain has been validated and they have accepted the nature of their condition, then there is real potential for a self-management app to be the empowering tool it has been claimed to be.
THEORETICAL FRAMEWORK

Self-management mobile apps for people with chronic low back pain

- **EMPOWERMENT**
  
  People with CLBP can feel empowered by a self-management app if the app is personal and relevant to their situation, can be accessed when and where they need it and is presented as an adjunct to ongoing care.

- **SELF-MANAGEMENT BURDEN**
  
  If people with CLBP have the capacity to engage with a mobile app then it can reduce the burden of having to self-manage CLBP by providing ongoing support, facilitating communication with HCPs, and mitigating feelings of abandonment.

- **TIMING**
  
  A person with CLBP is likely to benefit from a self-management app early on in their patient journey but not before they feel believed and reassured by HCPs and have accepted their condition cannot be cured.

Figure 5.1: Theoretical framework
Appendix A: Extract from reflective journal

I found the questions posed in existing quality appraisal checklists and tools were difficult to answer for non-academic data sources like newspapers, blogs or extracts from social media. Furthermore, I found the answers became perfunctory and didn’t help me advance my reasoning. I was left with a “so what?”; “what do I do now?”

As a result I created my own criteria for assessing rigour in non-academic sources which was guided and adapted from Miles, Huberman and Saldana (1994) (38). This criteria focused on the reliability and validity of the data. Importantly, to my mind, it allowed for extracts of data from potentially untrustworthy sources to be included in the review if their addition was deemed to be add value to theory development and the bias it introduced was balanced or countered by additional data.

• Look for author effects and bias – does this effect/bias undermine the credibility of what is being said? If so, what do you plan to do e.g. exclude/include? – If include, how are you going to redress the balance?
• Check for representativeness
• Get feedback from participants – a key component of realist review is to sense check with stakeholders
• Triangulating
• Look for ulterior motives
• Look for deception
• Check against alternative accounts – in realist review terms, I took this to mean look for rival theory, disconfirming case, counterfactuals, outliers etc.
• Sense check with research team and peers – As well as discussing the data and theory development with my research team, I presented a lot of my early work at training conferences to see if my inferences were logical or were too much of a leap.

I liked this criteria because it gave me an idea of what to do if the answer to the question was a yes or a no –
For example:
Q: Is there author bias in this blog?
A: Yes
Q: Is it still worth including, if yes, why and what are you going to do about it?
A: Yes, this person has been living with pain for 20 years and wants the NHS to improve its service. Their opinions are valid and they have a good way of expressing themselves, I want to include the data. I am going to sense check with stakeholders and find other sources to refine/refute/reinforce.
### Appendix B: RAMESES Quality Standards for Realist Synthesis

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<thead>
<tr>
<th>Section</th>
<th>Standard</th>
<th>Evidence</th>
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<tr>
<td>1. The research problem</td>
<td>The research topic is appropriate for a realist approach</td>
<td>Chapter 3, section 3.1 and Figure 3.1 outlines rationale for realist approach. Chapter 2 section 2.6.8 clarifies why a realist approach was taken over other forms of theory-led research such as Theory of Change.</td>
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<td></td>
<td>The research question is constructed in such a way as to be suitable for a realist synthesis</td>
<td>Chapter 3, section 3.1 clear and simple research question: why, how, for whom and in what context could a self-management app be beneficial for people living with CLBP</td>
</tr>
<tr>
<td>2. Understanding and applying the underlying principles of realist reviews</td>
<td>The review demonstrates understanding and application of realist philosophy and realist logic which underpins a realist analysis.</td>
<td>Chapter 3, sections 3.2 and 3.3 methods to obtain evidence comes from a wide range of sources to gain ontological depth and identify hidden causal mechanisms which is consistent with a realist philosophy of science</td>
</tr>
<tr>
<td>3. Focusing the review</td>
<td>The review question is sufficiently and appropriately focussed.</td>
<td>Stakeholder consultations helped to refine the scope of the review reducing the 16 initial rough programme theories to 6 (see Table 3.3).</td>
</tr>
<tr>
<td>4. Constructing and refining a realist programme theory</td>
<td>An initial realist programme theory is identified and developed.</td>
<td>Chapter 2, section 2.5.1 explains and justifies the choice of two substantive theories to help inform theory development. Chapter 3, section 3.3.2 describes the process of searching for substantive theories to guide the research. Programme theory refinement was helped by two rounds of stakeholder consultations. Appendices H, N, and O show examples of how initial rough programme theory were refined. Each programme theory is a created with a number CMOCs. The implication of the final theories for practise is illustrated in three Figures 4.1; 4.2 and 4.5 Programme theory refinement was helped further by two</td>
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5. Developing a search strategy

The search process is such that it would identify data to enable the review team to develop, refine and test programme theory or theories.

Chapter 3, section 3.3.1 details searches conducted outwith academic databases to find additional data that would enable further theory development. Database search was piloted and informed by subject librarian. Self-management apps for other long-term conditions (e.g. FMS, IBS) were included to learn from other programmes. Pick and place strategy search guided by C-I-M-O framework was used to supplement database search with data from background mapping phase to enrich the data and help to infer mechanisms in operation. See Table 3.5.

6. Selection and appraisal of documents

The selection and appraisal process ensures that sources relevant to the review containing material of sufficient rigour to be included are identified. In particular, the sources identified allow the reviewers to make sense of the topic area; to develop, refine and test theories; and to support inferences about mechanisms.

Selection and appraisal were based on how the data could contribute to programme theory development/testing/refinement. Judgement of relevance, richness and rigour see Appendix J and K. These judgements followed Dada et al.’s (2023) guidance (see Figure 2.7). Included sources came from published studies, non-academic sources and stakeholder transcripts.

7. Data Extraction

The data extraction process captures the necessary data to enable a realist review.

Bespoke data extraction forms were created and piloted for the different data sources. Data extraction and coding was guided by the Centre for Advancement in Realist Evaluation and Synthesis Data training course. Data extracted in the form of analytical memos which were comprehensive enough to identify main CMO patterns and supported later processes of analysis.

8. Reporting

The realist synthesis is reported using the items listed in the RAMESES Reporting standard for realist syntheses.

The research has been transparently reported with reference to the RAMESES reporting standards. Extensive supplementary material has been included in the
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<th>Section</th>
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<td>appendices to ensure there is sufficient detail for an external reader to understand and to judge the methods used and the plausibility and coherence of the findings.</td>
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Appendix C: Bespoke Data Extraction Forms

C.1 Twitter Data extraction form

Source: Pain Charity feed after they had hosted a webinar

Author: Initiated by a private musculoskeletal therapist who runs their own physical rehab clinic. Has website and testimonials from people who have attended the courses they run.

Date: Feb 2022

Metadata: 23 Comments (20 different users) / 143 Likes / 8 retweet

Document ID: Twitt01

Data extraction

“Back pain is definitely seen by the gen public as different to other types of injuries. I have found a bit of pain in rehab with the ankle, knee for example is ok but a no no for the back. This to me is fascinating & one of the key problems of back pain” Tweet01

Maybe the brain take nociception from the spine and adjacent structures a little bit more seriously than other sources? I've always thought that was a decent hypothesis that would explain a lot.

Maybe? Is the actual pain worse? Baseline pain scores can be pretty high for other conditions, but the disability bit is often much worse.

Knee pain doesn't stop me* from being able to do most things. Back pain could.

Pelvic pain could too.

* I am not in pain, have been in lots of different parts. Statement based on my own experience + patient reports.

I think we humans made such a story around it and we know it's potentially more dangerous than injury of the foot.

But I would not say it's ingrained in our brains. More in our belief systems (of course you can argue that's in brain too 😜).

It's learnt, not inherited.

Yep, maybe we "made such a story around it."
Or maybe it’s just just actually bloody awful on average. Maybe its characteristics actually inspire both rational AND irrational fears...like predators.

I don’t think we know. I don’t think we CAN know.

Again. If this is true, why would the brain take it more seriously? Biological or social?

It would make sense from what I’ve read with pain hypotheses and paid circuits. I think the spine plays a large part in it.

For sure people get spooked by back pain. Nocebic beliefs/messaging about spinal fragility can certainly wind that up...but may ALSO be a reaction to it. That is, we’re scared of back pain because it’s inherently more intimidating/disabling than other common problems.

I don’t know how we’d tell if this is true, but the idea that we have a protective system that reacts more vigorously to spine nociception sure resonates with many patients. Seems to help them feel safer in exploring movement again.

Agreed. I also think about the difference in back pain vs headaches.

Back pain: something wrong, needs protecting, avoid activities

Headache: annoying but keep going, just sleep it off

I hear you. Only difference is headaches don’t generally last for days/weeks.

Backs are so central to everything we do (physically and mentally). We see people without limbs coping. We hear about joint replacements. This doesn’t happen with backs. Pain is maybe then seen as a measure of how centrally we’re troubled?

Could be part of it. Can be tough to rest backs. But also, it is the way they are viewed at a societal level as well

Was treating an HR manager recently, who said they’d never appreciated how bad “real” back pain was until they had it. They used to get annoyed at people phoning in to say they couldn’t get in. Back pain in a way, is an invisible problem. Maybe in BPS model needs exaggeration??

Like what has been said. It’s seen as uniquely different and vulnerable. We also from a position of an injury. Do occasionally see relevant pathology but even then, is it injury.
Absolutely find this too! I think because society messages around minding your back and also loads of manual handling courses in many jobs. They never highlight minding your shoulder for example. always the back!

spine know that hurt does not mean harm and often times if it hurts do it more. So many patients I have seen in the past 30 years are victims of incomplete rehab-hence incomplete remodelling of tissue.

So many medical and quasi medical professionals have conditioned society that if it hurts don’t do it when it comes to the spine. This errored advice has negatively affected generations as this problematic advice is passed on. Any of us that has worked with subacute to chronic

My lived-experience—I had several sprained ankles and a ruptured patellar tendon. Nothing came close to the several episodes of acute back pain with neuropathic leg pain. Far more disabling. No idea why, but that’s what I experienced.

Unlike other peripheral injuries, some back injuries can indeed leave you quadriplegic or paraplegic etc so this might be a precursor for this perception. We actually categorized fears and perceptions of people with spinal pain in this study of ours.

The back is seen as central to everything, but it is also seen as being vulnerable - it can “go” with apparently innocuous movements. Not helped by well-meaning friends and family telling people to watch their backs, avoid lifting etc. This doesn’t happen with other joints.

Turn it on its head? Is this because patients feel knee pain and shoulder pain etc. is taken ‘more seriously’ or perhaps has solutions? so we try to ‘help ourselves’?

“The straw that broke the camel’s back” 🐫

The my pain is worse than yours or you get better or worse treatment narrative undermines everyone with chronic pain.

Did you ever experience back pain yourself?

Acute back pain often is extremely different and in no way comparable to ankle or knee pain. It really has nothing to do with that people view it differently, it is different.

A lot of people think back pain/injury automatically puts you at risk of becoming permanently paralysed, I think it’s that simple.
Twitter data extraction form (cont’d)

"...one of the key problems of back pain"Is PT itself

LBP exposes PT in ways that continue to be shrugged off as if 'out there', when really it is by its multiple layers of denial that have disconnected it from being more effective. Can PT admit it needs to change? If not?

Agree. I think peripheral joint pains are accepted more easily during exercise due to visibility. A painful, stiff, swollen knee is easy to reason with and accept. It’s a different ball game with spinal pain...

I wonder if the proximity to integral structures like spinal cord, if the brain tries to “protect” it more so 😊

Data analysis

What is the thread about?

This thread is discussing the nature of back pain and how it might be viewed and felt differently to other musculoskeletal complaints – like knee pain. The discussion was started by a physical therapist who, from his own experience in clinic, found that clients differed in their views on what was acceptable when it came to pain e.g., it was okay to challenge the knee in ways that might be a little painful, but it was not okay to do this with backs – the twitter user wanted to know why this might be.

What are the key issues being talked about?

There IS a difference between peripheral joint pain (e.g., knee/hip/shoulder) and back pain – the latter hurts a lot more

There is almost a primaeval response to hurting out backs – at an unconscious (and sometimes conscious) level humans know that an injury to our back could leave us paralysed – the impact from this would be far more devastating to our quality of life (and in primitive times, our survival in comparison to an injury to the knee. Therefore, the brain is ‘hard wired’ to take back pain more seriously and this message is reinforced by society.

Messages from society have made us overly protective about our backs - reinforced by manual handling courses at work etc. – this had led to a fear of hurting our backs and an erroneous impression that our backs are inherently fragile and need protecting.

In addition, back pain is all-consuming – it very hard to rest a back it is involved in all our movements – you can put an arm in a sling, use a walking stick for your leg etc but the back is ‘central to everything we do’.
Twitter data extraction form (cont’d)

It is easier to accept peripheral joint pain because you can see it – a swollen knee, an arm in a sling etc. but back pain is harder to deal with because there is nothing to see. This was supported by the anecdote that an HR manager considered people who called in sick with back pain to be annoying [speaks to the malingering theme] until they themselves experienced back pain.

What is coming through in this thread in addition to the above is the way our understanding of chronic pain has evolved but that this message has not filtered down into society and there is a conflict between the old and new ways of dealing with chronic back pain. The ‘old’ way was to see the back as something that needed protecting and was a fragile structure that could ‘go’ at any time. Pain was seen as a warning sign and meant ‘stop what you are doing’. Nowadays, the advice is to keep moving your back and that pain doesn’t necessarily mean harm – but this message seems to run counter to the visceral and primitive reaction ingrained in us that a/ pain means harm and b/ if you injure your back it could be an indication that something is seriously wrong.

Who is being represented here?

From the HPCs its mainly physical therapists who are dealing with people that have back pain. People who are living with back pain – but appear to be struggling. But also, there is a person who has had back pain and peripheral joint pain and is making a comparison of the two – the person has recovered from both seemingly but on reflection notes that the back pain was significantly worse.

What are the rigor implications of including this data?

There are some emotive and even angry responses in this thread from people who have/are experiencing back pain – it is their point of view – it is valid in the sense that it is their lived experience. This frustration/anger is echoed elsewhere in my findings (see MacCarthy and Yeowell 2017 and stakeholder transcripts). However, there is some semblance of balance in this thread between the emotive and more rational responses which leads to an informative discussion around the nature of back pain and what makes it different to other MSK complaints.

What value is this thread adding to my research?

This speaks to the nature of back pain and why it is different from other musculoskeletal complaints and therefore why it might be so difficult to self-manage. I have theories around fear and reassurance when it comes to back pain – fear that there might be something sinister going on, fear of doing something that will make their pain worse and need for reassurance however this thread explores why there is such fear around back pain specifically – it comes down to biological and social factors – our amygdala response to fear pain and society’s message to protect our backs. This is perhaps key to understanding healthcare utilisation when it comes to back pain – unlike knee pain, headaches etc people are more likely to put up with it knowing that it will go away but back pain perhaps the tolerance for accepting pain coming from the back is lower and
therefore people are more likely to seek medical advice leading to increase healthcare utilisation.

For self-management education to be effective it is important that we understand what is generating the fear that comes from back pain.

This anger/frustration is what I felt was lacking in the published 'official' literature coming from journal articles, policy papers and third sector reports. These emotions are what I bear witness to in my role as a pain specialist physiotherapist and is what I wanted to capture.

How does this thread add to my theory development? (Refine, Refute, Reinforce)

Refine – It’s not necessarily because ongoing back pain might be medically unexplained that creates fear and a need for reassurance it might be more to do with how back pain is experienced from a physical and social perspective that makes it so difficult to manage on our own without reassurance from medical professionals. The fear that you might have done something that has made the back worse can stop you from engaging in self-management activities. This is supported by stakeholder PS001’s comments:

“There were a few times when I thought ‘ooh that doesn’t feel quite right. Or that’s not, I don’t know, should do more or less?’ Or ‘I am not sure, maybe I shouldn’t’. And so, if I had had a sort of text or even a text to go ‘I’ve done this should I have done that?’ [Lines 309-311, PS001]

Reinforce – The idea that you need to be 'seen to be believed' is supported in this thread. The anecdote by the HR manager for instance and that back pain isn’t visible in the way that other joint pains might be which makes it harder for the sufferer to be believed by others. It is reinforcing the theory behind pain being difficult for outsiders to believe since it is invisible – it’s not until you have it yourself that you can understand what others are going through. The sense that people with back pain are ‘faking it’ or that the pain is not as bad as they are making it out to be. People compare the pain to having a ‘bad knee’ which does not reflect how debilitating and all-consuming it is – this lack of understanding and validation of symptoms if frustrating and can lead to anger.

What programme theories is this speaking to?
16/03/22 - Rough programme theory two
C.2 Newspaper Data extraction form

Source: The Daily Mail
Date: September 2019
Relevance: High

Daily Mail, September 2019 ‘Until recently, chronic pain was often dismissed as psychological because it often has no obvious physiological cause, with doctors telling patients ‘it’s all in your head’. That approach is being consigned to history. In the last two years, scientists have used technology known as fMRI (functional magnetic resonance imaging) to provide images of chronic pain patterns in the brain — and shown that it does have a biological basis and is the result of a dysfunctional signalling system. fMRI scans on people with back pain show that for the first ten to 15 weeks, the same part of the brain that is involved in the immediate response to an injury — the sensory brain regions — are involved,’ says pain management expert Professor Jane Ballantyne. ‘But as the pain continues, that pattern changes. After a year, it’s clear that chronic pain is experienced in the emotional part of the brain.’ Chronic pain increases activity in the brain areas that can amplify pain signals, adds Irene Tracey, a professor of pain research at the University of Oxford. ‘This mechanism is like a tap, and in chronic pain patients it’s turned all the way up and jammed there permanently.’ ‘The hope is that the combination of this new understanding, together with pain management, can bring relief to chronic pain sufferers.'
Data Analysis –

The way this article is written – in a way as to vindicate and validate patient’s experiences and pit them against doctors who have ‘dismissed’ them with the notion that their pain is not real and that it is ‘all in their head’. This is obvious reporting bias to generate reader interest. But putting that issue aside what this article does demonstrate is poor communication on the part of the healthcare professionals in explaining the nature of persistent pain it is ‘all in your head’ but not in the sense that the person is making it up (which is what they think they are being told) bit in the fact that pain is generated by the brain and in persistent pain – different parts of the brain are activated.

There is another point here that relates to my theory of ‘lack of a diagnosis’ being able to point to something tangible and say ‘that’s what’s physically wrong with me’ my stakeholders told me ‘it was a relief’ when they got a diagnosis of Fibromyalgia or they were told that the pain is due to a ‘slipped disc’ it *legitimises their pain experience and validates it*. No people with chronic back pain can say that there is a physical problem with a part of their brain that keeps generating a heightened response to pain. Will this make self-management easier to accept – if the the theory is that once the investigation reveals what is wrong then will know how to fix it – actually doesn’t alter treatment – the treatment is a PMP that includes self-management strategies on how to regulate the brains response to signals coming from the body and being interpreted as pain.
C.3 Art Data extraction form

Translating Pain

**Publishers:** Lancaster University and Arts & Research Council

UK AHRC funded research network Translating Chronic Pain: A Critical and Creative Research Network based at Lancaster University

**Date:** 2018/2019

**Abstract:** This eighteen-month interdisciplinary critical/creative project will bring together people living with persistent pain, representatives from pain charities, creative writers, academics, and medical practitioners. We aim to better represent chronic pain experience by disrupting existing expectations of illness memoir, and to challenge current tendencies in medical humanities scholarship of narrative and wellbeing. Unlike traditional longform illness narratives, our network will produce and explore what we are calling ‘flash’ illness writing: fragmentary, episode focused, short format work, both word and image.

**Source type:** #art

**URL:** [https://wp.lancs.ac.uk/translatingpain/anthologycollection/](https://wp.lancs.ac.uk/translatingpain/anthologycollection/)

**Location:** C:\Users\17027704\OneDrive - University of the Highlands and Islands\Literature search\Grey literature\Translating Pain

**Tags:** #grey literature,#art #realist synthesis

**Relevance/Usefulness:** High

**Notes**

I liked the idea of using art since it is a form of expression that transcends words and allows those who are suffering but lack the words to articulate their feeling a chance to express themselves – and arguably make more of an impact.

Again this is my axiological position coming through – pain is invisible and people who have long term pain struggle to get people to understand how debilitating and all-consuming it is – because to look at them, you wouldn’t see that anything is wrong. For me it was really important to capture that.
Reflective Notes

Black and white drawing with RED being the only use of colour for impact

Wings have been "torn off" there is violence in this as well as pain. Her wings were taken from her against her will. She had no say in what has become of her and she was powerless to prevent it. A part of her has gone and she is not whole she is not the same person as a result. There is a sense of loss, grief for what has been taken from her – she is no longer the person she once was.

Now that her wings have been torn off no longer able to free herself from her situation. Her wings were a means by which she could fly. There are no legs in this picture – she is stuck, captive, grounded, unable to move or go anywhere. Social isolation not able to leave her bed she drew this in bed she is a CAPTIVE
She is a drawing but the feather from her wings is real this is the only thing that feels real you have to see it to believe it a feather is something you can touch with your hands, it is tangible but pain is not.

Art data extraction form (cont’d)

‘The Medical record swallows the story’ by Sara Wasson

Reflective Notes

This reminds me of what the stakeholders (ES012?) when he was saying that the data that is kept when he recounts how his pain is affecting him gets boiled down to simple statements of how much medication he is on and for how long.

The 'story' being swallowed is like the emotional/social/psychological features of their condition isn't relevant to the medical record or can't be captured in the medical record that is more concerned about objective data. The experience of what is like to live with pain disappears inside the computer and is converted into data that holds no meaning to the patient.

Interestingly it both sides of the story the patient and the doctors get swallowed by the medical record. There is no longer any evidence of what was discussed in the consultation e.g the tone that the patient was spoken to kind or frustrated? The explanations they were given, or treatments offered.

**So what? Why does that matter?** Because people in pain often feel frustrated that they are not being believed, they struggle to convey how much their pain is taking over their life. It takes a lot of energy to attend a GP appointment and to try to put into words what they are feeling in the hope that they might be given some relief. By 'swallowing the story' all that effort and energy has been wasted only to be repeated in the next consultation. The data captured by the computer can't give you the full story and thus is not able to convey the lived experience. It takes the patient out of the picture and all that is left in the final frame is the computer with a medical record put not a patient story.

In this picture the patient is a lady and the GP a man and the computer is sitting between them. Through a gender and power 'lens' of interpretation this could represent the power differences in the relationships. The GP is a taller, bigger figure whose feet touch the ground whereas the lady's doesn't.
Executive Summary: Reflective piece looking back over the last 10 years of the Self-management fund administered by the Alliance. The Fund, which is administered by the Health and Social Care Alliance Scotland (the ALLIANCE), was introduced to provide third sector organisations and partnerships with an opportunity to develop and strengthen new project ideas and build upon existing approaches to support people with long term conditions. It was introduced after our self-management strategy, ‘Gaun Yersel’, set out the key drivers for change that would enable people living with long term conditions to live well – and on their own terms – with whatever conditions they have. Since then, the Scottish Government has provided around £18 million, through the Fund, to support the development of 272 new ideas and projects the length and breadth of Scotland.

Data Extraction

p. 6 "A new fund born from notions of co-production and empowerment where people living with conditions were recognised to have unique expertise and insight into community based solutions that would not only help themselves, but others too."

p. 8 "When the Self-management Fund was first opened as a recommendation of ‘Gaun Yersel!’ the Self-management Strategy for Scotland, there was no developed narrative about the significance of self-management in a progressive health and social care system in Scotland"

p.9 "One of the key pieces of learning around sustainability is that scaling approaches up isn’t always the answer. Although we often see successful pilot projects going on to be ‘scaled up’ and implemented in other areas of the country, our project learning has demonstrated that what works in one area of Scotland, or with one community (whether that be geographical or otherwise) may not be suitable in another"

p.10 "Flexibility is key, and this is particularly evident in implementing approaches in rural areas of Scotland, where there are unique challenges, including limited transport and slower roll out of broadband internet. Where digital could be most effectively utilised to support reduced isolation, and implementation of innovative
approaches to health and social care support, it is often most difficult due to the lack of infrastructure."

p.10 Peer support "key part of self-management is being able to hear from and have discussions with others who have a similar condition or experience, and being able to share what has and hasn't worked to support the management of life with a long term condition "......consistently people identify in feedback that one of the most useful and important aspects of projects has been the importance of meeting and hearing from other people who have similar experiences to them."  

p.11 "At the Self-management Four Nations Summit in Edinburgh in 2017, Derek Feeley, now Chief Executive of the Institute of Healthcare Improvement and former Chief Executive of NHS Scotland, said “The Self-management Fund was the best investment I ever made. It put the power where it ought to be.”#power

p.33 "Supported self-management is increasingly being recognised in the current evidence base as a preferred term to refer to interventions and approaches that help people to develop the skills, knowledge, confidence, and resilience to manage the impact of their long term condition(s). This includes aspects of medical, role and emotional management, behaviour change, and the management of multiple morbidities. The term ‘supported self-management’ represents a move away from traditional views of self-management as being merely about education or compliance with professionally driven treatment plans and goals. Rather, supported self-management focusses on the uniqueness of individuals’ experiences and responses in managing their conditions, and supports them to live their lives in a way that is personally meaningful and purposeful for them." # [supported self-management]

p.33 [supported self-management] "Contemporary approaches and interventions to support self-management are now embracing the idea of flexibility and tailoring to individual need rather than adhering to a model."

p. 33 "There is still a lot that we do not know about, including how hard to reach and marginalised groups engage in self-management and their preferences for being supported to do so. We also know little about how multimorbidity, low income, and health inequalities influence individuals’ priorities for, capacity in, and contexts conducive to self-management."

p.34 "Although the concepts of ‘minimally disruptive medicine’ and ‘Realistic Medicine’ have been coined, we need more research to understand how to design interventions and approaches that minimise treatment burden, that offer meaning and value for individuals, and that can be easily integrated into their lives. Self-management does not exist in a vacuum"

Data analysis

What is the document about?

This is a reflective piece looking back at the self-management fund that was created by the Alliance 10 years ago. The main focus of the document is on what has been learnt by the fund over the past decade about how best to serve people living with long term conditions.
What are the key issues being talked about?

- Patients living with long term conditions are the experts on their condition
- There is a need to move away from the term self-management, to supported self-management
- Peer support and learning from others who are going through the same thing is an essential component of a successful self-management programme.
- More needs to be know about the context in which under-represented groups are view and partake in self-management.
- Scotland is a geographically diverse country and this needs to be accounted for when rolling out programmes that rely on an infrastructure that may be missing in parts of the country – this is especially true of digital health technology.

Who is being represented here?

People living with long term conditions are being spoken about but from the author’s perspective. The author is an employee of The Alliance

Rigor considerations?

The Alliance is funded by the Scottish Government and tasked with over-seeing the distribution of grants to self-management projects it considers to be meaningful. Therefore, it is in the Alliance’s interest to paint a positive picture of how they have managed things over the past 10 years.

What value is this thread adding to my research?

There is an acknowledgement here that self-management may come as a burden to some and that a person’s life circumstances, their emotional and cognitive capacity and their health and digital literacy skills need to be considered when asking someone to manage their long-term condition,

How does this thread add to my theory development? (Refine, Revise, Refute, Reinforce)

Reinforces the importance of peer support in helping people to self-manage.

Reinforces the theory that there is tension around the term ‘self-management’ and a reframing of the concept as ‘supported self-management’ would help mitigate the feeling of abandonment and isolation many get when they are told that they need ‘self-manage’ their condition.

Reinforces the idea of a treatment burden and for the need for treatment to ‘fit into people lives’

Makes reference to the ethical consideration of digital health technology that it is not a means by which to widen the healthcare gap between the poor and marginalised groups – the very people who might benefit from this technology.

What programme theories is this speaking to?

Programme theory 1; Programme theory 3
C.5 Policy Paper data extraction form

**TEC: Digital Citizen Delivery Plan**

**Author:** Technology Enabled Care  
**Organisation:** Digital Health and Care Scotland  
**Year:** 2021/22  
**URL:**  
**Category:** Strategy document  
**Pages:** 1-41  
**Tags:** #RS Paper Policy paper  
**Location:** C:\Users\17027704\OneDrive University of the Highlands and Islands\Literature search\Government policy papers\Included

**Executive Summary:** The TEC Programme is part of the Scottish Government’s Digital Health and Care Directorate and is guided by the overarching Digital Health and Care Strategy.

The programme focuses on citizen facing digital solutions where “outcomes for individuals in home or community settings are improved through the application of technology as an integral part of quality, cost effective care and support to look after more people at home”.

It reports to the cross sector Digital Citizen Delivery Board as part of Digital Health and Care governance that oversees the programme.

**Relevant/usefulness:** Low

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**Data extraction**

> p.3 "Our ambition has always been to facilitate the use of technology to [shift the focus of health and care systems](#) from crisis intervention towards prevention, early intervention, enablement and [supported self-management](#)."

> p.3 "Working through the crisis presented by the pandemic has provided us with opportunities to [accelerate the mainstreaming of approaches](#) that were in the early stages of development and adoption in early 2020." #Covid

> p.4 "There has also been [greater focus on people self-managing conditions in their own home](#) and so to meet demand we have had to increase our digital capabilities significantly. Now, more people than ever before are accessing important health and care information on platforms such as NHS Inform." #Covid

> p.7 "Our aim for the next year is to [empower citizens to better manage their health and wellbeing](#), support independent living, and gain access to services through digital means. We know this is leading to a shift in the balance of care by using the tools and technologies that are already increasingly used for all other aspects of our lives."
Policy Paper Data extraction form (cont’d)

> p.24 " The pandemic has had a profound influence on the ways in which health and care has been delivered in Scotland. This has led, in many cases to greater focus on the design and delivery of services along with a much wider acceptance of digital channels as a primary option in accessing care services. It is important that we build on the momentum of the public and staff showing a willingness to utilise digital tools both in health and care but also in all of our day to day lives. This means developing a greater understanding of the digital tools that people want and need to be able to access health and care services. This could include but is not limited to – being able to access care records, update personal information, attend an appointment digitally, book or change an appointment online or order a prescription."

Data analysis

What is the document about?

It outlines how the Technology Enabled Care (TEC) has responded to the effects of the Covid pandemic and accelerated the role out of digital health technology to provide platforms for patients to access their health providers and records.

What are the key issues being talked about?

The authors stress that it is important to capitalise on the momentum created by the pandemic in the appetite and roll out of digital health technology.

Again, there is more reference to digital health technology as a means of empowering citizens to better manage their health and wellbeing. The inference being made is that digital technology enables a person to stay at home and to live independently with out the need to see a health practitioner face to face - they can access all the care that they need from their own home. Instead of the patient have to go to the healthcare provider the services can come to them.

Who is being represented here?

This document is written by civil servants working in the Scottish Government – they are talking about digital health care and how it would benefit the citizens of Scotland. These ‘citizens’ aren’t necessarily those living with long term conditions or back pain specifically – its referring to how all people will ‘benefit’ from digital health technology.

Rigor considerations?

This is almost a celebratory piece written to commend the response of the TEC programme to the demand placed on delivering healthcare services in a global pandemic. It is overwhelmingly positive about digital health and the potential it has to ‘empower’ citizens. ‘Citizens’ is a broad term and they don’t unpack it to specify how digital health could to a greater or lesser degree ‘empower’ certain patient groups. It has a rather narrow definition (if you can call it that since they don’t define the term) of empowerment – it is mainly about enabling people to stay in their own homes whilst still accessing healthcare.

What value is this thread adding to my research?

This adds further support to the idea of digital health technology becoming ubiquitous – a trend that has been accelerated by Covid. It also adds more data to support the idea that policy makers behind how they believe digital health programmes work – empowerment comes about as a result of enabling patients to stay at home and to live independently – whilst recognising that this may entail ongoing support but
arguing that this support could be provided by digital means so that they can look after more people at home.

How does this thread add to my theory development? (Refine, Revise, Refute, Reinforce)

**Revise**: Prog theory 1 doesn’t have ‘empowerment in it’ I have used the code ‘convenience’ in that a patient can access healthcare from home, but this TEC document would seem to argue that it is more than this – digital health enables a person to continue to live independently at home and that is not simply convenient – that is empowering.

**Reinforce**: Prog theory 6 references the impact on Covid in the acceleration of the eHealth agenda and due to the ubiquity of digital technology in general there is more acceptance of digital health delivery.

**What programme theories is this speaking to?**

Programme theory 1, Programme theory 6
C.6 Blog post data extraction form

Title: Self-Management – Abandonment or Empowerment

Author: Chris Bridgeford

Organisation: Affa Sair

Affa Sair is the only patient led and administered Charity in Scotland campaigning for and supporting all chronic pain sufferers. Current membership is at 603.

Affa Sair is a member of the Scottish Government’s National Advisory Committee on Chronic Pain.

Date: 24th March 2021

URL https://affasair.org/wordsofpain/2020/10/24/self-managementabandonmentorempowermentbychrisbridgeford

Category: #blog

Pages: 1-4

Tags: #blog; #Realist Synthesis] #Covid

Location: C:\Users\17027704\OneDrive University of the Highlands and Islands\Literature search\Blogs

Executive Summary

Blog post written by Chris Bridgeford who is the founder of the charitable organisation ‘Affa Sair’ which is a support group created to help people living with chronic pain. Chris has been a patient representative on the chronic pain advisory board to the Scottish Government.

Rigour

Chris does not have an overly favourable view towards the policies around chronic pain management put in place by the Scottish Government. This discontent was exacerbated in the Covid pandemic when the government suspended pain services as nonessential and redirected healthcare workers to my frontline department (e.g respiratory wards and A&E).

That said, Chris is very knowledgeable around chronic pain not only because he suffers with it himself but as part of his patient advocacy role he ensures he is up to date with political developments and policy initiatives. Affa Sair (and Chris as chairperson) were invited to speak at European Pain Summit in November 2021.

Chris is also working on a project with another person living with chronic pain to develop an app to help people self-manage long term pain conditions and in their R&D phase have spoken to a wide range of healthcare professionals in England and Scotland as well as complementary therapists and dieticians to develop a comprehensive self-management resource this is still in the development stage.

Relevant/usefulness: High
It is beyond doubt that during Covid, chronic pain sufferers will be at the bottom of the list as usual for any improvements in their treatments. Eight months in, Scottish Pain Clinics are only carrying out virtual consultations – no treatments for people suffering out of control pain whether Covid rages or not. It strikes me that to leave people suffering so much in the 21st century is completely immoral. I find it incomprehensible that professionals with a vocation for healing allow the faceless government advisors and NHS managers to put policies and budgets ahead of wellbeing. Such is the influence of these clandestine characters that people in total despair find themselves denied appropriate help available to the rest of society.

The two phrases currently being forced on sufferers in Scotland are “lived experience” and “self-management”. I don’t see the need for the first when the terms “patient” or “sufferer” tells it as it really is. What is included in “self-management” is never explained but it has become the current buzzword when treatment is mentioned. It would seem the term “sufferer” is too brutal and negative for politicians so the gentler “lived experience” is used to give a cosy, unchallenging feeling. The politicians and advisors don’t want any brutal realism spoiling the numerous workshops and committees making decisions that have excluded the opinions of actual pain sufferers.

The author is suggesting that people who are suffering in pain are excluded from decision making which would contradict the intention of the Scottish Government whose policies focused on including the patient voice and keeping the patient at the centre of health care decisions and policy. It is interesting that the author states this since his charity sits on the National Advisory Group for chronic pain does he feel that this contribution is worthless or tokenism or is this an example of inflammatory language being used in a blog post bent on a particular agenda?

This extract also speaks to my theory about self-management being a confusing and undefined term. To this author it is an empty phrase devoid of meaning for people living with persistent pain.
The “self-management” phrase may be self-explanatory but the Scottish Government, their Advisors and other proponents of the ideology, have never explained what treatments it covers. Until its meaning is explained, how can we judge its usefulness in helping over a million Scots suffering intractable pain which they wake up with and then try to go to sleep with every day and night until they die?

Note: The author makes a very good point here, if haven't got a working definition of self-management and a clear understanding of what this programme involves then how can we judge its effectiveness?

Initially, those taking part must have face-to-face contact with the programme instructors and this contact must be carried on at intervals throughout the programme. Outwith the initial and follow up “inperson” sessions, the remainder should be available virtually so that patients do not increase their pain in travelling long distances. A question-and-answer system should be provided so patients can ask individual and private questions. These questions need not be answered immediately but a reply guaranteed within a certain amount of time.

Note: It is interesting that the author stipulates the importance of having a face to face contact first with programme instructors the word 'must' implies that this is non-negotiable and therefore an important part of the programme architecture. Why is this such an important part of the programme architecture?

This extract also speaks to my theories about the importance of reducing travel and increasing convenience for the patient. Also that the information the app delivers has been personalised to the user.

"We feel a successful self-management programme should include:"

Note: Brilliant this is a self-management programme content as outlined by people who are in persistent pain this is what they want. Meditation/mindfulness; physiotherapy; psychotherapy; alternative therapy, diet, advice on disability benefits grants; hobbies; pharmacist

"[Individual psychotherapy] is key for so many patients to feel heard, particularly by medical professionals"...."This [psychotherapy] needs to be designed to ensure that the patient realises the psychotherapy is part of a full treatment regime and is not a way of suggesting that the pain is 'all in their head' – frequently heard from many chronic pain sufferers not fully understanding what the health professional means"

This extract references a repeated theory in the literature and stakeholder consultations that is the need to feel heard by the medical profession and the ability to communicate how sufferers are feeling in a way that is understood by healthcare professions. Psychotherapy can be that conduit and aid in communicating between the two reminds me of the poem that references the doctor speaking in 'medical language' as if its a different language from the patients'.
Blog post data extraction form (cont’d)

p.3 Physiotherapy  Individualised physiotherapy regimes would be developed in an individual session with a physiotherapist. This can reduce the long-term reliance on repeated physiotherapy referrals. The idea would be to have this initial consultation with provisions of what to do if you feel like the physio is too much (how to reduce the intensity of the exercises) or what to do if you feel like you can do more (how to increase the intensity). This would ideally be followed by online consultations initially monthly, then slowly decreasing the regularity until there is a biannual in person physio appointment. As much as this results in continued physiotherapy, it reduces time and cost with repeated referrals and hopefully the patient will benefit in a way which means they no longer feel they need the help of the other pain management services.”

There is a need for ongoing support and they mention in person reviews again there a sense that face to face contact (in between using the app) is important. The author recognises that the healthcare resources are limited but believes that the suggestions they make will ultimately lead to less healthcare utilization by not calling upon other pain management services.

p.4 "There have been welcome changes recently in the makeup of Scottish Government Advisory Groups. Firstly the National Advisory Committee for Chronic Pain has included patient representatives for the first time and have also invited three new 3rd Sector groups to sit on the Committee, The Centre for Integrative Care based in Glasgow, SAMH (Scottish Adult Mental Health) and I’m really honoured to say – Affa Sair – my own charity. I, and many others have been hugely critical of the NACCP in the past but we welcome these new developments and certainly Affa Sair looks forward to working progressively with the NACCP to better help Scottish Chronic Pain Sufferers.”

The author closes his blog by making a concession, an olive branch, taking the fire out of his language a little by acknowledging that encouraging steps are being made to include patient representatives on government advisory boards. However it does feel as if these concessions have been hard one and rather than being an integral part of policy development as it was claimed to be, patient representation on these boards had to be fought for.
### Title: Pain Self-Management for Veterans: Development and Pilot Test of a Stage-Based Mobile-Optimized Intervention

Author(s): Sara S. Johnson, Deborah A. Levesque, Lynne E. Broderick, Dustin G. Bailey, Robert D. Kerns  
Year: 2017  
Publication: JMIR Medical Informatics  
Roam Reference: @johnson2017pain  
Relevancy Rating: 3

### Appraisal Assessment  
Moderate

### Summary

<table>
<thead>
<tr>
<th>Data source</th>
<th>Pilot study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study location</td>
<td>USA</td>
</tr>
<tr>
<td>Patient group details</td>
<td>69 Veterans (81%) male</td>
</tr>
<tr>
<td>Brief Description of intervention</td>
<td>A CBT internet programme 'Health eRide lasting an average of 39.3 mins (SD 20min) and then two PAC 'Personal Activity Centre' 56 interactive activities designed to activate the process of change that are most appropriate for the user based on his or her state of change for each behaviour</td>
</tr>
<tr>
<td>Outcome measures</td>
<td>Pain intensity and pain impact, pain self-management skills, PTSD, WellWell-being, Stage of change for pain self-management stage of change for stress management, stage of change for practising healthy sleep habits, Global impression of change, programme acceptability and usability</td>
</tr>
<tr>
<td>Results</td>
<td>44 completed 30-day trial. significant reduction in pain intensity and pain impact - patients also showed significant pre post changes in readiness to engage in pain self-management an stress management and on readiness to fst the following four specific self-management strategies: exercise, relaxation cognitive control and use of proper body mechanics</td>
</tr>
<tr>
<td>Additional support?</td>
<td>text messaging - could opt in for this feature - tailored text messages for each of the three targeted behaviours</td>
</tr>
<tr>
<td>Setting</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**What definition of self-management do they use? (if any?)**

p.6 The stage of change measure for pain self-management was adapted from an algorithm developed in a previous work on pain self-management for patients with interstitial cystitis [66]. Participants were provided with a list of six effective self-management strategies (e.g., exercising regularly, controlling negative thoughts about the pain) and asked about their readiness to use at least three of them to manage their pain.
They have participants complete the MPRCQ2 (Multidimensional Pain Readiness to Change Questionnaire)

Each of the MPRCQ scales measure readiness to engage in coping strategies that are commonly taught in multidisciplinary pain management programs. 9 specific pain coping responses: Exercise; Task Persistence; Relaxation; Cognitive Control; Pacing; Avoid Contingent Rest; Avoid Asking for Assistance; Assertive Communication; and Proper Body Mechanics.

Not sure where they got these 9 from? need to look at original source for this

What is interesting about this paper?:
In terms of context, it alludes to when someone might be ready to take on self-management and they whether they might engage with a digital app to deliver this. If they are in the pre-contemplation stage, for example, it might be unlikely that they are ready for

25% showed a change in the readiness to engage in self-management strategies

Are the methods used to generate the results credible, trustworthy, and plausible?
Authors acknowledge that individuals in the precontemplation and contemplation stages were underrepresented

Any mention of theory or empowerment?
Based on the transtheoretical model of behaviour change- ties into what I have coded as 'patient journey' - where patients are in the state of readiness and preparedness to accept and implement self-management strategies

Articles of interest from their reference list: (snowballing)
None

2nd Round of Data Extraction looking for CMOs and creating if then statements. How does it relate to my IRPTS initial programme theories?

What works?
The authors repeat what the likes of du et al (2020), were arguing, that a lot of the digital self-management programmes are not incorporating evidence-based practise within the resources being offered by their digital self-management apps.

This could lead to a lack of trust by HCPs who do not feel the apps are providing their patients with the appropriate tools, skills, education that they would receive if they had had a self-management programme delivered by them,

Also, a lack of tailoring - neglecting individual preferences and differences in pain presentation and readiness for behavioural change.
The researchers used gaming principles and social networking to increase engagement - must activate meaning, mastery and autonomy to be effective (according to gamification literature)

Meaning and personal relevance - users had the option to upload a photo of something that would keep them going - like a picture of their family, or a mountain they wanted to climb etc. They chose a personal avatar to 'represent' them - drop down menu of personal goal 'become more in control of my pain'.

[RH] Is this trying to recreate that patient-provider relationship that is one of the six core components of self-management (Du et al. 2020) - It makes it meaningful and personal - is the digital programme becoming the social actor instead of the HCP?

Mastery - in this app it was about moving along a subway map and getting closer to the destination with the more activities that were completed. I see this aligning with the reasoning behind goal setting in a self-management programme - is the mechanism being generated 'mastery'?

In addition to wanting the information to be clear, concise and relevant p.10 - one of the comments was that they wanted to have videos of 'real people' and how they managed their pain in a health way - again it seems that testimonials are powerful in providing hope ***that others in similar situation have managed to their pain or improved their quality of life - provides **reassurance and comfort that you are not alone.

For Whom?
For these authors it is all about assessing person's level of motivation and readiness to adopt self-management strategies I like the fact that they acknowledge (by using the MPRCQ) that a person's readiness to engage in self-management strategies will depend on which of the strategies you are talking about - for instance they may be ready to engage with exercise, feel less ready to engage with pacing and not prepared at all to engage with relaxation techniques - so you can tailor the intervention to this state of readiness

Decisional balance in TTM - - When an individual is in the Precontemplation stage, the pros in favour of behaviour change are outweighed by the relative cons for change and in favour of maintaining the existing behaviour.

In what context?
Not everyone will be in the same state of readiness when it comes to behavioural change. Furthermore, a single individual may have multiple states of 'readiness' depending on the self-management behaviour they are focusing on. Adding to this is the fluctuating nature of this preparedness - some days a person will feel more ready than others. Having a self-management programme that can adapt to these changes is more likely to be effective because it will not ask a person to do something that they don't feel ready for and therefore they are likely to stick with the programme and remain engaged because they feel like they are still in control
If users are given a digital self-management programme that provides information that has personal meaning to them and gives them a sense of autonomy and mastery over the self-management tasks they choose then they are more likely to engage in self-management behaviour change because the programme is seen to be relevant to the users and builds their confidence and self-efficacy by achieving meaningful goals.

if a mobile app provided a self-management programme that was able to adapt to a person's readiness to engage in behavioural change then it is likely that users will be more engaged and motivated to stick with the programme because they are not being asked to do something that they don't feel they are ready for, and the task feels more relevant to their particular situation.
Journal article data extraction form (cont’d)

Decisional balance in TTM -- When an individual is in the Precontemplation stage, the pros in favour of behaviour change are outweighed by the relative cons for change and in favour of maintaining the existing behaviour.

In what context?
Not everyone will be in the same state of readiness when it comes to behavioural change. Furthermore, a single individual may have multiple states of readiness depending on the self-management behaviour they are focusing on. Adding to this is the fluctuating nature of this preparedness – some days a person will feel more ready than others. Having a self-management programme that can adapt to these changes is more likely to be effective because it will not ask a person to do something that they don’t feel ready for and therefore they are likely to stick with the programme and remain engaged because they feel like they are still in control.

Why?
meaning, mastery and autonomy to be effective - builds confidence, self-efficacy, improved self-image

If/then/because
If users are given a digital self-management programme that provides information that has personal meaning to them and gives them a sense of autonomy and mastery over the self-management tasks they choose then they are more likely to engage in self-management behaviour or change because the programme is seen to be relevant to the users and builds their confidence and self-efficacy by achieving meaningful goals.

If a mobile app provided a self-management programme that was able to adapt to a person’s readiness to engage in behavioural change then it is likely that users will be more engaged and motivated to stick with the programme because they are not being asked to do something that they don’t feel they are ready for, and the task feels more relevant to their particular situation.
<table>
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<th>Page</th>
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| p.2  | However, a major problem with existing interventions is that they tend to neglect individual differences in motivation and readiness to adopt self-management strategies [36], have limited input from end-users in the development, cautioning questions their usability [37], fail to address other contextual conditions [38], and are not based on evidence-based practices [39]. The authors repeat what the likes of Xu et al (2020), were arguing, that a lot of the digital self-management programmes are not incorporating evidence-based practices within the resources being offered by their digital self-management apps.

   This could lead to a lack of trust by HCPs who do not feel the apps are providing their patients with the appropriate tools, skills, education that they would receive if they had had a self-management programme delivered by them.

   Also, a lack of tailoring - neglecting individual preferences and differences in pain presentation and readiness for behavioural change. |
| p.3  | The Merakone [33, 54] and gamification experts stressed that gamification tactics must activate the meaning, mastery, and autonomy to be effective.

   Mastery - in this app it was about moving along a subway map and getting closer to the destination with the more activities that were completed. I see this aligning with the reasoning behind goal-setting in a self-management programme - is the mechanism being generated 'mastery'? |
| p.10 | Previous research demonstrates that primary care provider referrals significantly increased adherence to a recommended behaviour change intervention, particularly when accompanied by a regular follow-up [35]. Repeated theme that HCPs need to be supportive of the app and promote it. |
| p.3  | It was also decided at the outset that the intervention would be tailored to vodanas' readiness to self-manage pain, as well as their preferences regarding specific pain self-management strategies. The transtheoretical model (TTM) provided the theoretical framework.

   Not everyone will be in the same state of readiness when it comes to behavioural change. Furthermore, a single individual may have multiple stages of readiness depending on the self-management behaviour they are focusing on. Adding to this is the fluctuating nature of this preparedness - some days a person will feel more ready than others. Having a self-management programme that can adapt to these changes is more likely to be effective because it will not ask a person to do something that they don't feel ready for and therefore they are likely to stick with the programme and remain engaged because they feel like they are still in control.

   If a mobile app provided a self-management programme that was able to adapt to a person's readiness to engage in behavioural change than it is likely that users will be more engaged and motivated to stick with the programme because they are not being asked to do something that they don't feel they are ready for, and the task feels more relevant to their particular situation. |
| p.9  | Respondents were most likely to comment on the length of the program: confusion on how to answer some of the questions, confusion over the design of the program, and the idea that the information needs to be, 'new' to the user. In addition to wanting the information to be clear, concise and relevant p.10 - one of the comments was that they wanted to have videos of 'real people' and how they managed their pain in a health way - again it seems that testimonials are powerful in providing hope.

   "that others in similar situation have managed to their pain or improved their quality of life - provides reassurance and comfort that you are not alone." |
| p.10 | "Voices would be a good tool, seeing reactions of real people and how they manage pain the healthy way." |
Appendix D: Extract from Coding Journal (realist synthesis)

Programme theory 1

<table>
<thead>
<tr>
<th>Programme theory one</th>
<th>It takes ages to get an appointment with a HCP this makes a person reluctant to be discharged as they fear being sent to the back of the waiting list should they need input again. And the likelihood is they will need input again because back pain is a long-term condition that can flare and then stabilise. A mobile provides ongoing support, taking away that sense of fear that you are 'on your own' to self-manage. You can also access whenever you need it and wherever you need it. This gives you a sense of control - this resource suits you not the healthcare service</th>
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</table>

Source: Twit05

Reinforce: The theory that there is confusion over the term self-management and that it has become associated with a feeling of abandonment and isolation. As a result, there is a need for a change of emphasis and that it should become known as ‘supported self-management’ to recognise that to successfully manage persistent pain requires ongoing support.

Reinforce: The impact of Covid left people with persistent pain feeling that they had been abandoned as access to pain services were closed. This lack of ongoing support and access to resources was highlighted at this time.

Source: Thsec01

Reinforces the theory that there is tension around the term ‘self-management’ and a reframing of the concept as ‘supported self-management’ would help mitigate the feeling of abandonment and isolation many get when they are told that they need ‘self-manage’ their condition.

Source: PP3

This document shows how central the concept of ‘empowerment’ is within the Scottish Government’s digital health agenda – their theory is that digital tech will help people live independently and be able to take more ownership of their own health. This is what they mean by empowerment – being reliant on yourself rather than others. It doesn’t go into specifics as to how digital technology will enable people to do this. There is a lot of references to patients being ‘in control’.
Source: PP5
There is a need for pain services to be delivered in the community – not least to prevent the need for patients to travel but to provide ongoing support after the patients have been discharged to self-manage. This would necessitate (amongst other things) closer collaboration between the NHS and third sector services who could provide this ongoing support. This access to care in the community would also negate the long waiting times to access secondary pain services which are unnecessary for a vast proportion of chronic pain patients.

Source: PP6
There is an overwhelming number of patients living with chronic pain and not enough healthcare workers to support them. There are issues with recruitment and the number of GPs we have are feeling overwhelmed by the workload.

Source: PP2
Revise: Prog theory 1 doesn’t have ‘empowerment in it’ I have used the code ‘convenience’ in that a patient can access healthcare from home, but this TEC document would seem to argue that it is more than this – digital health enables a person to continue to live independently at home and that is not simply convenient – that is empowering.

Source: News15: The Guardian, June 2018

Over the next days and weeks, the pain lessened, but I was still terrified to move. It was most intense just above my left hip, but it had infused my whole being, taken my energy, taken any pleasure I had in life. It was exhausting, being in pain or worrying about being in pain. I felt very low.

I feel this supports the Twitter comments and stakeholder feedback that there is something particular about back pain – it’s so debilitating that it takes over your whole life and that makes people very afraid and desperate to try anything to take the pain away. This is where hope in a ‘magical cure’ comes from – the fear and terror that back pain causes.

Source: Blog1

Individualised physiotherapy regimes would be developed in an individual session with a physiotherapist. This can reduce the long-term reliance on repeated physiotherapy referrals. The idea would be to have this initial consultation with provisions of what to do if you feel like the physio is too much (how to reduce the intensity of the exercises) or what to do if you feel like you can do more (how to increase the intensity). This would ideally be followed by online consultations initially monthly, then slowly decreasing the regularity.
until there is a biannual in person physio appointment. As much as this results in continued physiotherapy, it reduces time and cost with repeated referrals and hopefully the patient will benefit in a way which means they no longer feel they need the help of the other pain management services.”

Source: PS01

Two key points here that support my programme theories – that there needs to be instant access to support and that those who are providing the support are known to the patient. The key mechanism in both instances would appear to be ‘trust’ according to PS001. Users would be happy with a mobile app if they could trust it to always be there for them whenever they needed it and the advice, they received was trustworthy.

Source: ES01

Giving patients a number, they can call acts as a safety net a resource they can use if they need additional support. In this way they do not feel abandoned to manage on their own. Rather than create dependency as some HCPs may fear, PS001 states, from her experience, that just knowing the safety net was there was enough, and patients rarely used it.

ES001 lists some criteria he would want from a mobile app; a lot of which I would put under the category of ‘convenience’. The programme has to be all-encompassing, a one-stop mobile app, that houses all the components necessary for effective self-management. He also stresses the importance of the intervention being personalised to the user and the ability for the user to share their health information (should they wish to) with their HCPs. A sense of control is not only in being able to access support.
GP's or physiotherapists or occupational therapists under certain circumstances so that I feel like I am in control of the data and patient consent for a lot of these things I think is, exceptionally important and people need to be reassured that they are in control of the data that is being recorded or they are recording at their own volition. when and where you want it but also what happens to your medical data.
Appendix E: Twitter Recruitment Advertisement

Can an app help you self-manage your back pain?

We are looking for people living in Scotland to take part in our research

Aim
Our aim is to see whether a mobile app could help people self-manage their chronic low back pain. Specifically who might benefit from an app, why and in what circumstances would it be helpful.

What will it involve?
You will be asked to use a self-management app for 12 weeks and then participate in a 45 min telephone call with the principal investigator to discuss your experience.

Why get involved?
Participating in this research may help to improve healthcare provision for people self-managing chronic back pain. More specifically, there is anecdotal evidence that users of the mobile app have experienced a decrease in pain and suffering.

Are you eligible?
- Are you over 18 years old and live in Scotland
- Self-managing chronic back pain (defined as pain in the back lasting > 3 months)
- Not currently undergoing medical treatment in the form of surgery, physiotherapy, scans, or other medical investigations for your back pain.
- Have a smartphone and are able to participate in a telephone interview

If you would like to take part, or wish to find out more, please contact a member of the research team for an informal discussion about what is involved:

Rebecca Hunter (Principal Investigator) - rebecca.hunter@uhi.ac.uk

Twitter @RealBackstory Please add us on twitter, or private message us for further information.
### Appendix F: Interview script (realist synthesis)

#### Interview script/prompts

| Introduction | • Principle investigator  
               | • UHI/NHS Highland Physiotherapist  
               | • Confirm read PIS, happy to proceed  
               | • Any questions before we start |
|--------------|--------------------------------------------------|
| Ice breaker  | • Tell me about your history with back pain, your experience to date |
| Introduce IRPTS | • Explain how teacher/learner cycle works  
                           | • Emphasise we are testing theories – agree, disagree, change them  
                           | • No right or wrong answers  
                           | • 8-10 theories to test |
| Probe for mechanisms | • “what is about about……”  
                        | • “Do you think X changed how you felt…”  
                        | • “Do you think you would have reacted differently if…””  
                        | • “What does X give you/not give you” |
| Context      | • Has Covid-19 pandemic made a difference?  
               | • Compare to introduction of mobile/online banking  
               | • Do they live in remote/rural location?  
               | • IT Infrastructure – what’s internet like  
               | • Digital literacy – familiar with tech? tech-phobe? |
| What works, for whom | • Who do you think an app would/wouldn’t work for? |
When would an app be a useful tool and not so good?

| Disconfirming cases/rivalry | Unintended consequences… “could this backfire?”
|---------------------------|------------------------------------------------------------------|
|                           | Present alternate theories/contradictory theories – “For HCPs X but for patients Y”
|                           | “Other stakeholders have suggested….”
|                           | “The theory behind the policy suggested X but….”

Examples of teacher/learner approach

Interview with ES01, lines 245-247

**Interviewer:** “So what do you think of that theory?”

**ES01:** “Yes, I am convinced by it to a certain extent. So, this is how it goes for me…”

Interview with ES09, lines 103-107

**Interviewer:** “Okay, so part of my research method is that I come up with theories, ideas and the way I test them is, I test the on the experts and that’s you. You’ve been dealing with your back pain. So I’ll give you a theory and what I’d like you to do if it’s okay is, “well based on my experience” yes I would say that’s true or no I wouldn’t say that’s true for these reasons” so you’re not necessarily saying in my experience I like this... you are sort of testing these theories yeah?”

Interview with ES010, lines 335; 341-342

**Interviewer:** “so some people have said in the interviews that back pain comes with that kind of connotation, like ‘are you skiving?’ So is there something actually in that face-to-face encounter, you know, at a subconscious level, at an unspoken level that is being generated by this encounter?”
## Appendix G: Coding strategy

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<th>Coding Activity</th>
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| Direct Coding   | A cut and paste coding strategy in which small but relevant passages from the data are exported for analysis  
|                 | e.g. "she told me it was all in my head!" |
| Indirect Coding | A strategy in which parts of a transcript or document is highlighted and annotated but not extracted. The annotation is extracted, and a traceable link is created back to the source.  
|                 | e.g.. The key mechanism in both instances would appear to be ‘trust’ according to PS01. Users would need to trust a mobile app before the outcome manifests – Ref: PS01, 283-286 |
| Holistic coding | The whole transcript or document is in a sense ‘highlighted’ that brings forth new theoretical insights that cannot be summed up by one passage of text alone.  
|                 | e.g. For me this poem captures the discordance between the policy that promotes patients as 'partners in their own health care' and the reality that many patients experience. This relates to (ES003) who felt that because she had a past medical history of anxiety that all her symptoms could be attributed to that. |

Coding strategy adapted from Jagosh, J. 2020. Coding Configuring and Conveying in Realist Analysis training slides. Centre for Advancement of Realist Evaluation and Syntheses
Appendix H: Mind mapping

Free writing and mind mapping on whiteboard
Mind mapping using Xmind software

If people with CLBP are not given a specific diagnosis that validates their condition then they are made to feel like a malingering, or someone who is making their illness up, that is "all in their head". This breaks down the trust between the patient and health-care provider which detrimentally affects the patient's ability to accept the therapist's endorsement of a self-management app.

If someone is made to feel like they are making their symptoms up or that their pain is "all in their head" then a self-management app could be seen as a way of getting rid of a nuisance patient.

If a self-management app was able to reassure and reduce a person with chronic low back pain's fear about their condition then the self-management app will have more utility and meaning for the user and therefore it will be more likely to be accepted.

If people with CLBP are given a self-management app to help them self-manage their condition and believe they are no longer entitled to ongoing care or think there is some alternative agenda at play—like a means of getting rid of a nuisance patient, or it is a cost-saving exercise then an unintended consequence could be a feeling of resentment amongst this patient group and a failure to engage with the self-management app.

What makes CLBP so difficult to self-manage is that it is invisible - you can't see pain. This makes it difficult to prove you are sick and in need of care. There is the idea here that the person needs to be "seen to be believed" before they will accept tools like an app to manage their CLBP.

An assessment from a HCP provide validation and reassurance in a way that a self-management app can't.

Being assessed face-to-face gives both HCPs and people with CLBP the reassurance they have been "assessed properly", and that "nothing has been missed". In addition, for many people with CLBP, a face-to-face assessment gives them further reassurance that their symptoms - although not visible - have been taken seriously and they are not being "fobbed off" (their words) (Context). If a mobile app can provide the empathy, reassurance, validation, and trust (Mechanism) that they get from a face-to-face therapeutic encounter with an HCP then they will find a mobile self-management app beneficial (Outcome).

If there is confusion in the term 'self-management' between policy makers believing it is an adjunct to ongoing healthcare treatment health care professionals who regard it as a successful outcome of treatment with the patient unlikely to return and patients seeing self-management as a means by which they are "fobbed off" then this confusion underlines the self-management agenda because no one is really clear as to what the outcome is supposed to be.

If a self-management app was offered after a patient had been seen face to face by a healthcare practitioner and discharged to self-manage then it may be more readily accepted by patients because they have had the reassurance that comes from a face to face contact and have been provided with a resource (the self-management app) that gives them ongoing support at home.

If a self-management app was given to a patient after they have been assessed by a doctor or physiotherapist face to face then it could be useful.

The idea of cost-saving and some ulterior motive didn't come up in the first stakeholder consultations. There was more emphasis on the idea that they are not believed - they need reassurance they have been taken seriously.

Rather than a programme theory this is more of a contextual backdrop - this feeling of being fobbed off keeps coming up - an app needs to make someone with CLBP feel they are being supported to self-manage not fobbed off.
Mind mapping to refine IRPT

This figure depicts the creation of the refined programme theory 1 'face to face vs. virtual' by extracting elements from the five initial rough programme theories (highlighted in blue). Annotated loops with causal inferences converge to create a refined programme theory.
Appendix I: Example of literature search

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## Appendix J: Relevancy Rating Scale

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Appendix K: Relevancy, Richness and Rigour
Rating Scale

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<tr>
<td>Moderate</td>
<td>Papers in this category make one or two contributions towards theory development and have a fair amount of detail. Regardless of the overall quality of the study, extracts that have been used to build programme theory are of sufficient quality to support the inferences.</td>
</tr>
<tr>
<td>Low</td>
<td>Although relevant in respect to the programme intervention (mobile apps) papers in this category make little contribution to theory development and/or have results that lack credibility raising uncertainty as to whether extracts from the study are of sufficient quality to use in the programme theory building or refinement. These papers may also lack enough detail to make them useful to the study.</td>
</tr>
<tr>
<td>None</td>
<td>Although relevant in respect to the programme intervention (mobile apps) papers in this category make no contribution to theory development.</td>
</tr>
</tbody>
</table>
Appendix L: Seven Rough Programme Theory Areas

One of the presusmed advantages of being treated by HCP in person is that HCP gets to know the patient, how they are moving, what their particular needs are. This, in turn, leads to an individualised programme of treatment and reassurance that the patient is "in good hands". The concern with a mobile app is that it would not give individualised information and advice to each user. Instead, generic data would be offered which is unlikely to be of any value to a user who has been self-managing their back pain for a long time and would have no doubt found the same information online via a Google search. However, with the increasing number of touchpoints HCPs are recruiting now patients are getting individualised care. HCPs are now able to go through the years and years worth of medical data that has accumulated over the course of their career, giving patients a more detailed history of back pain. This means that consultation time is spent getting the HCP "up to speed". If a mobile app had access to the user's medical history and could tailor its education and advice according to the individual user then trust and reassurance could come from a mobile app because it was providing relevant and meaningful information based on all the history it had reviewed.

Before the Covid-19 pandemic healthcare was moving towards using mobile. This was dramatically accelerated as a result of Covid. Similar to other initiatives to introduce apps and digital services (e.g. online banking) where their experience in some cases mobile apps would take away valued face to face contact with HCPs. Patients mistrust mobile health solutions and see it as a money saving exercise to avoid the costs of hiring more HCPs. However, the number of people living with long term pain (of which back pain makes up a large proportion) for the number of HCPs available to treat them. This is particularly true in remote and rural locations where recruiting and retaining HCPs is difficult. As an increasing number of touchpoints HCPs are being relied upon who are expensive and lack the familiarity with the patients and their condition. If a mobile app had access to the user's medical records and could provide individualised information and advice - the kind of advice that could be provided by a resource that is familiar with the patient’s condition - it could make the process of care more efficient and cost-effective. It could also provide a further - perhaps even the first - route for online banking as people become more familiar with the technology and the advantages it brings.

Many people with long term back pain become socially isolated. It is too painful to leave the house, too tiring to have a conversation. They are unable to focus on anything other than their pain. They don't want to be away from their families. A mobile app that could communicate in an empathetic, non-judgemental non-judgemental could address this isolation issue. The anonymity of communicating with an online app could mean people feel more comfortable asking for advice or expressing their emotions. The app could also provide company and reassurance even at an unreachable hour when many people in pain are awake all night with no-one to talk to.

It takes ages to get an appointment with a HCP, this makes a person reluctant to be discharged as they are still not in the back of the waiting list. It is still possible that once a long term condition that can flare and then stabilize. A mobile app provides ongoing support; taking away the sense of fear that you are "on your own to self-manage. You can also access whenever you need it and wherever you are. This resource suits not just the healthcare service but also the patient's need for self-management. Back pain is not a disease. Ongoing pain is medically explained for many people with back pain. Back pain has been culturally associated with maligning. Face to face contact is needed so people feel that they are being believed, that they are telling the truth. You can't appreciate how much help someone is until you see it in their faces. If the way they walk, the way they respond to your touch. Once they have been seen by a HCP they feel validated. They feel that they are not facing it, they trust the HCP understands what they are going through and are therefore more willing to accept any suggestions the HCP makes after that. A mobile app isn't, "the patient in the next room."

Patients need to feel able to self-manage (self-efficacy). They need to accept that they have a long term condition that may not have a medical solution. This takes time and can be overwhelming for some people. To expect someone to self-manage at this stage may lead to a burden of care. In order to feel empowered in the Scottish Government had laid some landholdings (weaknesses) that need to be built on. Self-management needs to be built on and needs to be a part of the consultation. The consultation needs to go further, need to be more individualised. A digital app that could respond to an individual's capacity could assist with this. Providing ongoing support is a slow and reassuring piece.

In the beginning of a patient's journey it is not a partnership. The HCP holds all the cards. The patient doesn't know enough about their condition to know the right thing to ask other than "can you tell me what's wrong", "how can I make the pain go away"? This is especially true in consultations where the patient feels rushed and with HCPs doesn't know them and their long, complex, medical history. There may also be a sense, on the patient's part, that "you're the expert, you tell me what to do", or "can't I just get you to tell me what's going on?" When these expectations have not been met the patient may feel that the HCP has not upheld their part of the relationship. Patients feel they are folded off with medication when they don't particularly want and they begin to stop going to their HCPs. They don't give anything useful to help them help their self-manage. Many aren't given any self-management education at all. With education comes power. Patients know more about their condition, they know more about why this is happening to them and what they can do about it. A digital app can provide this empowerment by giving patients the information and advice they need. Patients no longer feel abandoned to self-manage without the tools necessary to do so.
Appendix M: Synthesising the data
Appendix N: IRPT 4 refined to become CMOC 5

IRPT 4: If HCPs are unable to see the utility of a self-management app or see it as a threat to their position, then it is unlikely to be accepted and supported because HCPs and patients prefer to be seen face to face, and an app cannot replicate the benefit that comes from a face-to-face appointment.

This current pandemic, along with the increasingly ageing population, has highlighted a pressing need to consider alternative innovative ways of working which minimise direct patient contact or the need for older adults to travel distances to their care provider... \[p.2\]

Discussing creating an app for HCPs to deliver to people with CBP as an adjunct to care - people use the app and in times of acute flare ups can access the healthcare service again. Lines 358-363

There is the automatic assumption that face to face appointments are ‘better’ they provide a ‘better service’ and this dichotomy frustrates P03. They feel that this automatic assumption that face to face is better - better for who? The HCP or the patient? This assumption fails to take into account the circumstances when it might not be better for the patient. But why does it have to be an either/or why can’t it be a both/and - best of both worlds - an app used as an adjunct to care. Lines 358-362

Refined

If a self-management app was used as an adjunct to care and not a replacement (C) then HCPs are likely to welcome the tool as it helps them to deliver ongoing support remotely (M) thereby enabling them to treat more patients in their limited clinic time (O). CMOC 5

P502

P504

P506

P508

P510

Covid and the increase in numbers has made it obvious that HCPs need help and to embrace tools like self-management apps.

...I think its become more obvious to people, to professionals, that they need to look at how you manage patients in a different ways to what we’ve been doing before...” Lines 42-49

...I think that if people can make sure these sorts of things [apps] are monitored and that the health professional gets back to them regularly...” Lines 169-174

...I think there’s definitely a place for it but it doesn’t work for every patient and the more complex patients definitely need that face to face, so it is about assessment of the patient, fine-tuning it and choosing it for the right type of patient...” Lines 81-88

Not dismissing the idea of an app just as along as it is used with discretion

...we don’t want these people that we have to work harder. We want them to very much to work smarter not harder.” Lines 95-102

the ‘game changer’ is a crucial change in context - we are no longer able to recruit sufficient HCP staff to meet the demand(173,852),(855,932)

This has allowed digital health technology to become more acceptable when it was seen not as a means by which we could replace HCPs but a way in which we could help them to work smarter not harder.
Appendix O: IRPT 2 refined to become CMOC 13 and CMOC 14

Until recently, chronic pain was often dismissed as psychological because it often has no obvious physiological cause, with doctors telling patients ‘it’s all in your head’.

Why are women still being treated as hysterical, overly emotional, anxious and unreliable witnesses to their own wellbeing?

When I finally did get my diagnosis, it was a huge relief to have a name for what I was experiencing. However, that relief was tempered when I soon began to realise that many people do not consider fibromyalgia to be a real illness. If a condition does not have a medical test to confirm it, then that condition does not exist, they believe.

Pain is whatever the person in pain says it is – we should trust the person in pain.

Book 1

Patients need to be heard by the medical professional and not made to believe that the pain is ‘all in their head’.

Why does trust break down? Because HCPs don’t believe they have pain which makes people with CLBP feel like they are lying and no one is taking them seriously.

ESO lines 191-194
HCP doesn’t believe the pain that comes with FMS no longer bothers going to GP

ESO line 201 ‘I was just made to feel like I was lying’.

This programme was developed initially from my own clinical experience and background reading in the academic literature around the psychological impact on patients with medically unexplained symptoms.

First stakeholder consultation

IRPT #2 Taken to First stakeholder consultation if people with chronic low back pain are not given a specific diagnosis that validates their condition then a patient may fail to accept the need to self-manage because trust in the health care professional breaks down.

ESO lines 237-263
It wasn’t about a diagnosis it was about being believed

ESO lines 140-148

Unlike the NHS, her private consultant didn’t make her feel as if her pain wasn’t real

ESO lines 247-291
Patients need validation and good explanation for their persistent pain

ESO lines 409-410
The most important outcome from a patient consultation is they feel the HCP has listened to what they have to say (i.e. were they taken seriously)

ESO lines 68-73
Back pain traditionally associated with malignancies – people making it up so they can get out of work – hence the need to feel believed that it is ‘real’

ESO lines 335-342
“I need to know that its real, that you [GP] think its real’

Before a person with CLBP can accept the need to self-manage their condition they need to feel that HCPs believe them (C). Feeling believed triggers a sense of reassurance that they have been taken seriously (M) which makes them trust the HCP (O). CMOC #13

Ripple?

Second stakeholder consultation

Before a person with CLBP can accept the need to self-manage their condition they need to feel that HCPs believe them (C). Feeling believed triggers a sense of reassurance that they have been taken seriously (M) which makes them trust the HCP (O). CMOC #14
Appendix P: RAMESES II Quality Standards for Realist Evaluation

<table>
<thead>
<tr>
<th>Section</th>
<th>Standard</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The evaluation purpose</td>
<td>A realist approach is suitable for the purposes of the evaluation. That is, it seeks to improve understanding of the core questions for realist evaluation.</td>
<td>Chapter 4, section 4.1 clearly states findings could inform app development and guide programme implementation.</td>
</tr>
<tr>
<td>2. Understanding and applying a realist principle of generative causation in realist evaluations</td>
<td>A realist principle of generative causation is applied.</td>
<td>The evaluation has a simple and easily understood research question – who might benefit from a self-management app for CLBP, why, and in what context.</td>
</tr>
<tr>
<td>3. Constructing and refining a realist programme theory or theories</td>
<td>An initial tentative programme theory (or theories) is identified and developed. Programme theory is ‘re-cast’ and refined as realist programme theory.</td>
<td>The realist evaluation drew upon the theories developed from the preceding realist synthesis on self-management apps for CLBP. This synthesis used substantive theories and a diverse range of primary and secondary data to create the programme theories. These theories were used as a conceptual platform for the realist evaluation.</td>
</tr>
<tr>
<td>Section</td>
<td>Standard</td>
<td>Evidence</td>
</tr>
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<tr>
<td>4. Evaluation design</td>
<td>The evaluation design is described and justified.</td>
<td>The end result of the realist evaluation were three refined programme theories underpinned by 20 CMOCs. These CMOCs identified how mechanisms manifest depending on conducive contexts.</td>
</tr>
<tr>
<td>5. Data collection methods</td>
<td>Data collection methods are suitable for capturing the data needed in a realist evaluation.</td>
<td>Realist telephone interviews were conducted using a teacher/learner cycle. In this way the participants helped with theory development and were involved in the meaning-making process.</td>
</tr>
<tr>
<td>6. Sample recruitment strategy</td>
<td>The respondents or key informants recruited are able to provide sufficient data needed for a realist evaluation.</td>
<td>All participants had CLBP for many years making them well placed to comment on the programme theories under evaluation. Participants were deliberately chosen to evaluate juxtaposing views and to explore rival theories</td>
</tr>
</tbody>
</table>
| 7. Data analysis | The overall approach to analysis is retroductive. Data analyses processes applied to gathered data are consistent with a | Inferences were made from the data using abductive and retroductive logic and recorded in a series of analytical memos in a coding journal.
<table>
<thead>
<tr>
<th>Section</th>
<th>Standard</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>realist principle of generative causation.</td>
<td>A realist logic of analysis is applied to develop and refine theory.</td>
<td>Inferences and learning from the preceding realist synthesis was used to support data analysis in the realist evaluation. Figure 4.2 illustrates how the initial 16 CMOCs became 20 CMOCs during the course of the evaluation. In discussing the findings of the realist evaluation in Chapter 4 each CMOC is discussed in relation to how it had been developed from the realist synthesis in a series of visual depictions (see Figures 4.4-4.9, Figures 4.11-4.15, and Figures 4.17-4.21).</td>
</tr>
<tr>
<td>8. Reporting</td>
<td>The evaluation is reported using the items listed in the RAMESES II reporting standard for realist evaluations.</td>
<td>The research has been transparently reported with reference to the RAMESES II reporting standards. Extensive supplementary material has been included in the appendices to ensure there is sufficient detail for an external reader to understand and to judge the methods used and the plausibility and coherence of the findings.</td>
</tr>
<tr>
<td>Findings and implications are clear and reported in formats that are consistent with realist assumptions.</td>
<td>Implications for policy, programmes and/or practice Implications of the final programme theories are clearly explained by framing them in a What works? For whom? Why? And what context summary figure (Figure 4.22)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix Q: Realist Evaluation Participant Information Sheets

Q.1 App User Participant Information Sheet

Realist Evaluation of the Curable App

Participant Information Sheet

You are invited to participate in this research project which is part of a PhD through the University of the Highlands and Islands. This sheet is to provide you with the information you need to decide if you would like to take part.

Health boards world-wide are increasingly using digital technologies to help people with long-term conditions self-manage their own health and wellbeing. This research study is evaluating the Curable app to see if it helps people self-manage their long-term back pain. Specifically, the study is looking to develop ideas about why the app may or may not work, who it might work best for, in what circumstances does it work well (or not) and why does it work?

What is the aim of this research?
To produce recommendations for the design and implementation of effective mobile apps to help people self-manage long term back pain.

Who is funding the research?
The research is funded by the Inverness City Deal.

Do I have to take part?
No. It is up to you to decide if you want to take part. If you do decide to participate in the research project you can withdraw at any time without giving a reason.

What will you do in the research project?
You will be asked to download and use the Curable app for 12 weeks. If needed, guidance will be provided to help you download and install the app. Although we would encourage you to engage with the app, you can use it as much or as little as you would like during the 12 weeks. Afterwards you will be asked to take part in a recorded telephone interview with the researcher. This telephone interview
A one-hour audio interview will typically last between 45-60mins.

**What is the Curable app?**
The Curable app is a commercially available mobile app that can be used on a smartphone or tablet. It was designed to help people self-manage long term pain. More details can be found on the Curable App information sheet provided.

The content and services provided by the Curable app are for informational purposes. The app is designed to give education and information, and this does not constitute medical advice, diagnosis, or treatment.

**Why have you been invited to take part?**
You have been invited to participate because you have been diagnosed with back pain and have experience of self-managing your condition. We are interested to see whether the Curable app helps you manage your back pain and believe your contribution to the study will provide valuable insights. However, the app does not provide treatment, nor can it diagnose a medical condition. Should you have any medical concerns either before, during or after the study you should discuss them with your healthcare provider.

**What are the potential risks to you in taking part?**
There is a small risk that discussing issues around pain and self-management might be upsetting. In the unlikely event that this occurs Pain Association Scotland can provide you with support. Their details are Pain Association Scotland: 0800 783 6059 / info@painassociation.com.

The Curable app is designed to provide general advice and education. It is not considered a medical device and it is unlikely to worsen your symptoms.

**What are the benefits of you taking part in this research project?**
Participating in this research may help to improve healthcare provision for people self-managing chronic back pain. More specifically, there is anecdotal evidence that users of the Curable app have experienced a decrease in pain and suffering.

Participants will be given a free one-year’s subscription to the Curable app with a value of £43.80. After the year has ended the subscription will not automatically renew. However, should you wish to continue to use the app you may do so by making a personal purchase.

**What happens to the information in the research project?**
Interviews will be recorded with an encrypted Dictaphone and transcribed. All data will be kept securely and will remain confidential. No personal details will be made publicly available. Recordings and transcripts will be kept on a restricted University server which is accessible only to the research team and the University Archivist and Records Manager. In accordance with the UHI Partnership Retention and Disposal Policy (2019) transcript data will be kept for ten years after the year of data collection.

**What will happen to my personal data after the research project ends?**
Any personal data such as your name and email address will be deleted no later than
6 months after completion of the study.

**Who should I contact if I am concerned about my data?**
For any general data protection enquiries please contact UHI’s Data Protection Officer at dataprotectionofficer@uhi.ac.uk

**Thank you for taking the time to read this Participant Information Sheet. If you have any further questions or require more information, please ask before the stakeholder consultations begin. Further information can be obtained by contacting:**
Rebecca Hunter, rebecca.hunter@uhi.ac.uk, Department of Nursing and Midwifery, University of the Highlands and Islands, Centre for Health Science, Old Perth Road, INVERNESS. IV2 3JH.

**What happens next?**
If you are interested in taking part, please read the Curable Information sheet. Please consider the information before making your final decision. If you are happy to participate, please complete the two consent forms.

**Further contact details.**
If you have any questions/concerns, during or after the investigation or wish to contact an independent person to whom any questions may be directed, please contact:

University of the Highlands and Islands Research Ethics Committee (FREC)
UHI Research Ethics Officer
University of the Highlands and Islands, 12b Ness Walk, Inverness, IV3 5SQ.
Telephone: 01463-279349  Email: research.ethics@uhi.ac.uk
Q.2 Curable Inc Participant Information Sheet

Realist Evaluation of the Curable App

You are invited to participate in this research project which is part of a PhD through the University of the Highlands and Islands. This sheet is to provide you with the information you need to decide if you would like to take part.

Health boards world-wide are increasingly using digital technologies to help people with long-term conditions self-manage their own health and wellbeing. This research study is evaluating the Curable app to see if it helps people self-manage their long-term back pain. Specifically, the study is looking to develop ideas about why the app may or may not work, who it might work best for, in what circumstances does it work well (or not) and why does it work?

What is the aim of this research?
To produce recommendations for the design and implementation of effective mobile apps to help people self-manage long term back pain.

Who is funding the research?
The research is funded by the Inverness City Deal.

Do I have to take part?
No. It is up to you to decide if you want to take part. If you do decide to participate in the research project you can withdraw at any time without giving a reason.

What will you do in the research project?
You will be asked to take part in a recorded telephone interview with the researcher. This telephone interview typically lasts between 45-60mins.

Why have you been invited to take part?
You have been invited to participate because you were involved in the development of the Curable App.

What are the potential risks to you in taking part?
There is a small risk that you may, inadvertently, divulge commercially sensitive information during the interview. Should you wish, you have the right to review the
interview transcript and retract any information you believe may be commercially sensitive.

**What are the benefits of you taking part in this research project?**
Participating in this research may help to improve healthcare provision for people self-managing chronic back pain. The research findings may also benefit future development of the Curable app.

**What happens to the information in the research project?**
interviews will be recorded with an encrypted Dictaphone and transcribed. All data will be kept securely and will remain confidential. No personal details will be made publicly available. Recordings and transcripts will be kept on a restricted University server which is accessible only to the research team and the University Archivist and Records Manager. In accordance with the UHI Partnership Retention and Disposal Policy (2019) transcript data will be kept for ten years after the year of data collection.

**What will happen to my personal data after the research project ends?**
Any personal data such as your name and email address will be deleted no later than 6 months after completion of the study.

**Who should I contact if I am concerned about my data?**
For any general data protection enquiries please contact UHI’s Data Protection Officer at dataprotectionofficer@uhi.ac.uk

Thank you for taking the time to read this Participant Information Sheet. If you have any further questions or require more information, please ask before the stakeholder consultations begin. Further information can be obtained by contacting:
Rebecca Hunter, rebecca.hunter@uhi.ac.uk, Department of Nursing and Midwifery, University of the Highlands and Islands, Centre for Health Science, Old Perth Road, INVERNESS. IV2 3JH.

**What happens next?**
If you are happy to participate, please complete the Curable Inc consent form

**Further contact details.**
If you have any questions/concerns, during or after the investigation or wish to contact an independent person to whom any questions may be directed, please contact:

University of the Highlands and Islands Research Ethics Committee (FREC)
UHI Research Ethics Officer
University of the Highlands and Islands, 12b Ness Walk, Inverness, IV3 5SQ.
Telephone: 01463-279349 Email: research.ethics@uhi.ac.uk
Q.3 Curable App Information sheet

Realist Evaluation of the Curable App

Curable app Information Sheet

What is the Curable app?
The curable app is a mobile app designed to help people self-manage long term pain. The app can be installed on both a smartphone and a tablet.

It offers users hundreds of audios, visual, and text exercises — including meditations, controlled breathing techniques, and journaling that are tailored to treat different types of chronic pain. Users are guided through each experience by a digital avatar, that offers words of encouragement and advice on which activities to try (or reattempt). The participants can choose to complete as many or as few as they would like.

Is it a medical device?
No. The content and services provided by the Curable app are for informational purposes. The app is designed to give education and information, and this does not constitute medical advice, diagnosis, or treatment.

What personal data does it collect?
According to Curable’s website when participants visit, download, register with, subscribe to, purchase, access, or use the Websites, Apps, or other Services, Curable may ask the participants to provide (or if not required, the participant may choose to provide) the following information:

“The user’s name, date of birth, home or business postal address, city or town, email address, telephone number, videos, photos, stories, GIFs, personal information of individuals for whom you purchase gift subscriptions or refer to our Sites or other Services, usernames, passwords, medical conditions, other health information (including illnesses, symptoms, treatments, and feelings about your medical conditions and/or yourself), any other identifier by which you may be contacted.

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online or offline, and other data that you provide when using our Sites or the other Services (collectively, “personal information”)."

More information can be found in their terms and conditions: https://www.curablehealth.com/terms

**Will it cost me anything?**
No. The annual subscription currently costs £43.71 but this will be paid for by the research project. After the 12-week study period you do not have to continue to use the app if you do not wish to.

**How can I find out more?**
More information about the Curable app can be found on their website: https://www.curablehealth.com/about

**What happens now?**
If you would still like to proceed with the study, please sign the consent form
Appendix R: Realist Evaluation Consent Forms

R.1 App user consent form

Realist Evaluation of the Curable App

App user consent Form

For: Participants in a 12-week realist evaluation of the Curable app

Name of Department: Department of Nursing and Midwifery

Title of the study: Realist Evaluation of the Curable mobile app for self-managing long-term back pain.

Participant ID: .................................................................

<table>
<thead>
<tr>
<th>Please initial EVERY box if you agree</th>
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<tbody>
<tr>
<td>I confirm that I have read and understood Curable Inc Participant Information Sheet Version 1 dated 18th Jan 2022.</td>
</tr>
<tr>
<td>I confirm that that I’ve had the opportunity to ask questions, and these have been answered to my satisfaction.</td>
</tr>
<tr>
<td>I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.</td>
</tr>
<tr>
<td>I understand that any information recorded in the interview will remain confidential and no information that identifies me as an individual will be made publicly available.</td>
</tr>
</tbody>
</table>
I consent to take part in the interview

I consent for the interview to be recorded and transcribed.

I consent to my data being used (in anonymised form) for the specific research outlined in the Participant Information Sheet Version 1 dated 18th Jan 2022

If I withdraw, I consent to the retention of anonymised data but expect any identifiable data to be erased.

**I agree to take part in the above study**

I am willing to be contacted to discuss my potential participation in future research studies

I consent to my contact details being retained for 12 months so that the research team can contact me and discuss opportunities to participate in future research studies.

<table>
<thead>
<tr>
<th>Name of participant</th>
<th>Date</th>
<th>Signature</th>
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<table>
<thead>
<tr>
<th>Name of researcher</th>
<th>Date</th>
<th>Signature</th>
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</table>
R.2 Curable Inc Consent Form

Realist Evaluation of the Curable App

Curable Inc Consent Form

For: Curable Inc employees

Name of Department: Department of Nursing and Midwifery

Title of the study: Realist Evaluation of the Curable mobile app for self-managing long-term back pain.

Participant ID: .................................................................

<table>
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<tr>
<td>I consent to take part in the interview</td>
</tr>
<tr>
<td>I consent for the interview to be recorded and transcribed.</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>I consent to my data being used (in anonymised form) for the specific research outlined in the Participant Information Sheet Version 1 dated 18th Jan 2022</td>
</tr>
<tr>
<td>If I withdraw, I consent to the retention of anonymised data but expect any identifiable data to be erased.</td>
</tr>
<tr>
<td>I agree to take part in the above study</td>
</tr>
<tr>
<td>I am willing to be contacted to discuss my potential participation in future research studies</td>
</tr>
<tr>
<td>I consent to my contact details being retained for 12 months so that the research team can contact me and discuss opportunities to participate in future research studies.</td>
</tr>
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<th>Name of participant</th>
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**R.3 Curable App data collection consent Form**

**Realist Evaluation of the Curable App**

Curable App data collection consent Form

For: Participants in a 12-week realist evaluation of the Curable app

Name of Department: Department of Nursing and Midwifery

Title of the study: Realist Evaluation of the Curable mobile app for self-managing long-term back pain.

Participant ID: ..............................................................

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<tr>
<th>Please initial EVERY box if you agree</th>
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<tr>
<td>I confirm that I have read and understood the Curable Information Sheet Version 1 dated 15th Jan 2022.</td>
</tr>
<tr>
<td>I understand and consent to Curable collecting my personal data as outlined in their terms and conditions.</td>
</tr>
<tr>
<td>I agree to take part in the above study</td>
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</table>

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<th>Name of participant</th>
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Appendix S: NOSRES Communication

S.1 NOSRES Confirmation re: NHS Ethics not required

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BECKY HUNTER 17027764

From: GRAM NOSRES <gram.nosres@nhs.scot>
Sent: 10 August 2021 17:50
To: BECKY HUNTER 17027764
Subject: Re: Ethics Query re: Digital App for participants with back pain.

Hi Becky

Thank you for confirming those points.

Based on the information that you have provided, I would consider that your project is Research but would not require NHS Ethical Approval as there is no NHS involvement.

As you mentioned in your initial email the HRA/MRC tool for defining research does state where participants have been identified independently of the NHS but because they have a condition that was diagnosed by the NHS (e.g. patients with cancer) which may have been diagnosed by the NHS but who are identified from a cancer charity's contact list to be participants in a research project is otherwise being conducted independently of the NHS.

I would recommend that your project is reviewed by the University of Highlands & Islands Ethics Committee.

Please let me know if you need any further information or clarification.

Good luck with your project.

Best wishes,

Rachel

Rachel Hanlie PhD
Scientific Officer/Regional Manager

North of Scotland Research Ethics Service
Summerfield House
2 Elsay Road
Aberdeen
AB15 6RE
Tel: 01224 558458

Please note - we are not always based in the office - if you wish to speak to us, include your contact number in your email and we will contact you.

It is extremely important that the version numbers and dates of all documents recorded on the IRAS Checklist are accurate and reflect the version numbers/dates recorded on the documents, as this may cause ongoing problems with other departments/agencies, eg R&D, MHRA etc.

The HRA is keen to know your views on the service you received – our short feedback form is available here
S.2 NOSRES Confirmation re: Curable App Data Collection

BECKY HUNTER 17027704

From: GRAM Nosres <gram.nosres@nhs.scot>
Sent: 02 September 2021 10:42
To: BECKY HUNTER 17027704
Subjects: Re: Ethics Query re: Digital App for participants with back pain.
Attachments: HRA - data and research patient information guidance.pdf

Hi Becky

I think you have everything covered with regards to data. If the participants are aware of what you are collecting and the app then they can make a choice (informed) about whether to participate or not. I have attached a copy for your information.

Let me know if you need anything further.

Best wishes

Rachel

Rachel Hardie PhD
Scientific Officer / Regional Manager

North of Scotland Research Ethics Service
Summerfield House
2 Eday Road
Aberdeen
AB15 6RE
Tel: 01224 558458

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It is extremely important that the version numbers and dates of all documents recorded on the IRAS Checklist are accurate and reflect the version numbers/dates recorded on the documents, as this may cause ongoing problems with other departments/agencies, eg R&D, MHRA etc.

The HRA is keen to know your views on the service you received – our short feedback form is available here

From: BECKY HUNTER 17027704 <rebca.m.hunter@hib.ac.uk>
Sent: 01 September 2021 3:05 PM
To: GRAM Nosres <gram.nosres@nhs.scot>
Subject: RE: Ethics Query re: Digital App for participants with back pain.

Thank you so much for your help and speedy response Rachel.
Hi Becky

Thanks for your email.

The MHRA don't make things easy, and their guidance does take some navigating around!

However, I think I have found the information that you need.

In their guidance document relating to is the app a device, following it through and under Treatment & Alleviation, it states that the following apps would not be considered a Medical Device.

- Apps and software that are intended to treat non-medical conditions e.g non-specific stress.
- Apps and software that are intended to just provide tips or advice or link to support groups.

The app you are planning to use I think would fit into this category and therefore would not be considered a Medical Device. If you want a definitive response about this, you will need to contact the MHRA directly.

My only recommendation would be to ensure that the participants are fully informed of what information they will be passing to the company and how this will be used.

I hope this answers your questions.

Best wishes

Rachel

Rachel Hardie PhD
Scientific Officer/Regional Manager

North of Scotland Research Ethics Service
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The HRA is keen to know your views on the service you received – our short feedback form is available here

1
Appendix T: Realist Evaluation interview script

| Introduction | - Principle investigator  
|             | - UHI/NHS Highland Physiotherapist  
|             | - Confirm read PIS, happy to proceed  
|             | - Any questions before we start |
| Ice breaker | - How did you get on with the Curable app? What did you think of it? |
| Introduce theories from realist synthesis | - Explain how teacher/learner cycle works  
|             | - Emphasise we aren’t testing the Curable app – is it effective etc we are using your experience of self-managing with the app to test theories – agree, disagree, change them  
|             | - No right or wrong answers  
|             | - 16 CMOCs from realist synthesis to test |
| Probe for mechanisms | - “what is about about……  
|             | - “Do you think X changed how you felt…  
|             | - “Do you think you would have reacted differently if…”  
|             | - “What does X give you/not give you” |
| Context | - Has Covid-19 pandemic made a difference?  
|             | - Does this app compare to other apps you’ve used?  
|             | - How does this compare with advice you have been given about your back from other HCPs  
|             | - My initial theory suggests in this context X is likely, now that you have used the app what do you think about that theory?
| What works, for whom | • Who do you think an app like Curable would/wouldn’t work for?  
• When would an app like Curable be useful tool and not so good?  
• My initial theory suggests the app would work because of X now that you have used the app what do you think about that theory? |
|---------------------|---------------------------------------------------------------|
| Disconfirming cases/rivalry | • **Look for Unintended consequences/alternate explanations  
• Present alternate theories/contradictory theories – “For older people X but for younger people Y”  
• “Other participants suggested/found….”  
• “The co-founder of Curable suggested X what are your thoughts about that assumption?” |
Appendix U: Extract from coding journal (realist evaluation)

<table>
<thead>
<tr>
<th>ID</th>
<th>Lines</th>
<th>Quote</th>
<th>Analytical Memo</th>
<th>CMO</th>
</tr>
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<tbody>
<tr>
<td>01</td>
<td>63-67</td>
<td><em>I mean because I think it’s, well it’s going to be an App for everyone so it wasn’t frustrating or anything it was just kind of like okay, but you listened to it anyway because you know there might have been something you know a couple of new sentences different or something in it you know. So no it wasn’t, it wasn’t frustrating it was just kind of oh okay yes I’ve heard of that before.</em></td>
<td>Even though the information she was getting from the app wasn’t new, she did not find this frustrating. She has been on the journey for 11 years so it didn’t come as a surprise that she had heard this information before - is this what acceptance looks like? An absence of frustration and disappointment when ‘new’ modalities come on the market but aren’t actually ‘new’ at all? Also, it might not be telling you anything ‘new’ but it might be presenting the information in a different way that makes more sense and is more meaningful.</td>
<td>4</td>
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<td>Page</td>
<td>Lines</td>
<td>Text</td>
<td>Answer</td>
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<td>01</td>
<td>104-106</td>
<td><em>everybody’s back pain is different. So what they said in one of the speaking things to me is you know is that going to be the same for someone else because yes I might have lower back pain but somebody might have upper back pain</em></td>
<td>Does this apply to <em>my type of back pain</em>? Is this generic and not unique to me? Even though self-management strategies are the same regardless of the presenting condition they need to be 'packaged' in a way that is unique to each user. This was repeated by Curable CEO - [lines 332-335] - the need for personalisation all the way through.</td>
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<td>01</td>
<td>153-156</td>
<td><em>You know but that’s the same exercise for you know like say my next door neighbour had the same problem but she’s going to get told the same thing so you know how is that any different to not being believed or helped or you know?</em></td>
<td>To be given the same advice, the same information as everyone else is tantamount to <em>feeling not believed</em> - lumping everyone in the same boat. How can all back pain be treated the same? This is a hard concept for people to understand. Although it might have started as a disc prolapse for one person and a facet joint degeneration for another - by the time you have had pain for years the mechanical driver becomes less significant than the central driver - neuroplasticity is likely to have increased the pain sensitization for both people regardless of the different origin. So it’s the same treatment because it is the same driver but people with CLBP don’t know that.</td>
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<td>01</td>
<td>185-187</td>
<td><em>I would have at that point because nobody was you know not helping me but nobody could give me the answers. I would have seen that as, go home and take this App I would have seen as, that as them just giving up and leaving me to it.</em></td>
<td>If the app was introduced too early in this person's journey then she would have felt insulted, not taken seriously and fobbed off. Even though she had two spinal surgeries and spinal injection to follow - all we a poor outcome from both she still would have preferred to have the app after all the 'traditional, biomedical' options had been exhausted. There was no realisation that if she had perhaps had the information contained in the app sooner then she may not have needed the surgeries or the injections at all.</td>
<td>11/15</td>
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<tr>
<td>01</td>
<td>204-206</td>
<td><em>and then it was kind of no there's nothing else that we can do for you. So I think maybe for me once I had had everything done it might have been here Kat look at this, this might you know help you going forward.</em></td>
<td>Only after all medical treatment had been exhausted - would she accept the need to self-manage and be receptive to using an app</td>
<td>11/15</td>
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<td>01 212-215</td>
<td>, if someone had given that to me after my first back surgery I would have, I wouldn’t have you know I wouldn’t have used it, I would have probably been quite offended at it because it’s like well okay but so is that it? You’re just going to leave me with an App. You know for the rest of my life you’re just going to leave me with an App, that’s it.</td>
<td><strong>GOOD QUOTE</strong> - There is a sense of abandonment ringing out in this statement - a fear of being left alone, to manage her back pain with an app. That the medical profession are giving up on her - that the app is not a treatment but some sort of consolation prize - the only thing left to offer. She would have been offended by this - goes to support that feeling of disappointment and bitterness people feel when the app does not provide them anything new - there is anger if there aren't any further biomedical treatments being offered - only an 'app'.</td>
<td>8</td>
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Appendix V: Realist Evaluation CMOCs

Refined programme theory one: Empowerment
People with CLBP can feel empowered by a self-management app if the app is personal and relevant to their situation, can be accessed when and where they need it and is presented as an adjunct to ongoing care. (CMOCs 1-7).

CMOC 1 Choice and flexibility
Each person with CLBP is likely to engage with the app's content differently (C). The app must adapt to a user’s preferences so they feel they have agency, choice, and control over their self-management programme (M) which can lead to greater engagement with the app (O).

CMOC 2 Knowledge is empowering
By improving a person’s knowledge of CLBP and providing strategies to self-manage (O) an app gives a person with CLBP the confidence and agency to help themselves (M) making them less reliant on HCPs (O).

CMOC 3 Knowledge reduces fear
Many people with CLBP are uncertain as to what is causing their ongoing pain (C). The app provides education to improve the user’s understanding of CLBP which helps to reduce their fear and anxiety (M) increasing their confidence and agency to self-manage (O).

CMOC 4 Personalisation
A person with CLBP needs to be able to recognise themselves in the advice and information an app provides (C). This personalisation enables them to see the app as relevant and trustworthy to them (M) which increases their engagement (O).

CMOC 5 Biomedical mindset
A self-management app that presents an alternate way of understanding and managing CLBP (O) may lead to frustration, annoyance, and disappointment for people with a biomedical mindset (M) as the hope they had for meaningful solution to their back pain is not realised (O).

CMOC 6 HCP buy-in needed
If a HCP does not see the value in the app’s recorded data or dismisses its utility (C) then this disempowers the person with CLBP by devaluing their contribution to the consultation (M) which can adversely affect the therapeutic relationship (O).

CMOC 7 Reduce HCP workload

Giving a person with CLBP a self-management app to use between review appointments (C) reassures them that they have timely and convenient access to ongoing support (M) making them more confident to go longer before they need to see a HCP (O).

Refined programme theory two: Self-management burden

If people with CLBP have the capacity to engage with a mobile app then it can reduce the burden of having to self-manage CLBP by providing ongoing support, facilitating communication with HCPs, and mitigating feelings of abandonment. (CMOCs 8-15).

CMOC 8 Voice activation

A voice activated app would be useful during flares of CLBP (C) because it requires less energy to engage with the app by voice than by text (M), thereby enabling access to support even in times of extreme pain (O).

CMOC 9 Proactive support

If an app proactively selected and played content the user had found helpful in the past (C) it would alleviate the energy needed to make decisions (M) thereby reducing the cognitive burden of engaging with an app during flare ups of CLBP (O).

CMOC 10 Consultations

Using an app to record and share data with an HCP (C) can reduce the frustration felt when valuable consultation time is wasted bringing HCPs ‘up to speed’ thereby maximising the effectiveness and efficiency of the consultation (M) leading to a more satisfactory appointment (O).

CMOC 11 Improved communication

Using an app to record and share data with an HCP (C) can help to reduce the stress and pressure felt by people with CLBP at having to ‘look ill’ as well as having to recall details about how they have been managing (M) which improves the communication and quality of the healthcare consultation (O).
CMOC 12 Monitoring worsens pain

Repeated prompts by an app to record symptoms (C) adds an additional burden to self-managing CLBP and serves as a constant reminder of their ill health (M) which can worsen the pain experience (O).

CMOC 13 Ongoing support

After discharge, a person with CLBP needs occasional reviews from a HCP in addition to a self-management app (C) to reassure them that they have not been left to manage their condition on their own (M) and prevent feelings of abandonment (O).

CMOC 14 Chatbot is supportive

Conversing with an app’s chatbot without fear of criticism or judgement and without the effort of adhering to social politeness (C) can be less tiring for people with CLBP and can reduce sensations of shame, guilt and loneliness (M) and mitigate feelings of social isolation (O).

CMOC 15 Chatbot is poor proxy

For some people with CLBP, an app’s chatbot cannot convey the warmth and empathy they get from supportive conversations with humans (C) resulting in an interaction that is fake, cold, and devoid of meaning (M) and making a chatbot a poor proxy for human support (O).

Refined programme theory three: Timing

A person with CLBP is likely to benefit from a self-management app early on in their patient journey but not before they feel believed and reassured by HCPs and have accepted their condition cannot be cured. (CMOCs 16-20).

CMOC 16 Expectations of a cure

People with CLBP who retain the cultural expectation that the healthcare service can and should cure their pain and struggle to accept otherwise (C) will be disappointed by an app that fails to meet these expectations (M) resulting in a lack of engagement (O).

CMOC 17 A proper diagnosis

A person with CLBP needs a diagnosis that adequately explains their ongoing pain (C). This validates their pain experience to themselves and
others helping them to accept their condition (M) and making them more likely to engage with a self-management app (O).

CMOC 19 Reassurance
A person with CLBP needs an assessment from an HCP (C) to provide trust and reassurance that nothing sinister has been missed (M) before they use an app to self-manage their CLBP (O).

CMOC 18 Trust the messenger
A person with CLBP need to trust the person recommending a self-management app (C) to reassure them that the app is credible (M) before they are willing to give it a try (O).

CMOC 20 Early in the journey
Early introduction to a self-management app—whilst medical management and investigation are ongoing (C)—gives a person with CLBP more time to embed self-management strategies into their life (M) thus providing an opportunity to improve their quality of life sooner (O).
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