AN EXPLORATION OF THE FEASIBILITY OF A DIGITAL SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH PREGNANCY-RELATED LUMBOPELVIC PAIN

M C Moffatt

PhD 2022

An exploration of the feasibility of a digital self-management intervention for women with pregnancy-related lumbopelvic pain

Maria Clare Moffatt

A thesis submitted in partial fulfilment of the requirements of Manchester Metropolitan University for the degree of Doctor of Philosophy

Manchester Metropolitan University

Faculty of Health and Education

Department of Health Professions

2022

Acknowledgements

This study would not have been possible without the support and collaboration of the app-development company Living With Ltd. I would also like to thank Mrs Myra Robson (Pelvic Health Lead for Lewisham and Greenwich NHS Trust), without whom the app developed in this study would not have been implemented as part of the pandemic response. Myra was also instrumental in supporting the app's development and provided clinical guidance throughout.

I would also like to thank Mrs Leah Guy, Dr Holly George, and Mr Tony Clayson for their support and contributions to the app content development. Mrs Guy (medicines safety pharmacist) provided advice regarding the pharmacological management of pregnancy-related musculoskeletal pain. Dr George (Obstetric and gynaecological registrar) reviewed the section of app content relating to labour and birthing. Mr Tony Clayson (consultant orthopaedic surgeon) reviewed and amended drafts of content about the role of orthopaedic surgeons in managing pregnancy-related lumbopelvic pain.

I would also like to acknowledge the participation and support of the women's health physiotherapy team at Wrightington, Wigan and Leigh NHS Trust and the antenatal midwifery team at St Mary's Hospital in Manchester.

I want to thank my supervisory team, Professors James Selfe and Claire Hamshire. Without their unwavering support, I would not have completed this thesis. Their patience, guidance, and contributions have been pivotal to my learning and development throughout this process.

Finally, I would like to thank my family for supporting me throughout this process.

Abstract

Background: Pregnancy-related lumbopelvic pain (PLPP) is a common condition resulting in reduced function and health-related quality of life. Many women with PLPP self-manage the condition, and evidence suggests that improved information provision may facilitate this. Digital technology offers opportunities to deliver health information to large audiences with minimal clinical time commitment. A digital intervention to support the self-management of PLPP is therefore worthy of consideration.

Aim: This research aimed to explore the feasibility of a digital self-management intervention for women with PLPP.

Study design: A systematised review was undertaken to inform the design of a mixed-methods study using an exploratory sequential design.

Methods: Systematised review: RCTs examining the effectiveness of digital interventions for the management or self-management of low back pain (LBP), pelvic girdle pain (PGP), or lumbopelvic pain (LPP) were included. A narrative synthesis was undertaken.

Phase 1: Semi-structured interviews with NHS service users and focus groups with NHS-based physiotherapists and midwives.

Phase 2: Development of an app-based intervention to support the self-management of PLPP using the Behaviour Change Wheel approach.

Phase 3: Retrospective quantitative analysis of pseudonymised app user engagement data from March 2020 to November 2021.

Findings: Systematised review: 26 RCTs were included. No RCTs testing digital interventions for PGP or LPP could be located. No included trials explicitly stated the inclusion of pregnant women. Six of the 26 included RCTs reported the effectiveness of digital interventions in improving pain and disability in individuals with LBP. Effective interventions included mobile/tablet apps, social media, and multimodal interventions. Two of the six trials reporting effective interventions were at high risk of bias.

Phase 1: Seven NHS service users and ten clinicians (six midwives and four physiotherapists) viewed the use of digital technologies for information provision positively. A preference for apps for information provision was reported, and clinicians were willing to integrate digital interventions into their practice. Service users highlighted their PLPP-related information needs.

Phase 3: 167 NHS service users were invited to use the app during the study period; 106 (63.5%) chose to register for use. Thirty-five engaged with the self-monitoring

feature on a single occasion; five engaged with this feature more than once. Two users engaged with the goal-setting function. No users exchanged any in-app messages with their clinicians.

Conclusions: The systematised review highlighted the lack of attention given to women with PLPP in the digital self-management literature and underscored the need for targeted intervention development and evaluation for this population. The findings of this review also suggested that mobile apps may be worthy of consideration for intervention delivery for women with PLPP.

Phase 1 found a high level of acceptability and a willingness of clinicians to integrate a digital intervention into practice. Overall, uptake of and engagement with the app aligned with expectations. Implementation of the app demonstrated practicability in an NHS setting. Further work is needed to understand the levels of engagement reported and whether in-app information met users' needs.

TABLE OF CONTENTS

LIST OF INCLUDED TABLES

LIST OF INCLUDED FIGURES

LIST OF ABBREVIATIONS USED

AMED	Allied and Complementary Medicine Database
APA	American Psychological Association
APEASE	Affordability, Practicability, Effectiveness and cost effectiveness, Acceptability, Side effects/Safety, Equity
Apps	Mobile phone applications
BCT	Behaviour Change Technique
BCW	Behaviour Change Wheel
CBT	Cognitive Behavioural Therapy
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CLBP	Chronic Low Back Pain
COM-B	Capability, Opportunity, and Motivation Model of Behaviour
COS	Core Outcome Set
COVID-19	Coronavirus disease (COVID-19); an infectious disease caused by the SARS-CoV-2 virus
DTAC	Digital Technology Assessment Criteria for Health and Social Care
E-Health	Electronic Health
GCP	Good Clinical Practice
HCP	Health Care Professional
HRA	Health Research Authority
INVOLVE	INVOLVE was a national advisory group funded by the Department of Health that promotes public involvement in health

	and social care research. The NIHR Centre has now superseded this for Engagement and Dissemination.
IP	Intellectual Property
IRAS	Integrated Research Application System
LBP	Low Back Pain
LPP	Lumbopelvic Pain
M-Health	Mobile Health
MEDLINE	Medical Literature Analysis and Retrieval System Online
MMR	Mixed Methods Research
MRC	Medical Research Council
MSK	Musculoskeletal
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NHS	National Health Service
NPRS	Numerical Pain Rating Scale
NSLBP	Non-Specific Low Back Pain
PGP	Pelvic Girdle Pain
PGQ	Pelvic Girdle Questionnaire
PhD	Doctorate in Philosophy
PLBP	Pregnancy-related Low Back Pain
PLPP	Pregnancy-related Lumbopelvic Pain
POGP	Pelvic Obstetric and Gynaecological Physiotherapy
PPGP	Pregnancy-related Pelvic Girdle Pain

RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
RoB-2	Cochrane Risk of Bias Assessment Tool for Randomised Controlled Trials version 2
SCOPUS	Elsevier's abstract and citation database
SCT	Social Cognitive Theory
SD	Standard Deviation
SMS	Short Messaging Service
SoMe	Social Media
SPD	Symphysis Pubis Dysfunction
SPORTDiscus	The leading bibliographic database for sports and sports medicine research
UK	United Kingdom
VAS	Visual Analogue Scale

GLOSSARY OF TERMS USED

Term	Description of how the term is used in this thesis
Anonymised data	Data with all personal identifiers (both direct and indirect) removed, such that reidentification of the data is impossible.
Behaviour change intervention	An intervention that aims to bring about any sort of change to the user's behaviour.
Behaviour change technique	The irreducible active components that constitute complex behaviour change interventions.
Classical pragmatism	The philosophy of early pragmatists such as Charles Sanders Peirce and John Dewey.
Conceptual map	A diagram that shows the relationships between different ideas.
Condition-related anxiety	Feelings of anxiety relating to the potential negative consequences of a health condition.
Core outcome set	A consensus-based agreed minimum set of outcomes that should be measured and reported in all clinical trials of a specific disease or trial population.
COVID-19 national lockdown	The period when individuals' freedoms were restricted in the United Kingdom in an attempt to ensure social distancing and prevent the spread of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
COVID-19 pandemic	Also known as the coronavirus pandemic, is an ongoing global pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Data security	The practice of protecting digital information from unauthorised access, corruption, or theft throughout its entire lifecycle.
Digitally active	Those who engage in online activities using digital technologies on a regular basis for work, leisure, or practical purposes. Many consider those who have not used the internet in the last three months to be digitally inactive.
Digital exclusion	Lack of the necessary digital skills, resources, connectivity, accessibility, or motivation to engage in digital activity. An individual can choose to be digitally excluded if they decline to engage in digital activity for whatever reason.
Digital inclusion	This includes the necessary digital skills, resources, connectivity, and accessibility to engage in digital activities.
Digital literacy	Digital literacy is the ability to use information and communication technologies to find, evaluate, create, and communicate information; requiring both cognitive and technical skills.
Digital media	Video, audio, software, or other content that is created, edited, stored, or accessed in digital form, through numeric encoding and decoding of data.
Digital technology	All electronic tools, automatic systems, technological devices and resources that generate, process or store information.
Electronic-health interventions/ e-health interventions	Health services and information delivered or enhanced through the internet and related technologies.

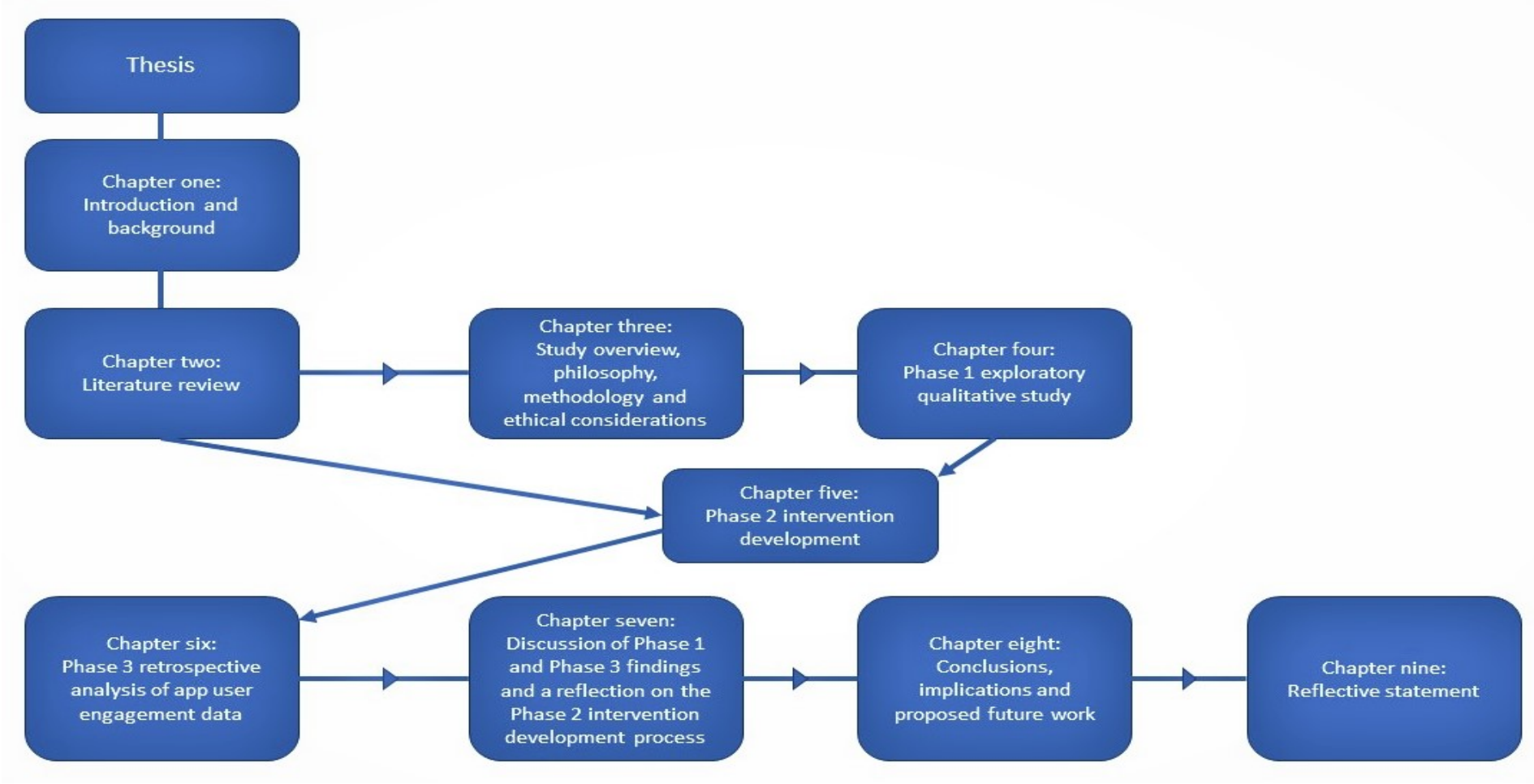
Gold standard test	The best available diagnostic test for determining whether a patient does or does not have a disease or condition.
Hawthorne effect	When individuals modify an aspect of their behaviour in response to their awareness of being observed.
Health literacy	The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others.
Health-related quality of life	A multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning; it concerns the impact health status has on quality of life.
Intervention	Any activity undertaken with the objective of improving the health of an individual by either reducing the severity of condition-related symptoms, reducing the impact of symptoms, or improving physical function.
Low back pain	Low back pain (LBP) is defined as pain localised between the 12th rib and the inferior gluteal folds, with or without leg pain.
Lumbopelvic pain	An umbrella term that encompasses both low back pain and pelvic girdle pain.
Mobile apps	A type of application software designed to run on a mobile device, such as a smartphone or tablet computer.
Mobile health interventions/m-health interventions	Healthcare or health-related information delivered using mobile or wireless devices.

Multimorbidity	The coexistence of two or more chronic health conditions.
Online forum	An online discussion site where people can hold conversations in the form of posted messages.
Patient empowerment	A process through which people gain greater control over decisions and actions affecting their health.
Pelvic girdle pain	Pain between the posterior iliac crest and the gluteal fold, particularly in the vicinity of the sacroiliac joints.
Personal data	Any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
PhD study	Body of research completed to fulfil the requirements of the award of Doctorate in Philosophy that is reported in the PhD thesis.
Pregnancy-related lumbopelvic pain	Lumbopelvic pain that occurs either during pregnancy or in the early postpartum period.
Prototype	A prototype is an early sample, model, or release of a product built to test a concept or process.
Pseudonymised data	A dataset where all personally identifiable data is replaced with a reference number so that re-identification of the data, or attribution of the data to any identifiable individual, would require access to additional information.

Push messages	(Also known as push notifications) are any notifications from a mobile application that display while that app is not actively in use.
Safety-netting	Safety-netting is information given to a patient or their carer during a healthcare consultation, about actions to take if their condition fails to improve, changes, or if they have further concerns about their health in the future.
Self-management	An individual's ability to manage the symptoms, treatment, and physical and psychosocial consequences of a healthcare condition.
Smartphones	A mobile phone that performs many of the functions of a computer, typically having a touchscreen interface, internet access, and an operating system capable of running downloaded apps.
Social deprivation	Limited access to society's resources due to poverty, discrimination, or other disadvantages.
Social desirability bias	The tendency of questionnaire respondents to answer questions in a manner that will be viewed favourably by others.
Social media	Websites and applications that enable users to create and share content or to participate in social networking.
Stakeholders	People or organisations who have an interest in the research project, or who affect or are affected by its outcomes. In Phase 1 of this thesis, the term stakeholders refers to NHS service users, Midwives and Physiotherapists.
Telehealth platforms	The technology, infrastructure, services, and support that allow private, secure, and high-

	quality virtual healthcare consultations via videoconference.
Thesis	A long essay or dissertation, written by a candidate for a university degree.
Virtual reality	The computer-generated simulation of a three-dimensional image or environment that can be interacted with in a seemingly real or physical way by a person using special electronic equipment.
Virtual reality hardware	The equipment needed to support sensory stimulation and simulation such as sounds, touch, smell, or heat intensity. Such hardware might include headsets and hand trackers.

THESIS STRUCTURE



CHAPTER ONE: INTRODUCTION AND BACKGROUND

1.1 INTRODUCTION

Pregnancy-related lumbopelvic pain (PLPP) is a common problem, with 70 to 90% of pregnant women reporting symptoms (Al-Sayegh *et al.*, 2012; Kovacs *et al.*, 2012; Pierce *et al.*, 2012; Gutke et al., 2018; Daneau et al., 2021). PLPP can cause substantial pain-related disability (Gutke et al., 2006; Robinson, Mengshoel, Bjelland, et al., 2010; Robinson, Mengshoel, Veierød, et al., 2010) and can result in reduced health-related quality of life (Fatmarizka et al., 2021; Robinson et al., 2018). PLPP is a common cause of work absence in European countries (Gutke et al., 2006; Malmqvist et al., 2015; Backhausen et al. 2018) and may confer significant socioeconomic consequences if symptoms are not adequately managed.

Despite the high prevalence of PLPP and the known impact on quality of life, there is a dearth of literature relating directly to self-management strategies for the condition (Gutke et al., 2015). The importance of information provision for women with PLPP is acknowledged (Elden et al., 2014), and the role of information provision in self-management is widely accepted (Slama-Chaudhry and Golay, 2019). Therefore, priority should be given to ensuring the information needs of women with PLPP are met to facilitate self-management.

Self-management has been widely studied in the general (non-pregnant) population (Dickson and McDonough 2019). Tailored self-management advice is recommended by the National Institute for Health and Care Excellence (NICE) as the first line of treatment for low back pain and sciatica (NICE 2016), and self-

management interventions are effective for improving pain and physical disability (Du *et al.*, 2017). This PhD study, therefore, aimed to explore the feasibility of a digital self-management intervention for women with PLPP. This chapter will provide background information about the condition and an overview of the context of this research. The aims and objectives of the PhD study will then be stated.

1.2 Background

1.2.1 The definition of pregnancy-related lumbopelvic pain

Pregnancy-related lumbopelvic pain (PLPP) is an umbrella term encompassing both pregnancy-related lower back pain (PLBP) and pregnancy-related pelvic girdle pain (PPGP) (van Benten et al., 2014).

1.2.2 The postulated causes of PLPP

No gold standard test exists to differentiate PLBP from PPGP. These conditions often occur together (Noren et al., 2002; Gutke et al., 2006), and the symptoms often overlap. The exact cause of PLPP is not fully understood, but it is considered to be multifactorial, with biomechanical, hormonal, neuromuscular and cognitive-behavioural components involved (Vermani et al., 2010; Kanakaris et al., 2011; Olsson et al., 2012; Rashidi Fakari et al., 2018; Daneau et al., 2021). More recently, Meijer et al. (Meijer, Barbe, et al., 2020; Meijer, Hu et al., 2020) have argued that a local inflammatory driver should also be considered.

Pregnancy results in an alteration to the length-tension relationship of several trunk muscles (most notably the muscles of the anterior abdominal wall) and an increase in anterior pelvic tilt (Gilleard and Brown, 1996; Biviá-Roig et al., 2019;

Morino et al., 2019; Fukano et al., 2021). An increase in pelvic joint laxity is also seen due to the influence of the hormone relaxin (Calguneri et al., 1982; Damen et al., 2001; Vleeming et al., 2012; Vøllestad et al., 2012; Cherni et al., 2019). Lumbopelvic stability is impacted by several muscles of the trunk, pelvis, and lower limb (Snijders et al., 1993a; 1993b; Pool-Goudzwaard et al., 1998; Richardson et al., 2002; Pool-Goudzwaard et al., 2004; van Wingerden et al., 2004; Pel et al., 2008) and altered muscle recruitment patterns are reported in pregnant and non-pregnant individuals with lumbopelvic pain (Hodges and Richardson, 1999; O'Sullivan et al., 2002; Hungerford *et al.*, 2003; Beales et al., 2009; Stuge et al., 2012, 2013). It is, therefore, reasonable to postulate that altered load transfer through the lumbopelvic region may contribute to PLPP.

Psychosocial factors are also thought to contribute to the development and severity of PLPP (Bakker et al., 2013). Women with PLPP have significantly higher levels of catastrophising and fear-avoidance behaviour than healthy controls (Olsson et al., 2009). The level of catastrophising is also associated with pain severity and health-related quality of life (Doğru et al., 2018). Perceived stress is associated with the development of PLPP (Bakker et al., 2013), and a lower educational level is associated with higher pain intensity (Chang et al., 2012). This underscores the complexity of PLPP and highlights the need to provide adequate support to women with this condition.

1.2.3 The prognosis of PLPP

For most women who experience PLPP during pregnancy, the problem will resolve spontaneously after delivery (Gausel et al., 2020); over half of symptomatic women

will experience a complete resolution of symptoms within one month (Albert et al., 2001). However, between 8.5% and 20% of symptomatic women report ongoing pain three years postpartum (Norén et al., 2002; Wuytack et al., 2018). Around one in ten women who report PPGP during pregnancy may still report persistent symptoms eleven years after delivery (Elden et al., 2016). For this reason, developing appropriate management strategies for PLPP is an important area of research focus.

1.2.4 Current management of PLPP and the role of self-management

The Pelvic Obstetric and Gynaecological Physiotherapy (POGP) group is a UK-based professional network affiliated with the Chartered Society of Physiotherapy. Drawing on the available evidence, the POGP published a care pathway for women with PLPP, shown in Figure 1.1 below. This pathway acknowledges the central role of physiotherapy services in PLPP management; however, several healthcare professionals may be involved depending on the severity of the symptoms and the level of difficulty experienced with everyday activities.

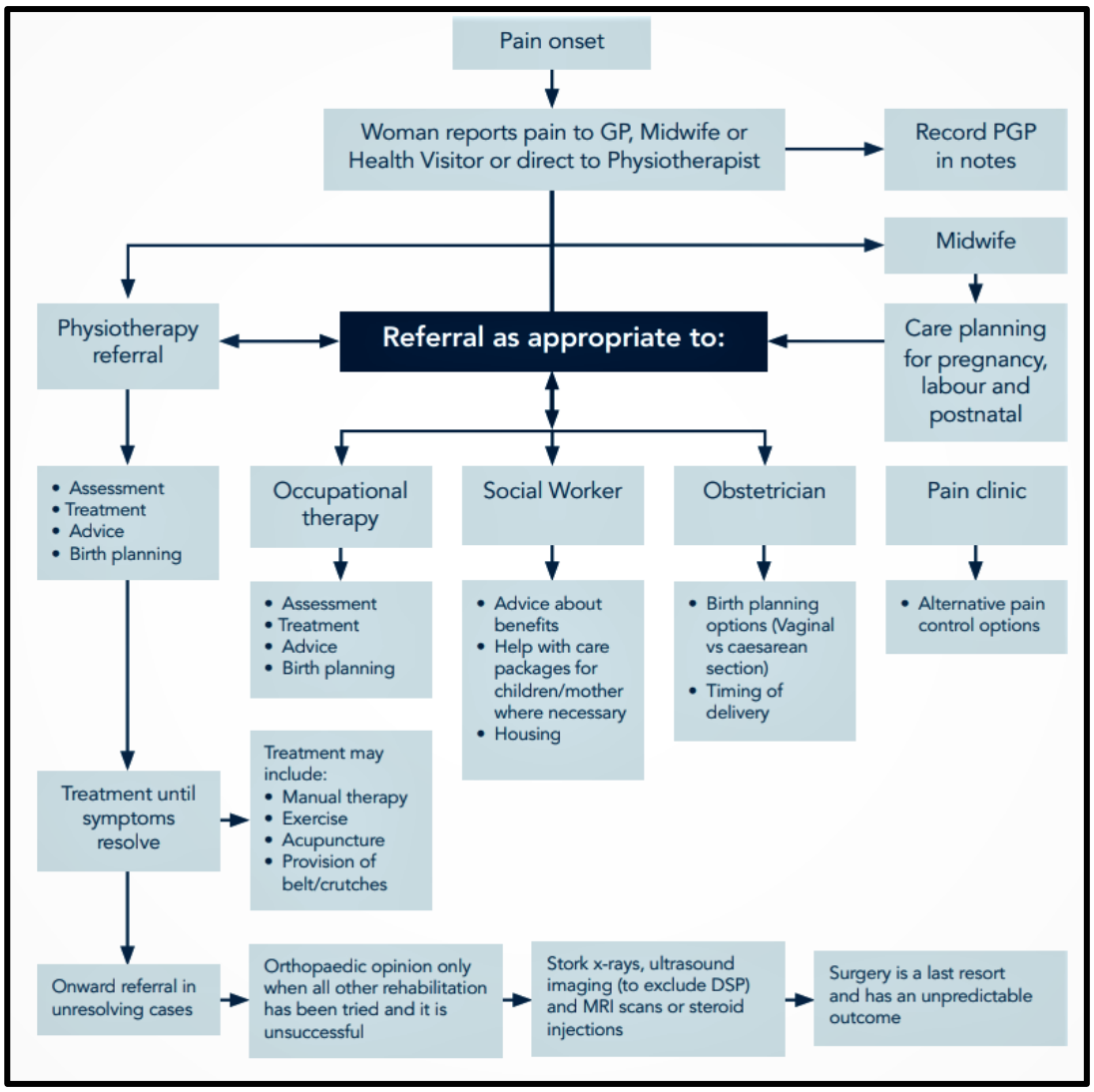


Figure 1.1. Care pathway for women with PLPP recommended by the POGP (POGP, 2015)

A 2016 survey of physiotherapy practice demonstrated that standard care in the United Kingdom (UK) for women experiencing PLPP commonly included a home exercise program, self-management advice (written and/or oral), manual therapy, and the use of a pelvic support belt (Bishop et al., 2016) in line with POGP recommendations (POGP, 2015). However, only 28% of UK women experiencing PLPP will receive active treatment, despite antenatal healthcare providers recommending treatment in 64% of cases (Gutke et al., 2018). PLPP can also be

under-reported, often due to the mistaken belief that symptoms are a normal part of pregnancy (Pierce et al., 2012). Consequently, many women self-manage their symptoms independently. Therefore, timely access to trusted information and advice would facilitate independent self-management of PLPP (Elden et al., 2014) and may help to minimise the impact of PLPP on physical function and health-related quality of life.

1.2.5 Conceptualisation of self-management in this thesis

The term self-management covers a range of behaviours that facilitate those with a health complaint to take responsibility for their condition and optimise their level of function (Lorig and Holman, 2003; Jonkman et al., 2016). According to Lorig and Holman (2003), such behaviours may include adhering to an appropriate medication regime, changing the way one participates in leisure activities, or dealing with the emotional sequelae of the condition. A self-management intervention must therefore be more than a simple transfer of knowledge from the healthcare provider to the patient; instead, such interventions aim to equip individuals with the skills needed to take control of the management of their health condition and to function optimally (Brady, 2012; Mann et al., 2013; Jonkman et al., 2016; Hutting et al., 2019).

There is currently no internationally agreed definition of a self-management intervention (Jonkman et al., 2016). However, six core self-management skills have been identified (Lorig and Holman, 2003) and are widely cited in the literature (May, 2010). These skills are often the focus of self-management interventions and include:

- Problem-solving: such as establishing ways to manage a flare-up of symptoms
- Decision-making: such as deciding when further medical intervention is needed
- Resource utilisation: informing individuals of helpful resources and how to use them
- Forming a patient/healthcare provider relationship
- Taking action: developing action plans and learning how to implement them
- Self-tailoring: applying self-management knowledge and skills to one's situation

These six core skills allow individuals to better control their symptoms (Lorig and Holman 2003). However, the development and utilisation of these skills require a behaviour change on the part of the individual. Consequently, self-management interventions are a form of behaviour change intervention (Serlachius and Sutton 2009) and, as such, should be based on behavioural theory (Michie et al., 2011).

Many traditional self-management interventions for low back pain are underpinned by Bandura's Social Cognitive Theory (Keogh et al., 2015)). In the context of self-management, SCT posits that individuals can foresee the outcome they desire (i.e., set desired rehabilitation goals) and make plans of how that outcome might be achieved (i.e., create an action plan). However, for these plans to be carried out, the individual must believe that they can do so (i.e., they must have sufficient self-efficacy) and that the plan will result in the desired outcome (outcome expectancy) (Bandura, 1998a; 1998b). Therefore, self-management

interventions often centre around condition-related information provision (May, 2010; Mann et al., 2013). This approach serves several purposes, including (i) ensuring that outcome expectancy is appropriately managed; (ii) describing the self-management behaviours that may be of benefit; and, importantly, (iii) explaining *why* these behaviours are likely to help (Mann et al., 2013; Kongsted et al., 2021).

1.2.6 Limitations of PLPP self-management interventions delivered in an NHS setting

Self-management interventions are often delivered directly by healthcare professionals and may be supported by written materials (Kongsted et al., 2021). This model has been implemented by some NHS Trusts for women with PLPP in the form of group physiotherapy sessions supported by written advice leaflets (East Sussex NHS Trust provides one such example (East Sussex NHS Trust, 2021)). This mode of service provision does, however, require a commitment of clinical time from the physiotherapist and funding for the purchase or production of supporting materials. This format for PLPP self-management intervention delivery is also limited as only a small number of women can be accommodated at each session (Norfolk and Norwich University Hospitals NHS Foundation Trust, 2019; Oxford University Hospitals 2022). Additionally, variation in local service provision (NICE, 2021) may force the prioritisation of women with more severe symptoms. It is, therefore, necessary to consider alternative options for the delivery of self-management advice to women with PLPP to make efficient use of NHS resources. Modes of delivery that allow wider information distribution and require less

resource-intensive input from healthcare professionals would support this agenda (Health Education England, 2019).

1.2.7 PATIENT AUTONOMY AND EMPOWERMENT

Empowering patients to play a more active role in their care has been an objective of successive UK governments over many years to help reduce the burden of non-communicable diseases on NHS healthcare systems (All Party Parliamentary Groups of Global Health, 2014). Therefore, developing an intervention to support PLPP self-management is in keeping with this empowerment agenda.

The emergence of 'patient empowerment' as a concept in modern healthcare literature represents a departure from the traditional paternalistic model of medical care to a more patient-centred approach (Anderson and Funnell, 2005; Pulvirenti et al., 2014; Bravo et al., 2015). A key characteristic of the 'patient empowerment' approach is that patients are not treated as passive recipients of healthcare services (Collins and Rochfort 2011) but as active members of a patient-provider partnership who control their own health (Bravo et al., 2015).

Patient empowerment can be viewed as both a process and an outcome (Anderson and Funnell 2010): it is a process when an intervention aims to empower a patient by increasing their ability to think critically and act autonomously. It is an outcome when a patient's self-efficacy and ability to manage their own health are enhanced because of an intervention (Anderson and Funnell 2010). Self-management and patient empowerment are therefore closely interrelated concepts. Bravo et al. (2015) proposed a conceptual model of patient empowerment that views successful self-management as an outcome of patient empowerment. This is

because empowered patients possess the knowledge, skills, and attitudes required to adequately manage their condition (Bravo et al., 2015). Therefore, providing the knowledge and skills necessary to manage a particular health condition (i.e., via a self-management intervention) must also be construed as a form of patient empowerment.

1.2.8 An overview of the use of digital technologies in healthcare

The term 'digital technologies' applies to any electronic tool, system, device or resource that generates, stores or processes data (Tulinayo et al., 2018). Common examples include social media platforms, online games, and smartphones. A 2020 report by the Office for National Statistics (Office for National Statistics, 2020) suggests that 96% of UK households have access to the internet. Ofcom (2021) reported that the average length of time spent online each day by UK adults before the start of the COVID-19 pandemic was three hours and twenty-nine minutes. It was also reported that over 70% of the time spent accessing the internet was done using smartphones. Therefore, interaction with digital technologies is common in everyday life for many UK adults.

Over the last decade, digital technologies have gained increasing attention in healthcare research (Patrick et al., 2016), owing to the potential for such technologies to help support healthcare service delivery (Carter et al., 2019). Digital health interventions (referred to as digital interventions) are defined as healthcare interventions delivered using digital technologies (Nicholl et al., 2017). Common examples of digital interventions include educational websites and smartphone applications (apps). Such interventions present an attractive proposition for those

designing healthcare services as they may facilitate the delivery of healthcare support directly to users without the need for hospital visits or in-person clinician contact. Evidence suggests that digital interventions can be cost-effective (Jiang et al., 2019) and may therefore allow more efficient use of NHS resources. The accessibility of digital interventions via mobile devices also maximises convenience for users and ensures that information provided via these channels is continually available. For this reason, digital interventions are viewed favourably by healthcare service users (Carter et al., 2019).

Nonetheless, multiple factors may result in individuals being unintentionally excluded from the benefits of digital healthcare interventions (Watts, 2020). Lower educational level, low income (Fang et al., 2019), and lower levels of digital literacy (Jaeger et al., 2012) are all known to contribute to digital exclusion. In the UK, lack of access to hardware, lack of internet connectivity, and insufficient digital skills have been identified as key barriers to digital inclusion (NHS Digital, 2019). The accessibility of online information for people with learning disabilities is also known to be problematic (Lussier-Desrochers et al., 2017). Therefore, the potential for unintended consequences associated with the digitisation of healthcare services, including the exclusion of particular societal groups, must be considered by digital intervention developers (NHS Digital, 2019).

The volume of literature relating to the use of pregnancy-related websites, social media platforms (SoMe) and apps (collectively referred to as digital media) is growing rapidly, in keeping with the widespread uptake of these media amongst the pregnant population (Sayakhot and Carolan-Olah, 2016). Pregnant women use

digital media in a healthcare context for multiple purposes, including self-screening (Peyton et al., 2014) and preparing for healthcare appointments (Maslen and Lupton, 2018). Therefore, healthcare providers and commercial companies have capitalised on this knowledge, developing multiple interventions for pregnancy-related conditions (such as gestational diabetes) using various forms of digital media for delivery (Chan and Chen, 2019). Therefore, the notion of a digital self-management intervention for women with PLPP is in keeping with this trend and is worthy of consideration. However, to date, there is a shortage of relevant empirical evidence relating directly to this topic.

1.3 AIMS AND OBJECTIVES OF THIS PHD STUDY

This PhD study aimed to explore the feasibility of a digital self-management intervention for women with PLPP. The specific objectives are as follows:

Objective 1. To review the existing literature relating to digital interventions for low back pain in the general population to inform the development of a digital self-management intervention for PLPP (Chapter two).

Objective 2. To explore the PLPP-related information-seeking practices of women currently experiencing this condition (Chapter four).

Objective 3. To explore the attitudes of NHS service users and NHS-based antenatal HCPs regarding the use of digital media to provide PLPP-related information (Chapter four).

Objective 4. To explore the acceptability and perceived utility of the notion of a digital intervention to support the self-management of PLPP (Chapter four).

Objective 5. To develop a prototype digital intervention based on the outcomes of objectives 1-4 (Chapter five).

Objective 6. To examine how users engage with the prototype intervention to inform a preliminary judgement of its feasibility and any necessary future modifications (Chapter six).

1.4 Overview of the research process

The PhD study included the following five steps to help achieve the above objectives:

1. A systematised literature review to explore the potential usefulness of a digital self-management intervention for women with PLPP (Objective 1) (Chapter two).

2. A qualitative phase to explore the perceptions of three key stakeholder groups regarding the use of digital media as a platform for PLPP-related information provision. This study also explored the requirements of a digital self-management intervention for PLPP from the perspectives of these three groups (Objectives 2,3,4) (Chapter four).

3. Development of the digital intervention content and features using the 'Behaviour Change Wheel' approach developed by Michie et al. (2014) (Objective 5) (Chapter five).

4. Patient and public involvement to help refine the content of the prototype intervention (Objectives 5, 6) (Chapter five).

5. A descriptive quantitative analysis of retrospective pseudonymised user engagement data to help establish the feasibility of the prototype intervention developed. (Objective 6) (Chapter six).

1.5 USE OF THE MRC GUIDANCE ON THE DEVELOPMENT AND EVALUATION OF COMPLEX INTERVENTIONS IN THIS THESIS

The Medical Research Council (MRC) has produced guidance to support researchers in developing and evaluating complex interventions (Craig et al., 2008). This guidance has recently been updated (Skivington et al., 2021); however, the iteration available at the time this PhD study was planned was that published in 2008. The MRC defines *complex interventions* as those that contain several interacting components, require multiple behaviour changes, involve multiple organisational levels, or influence multiple outcomes (MRC, 2008).

The MRC guidance (MRC, 2008) highlights the importance of appropriate intervention development activities, including identifying appropriate theory and the necessity of adequate feasibility testing before undertaking a definitive evaluation of intervention effectiveness. Figure 3.3 below highlights that the intervention development and evaluation process is not necessarily cyclical, and that iteration may be required at multiple stages.

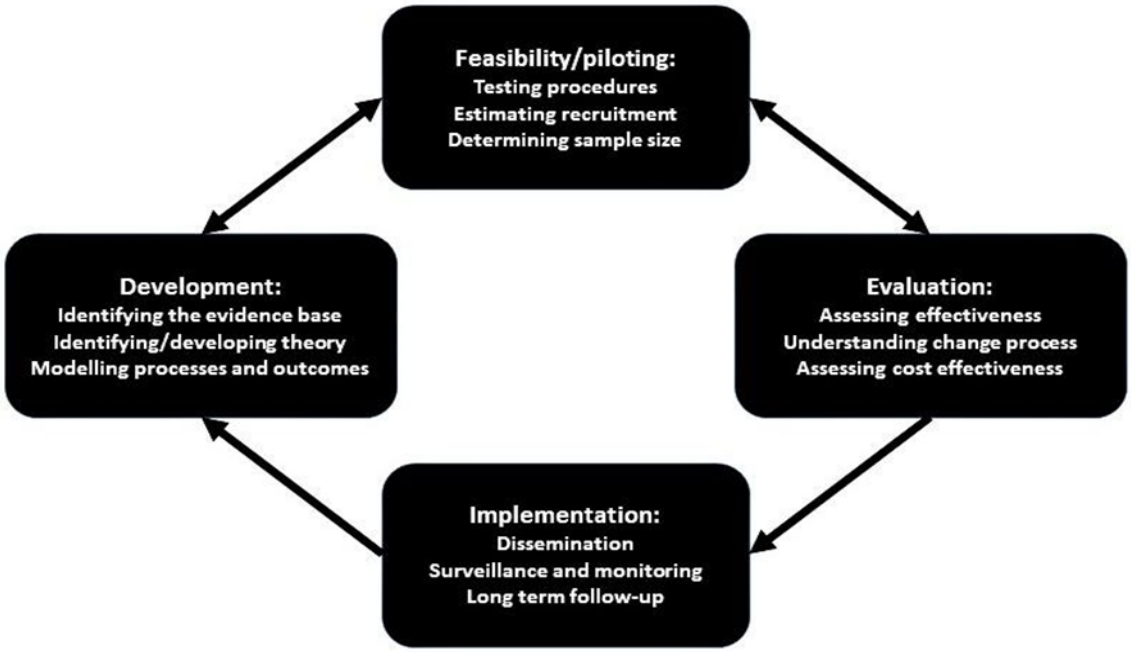


Figure 1.2. MRC complex intervention development and evaluation process (MRC 2008)

This PhD study aimed to develop a digital self-management intervention for women with PLPP. Such an intervention therefore aligns with the definition of a complex intervention described by the MRC (MRC 2008). The guidance was therefore used to guide the planning of this PhD study.

As recommended in the MRC guidance (2008), this PhD study began by gaining a thorough understanding of the evidence of effectiveness of digital interventions for the self-management of low back pain, pelvic girdle pain, and lumbopelvic pain. The intervention development phase of this PhD study was also based on sound behavioural theory. A structured approach to intervention development was identified and utilised; the Capability, Opportunity, and Motivation model of behaviour (COM-B) (Michie et al. 2011) and the Behaviour Change Wheel approach

to intervention development described by Michie et al. (2014) were selected for use in this study. These are described further in Chapter five.

1.6 Structure of this thesis

Thus far, the background to this PhD study has been discussed and a case made for research in this area. An overview of the thesis structure is presented on page one for reference.

Chapter two addresses objective number one (page 11): Evidence from the qualitative literature supporting the need for improved information provision and self-management support for women with PLPP will be presented. An overview of the available systematic review evidence demonstrating the potential of digital health interventions in supporting antenatal behaviour change and the management of low back pain in the general population is also given. This is followed by a discussion of the limitations of previous evidence for informing the current project. A systematised review of the literature examining the content and effectiveness of digital interventions for the management or self-management of LBP, PGP, or LPP is then reported.

Chapter three describes the philosophical underpinnings of this PhD study, followed by a description and justification of the study design chosen. The ethical considerations relevant to this PhD study are discussed, and a brief description of the relevant approvals secured is also given.

Chapter four (which addresses Objectives two to four) describes the data collection, analysis, and findings of the exploratory qualitative study, whilst Chapter

five (which addresses objective five) describes how these findings informed the development of an app-based intervention. Chapter five will also describe the decision-making process relating to the content and features of the intervention and how relevant self-management and behaviour change literature were used to inform this process.

Chapter six (which addresses objective six) reports the retrospective analysis of pseudonymised user engagement data accessed after implementing the intervention in response to the COVID-19 pandemic. Chapter seven contextualises the findings reported in the thesis and discusses what can be inferred about the feasibility of the intervention to support PLPP self-management. Chapter eight details the further work required to confirm the feasibility of the intervention and highlights the conclusions and implications of this thesis. Finally, Chapter nine contains the researcher's reflections on the transformational nature of this PhD journey.

1.7 Changes to this PhD study due to the COVID-19 pandemic

In response to the COVID-19 pandemic, two significant changes occurred to the planned PhD study:

1. The quantitative analysis of intervention user engagement data was undertaken retrospectively (rather than prospectively as planned)
2. A second qualitative study, planned to explore the acceptability of the intervention developed in this PhD study and reasons for user engagement/non-engagement, was deferred until the post-doctoral period

The original plan for the final phase of this PhD study was the prospective collection of user engagement data. However, government guidelines that halted non-essential healthcare appointments during the strict national lockdown meant that the planned recruitment strategy was no longer feasible. Nonetheless, during this period, when physiotherapy services for women with PLPP were paused within the NHS, the prototype intervention was implemented within the Lewisham and Greenwich NHS Trust to provide condition-related information to those unable to access physiotherapy treatment. The decision to implement the intervention was driven by clinical need. This decision was made independently of the student or supervisory team, following discussions between the student's primary clinical collaborator and the broader team of pelvic health service leads within the host NHS Trust.

Implementing the intervention into clinical practice meant that user engagement data automatically collected via the online platform to which the intervention is connected (see Chapter 5) were available for retrospective analysis. Data reflective of real-world engagement with the intervention could therefore be analysed.

The pandemic did however create some insurmountable challenges; a second qualitative study was intended to run alongside the quantitative assessment of user engagement data to establish the retrospective acceptability of the intervention and explore reasons for engagement/non-engagement. However, the COVID-19 pandemic meant that the planned recruitment strategy was no longer feasible. This work is now scheduled to be completed in the post-doctoral period to

allow timely completion of the PhD. Details of the further work planned can be found in Chapter eight.

1.8 CONTRIBUTION TO KNOWLEDGE

Evaluation of the evidence base revealed that no previous study had been published exploring the feasibility of a digital self-management intervention for women with PLPP. This thesis, therefore, represents a unique contribution to knowledge and is the first to attempt to empower women with PLPP to self-manage their condition using digital technology. Two themes from the exploratory qualitative phase relevant to health information-seeking have been published in a peer-reviewed journal to help raise awareness amongst clinicians about the condition-specific information-seeking practices of women with PLPP (Moffatt et al., 2021). An overview of the findings of Phase 1 has also been presented at a national peer-reviewed conference (Moffatt et al., 2022). The findings of the systematised literature review have been submitted to an international peer-reviewed journal. This PhD study has also resulted in the development of a novel digital intervention to support the self-management of PLPP (Chapter 5) which is now in use in clinical practice.

CHAPTER TWO: REVIEW OF THE LITERATURE CONCERNING INFORMATION PROVISION IN THE CONTEXT OF PLPP AND THE USE OF DIGITAL HEALTHCARE INTERVENTIONS

The aim of this PhD study was to assess the feasibility of a digital self-management intervention for women with PLPP. To examine the need for this and to inform the design of this research, the relevant literature was reviewed. In this chapter, the following information will be presented:

- Evidence from qualitative research suggesting the need for improved information provision for women with PLPP
- A summary of evidence from existing systematic reviews examining the utility of digital interventions to promote behaviour change in the antenatal period
- An overview of existing systematic reviews examining the effectiveness of digital interventions for the management of LBP in the general population
- A discussion of the limitations of previous systematic reviews of the effectiveness of digital interventions for LBP in informing this thesis
- A systematised review of randomised controlled trials examining the effectiveness of digital interventions for the management of LBP, PGP, and LPP, and evaluating the content and features of included interventions

2.1 Introduction

For many years, researchers have been exploring the role of information provision in improving outcomes in adults with lower back pain (Burton et al., 1999). Systematic reviews have demonstrated the utility of information provision in facilitating the self-management of non-specific lower back pain in the older adult population (Zahari et al., 2020) and authors have proposed that patient education should form the core of any successful self-management intervention (May, 2010). In the following section, evidence supporting the need for improved condition-related information provision in the context of PLPP will be presented. The reported impact of insufficient information provision on condition-related anxiety and self-management ability will also be highlighted.

2.2 The need for improved self-management information provision for women with PLPP

In 2005, a UK-based study by Shepherd (2005) explored women's experiences of pelvic girdle pain (PGP) and how interactions with various healthcare professionals were perceived. Data highlighted women's disappointment at the lack of acknowledgement of PGP amongst healthcare professionals and the lack of condition-related information offered. Women in this study called for information about the condition to be made part of standard antenatal information provision and for healthcare professionals to provide information leaflets to those reporting symptoms (Shepherd, 2005).

Despite this call for improved information provision, much of the subsequent literature regarding the experiences of women with PLPP reports a perceived lack

of condition-related information (Sadr et al., 2012; Elden et al., 2014; Clarkson and Adams, 2018). PLPP is not talked about as openly as other pregnancy-related issues (Wuytack et al., 2015a, 2015b) and several studies have highlighted that women are often unaware of PLPP's existence prior to the onset of symptoms. Consequently, condition-related anxiety is common as the cause of the pain is not known (Wellock and Crichton, 2007; Elden et al., 2014; Close et al., 2016; Clarkson and Adams, 2018). The severity of the pain associated with PLPP is also often unexpected; this has caused some women to suspect a serious pregnancy-related complication affecting the welfare of their unborn baby. For example, one participant in Clarkson and Adams (2018) stated:

> *'I just thought I was losing my baby'* (Clarkson and Adams, 2018, Page 343).

Healthcare professionals do not give PLPP the same attention as other pregnancy-related pathologies (such as pelvic floor dysfunction), despite the symptoms being of primary concern to the women experiencing them (Wellock and Crichton, 2007; Wuytack et al., 2015a, 2015b)). Information is routinely provided about pelvic floor dysfunction in line with the NICE guidance (National Institute for Health and Care Excellence, 2021), but information needs relating to PLPP are often unaddressed. The feelings expressed by participants in the study by Wuytack et al., (2015a) are captured in the following quote:

> *'…It was all about the pelvic floor and doing the pelvic floor exercises, but that isn't really what's been impacting on me; it's more the joints and the skeleton, kind of the hips and the back of the pelvis, the tailbone, that sort of thing'* (Wuytack et al., 2015a, page 1360)

The lack of available information and subsequent confusion surrounding PLPP is equally evident in a Norwegian study published by Fredriksen et al. (2008). This

study explored the online discussions about PLPP in an internet-based forum. Participants in this study were unclear about the symptoms of PLPP, the prognosis of PLPP, and whether continuing with work-related activities would worsen the outcome (Fredriksen et al., 2008). The online comments captured in this study also highlight the anxiety provoked through a lack of understanding about the condition.

> *'…I am 9 weeks pregnant and have extreme pain in my tailbone when I stand up and sit down. I am terrified that this is the start of PGP [pelvic girdle pain]. But surely it must be too early for this to start already? I reckon I will be unable to walk in a few months' time. I have heard so many dreadful stories! Is this true? Can it stop at this level and not get worse?'* (Fredriksen et al., 2008, page 296).

Elden et al. (2014) demonstrate that some women with PLPP feel 'cheated' at not being provided with information about PLPP early in their pregnancy, given that it is a problem experienced by a large proportion of pregnant women. Additionally, the provision of adequate condition-related information appears to strengthen women's ability to cope with PLPP (Sadr et al., 2012; Elden et al., 2014; Clarkson and Adams, 2018). The following quotes highlight the relief women experienced when an adequate explanation of PLPP was received:

> *'It's been emotionally helpful because at the same time I'm getting advice…there's been explanations of 'physiologically this is what is happening to your body' and 'this is why your ligaments are pulling', 'this is why you're compensating with the extra weight at the front', 'this is why your posture is changing'…and things like that'* (Sadr et al., 2012, page 4).
>
> *'…hearing that it is manageable was quite a relief'* (Clarkson and Adams, 2018, page 343).

Based on this evidence, ensuring PLPP-related information needs are met should be of utmost importance to antenatal healthcare providers. However, evidence from UK and European studies suggest that a minority of healthcare professionals still endorse the pervasive myth that PLPP is just a normal part of pregnancy (Wellock and Crichton, 2007; Fredriksen et al., 2008; Engeset et al., 2014; Fredriksen et al., 2014). This approach to PLPP may indirectly deny access to beneficial information and services, as the need for advice and education goes unacknowledged.

> *'One of the doctors I went to asked me to remember that it actually was not a disease that I had – that I was ONLY pregnant!'* (Fredriksen et al., 2008).
>
> *'GP said that SPD [old name for PGP] was one of those things that will pass when you have had the baby…you just have to grin and bear it'* (Wellock and Crichton, 2007).

It is difficult to establish whether this dismissive attitude to PLPP continues to be problematic as no studies published after 2014 were found that specifically explored this issue. Nonetheless, a lack of condition-related information may drive women with PLPP to independently seek information from other potentially inaccurate sources, such as family members, peers, or the internet (Chu et al., 2017).

The findings of qualitative research may not be generalisable beyond the context in which the data were generated (Sullivan and Sargeant, 2011). However, the evidence presented in this section suggests that there is currently a lack of information for pregnant women to support self-management. More needs to be done to ensure that women with PLPP have timely access to accurate condition-

related information. Therefore, an evidence-based information resource that could be provided to women as part of routine antenatal care is worthy of further exploration.

2.3.1 The use of digital interventions to facilitate antenatal behaviour change

Pregnant women are acknowledged as mass consumers of online health-related information (Gleeson et al., 2019; Mackintosh et al., 2020) and are thought to use the internet for multiple purposes, including searching for information relating to pregnancy symptoms (Kraschnewski et al., 2014), and to aid decision-making regarding pregnancy, childbirth and future parenting (Prescott and Mackie, 2017; Wright et al., 2019). Around 95% of digitally active women search the internet for health-related information during the antenatal period (Mackintosh et al., 2020). Evidence also suggests that parity (Camacho-Morell and Esparcia, 2020), educational attainment (Sayakhot and Carolan-Olah, 2016), and level of health literacy (Shieh et al., 2009) may all influence such information-seeking behaviours.

The volume of literature relating to pregnancy-related digital media use is growing rapidly (Schnitman et al., 2021). Healthcare providers are increasingly looking to digital media as an alternative platform for intervention delivery. Once developed, digital interventions require less time-intensive input from clinicians and can facilitate healthcare delivery to users in remote locations who might otherwise have difficulty accessing services (Butzner and Cuffee, 2021). Recent systematic reviews have evaluated numerous digital interventions aiming to bring about behaviour change in the antenatal period with inconsistent results.

A systematic review (Lee et al., 2016) examined the effectiveness of mobile health (m-health) interventions (including mobile apps, text messaging (SMS), and voice calls) for improving maternal, newborn and child health in low-middle income countries. This review examined multiple health-related outcomes, in addition to behavioural outcomes such as breastfeeding practices and compliance with nutritional supplementation. A meta-analysis of three studies (with a total of 1573 participants) relating to infant feeding demonstrated that antenatal interventions using SMS messaging and voice calling improved rates of breastfeeding within one month after birth, and improved the rates of exclusive breastfeeding for up to six months (Lee et al., 2016). These findings suggest that simple mobile health strategies such as SMS text messaging delivered during pregnancy can, in some contexts, influence healthy behaviour choices throughout the early postpartum period. Whether such findings would be replicated for other health behaviours would require further empirical exploration.

A systematic review by Overdijkink et al. (2018), that included 29 papers with a total of 36,886 participants, demonstrated that mobile apps relating to medical and lifestyle issues are feasible and acceptable to pregnant women. This review also explored the effectiveness of numerous pregnancy-related medical and lifestyle apps designed to address issues such as asthma, diabetes, gestational weight gain, smoking, and alcohol consumption. The authors report inconsistent findings across included studies (Overdijkink et al., 2018). It is noteworthy that many included studies had small sample sizes and may therefore not have been adequately powered to detect a meaningful difference in outcomes. The inclusion of interventions targeting multiple health conditions and behaviours may have also

contributed to the inconsistent findings, as it cannot be assumed that all health behaviours will be influenced by digital interventions to the same degree (Thomas Craig et al., 2021).

Daly et al. (2018) published a systematic review examining the effect of m-health interventions on maternal health behaviours and perinatal health outcomes. Inclusion was limited to studies involving mobile app-based interventions. The primary outcome was a change in maternal health behaviour (as defined by trial authors) relating to the stated intervention goals. Despite a comprehensive search strategy, only four randomised controlled trials (RCTs) with a total of 456 participants were eligible for inclusion. Each included trial reported superior results for the intervention groups compared to controls. Therefore, given the popularity of pregnancy-related apps (Hughson et al. 2018) and the ubiquity of smartphones (Statista, 2021), this review suggests that a mobile app may be worthy of consideration as a platform for a future intervention to support the self-management of PLPP. Once again, however, establishing whether such findings would be observed in a different context requires further enquiry.

A similar systematic review was published in 2020 (Hussain et al., 2020), exploring the effects of m-health intervention use in high-income countries on maternal health behaviours and maternal-foetal health outcomes. Studies with a broad range of evaluation methods (including RCTs, non-randomised comparative studies and observational studies) were included. Of the 28 included studies, nine related to the control of gestational weight gain, the promotion of physical activity, or both - behaviours more relevant to this thesis. These nine studies included 1112

participants. Seven of these nine studies were at 'fair' or 'high' risk of bias, and outcomes across relevant studies were inconsistent. Three of the four interventions found to be effective were multimodal, making it difficult to establish the specific effect of m-health interventions on relevant outcomes.

Rhodes et al. (2020) examined the effectiveness of exclusively digital interventions in improving maternal lifestyle behaviours or avoiding excessive gestational weight gain. This review also examined the types of behaviour change techniques (BCTs) included in those interventions found to be effective. Of the seven studies reporting physical activity outcomes, three showed a positive effect of the digital intervention. Of the six studies reporting outcomes relating to gestational weight gain, two reported positive effects of the digital intervention. Successful interventions were found to include a total of seven BCTs: goal setting, problem-solving, review of behaviour goals, feedback on behaviour, social support, information about health consequences, and information about emotional consequences. However, the only BCT used consistently across the three successful digital interventions was 'review of the behaviour goal'. Additionally, the three interventions that included no active or interactive BCTs, were ineffective. This raises two important questions: whether insufficient consideration of appropriate BCTs during intervention development may have resulted in the null findings reported across most included studies, and whether particular combinations of BCTs may be more effective in specific contexts. This review, therefore, highlights the importance of understanding the best BCTs to include in a future digital self-management intervention for PLPP and of using intervention development theory to guide decision-making.

More recent systematic reviews by Wu et al. (Wu et al., 2021) and Schnitman et al. (Schnitman et al., 2021) have demonstrated that although the impact of digital interventions on behavioural outcomes is inconsistent, satisfaction with digital educational materials can be high amongst pregnant women (Schnitman et al., 2021). Conversely, 'readily available' online information accessible via social media platforms, which may not have been reviewed or developed by clinicians, can confuse users and may result in increased anxiety (Wu et al., 2021). These reviews, therefore, suggest that high-quality, trustworthy information provided via digital platforms may be capable of meeting the information needs of pregnant women in a convenient format, whilst avoiding the pitfalls of independent online information-seeking.

The evidence presented in this section suggests there is some merit in exploring a digital intervention to support the self-management of PLPP. However, digital health research has previously been criticised for being under-theorised, poorly specified, or vaguely described (Lee et al., 2016). Calls have also been made for developers to work closely with academics, clinicians, and service users to ensure intervention content is evidence-based and engaging (Machado et al., 2017). For this reason, the design features of a digital self-management intervention for PLPP would require careful consideration of relevant behaviour change literature and selection of appropriate behaviour change techniques. The specific information needs of the target population would also need to be adequately explored and understood.

2.3.2 The use of digital interventions for low back pain

As the notion of a digital intervention for PLPP is novel, there is a lack of specific relevant literature to guide intervention development or indicate whether such an intervention could prove effective. Therefore, it is necessary to look to the broader back pain literature to understand how digital interventions have been used to support the management/self-management of low back pain in the general population. This section will provide an overview of existing systematic reviews of digital interventions for back pain. An explanation of the limitations of these reviews for informing this thesis will also be given.

Beatty and Lambert (2013) examined the evidence relating to the effectiveness of internet-based psychosocial therapeutic interventions in improving distress and disease control in chronic conditions. Two of the nine included studies involved participants with low back pain (LBP). Neither of the two back pain studies reported a statistically significant reduction in pain intensity; however, overall, the authors concluded that there was moderate support for internet-based interventions in improving outcomes in those with chronic pain. This review focused predominantly on pain coping and participant anxiety levels, but the impact of digital interventions on physical function was not reported. Pain intensity and physical function (pain-related disability) have been identified as patient-important outcomes for women with PLPP (Remus et al., 2021); therefore, understanding the impact of digital interventions on these outcomes is essential to inform the current study.

Garg et al. (2016) undertook a systematic review of RCTs of web-based interventions for adults with chronic low back pain (CLBP). Nine studies were included in the narrative synthesis. Trials were divided into two groups: those involving interventions based on cognitive behavioural therapy (CBT) principles and those using other web-based approaches. It was reported that interventions based on CBT principles improved the level of catastrophising amongst participants. Nevertheless, pain intensity and physical function outcomes were inconsistent across both groups of included studies. There was substantial variation in the types of intervention employed across both groups of studies and no clear link between intervention sub-type and outcome. Therefore, it will be necessary to examine the specific features of digital interventions that positively affect pain and physical function to inform the current thesis.

Nicholl et al. (2017) published a systematic review of digital interventions for the self-management of non-specific LBP (NSLBP) in the general population. This review had two aims relevant to this PhD study:

1. To examine the characteristics of digital self-management interventions for NSLBP
2. To explore the specific characteristics of digital interventions associated with positive outcomes

This review included six completed RCTs (with a total of 2706 participants), only one of which reported a significant between-group difference favouring the intervention group for the nominated primary outcome. The authors concluded that the heterogeneity of interventions, participants, and outcomes, limited the potential to determine which interventions work best for whom and under what

circumstances. This limited the utility of this review to inform this PhD study. Additionally, the literature searches for this review were performed in 2016; as digital health research is so rapidly growing, the findings of this review are likely to be outdated.

In 2020, a meta-analysis of eight RCTs (including 1238 participants) was undertaken (Du et al., 2020) to examine the effectiveness of e-health-based self-management programs for chronic low back pain. Evidence of a clinically significant effect of e-health interventions on pain and disability was reported at the immediate post-intervention time point. This effect was still evident for pain at the short-term follow-up time point. A sub-group analysis revealed that m-health interventions were superior to other web-based interventions in improving pain and disability at the immediate post-intervention follow-up. This evidence suggests that m-health technologies may be valuable platforms for digital intervention delivery. However, long-term follow-up was lacking in this review.

Hewitt et al. (2020) undertook a review of 19 RCTs examining the effectiveness of digital interventions for MSK conditions; 10 of which related to back pain. A total of 3361 participants were included. Interventions not containing interactive features and those requiring direct input from a health care professional were excluded. Each included study reported MSK pain as an outcome, nine of which reported statistically significant reductions in pain intensity favouring the digital intervention group. Sixteen included RCTs investigated functional disability, of which ten showed a statistically significant improvement favouring the intervention group. The more favourable findings reported in this review may result from limiting inclusion to interventions featuring an interactive component as evidence suggests

that user engagement with digital interventions may improve if interactive features are employed (Wei et al., 2020). However, pooling multiple pain sub-types in the analysis makes it difficult to establish the effect of digital interventions on back pain specifically.

Pfeifer et al. (2020) undertook a systematic review examining the effectiveness of digital interventions delivered via mobile phone apps for multiple chronic pain conditions, including LBP. Twenty-two studies (with varying research designs) were included in the review, totalling 4679 participants. The primary outcome for this review was pain intensity, and all studies that included comparable rating scales for this outcome were included in a meta-analysis. A small but significant effect of app-based interventions on pain intensity was reported. It is, however, difficult to confidently attribute this effect to the apps alone, as most included studies involved multimodal interventions. In addition, data for multiple pain conditions were pooled in the meta-analysis, and no subgroup analyses were performed. Therefore, it is unknown whether effect sizes might have varied for different pain sub-types.

More recently, Chen et al. (2021) undertook a meta-analysis of nine randomised controlled trials (including 792 participants) to examine the effectiveness of m-health interventions for improving pain and disability in adults with low back pain. It was determined that m-health interventions delivered in addition to usual care were superior to usual care alone in reducing pain and disability. A sub-group analysis also revealed that m-health interventions involving voice calls were superior to other m-health interventions and usual care. Again, this suggests that m-health interventions may be worthy of consideration for delivering a future

digital intervention. However, this review excluded studies involving pregnant women with no explicit justification. The generalisability of the findings to the current target population is therefore questionable.

2.4 SUMMARY OF EXISTING RELEVANT SYSTEMATIC REVIEWS AND LIMITATIONS IDENTIFIED

Based on the seven systematic reviews presented in section 2.3.2, evidence of the effectiveness of digital interventions for LBP management is inconsistent. The reviews presented also have several limitations affecting their utility in informing this PhD study:

1. Several reviews synthesised the findings of LBP studies with those of other MSK pain sub-types, making the effect of digital interventions on LBP unclear.

2. Different intervention inclusion criteria were applied across the relevant reviews. This means that papers relevant to the current thesis may have been omitted or that reviews focusing on specific digital intervention subtypes may have revealed different findings to those with broader inclusion criteria.

3. Pain and physical function are important outcomes for pregnant women with PLPP (Remus et al., 2021). However, not all reviews reported either of these outcomes, limiting the utility of the findings to this thesis.

4. Not all reviews included an assessment of intervention characteristics. This made it difficult to establish which specific intervention features might be

worthy of consideration for the digital intervention developed in this PhD study.

Considering the above, the decision was made to undertake a further systematised review of the literature to inform this PhD study. The systematised review described in section 2.5 addressed the four stated limitations of previous systematic reviews in the following ways:

1. The review examined the effectiveness of digital interventions for the management or self-management of LBP, PGP or LPP, all of which are pain sub-types relevant to the current thesis. Due to the anticipated paucity of evidence relating to pregnancy-related LPP specifically, this review examined the evidence relating to both pregnant and non-pregnant participants and included all back-pain durations.

2. This review included digital interventions delivered via a range of widely available digital technologies.

3. This review included only trials reporting outcomes of pain, physical function, or both.

4. This review included an assessment of the main characteristics of included digital interventions to inform the development of a future intervention to support the self-management of PLPP.

Full details of the systematised review undertaken are given in the following section.

2.5 Systematised literature review of digital interventions for the management of low back pain, pelvic girdle pain, or lumbopelvic pain

To inform this PhD study a systematised literature review was undertaken to address the following objectives:

1. To narratively synthesise the literature examining the effectiveness of digital interventions in improving pain and physical function in adults with LBP, PGP or LPP.
2. To identify the main features of those digital interventions highlighted as effective in improving pain and physical function in adults with LBP, PGP or LPP.
3. To explore the generalisability of the current evidence to the target population of women experiencing pregnancy-related lumbopelvic pain.

2.5.1 Materials and methods

A systematised review approach (Grant and Booth 2009) was used to locate and synthesise available evidence of effectiveness from existing primary research. Systematised literature reviews include several features of systematic reviews (Grant and Booth, 2009) and thus increase transparency and reduce bias compared to traditional narrative reviews. However, unlike systematic reviews, they may be undertaken by a single reviewer (Grant and Booth, 2009). This approach was therefore suited to this PhD study, where the researcher was working independently. This review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance and a completed PRISMA checklist can be found in Appendix 1.

Relevant articles were selected for inclusion according to the following eligibility criteria:

Participants: Adults with LBP, PGP or LPP of musculoskeletal origin. This could be self-reported or confirmed by a clinician. Any study involving participants awaiting surgery for back pain were excluded.

Interventions: Digital interventions designed to facilitate the management or self-management of LBP, PGP, or LPP, delivered using any form of digital media (e.g., websites, mobile phone applications (apps), social media platforms, etcetera) were eligible for inclusion. Interventions using a combination of digital and non-digital modalities were also considered.

Interventions that did not involve a digital component were excluded. Interventions delivered directly by clinicians using telehealth platforms (e.g. virtual consultations) or that included immersive technologies such as 'virtual reality' were also excluded. These decisions were made pragmatically. Although telehealth platforms reduce the burden of travel associated with treatment, they still require the same use of clinical time. Therefore, telehealth platforms are an alternative mode of treatment delivery but are not resources that service users can access independently to support their care. Additionally, digital interventions are an attractive alternative for care provision due to the ubiquity of smartphones, laptops, and computers (Statista, 2021). However, virtual reality hardware is not as widely used and was therefore not considered a viable platform for delivery of a future PLPP self-management intervention.

Comparators: Eligible comparators included, but were not limited to, waiting list control, no intervention, standard care, alternative means of intervention delivery, and non-digital interventions.

Outcomes: Trials involving patient reported outcomes of pain intensity and physical function/pain-related disability were eligible for inclusion. Trials that reported neither of these outcomes were excluded.

Study design: Only randomised controlled trials were eligible for inclusion as they provide the highest level of evidence of effectiveness (Burns et al., 2011).

Search strategy

A comprehensive literature search was undertaken using six electronic databases using the EBSCO platform, namely: MEDLINE, AMED, CINAHL, SPORTDiscus, APA PsycArticles and APA PsycINFO. Google Scholar was also searched. The searches were carried out from inception to the 25th of May 2021. Reference lists of potentially eligible studies were hand-searched, and the grey literature was searched via OpenGrey and ClinicalTrials.gov. The search was limited to papers published in English. Table 2.1. below shows the search strings used in each of the online academic databases. No filters or search limits were applied.

Table 2.1. Search strings used for electronic academic databases

Search	Search terms used
#1	**Low* back pain** OR **back pain** OR **non-specific back pain** OR **LBP** OR **NSLBP** OR **lumbopelvic** OR **pelvic girdle** OR **PGP** OR **sacroiliac joint** OR **SIJ** OR **lumbar**
#2	**E-health** OR **ehealth** OR **m-health** OR **mhealth** OR **telemedicine** OR **mobile applications** OR **mobile apps** OR **apps** OR **website*** OR **social media** OR **online** OR **web-based** OR **smartphone** OR **digital** OR **FaceBook** OR **Twitter** OR **Instagram**
#3	**Randomised controlled trial** OR **randomized controlled trial** OR **RCT** OR **trial** OR **controlled trial** OR **clinical trial** OR **pragmatic trial** OR **cluster randomised** OR **cluster randomized**
#4	#1 AND #2 AND #3

All retrieved articles were imported into EndNote Online and duplicates manually removed. References were then uploaded to rayyan.qcri.org to allow screening of the titles and abstracts. This was completed by the researcher independently as the resources to allow dual screening were not available. Potentially eligible articles were retrieved in full text format and reviewed to determine inclusion. If the full text paper was not available, corresponding authors were contacted by email to request a copy. Screening of full text articles was also completed by the researcher independently.

Assessment of risk of bias

Risk of bias assessment was undertaken using the revised Cochrane risk-of-bias tool for randomised controlled trials (ROB-2). The Cochrane handbook recommends that all relevant outcomes are assessed individually (Sterne et al., 2019). However, only patient reported outcomes of pain and physical function are being reported in this review; these are both collected via similar means and will therefore be

similarly affected by methodological issues relating to internal validity. A single risk of bias assessment rating for each RCT is therefore presented.

The ROB-2 includes five domains: 1) the randomisation process, 2) deviations from the intended intervention, 3) missing outcome data, 4) measurement of the outcome, and 5) selection of the reported result. For each included study, each domain was classified as 'low risk', 'some concerns' or 'high risk' according to the Cochrane Handbook (Sterne et al., 2019). No RCTs were excluded from the analysis based on their risk of bias assessment rating. Completion of the risk of bias assessments were undertaken by the researcher independently.

Data extraction

The following data relating to the characteristics of included RCTs were extracted by the researcher independently: author, year of publication, title, population, sample size, mean age of participants, the percentage of the study sample that were female, and whether the sample included pregnant women. If the mean age for the entire sample was not reported, then the mean age of participants in each treatment group was recorded instead.

Details of the study intervention (reported according to the TIDieR guidance (Hoffman et al., 2014)), comparator, outcome measures (i.e., the patient reported outcome measures used to report pain and disability), and key findings of each included RCT (i.e., the level of pain and disability at each reported timepoint) were recorded. The discernible behaviour change techniques (BCTs) employed in each trial intervention (coded in line with the behaviour change taxonomy developed by Michie et al (2013)) were also recorded.

Data synthesis

Where available, descriptive statistics were used to summarise variables extracted. For the majority of included RCTs, the mean pain and disability scores at each timepoint were extracted alongside either the standard deviation or the 95% confidence interval, depending upon the data available. Where these data were unavailable, the data reported in the published papers, such as the least squares mean and standard error, were extracted. Where possible, the point estimates of the mean between-group differences and 95% confidence intervals were reported. However, due to the heterogeneity identified in the systematic review by Nicholl et al (2017) in terms of interventions, outcome measures, and participants, it was foreseen that a meta-analysis would be inappropriate. A narrative synthesis was therefore planned. For clarity, the findings of each included RCT were tabulated to display the following four pieces of information:

1. The key characteristics of the RCT and included sample
2. The intervention under test in the RCT and its comparator
3. The behaviour change techniques discernible within each RCT intervention
4. The outcomes of pain and disability reported at each follow-up timepoint for each included RCT

No formal assessment of the certainty of evidence, such as the Grading of Recommendations, Assessment, Development and Evaluations (GRADE) assessment, was undertaken in this review. However, the levels of evidence as defined by Van Tulder et al. (2003) are reported.

Ethical Approval

This was a desk-based secondary research study using publicly available data therefore no ethical approval was required.

This review could not be registered on the PROSPERO database, as reviews undertaken by a single reviewer are not accepted. Consequently, there is no publicly available version of the review protocol.

Financial Support

No funding was sought or received to support completion of this review. Neither the researcher nor the supervisory team have any competing interests to declare.

2.5.2 RESULTS

The process of study selection is summarised in **Figure 2.1** below. Twenty-eight papers relating to 26 unique studies were eligible for inclusion. For simplicity, when reporting the findings of this review, the three papers relating to the same trial have been grouped together to avoid duplication. One paper could not be retrieved in full text format (Bernardelli et al., 2020), so the corresponding author was contacted to request a copy. No response was received. Based on the assessment of the abstract, this RCT may have met the inclusion criteria. However, this paper was excluded as the full-text version was unavailable for screening or data extraction.

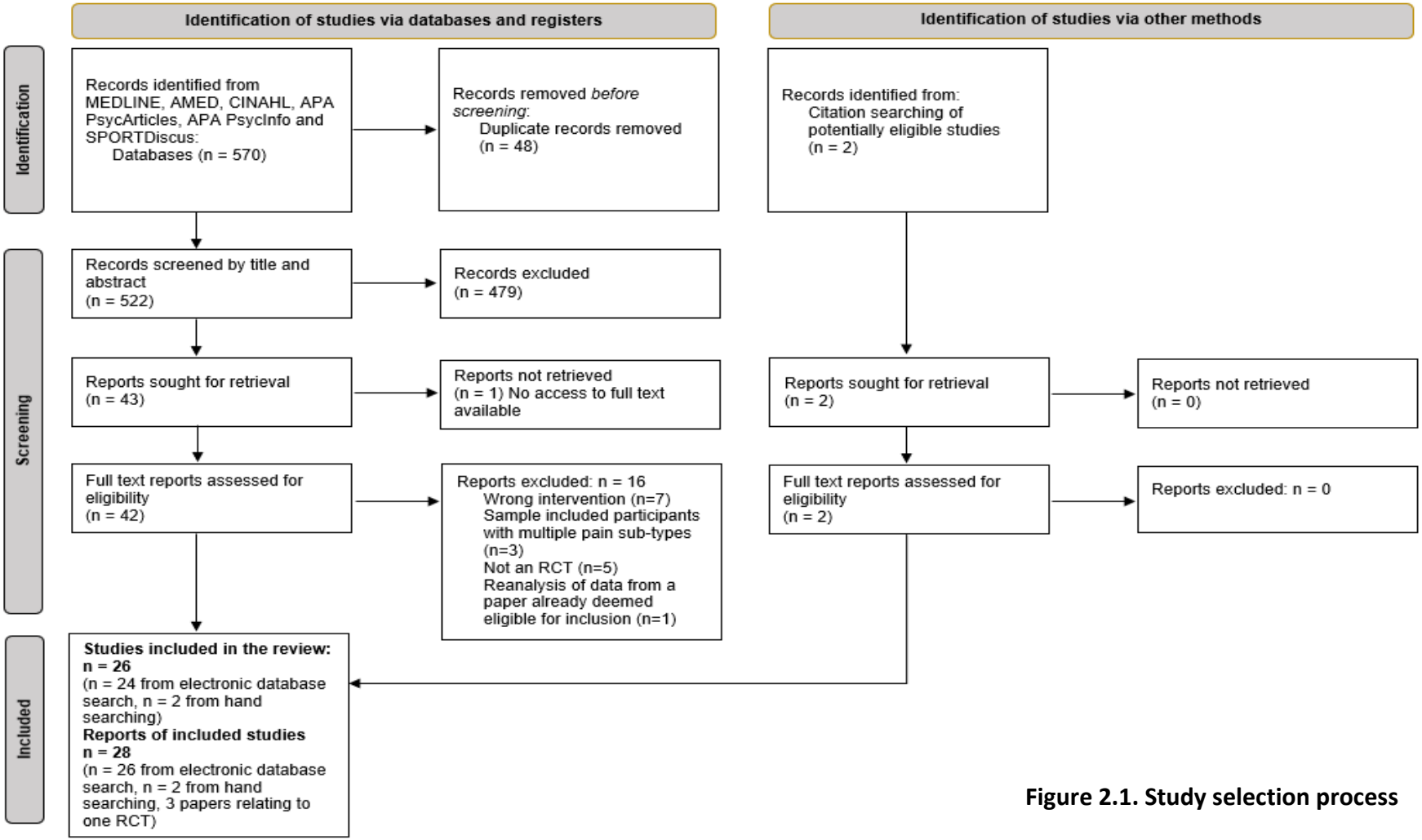


Figure 2.1. Study selection process

Characteristics of included studies

Table 2.2 below provides an overview of the characteristics of included RCTs.

No RCTs were identified that examined the effectiveness of digital interventions for PGP or LPP.

Included RCTs were published between 2002 and 2021. These were undertaken in Europe (n=11), America (n=8), Asia (n=3), The Middle East (n=2) and Australia (n=2).

Sample sizes varied widely, ranging from just eight (Yang *et al.*, 2019) to 1245 (Priebe *et al.*, 2020). The total sample size across the 26 included RCTs was 5893.

Twenty five of the 26 RCTs included both males and females, and all but three had greater than 50% female participants. Mean ages of participants ranged across studies from 35 to 60.3 years. Ten RCTs explicitly named 'pregnancy' as an exclusion criterion with no explicit justification (Lorig et al., 2002; Krein et al., 2013; Geraghty et al., 2018; Amorim et al., 2019; Hou et al., 2019; Petrozzi et al., 2019; Suman et al., 2019; Toelle et al., 2019; Almhdawi et al., 2020; Kazemi et al., 2021); of the 16 RCTs that did not actively exclude pregnant women, none stated whether pregnant participants were included in the final sample.

Participants with various types of lower back pain were recruited across the 26 RCTs, with the majority (16 out of 26) focusing on chronic lower back pain (Buhrman et al., 2004, 2011; Chiauzzi et al., 2010; Carpenter et al., 2012; Krein et al., 2013; Riva et al., 2014; Heapy et al., 2017; Chhabra, Sharma and Verma, 2018; Amorim et al., 2019; Petrozzi et al., 2019; Yang et al., 2019; Almhdawi et al., 2020;

Licciardone and Pandya, 2020; Sander et al., 2020; Schlicker et al., 2020; Baumeister et al., 2021).

Table 2.2 Overview of characteristics of included studies

Study Number	Author	Title	Year	Population	Sample size	Age of participants recruited (Years)	% of trial participants who are female	Sample excludes pregnant women Yes/No/ Not specified	Overall risk of bias for patient-reported outcomes
1	Almhdawi	Efficacy of an innovative smartphone application for office workers with chronic non-specific low back pain: a pilot randomised controlled trial	2020	Office workers with chronic non-specific low back pain in Jordan	41	Age range 30-55	53.60%	Yes	Some concerns
2	Amorim	Integrating mobile health, health coaching, and physical activity to reduce the burden of chronic low back pain (IMPACT): a pilot randomised controlled trial	2019	Adults with chronic low back pain in Sydney, Australia	68	Mean (SD) age 58.4 (13.4)	50%	Yes	Some concerns
3	Baumeister	Effectiveness of a Guided Internet- and Mobile-Based Intervention for Patients with Chronic Back Pain and Depression (WARD-BP): A Multicenter Pragmatic Randomised Controlled Trial	2020	Adults with chronic low back pain and mild-moderate depressive disorder in Germany	210	Mean (SD) age intervention group 50.3 (9.39) Mean (SD) age control group 49.6 (9.36)	60%	Not specified	Some concerns
4	Buhman	Controlled trial of internet-based treatment with telephone support for chronic back pain	2004	Adults with chronic low back pain in Sweden	56	Mean (SD) age 44.6 (10.4)	62.50%	Not specified	High

5	Buhrman	Guided internet-based cognitive behavioural treatment for chronic back pain reduces pain catastrophising: A randomised controlled trial	2011	Adults with chronic neck, thoracic or lower back pain in Sweden	54	Mean (SD) age 43.2 (9.8)	68.50%	Not specified	Some concerns
6	Carpenter	An online self-help CBT intervention for chronic lower back pain	2012	Adults with chronic lower back pain for at least 6 months in the U.S.	164	Mean (SD) age 42.5 (10.3)	83%	Not specified	High
7	Chhabra	Smartphone app in self-management of chronic low back pain: a randomised controlled trial	2018	Adults with chronic lower back pain in New Delhi	93	Mean (SD) age intervention group 41.4 (14.2) Mean (SD) age control group 41.0 (14.2)	Not stated	Not specified	Some concerns
8	Chiauzzi	painACTION-Back Pain: A Self-Management Website for People with Chronic Back Pain	2010	Adults with chronic lower back pain in the U.S.A	199	Mean (SD) age 46.14 (11.99)	67.68%	Not specified	High
9	Del Pozo-Cruz	A Web-Based Intervention to Improve and Prevent Low Back Pain Among Office Workers: A Randomized Controlled Trial	2012	Office workers with sub-acute non-specific low back pain (NSLBP) in Spain	100	Mean (SD) age intervention group 46.83 (9.13) Mean (SD) age control group 45.50 (7.02)	86.70%	Not specified	Some concerns
9 (2nd paper for same RCT)	Del Pozo-Cruz	An Occupational Internet-Based Intervention to Prevent Chronicity in Subacute Lower Back pain: A Randomized Controlled Trial	2012						

9 (3rd paper for same RCT)	Del Pozo-Cruz	Clinical effects of a nine-month web-based intervention in subacute non-specific low back pain patients: a randomised controlled trial	2012						
10	Geraghty	Using an internet intervention to support self-management of low back pain in primary care: findings from a randomised controlled feasibility trial (SupportBack)	2018	Adults with a current episode of low back pain in a UK primary care setting	87	Mean (SD) age Group 1 (internet-based intervention group) 54.5 (13.7) Mean (SD) age Group 2 (internet-based intervention plus telephone support from HCP group) 59.3 (10.4) Mean (SD) age Group 3 (usual care group) 60.3 (16.3)	61.4%	Yes	Some concerns
11	Heapy	Interactive Voice Response-Based Self-Management for Chronic Back Pain	2017	Veterans with chronic low back pain from one 'veterans affairs' healthcare system in the U.S.A.	125	Mean (SD) age 57.9 (11.6)	22.40%	Not specified	Some concerns
12	Hou	The Effectiveness and Safety of Utilizing Mobile Phone-Based Programs for Rehabilitation After Lumbar Spinal Surgery: Multicenter, Prospective, Randomised Controlled Trial	2019	Adults recovering from recent spinal surgery in China	168	Mean (SD) age intervention group 51.11 (9.54) Mean (SD) age control group 49.36 (9.52)	53.60%	Yes	Some concerns

13	Irvine	Mobile-Web App to Self-Manage Low Back Pain: Randomised Controlled Trial	2015	Adults at risk of Chronic low back pain due to a recent episode of sub-acute non-specific low back pain in the U.S.A.	597	Age range 18-65 (actual mean age of those recruited not stated)	60%	Not specified	High
14	Kazemi	The effectiveness of social media and in-person interventions for low back pain conditions in nursing personnel (SMILE)	2020	Nurses with occupational low back pain, without a specific back pain diagnosis (i.e., Non-specific back pain) in Iran	180	Mean (SD) age intervention group 37 (5.74) Mean (SD) age in-person group 36 (5.84) Mean (SD) age control group 36.98 (7.80)	100%	Yes	High
15	Krein	Pedometer-Based Internet-Mediated Intervention for Adults with Chronic Low Back Pain: Randomised Controlled Trial	2013	Adults with chronic low back pain in the U.S.A	229	Mean (SD) age intervention group 51.2 (12.5) Mean (SD) age control group 51.9 (12.8)	Intervention group 11% Control group 14%	Yes	Some concerns
16	Licciardone	Feasibility Trial of an ehealth Intervention for Health-Related Quality of Life: Implications for Managing Patients with Chronic Pain During the COVID-19 Pandemic	2020	Adults with chronic low back pain in the U.S.A	102	Mean (SD) age intervention group 51.3 (13.7) Mean (SD) age control group 50.7 (13.0)	Intervention group 81% Control group 88%	Not specified	Some concerns
17	Lorig	Can a Back Pain Email Discussion Group Improve Health Status and Lower Health Care Costs? A Randomised Study	2002	Adults with non-specific low back pain in the U.S.A	580	Mean age intervention group 46 Mean age control	Intervention group 38% Control group 39%	Yes	Some Concerns

						group 45			
18	Petrozzi	Addition of MoodGym to physical treatments for chronic low back pain: A randomized controlled trial	2019	Adults with chronic non-specific low back pain in Sydney, Australia	108	50.4 (13.6)	50%	Yes	Some concerns
19	Priebe	Digital treatment of back pain versus standard of care: The cluster randomised controlled trial, Rise-uP	2020	Adults with non-specific low back pain lasting up to 12 weeks in a primary care setting in Germany	1245	Mean (SD) age intervention group 42.0 (12.4) Mean (SD) age control group 37.0 (12.6)	Intervention group 65% Control group 64%	Not specified	High
20	Riva	Interactive Sections of an Internet-Based Intervention Increase Empowerment of Chronic Back Pain Patients: Randomized Controlled Trial	2014	Adults with chronic lower back pain in Switzerland	51	Mean (SD) age intervention group 44 (13.6) Mean (SD) age control group 51 (14.1)	Intervention group 51.9% Control group 50.0%	Not specified	High
21	Sander	Effectiveness of a Guided Web-Based Self-Help Intervention to Prevent Depression in Patients with Persistent Back Pain. The PROD-BP Randomized Clinical Trial	2020	Adults with Chronic low back pain and co-morbid mild-moderate depression in Germany	295	Mean (SD) age 52.8 (7.7)	62.40%	Not specified	Some concerns
22	Shebib	Randomized controlled trial of a 12-week digital care program in improving low back pain	2018	Adults with low back pain for at least 6 weeks in the last 12 months, working in 12 participating employing	177	Mean (SD) age 43 (11)	41%	Not specified	Some concerns

				organisations in the U.S.A.					
23	Schlicker	A Web and Mobile-Based Intervention for Comorbid, Recurrent Depression in Patients with Chronic Back Pain on Sick Leave (Get.Back): Pilot Randomized Controlled Trial on Feasibility, User Satisfaction, and Effectiveness	2020	Adults with chronic back pain and at least moderate depressive symptoms recruited via a health insurance provider in Germany	76	Mean (SD) age intervention group 51.3 (8.60) Mean (SD) age control group 50.1 (7.00)	Intervention group 65% Control group 81%	Not specified	Some concerns
24	Suman	Effectiveness and cost utility of a multifaceted e-Health strategy to improve back pain beliefs of patients with non-specific low back pain: A cluster randomised controlled trial	2019	Adults with low back pain of up to 3 months duration in The Netherlands	779	Mean (SD) age intervention group 55.7 (13.9) Mean (SD) age control group 56.6 (14.6)	Intervention group 59% Control group 57%	Yes	Low
25	Toelle	App-based multidisciplinary back pain treatment versus combined physiotherapy plus online education: a randomized controlled trial	2019	Adults with non-specific low back pain (duration of 6 weeks to 12 months) in a primary care setting in Germany	101	Mean (SD) age intervention group 41 (10.6) Mean (SD) age control group 43 (11)	Intervention group 72.9% Control group 67.4%	Yes	High

26	Yang	Smartphone-based remote self-management of chronic low back pain: A preliminary study	2019	Adults with chronic low back pain in Hong Kong	8	Mean (SD) age intervention group 35 (10.93) Mean (SD) age control group 50.33 (9.29)	50%	Not specified	High

Risk of bias

A summary of the risk of bias assessment can be found in Figure 2.2 below.

Nine RCTs were given an overall rating of 'high risk of bias' (Buhrman et al., 2004; Chiauzzi et al., 2010; Carpenter et al., 2012; Riva et al., 2014; Irvine et al., 2015; Toelle et al., 2019; Yang et al., 2019; Priebe et al., 2020; Kazemi et al., 2021), 16 RCTs were rated as 'some concerns' and one was rated as 'low risk of bias' (Suman et al., 2019). It is important to note that inability to blind participants in 25 of the 26 RCTs meant that domain four of the ROB-2 tool had to be scored as 'some concerns' as participants would have been aware of group allocation when completing the patient reported outcome measures (Higgins et al., 2019).

Figure 2.2 Overview of risk of bias assessment

STUDY AUTHOR	EXPERIMENTAL	COMPARATOR	OUTCOME	D1	D2	D3	D4	D5	OVERALL
ALMHDAWI	Relieve my back app	Placebo app content	VAS, ODI	+	!	+	+	!	!
AMORIM	Health coaching supported by fitbit and app	Physical activity booklet and advice to increase PA levels	Care-seeking, pain, activity limitation	+	+	!	!	+	!
BAUMEISTER	eSano BackCare-D internet and mobile based CBT based intervention	Treatment as usual	NPRS, ODI	+	+	!	!	+	!
BUHRMAN (2004)	Web-based CBT with weekly telephone support	Waiting list control	NPRS, PAIRS	+	-	!	!	!	-
BUHRMAN (2011)	Web-based CBT treatment	Waiting list control	NPRS	+	+	+	!	!	!
CARPENTER	Web-based CBT intervention	Waiting list control	Pain intensity and RMDQ	!	-	-	!	!	-
CHHABRA	Snapcare app	Written HEP prescription from physician	NPRS, Modified ODI	+	+	+	!	!	!

CHIAUZZI	painACTION Back Pain Website	Back pain guide was emailed to participants	BPI, ODI, Global rating of perceived improvement	!	-	-	!	!	-
DEL POZO-CRUZ	Daily emails with links to online content including video-based educational content and a daily exercise program.	Usual access to employer preventative medicine website	RMDQ	+	+	+	!	!	!
GERAGHTY	Internet-based intervention/internet-based intervention plus telephone support from physiotherapist	Usual primary care treatment for LBP	RMDQ, NPRS, Pain index	!	+	+	!	+	!
HEAPY	Interactive voice response-delivered CBT for veterans with LBP	In-person CBT	NPRS, RMDQ, SF-36	+	+	+	!	!	!
HOU	E-health intervention - patient app and clinician web-based interface to support rehab after spinal surgery	Usual care	VAS for pain severity, ODI	+	+	!	!	!	!
IRVINE	FitBack mobile website	Email links to resources about LBP management	Pain, function	!	+	-	!	-	-
KAZEMI	Social media-based education for occupational LBP	In-person education for occupational LBP	VAS, Quebec back pain disability scale	+	-	-	!	!	-

KREIN	Wearable pedometer with online submission of data plus access to website and online peer support forum	Wearable pedometer with online submission of data	RMDQ and MOS	!	+	+	!	!	!
LICCIARDONE	HRQoL reports provided via the SPADE cluster of the PROMIS-29 system	Waiting list control	SPADE cluster score, NPRS, RMDQ	!	+	+	!	+	!
LORIG	E-mail discussion group	Usual care plus non-health-related magazine subscription	0-10 Visual numerical scale, RMDQ	!	+	!	!	!	!
PETROZZI	Up to 12 sessions of physiotherapy/chiropractic treatment plus access to the MoodGym online educational resource	Up to 12 physiotherapy/ chiropractic sessions only	RMDQ, NPRS	+	+	+	!	+	!
PRIEBE	RISE-up multimodal intervention combining E-health and M-health	Treatment as usual guided by German national back pain guidance	Pain intensity	!	-	-	!	!	-
RIVA	ONESELF website - active version with interactive features	Modified version of the ONESELF website with only static content such as info library	Pain burden	!	-	-	+	!	-
SANDER	eSano BackCare-DP	Treatment as usual in line with German national back pain guidance	NPRS, ODI	+	+	+	!	+	!

SHEBIB	12 week digital care program - tablet-based app for adults with LBP. Included educational content, exercises with accompanying bluetooth sensors to be worn on the back, access to a health coach via email and in-app messaging. In-app symptom logging	Access to 3 of the educational articles from the digital care program only	Korrf pain score, Korrf disability score, ODI, VAS pain, VAS pain interference	!	+	+	!	+	!	
SCHLICKER	Modifed version of the eSano BackCare-D (Get.Back)	Waiting list control	NPRS and ODI	+	+	+	!	!	!	
SUMAN	Multifacted e-health intervention including educational website, educational video content and social media platforms	Access to a digital patient information letter	BBQ, RMDQ, (EQ-5D)	+	+	+	+	+	+	
TOELLE	Kaia app, including educational content, video content, tailored physiotherapy exercise program, and pushed daily content	Standard physiotherapy treatment in line with national and international guidance and email links to online education content about LBP	Pain intensity, pain index, HFAQ, VR-12P	-	!	!	!	+	-	

YANG	4 weeks of physiotherapy supplemented with use of the BackCare app to remind participants to do their exercises 4 x daily	4 weeks of physiotherapy only	Pain VAS, RMDQ, SF-36	

Table 2.3 Overview of intervention content, behaviour change techniques identified, and findings

Study Number	Author	Year	Category of intervention	Behaviour-change techniques identified (Coded using The Behaviour change taxonomy version 1. Michie et al (2013))	Do the study findings indicate a positive effect of the intervention on pain compared to control using the selected outcome measures at final follow-up? Yes/No	Do the study findings indicate a positive effect of the intervention on disability compared to control using the selected outcome measures at final follow-up? Yes/No
1	Almhdawi	2020	Mobile app	Body changes Demonstration of the behaviour [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues	Yes	Yes
2	Amorim	2019	Multimodal intervention: ● Educational booklet ● Input from health coach ● Mobile app	Action planning Feedback on behaviours Goal setting [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Review behaviour goals Self-monitoring of behaviour Social support	No (NB. Feasibility and pilot study therefore may not have been powered to detect meaningful between-group difference)	No (NB. Feasibility and pilot study therefore may not have been powered to detect meaningful between-group difference)
3	Baumeister	2020	Multimodal intervention: ● Input from HCP ● Optional motivational text messages	Feedback on behaviour [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues	No (effect no longer detectable at 6-month follow-up)	No (effect no longer detectable at 6-month follow-up)

			● Website/online educational platform (accessible via computer or mobile device)	Reduce negative emotions		
4	Buhman	2004	Multimodal intervention: ● Email interaction with HCP ● Telephone interaction with HCP ● Website	Feedback on behaviour Goal setting Instructions on how to perform a behaviour Reduce negative emotions Social support	No	N/A No specific measure of physical function alone undertaken
5	Buhrman	2011	Multimodal intervention: ● CBT website ● Email interaction with HCP	Feedback on behaviours Instructions on how to perform a behaviour Prompts and cues Reduce negative emotions Social support (general)	No	No
6	Carpenter	2012	Website/online educational platform	Demonstration of a behaviour [Information about] health consequences Instructions on how to perform a behaviour Reduce negative emotions	No	Yes
7	Chhabra	2018	Multimodal intervention: ● Input from HCP ● Mobile app	Body changes Demonstration of the behaviour Feedback on behaviours Goal setting Instructions on how to perform a behaviour Prompts and cues Reward completion Self-monitoring of behaviour	No	Yes
8	Chiauzzi	2010	Website/online educational platform	Feedback on behaviour [Information about] health consequences Instructions on how to perform a behaviour Reduce negative emotions	No	No

9	Del Pozo-Cruz	2012	Website/online educational platform	Body changes [Information about] health consequences Instructions on how to perform a behaviour Monitoring of behaviour Prompts and cues Self-monitoring of behaviour	N/A No specific pain measure reported	Yes
10	Geraghty	2018	Group 1 – Multimodal intervention: ● Web-based intervention ● Weekly email reminders Group 2 – Multimodal intervention: ● Telephone input from a Physiotherapist ● Web-based intervention ● Weekly reminder emails	Group 1 – Body changes Demonstration of the behaviour Feedback on behaviour Goal setting [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Group 2 – Body changes Demonstration of the behaviour Feedback on behaviour Goal setting [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Social support (general)	No (NB. Feasibility study therefore may not have been powered to detect meaningful between-group difference)	No (NB. Feasibility study therefore may not have been powered to detect meaningful between-group difference)
11	Heapy	2017	Multimodal intervention: ● Educational manual ● Input from a HCP ● Interactive voice response technology	Feedback on behaviour Feedback on outcomes of behaviour [Information about] health consequences Instructions on how to perform a behaviour Self-monitoring of behaviour Self-monitoring of outcome of behaviour	No	No

12	Hou	2019	Multimodal intervention: ● Input from HCP ● Mobile app connected to online platform	Body changes Demonstration of the behaviour Feedback on behaviour Feedback on outcomes of behaviour [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Self-monitoring of behaviour Social support (general)	Yes (At 24-month follow-up only)	Yes (At 24-month follow-up only)
13	Irvine	2015	Multimodal intervention: ● CBT website/online educational platform ● Email reminders	Demonstration of the behaviour Feedback on behaviours [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Reducing negative emotions Self-monitoring of behaviour Self-monitoring of outcomes of behaviour	Yes (At 4-month follow-up)	Yes
14	Kazemi	2020	Social media platform used for information provision	[Information about] health consequences Instructions on how to perform a behaviour Prompts and cues	Yes	Yes
15	Krein	2013	Website/online educational platform	Body changes Demonstration of the behaviour Feedback on behaviour Goal setting [Information about] health consequences Instructions on how to perform a behaviour Monitoring of behaviours Prompts and cues Social support	No	No

16	Licciardone	2020	Delivery of health-related quality of life report via an online platform	Feedback on outcomes of behaviour	No (NB. Feasibility study therefore may not have been powered to detect meaningful between-group difference)	No (NB. Feasibility study therefore may not have been powered to detect meaningful between-group difference)
17	Lorig	2002	Multimodal intervention: ● Email discussion forum moderated by HCPs (HCP input) ● Book and video tape providing information about low back pain	Body changes Demonstration of the behaviour [Information about] health consequences Instructions on how to perform the behaviour Social support	Yes	Yes
18	Petrozzi	2019	Multimodal intervention: ● Input from research assistant to encourage adherence to online program ● Website/online educational platform	[Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Reduce negative emotions (Possible reward depending on nature of gamification)	No	No
19	Priebe	2020	Multimodal intervention: ● Mobile app ● Online platform accessible to HCP ● Teleconsultation between HCPs to facilitate optimal treatment	Body changes Demonstration of the behaviour [Information about] health consequences Instructions on how to perform a behaviour Self-monitoring of outcomes of behaviour	Yes	N/A No specific measure of physical function alone undertaken

20	Riva	2014	Website/online educational platform	Activity planning Body changes Demonstration of the behaviour Goal setting [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues (Possible reward depending on nature of gamification)	No (Where pain burden is used as a composite measure of pain and pain interference)	No (Where pain burden is used as a composite measure of pain and pain interference)
21	Sander	2020	Multimodal intervention: ● CBT website/online educational platform (accessible via computer or mobile device) ● Input from HCP	Feedback on behaviour [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Reduce negative emotions Social support (general)	No	Yes
22	Shebib	2018	Multimodal intervention: ● Bluetooth motion sensors to be worn whilst undertaking back exercises Input from health coach ● Tablet app ● Input from health coach	Body changes Feedback on behaviour Feedback on outcomes of behaviour [Information about] health consequences Instructions on how to perform a behaviour Reduce negative emotions Self-monitoring of outcomes of behaviour Self-monitoring of behaviour Social support (general)	Yes	Yes
23	Schlicker	2020	Multimodal intervention: ● CBT website/online educational platform (accessible via computer or mobile device) ● Input from HCP	Feedback on behaviour [Information about] health consequences Instructions on how to perform a behaviour Prompts and cues Social support (general)	No (NB. Feasibility study therefore may not have been powered to detect meaningful	No (NB. Feasibility study therefore may not have been powered to detect meaningful

					between-group difference)	between-group difference)
24	Suman	2019	Multimodal intervention: ● Digital newsletter ● Use of social media for information provision ● Website	Demonstration of the behaviour [Information about] health consequences Instructions on how to perform a behaviour Social support (general)	N/A No specific measure of pain intensity reported	No
25	Toelle	2019	Mobile app	Body changes Demonstration of the behaviour [Information about] health consequences Instructions on how to perform a behaviour Self-monitoring of outcomes of behaviour	Yes	No
26	Yang	2019	Mobile app	Prompts and cues Self-monitoring of behaviour Self-monitoring of outcomes of behaviour	No (A significant difference was seen when measured using the bodily pain subscale of the SF-36, but not the VAS)	No

Table 2.4 Full details of RCT interventions and comparators reported according to the TIDieR guidance

Author	Year of publication	TIDieR checklist item	Description of the RCT intervention (NB. Where the relevant information was not available in the published paper or supplementary online material, the item was marked with the letters 'NR' to signify that the information was not reported)	Description of the comparator
Almhdawi	2020	Brief name	Relieve my back; a tailored smartphone application for those with low back pain	Placebo version of the app. All processes and procedures were identical to the intervention group except that the placebo version only included posts of general nutrition advice in the first section along with four notifications (sound and vibration along with an instruction pop-up screen) containing nutritional facts that would pop up through the day and were not related to low back pain management
		Why	The intervention aimed to provide lower back pain self-management advice and information with the aim of improving pain, disability, mental health, sleep quality, and health-related quality of life	
		What	Tailored smartphone application. The app contained self-management advice included general advice and instruction, office-based stretching exercises and home-based strengthening exercises for lower back and abdominal muscles. Furthermore, the version of the app received by the intervention group had four phone notifications (sound and vibration along with instruction pop-up screen) through the day to notify participants to take a walk break, a reminder of the right posture, a reminder of the stretching exercises and a reminder of the home-based exercises in the evening	
		Who provided	The link for downloading 'Relieve my back' was sent to participants by a member of the research team	
		How	Self-management advice was delivered via a tailored smartphone app. Participants accessed the smartphone app software via the download link provided	
		Where	The smartphone application could be accessed at any location of the participants' choosing	
		When and how much	The participants were asked to use the app for six weeks, but the frequency of recommended app use within that 6-week period is not documented in the published paper	

		Tailoring	The intervention is referred to as a tailored smartphone app, but the degree of personalisation or the detail of which specific aspects of the app were able to be personalised is not detailed in the published paper	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	Average daily usage of the intervention (in minutes) was reported using Google Firebase logs (logs of user engagement data), however, as the frequency at which the intervention was recommended to be used was not reported, it is not possible to comment on intervention adherence. The average daily usage in minutes for the intervention group was six minutes and forty seconds	
Amorim	2019	Brief name	IMPACT app (part of a multimodal intervention)	The control group received the 'Make your move – Sit less, be active for life!' booklet (based on Australian Government recommendations for physical activity exercise) and brief advice to stay active which was delivered right after baseline completion and before randomisation by a study investigator
		Why	This multimodal intervention aimed to improve back pain self-management by combining health coaching (based on behavioural theory), provision of self-management advice via the use printed educational materials, and a mobile web application designed to monitor physical activity goals and record goal attainment in order to improve pain, disability, and care-seeking in those with low back pain	
		What	Participants in the intervention group received the following: • Printed information booklet containing back pain education and self-management advice • Input from a health coach, that included a home-based face-to-face initial coaching session lasting 1-2 hours, that included motivational interviewing and solution-focused goal setting, in addition to fortnightly telephone calls to monitor goals and review goal progress • Use of the IMPACT app which is a mobile web application designed to allow users to record their levels of physical activity and to record their goal progress. The information entered into the app by the users was visible to the health coaches and they used this to direct their coaching sessions. Personalised messages were also sent from the health coaches to the users via the app on a weekly basis	

		Who provided	Three health coaches with professional backgrounds in physiotherapy and exercise physiology delivered the intervention	
		How	The health coaching was delivered during one face-to-face session plus 12 fortnightly telephone-based sessions. Access to the mobile web app was provided by the study team – the details of access was not given in the published paper	
		Where	The intervention was delivered to people with chronic low back pain after discharge from treatment from hospitals and the general community in Sydney and its surrounding area, Australia. The telephone-based health-coaching sessions and access to the mobile web application could take place at any location of the participants' choosing.	
		When and how much	The face-to-face assessment and interview occurred at the beginning of the intervention period and lasted for approximately 2 hours. The telephone-based health coaching occurred after the face-to-face assessment and interview, once every 2 weeks for approximately 20 min for a total duration of 6 months. The mobile web application was also used for 6 months	
		Tailoring	The physical activity plan was tailored to participant goals, current physical ability, and preferences. Details of personalisation of the mobile web application is not given in the published paper	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	No measures of adherence to use of the mobile app were reported in the published paper	
Baumeister	2020	Brief name	eSano BackCare-D	The comparator group had unrestricted access to local healthcare services, but there was no defined protocol for treatment as usual.
		Why	This internet and mobile-based intervention was developed to deliver cognitive behavioural therapy (CBT)-based self-management to participants with low back pain and co-morbid depression. The rationale for the intervention was that CBT has shown some promise as an effective treatment for individuals with low back pain, but the availability and accessibility of psychotherapeutic interventions is often limited: delivering	

			the intervention via a digital platform allows greater reach and reduces the clinical time-burden.	
		What	eSano BackCare-D is a guided self-help internet and mobile-based intervention (IMI) based on CBT with six regular and three optional sessions, including (homework) assignments, exercises, and two booster sessions following the intervention. eSano BackCare-D focuses on psychoeducation, behaviour activation, and problem-solving as well as including pain-specific content on psychoeducation, coping and acceptance, physical activity, and communication with health care professionals. Additional optional sessions target sleep, partnership and sexuality, and return to work. Individuals could choose to receive the booster sessions 2, 4, or 6 weeks after the last regular session. They aimed at encouraging participants to reflect on changes and to update and continually practice their intervention plans. Participants were given the option to receive motivating automated text messages (the frequency and content of these messages is not described). During the intervention period, participants received semi-structured written feedback after completion of each online session from trained and supervised psychologists (eCoaches) plus contact on-demand (via the platform). eCoaches sent reminders when session completion was overdue. The intervention was provided using Minddistrict (www.minddistrict.com), a password protected, secured platform	
		Who provided	The feedback to participants was provided by trained and supervised psychologists (eCoaches) via the online platform. Access to the platform was provided to participants by a member of the study team	
		How	The CBT-based intervention was delivered via an online platform that is accessible via any smartphone, tablet, laptop, or desktop computer	
		Where	The online sessions could be accessed at any location of the participants' choosing	
		When and how much	Participants were advised to complete one session per week (for 6-9 weeks) and the mean completion time for each session was 54 minutes (SD 23.7 minutes)	

		Tailoring	No tailoring of the informational content was detailed, however, the feedback from the online eCoaches was described as semi-standardised, suggesting some degree of personalisation. The degree of personalisation is, however, not described	
		Modifications	There were no stated modifications during the study period	
		How well	Treatment adherence (i.e., completion of each online session) was reported as follows: 78% completed the first, 71% the second, 65% the third, 63% the fourth, 58% the fifth, and 55% the final module	
Buhrman	2004	Brief name	Internet-based self-management with telephone support	Waiting list control
		Why	Supported self-management has shown promise as a potential management strategy for low back pain. Delivering the intervention using online methods, affords greater reach of the intervention and reduces clinical time-burden.	
		What	The treatment model was mainly derived from a cognitive-behavioural model of chronic pain. The pain management program used in the study was derived from the cognitive-behavioural literature, and included psychological components (e.g. dealing with unhelpful thoughts and beliefs, changing focus) as well as stretching and physical exercises. Participants were taught different coping strategies, which was the main component of the program. The aim was to identify more active ways of coping with their pain and to improve their level of functioning. Participants were also offered a program of applied relaxation. The programme was broken down into eight weekly segments: In week one, participants recorded their daily pain levels via daily pain diaries. In weeks two to seven, participants engaged with online information content related to the topics described above, in addition to a weekly telephone session with a therapist where topics could be discussed, questions asked, and activity goals set. Then in week eight, participants once again monitor their pain levels daily.	
		Who provided	The telephone support was provided by post-graduate psychology students trained in CBT. These were supervised by a qualified clinical psychologist.	
		How	Weekly segments of informational content were delivered via a password-protected online platform.	

			Telephone support was provided once per week via the participants' preferred telephone number (landline or mobile). Participants were encouraged to provide information about their progress with the treatment to their therapist weekly, via email.	
		Where	The internet-based content and telephone support could be accessed at any location of the participants' choosing.	
		When and how much	The six segments of informational content were delivered on a weekly basis to participants. Participants were encouraged to send information about their treatment to their therapists weekly, via email. The approximate duration of each telephone call was not reported. The approximate time required to complete each online session was not reported.	
		Tailoring	The content of the telephone calls was tailored to everyone's goals and progress, and to address individuals' questions. No tailoring of the online content is reported.	
		Modifications	There were no stated modifications during the study period	
		How well	No measures of treatment adherence are reported. The therapists were supervised by a qualified clinical psychologist to ensure the telephone support was delivered as intended.	
Buhrman	2011	Brief name	Internet-based cognitive behavioural therapy with email support	Waiting list control
		Why	Supported self-management has shown promise as a potential management strategy for low back pain. Delivering the intervention using online methods, affords greater reach of the intervention and reduces clinical time-burden.	
		What	During the treatment, participants followed a scheduled programme of online learning and submitted weekly reports on treatment progress and homework assignments via email. Reminders were sent to participants when reports on progress were not delivered as expected. The intervention was a self-help management programme administered via the Internet. The programme was based on a cognitive behavioural model of chronic pain and was derived from the CBT literature on chronic pain. Participants were instructed to test and practice different coping strategies, such as relaxation, cognitive skills, stress management, as well as stretching	

			and physical exercise techniques, on an individualized graded activity basis with structured instructions. The text was divided into 8 modules.	
		Who provided	The therapists involved were 4 clinical psychologists with experience in behavioural medicine who were trained in CBT.	
		How	Educational content was delivered via a password-protected online platform. Feedback from, and questions to therapists were exchanged via email.	
		Where	Participants could access the online content from a location of their choosing.	
		When and how much	The online educational content consisted of 8 weekly modules. The estimated time for the completion of each was not reported. All treatment contact with participants was via e-mail. The therapist responded to questions and provided feedback and encouragement on a weekly basis. Approximately 10–15 minutes per week was spent on each participant, giving a total maximum e-mail correspondence time of 7 × 15 min (105 min), as the last treatment module did not contain any homework to submit for the therapist to feedback on	
		Tailoring	Feedback from therapists was tailored to individual participants dependent upon their questions and progress Tailoring on online informational content was not reported	
		Modifications	There were no stated modifications during the study period	
		How well	No measure of treatment adherence was reported. No measure of treatment fidelity was reported.	
Carpenter	2012	Brief name	'Wellness workbook' – this is described as an interactive web-based self-help intervention	Waiting list control
		Why	Self-help interventions have shown promise in the management of Chronic low back pain (CLBP) and internet-based self-help interventions had been shown to be effective for other chronic pain conditions such as headache and RA, therefore the rationale for this intervention was to try to deliver a self-help intervention to those with CLBP via the internet to improve the reach of interventions and reduce the burden of treatment for users and clinicians	

		What	Wellness Workbook consisted of six sequential chapters comprising 189 pages: 1. Introduction. Defines chronic pain, describes differences between acute and chronic pain. 2. All About Pain. Defines pain and its functions and introduces a mind/body treatment rationale. It includes a summary and description of a variety of approaches to pain treatment and ends with a justification for taking a biopsychosocial approach to pain management. 3. Thoughts and Pain. Presents the rationale for intervening with thoughts to affect pain and mood and delivers skills training for increasing awareness of thinking patterns, evaluating thoughts, disputing and replacing thoughts, and cognitive reframing as well as training in accepting and disregarding thoughts. 4. Stress and Relaxation. Presents a rationale for the use of stress management as a pain management strategy and offers skills training in diaphragmatic breathing and instruction on how to use breathing as a stress management tool during daily life. 5. Getting Active. Teaches behavioural activation and includes emphases on increasing physical activity, values clarification, and pleasant events scheduling as well as goal setting training and motivation. 6. Relaxation and Meditation. This chapter includes examples of longer (15 to 20 minutes) relaxation exercises such as progressive muscle relaxation, guided imagery exercises, and mindfulness meditation. To maximize participant engagement and learning, a variety of instructional modalities were incorporated: • Didactic instruction. Text and graphics supplemented by audio narration. • Animation. Information is presented in animated pictorial format. • Patient stories • Reflective exercises. Users are asked a question and respond by typing their answer in a text box. • Interactive exercises. Users are asked to interact with material presented on the computer. • Guided relaxation and meditation exercises.	

			Therapeutic content was drawn from established and empirically-supported cognitive and behavioural strategies, including cognitive therapy, behavioural activation, acceptance and commitment therapy, and mindfulness-based stress reduction.	
		Who provided	Access to the Wellness Workbook online platform was provided by study staff.	
		How	The Wellness Workbook is an online educational platform used to deliver back pain education and CBT, this was accessed by study participants	
		Where	Participants could access the website from a location of their choosing as long as they had access to the internet	
		When and how much	The intervention lasted 3 weeks; participants were encouraged to complete 2 chapters of Wellness Workbook content per week	
		Tailoring	No tailoring on online content was described in the published paper	
		Modifications	There were no stated modifications during the study period	
		How well	81% of participants completed all six chapters. The percentage of participants completing each chapter ranged from 84% (Chapter 5) to 94% (Chapter 1)	
Chhabra	2018	Brief name	'Snapcare app'; a smartphone app to support the self-management of LBP	Written prescription of exercises from their treating clinician; not further details given
		Why	M-health interventions are a convenient way of delivering rehabilitation services without the need for in-person clinic visits. This intervention was developed to deliver self-management advice to individuals with LBP in a convenient format	
		What	Written prescription of exercises from a physician in addition to access to the Snapcare app. Through the Snapcare app, patients received daily activity goals (including back and aerobic exercises), which were developed based on the health status, ADL, and daily activity progress data entered into the app. Participants were also advised to continue with their medicines as usual. The app intervention was aimed at motivating, promoting, and guiding the participants to increase their level of physical activity and exercise adherence.	

			Daily achievable physical activity goals (including home exercises) were set, working towards a general long-term goal of 4 km daily walking and 2 sets daily of 7 back exercises which were set for all patients by the advising physician. Performance against goals was monitored, and intelligent reinforcement was provided via auto-generated app notifications and reminders prompted by data deviations. Goal attainment was assessed by comparing the records of actual daily physical activity with the target set. This information was also available to the patients at the end of each session of aerobic and home exercises. Snapcare used gamification to increase engagement as well as compliance with the prescribed activity plan, through a system of rewards for each action completed and every milestone achieved	
		Who provided	Exercise recommendations were provided by the participants' treating physician. Access to the app was provided by study staff.	
		How	Face-to-face assessment with the treating physician at the start of the study. Snapcare app was then accessed via the user's mobile device	
		Where	Screening appointment/initial study visit took place in an orthopaedic outpatient department in New Delhi. The Snapcare app could be accessed at any location of the participants' choosing via their mobile device	
		When and how much	Participants were encouraged to engage with the Snapcare app daily over a 12-week period	
		Tailoring	Activity recommendations and daily activity goals were personalised for each user based on the activity data entered into the app	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	No measure of treatment adherence or fidelity were reported in the published paper	
Chiauzzi	2010	Brief name	painACTION-Back Pain: A Self-Management Website for People with Chronic Back Pain	The control group participants were e-mailed a

		Why	CBT-based approaches have shown to be effective in reducing outcomes such as catastrophising, disability and pain coping in those with LBP, however, these approaches are limited due to the limited number of trained staff and the cost of service delivery. Web-based interventions may be able to improve this situation by making CBT more readily accessible to those with CLBP	back pain guide (National Institute of Neurological Disorders and Stroke) after baseline. The guide is typical of what is given to patients and covers topics such as the structure of the back, causes and associated conditions, treatments, prevention, practical tips, and additional resources. Control participants were asked to read the guide over a 4-week period
		What	The pain-ACTION Back Pain website is based on CBT and self-management principles, and includes components that help people cope with chronic low back pain: 1) Collaborative decision-making with health professionals 2) CBT to improve self-efficacy, manage thoughts and mood, set clinical goals, work on problem-solving life situations, and prevent pain relapses (3) Motivational enhancement through tailored feedback (4) Wellness activities to enhance good sleep, nutrition, stress management, and exercise practices.	
		Who provided	Study staff provided access to the painACTION-Back Pain website to participants via email	
		How	The website was accessed via an internet-connected device such as a tablet, laptop, or desktop computer It is implied that the tailored feedback is received by participants via the online platform, but this is not explicitly stated. It also not clear if the feedback is manually tailored by the study staff, or whether this is automatically generated by the platform based on data entered by the participant	
		Where	The website could be accessed at any location of the participants' choosing via an internet-connected device	
		When and how much	Participants in the Website condition were instructed to log onto the painACTION-Back Pain study Website, in their own environment, for two weekly sessions across 4 weeks (total = 8 sessions). Participants were asked to spend at least 20 minutes in each session and were able to spend a longer time if they wished	

		Tailoring	Information is tailored through a recommendation engine that matches self-reported user characteristics to lessons, interactive tools, personalized assessments, and articles	
		Modifications	There were no stated modifications during the study period	
		How well	Following each session, participants reportedly completed an online session log that required completion of a checklist of tasks linked to that session; the outcomes of this are not reported in the published paper	
Del Pozo-Cruz	2012	Brief name	Internet-based secondary prevention intervention for LBP	Access to standard institutional preventative care medicine procedures (no further detail given)
		Why	The subacute phase of LBP has been identified as a teachable moment to intervene with secondary prevention strategies for CLBP. An internet-based intervention for office workers to prevent CLBP was therefore developed to provide information and advice to workers in a convenient format.	
		What	The exercise and education information used in the treatment programme were developed as an online resource and included video demonstrations recorded in a laboratory. The resources were loaded onto a dedicated section of the University preventive medicine service website. All sessions included exercises combining postural stability (for abdominal, lumbar, hip and thigh muscles), strengthening, flexibility, mobility, and stretching. All the exercises were explained both by oral instruction and by written subtitles. Postural education reminders, addressing and promoting how best to sit at a computer and the adjustment and rearrangement of the office workstation layout were also included. A short e-mail was sent every day with a reminder message (which did not change throughout the intervention) containing a link to the online "session of the day". The sessions were structured in real-time, first playing a video of postural reminders (2 min), then a video of the exercise(s) for the day (7 min), followed by postural reminders once again (2 min). The videos were available Monday to Friday, weekly, for 9 months. Participants were asked not to perform any formal physical activity routine during the training period.	

		Who provided	Each participant was assigned a user-name and password to access the system by a member of the study team.	
		How	A daily email was sent to participants by the research team with a link to the session of the day. This link took participants to the relevant section of the University Preventative Medicine Service website. The participants then logged into the online system and watched the instructional videos	
		Where	Participants were encouraged to access the website and undertake the exercise during their office hours using their work computer	
		When and how much	Participants were sent links to content on a daily basis and were encouraged to undertake the recommended exercises on a daily basis for nine months	
		Tailoring	No tailoring of intervention content is described in the published paper	
		Modifications	There are no stated modifications to the intervention during the study period	
		How well	The authors state that compliance was high (92%) in the intervention group; they state that interaction with the online content was automatically collected by recording the number of times each participant logged into the system	
Geraghty	2018	Brief name	Internet intervention plus physiotherapist telephone support plus usual care	Comparison group 1: Access to SupportBack internet-based intervention (as described opposite) and usual care without the additional telephone support from physiotherapists
		Why	In primary care, general practitioners (GPs) are unlikely to have the time or the training to deliver effective self-management support, and access to National Health Service (NHS) such as physiotherapy is often limited, with long waiting times for patients. There is a critical need for novel interventions enabling primary care practitioners to provide their patients with LBP immediate access to evidence-based, accessible self-management advice and support. This internet-based intervention was therefore developed to meet this need.	
		What	Participants had unrestricted access to usual care, but as this was a pragmatic trial, this varied across the sample and between recruitment sites. In addition, patients received access to SupportBack, a tailored multisession internet intervention designed to support self-management of LBP. SupportBack focuses on self-regulatory processes including goal setting, self-monitoring and tailored feedback to support physical activity. There is also a focus on cognitive reassurance and self-efficacy for activity in the presence of	

			pain throughout; addressing concerns with evidence-based feedback and modelling success through patient activity stories. The intervention has 6 sessions: The first session introduces the rationale for physical activity being key in the self-management of LBP and allows patients to select goals for the next week. Each of the following five sessions consists of patients reviewing and amending their activity goals for the coming week with automatic feedback. From session 2 onwards, after the goal review, patients have access to one new module per week from the SupportBack menu. The modules on the menu focus on a broad range of LBP-related topics including: mood; managing pain at work; sleep; relieving pain through medication and dealing with flare-ups. Participants received automated weekly email reminders to log in, and any technical difficulties were addressed by the study manager. Participants also received up to a total of 1 hour of physiotherapist telephone support, split into three calls, with approximately 30min for call 1, and 15min for calls 2 and 3. The purpose of the physiotherapists' calls was to provide support and encouragement to participants to use the SupportBack internet intervention, to address participants' concerns and provide additional reassurance.	
		Who provided	Access to the SupportBack intervention was provided by a member of the study team, but participants accessed the site independently. Two senior musculoskeletal physiotherapists (male and female, NHS bands 6 and 7) provided the telephone support	
		How	Physiotherapist support provided via telephone. The SupportBack intervention was delivered via a secure online platform	
		Where	Participants could access the SupportBack intervention at any location of their choosing via any internet-connected device.	Comparison group 2: Access to usual care only. As this was a pragmatic trial, this varied between individual participants and across recruitment sites
		When and how much	It was recommended that participants completed one session of the SupportBack intervention per week for 6 weeks. The Physiotherapists' telephone calls were designed to be delivered approximately after week 1, between weeks 2–3 and after week 4.	

		Tailoring	Within the SupportBack online intervention, goal options, including gentle back exercises or walking, are automatically tailored, based on how patients report their LBP is affecting their functioning at the time. The content of the physiotherapist telephone calls was also tailored to address individual patient concerns	
		Modifications	There were no stated modifications to the interventions during the study period	
		How well	The proportion of participants who completed each online session ranged from 32% to 54%	
Heapy	2017	Brief name	Interactive voice response-delivered CBT	The comparator group for this study receive the same care as the study group except that the weekly feedback is provided in a face-to-face format by a therapist during a 30-minute session. The weekly module content (as provided in the handbook) is also discussed at this session. No further detail is provided.
		Why	CBT approaches have been shown to be efficacious for people with LBP, however access to CBT is often limited. Using telephonic technology such as interactive voice response many be a useful way of increasing reach of and access to CBT for individuals with LBP.	
		What	Participants receive a handbook containing information organised into 10 treatment modules, designed to be delivered over 10 weeks. Each week, participants are assigned a daily skill practice goal that corresponds to the specific pain coping skill presented in treatment that week (e.g., Week 4: practice deep breathing for 5 minutes each day). The *skill practice goal* for each week is described in the patient handbook. They also participate in a paced walking programme where the daily step goal is set by the therapist and their actual step count is recorded using a pedometer (Omron Go Smart Model HJ-112 pocket pedometer). The handbooks also contain information on the IVR protocol and how this will be implemented during the study period: Starting on the first day of treatment and continuing for 70 days, participants receive daily IVR calls to answer seven daily questions that assess pain intensity, sleep quality and duration, pedometer-measured step count, catastrophizing (I worried my pain would never end", "I felt my pain was so bad I could not stand it anymore") and adherence to the current week's skill practice goal.	

			Once per week participants are asked to report: 1) any adverse events associated with the graduated walking portion of the treatment 2) any increase or decrease in pain medication dose made on the advice of their physician or their own initiative 3) how often they practiced their weekly, self-selected pleasant or meaningful activity goal and if it improved their happiness or satisfaction 4) if they continued to use any of the pain coping skills learned in prior weeks 5) their comprehension of the module material via five true/false questions about the week's pain coping skill. All of the information reported during a call is automatically captured in a database and time and date-stamped for later review by a therapist. Participants then receive weekly tailored pre-recorded therapist feedback via the IVR related to treatment engagement and goal completion reported during the previous week.	
		Who provided	Feedback is developed and recorded by a either PhD-level psychologist, or the study nurse trained and supervised by a clinical psychologist with specific competencies and experience in delivering CBT for chronic pain.	
		How	Participants in the IVR-CBT condition receive a weekly, two-to-five-minute pre-recorded personalized message from their therapist via the IVR system. On the last day of each week, participants are told that they have a message from their therapist. This message may be accessed and replayed as often as the participants want. If participants miss the call that contains the feedback message, they are prompted to listen to the message during their next call	
		Where	Participants can access the IVR system from their mobile or landline telephone, therefore the location of the intervention can be selected by the participant	
		When and how much	Daily IVR data capture. Weekly IVR therapist feedback. Weekly informational modules contained within the handbook designed to be accessed over 10 consecutive weeks	

		Tailoring	Therapist feedback is tailored to the individual based on their answers to the questions posed during the daily IVR telephone calls	
		Modifications	There are no stated modifications to the intervention during the study period	
		How well	Of those randomized, 82% completed at least 3 sessions, which was stated to constitute receiving a per-protocol "dose" of treatment Treatment fidelity was assessed by qualified clinical psychologists who listened to the tailored feedback recorded by the study therapists to ensure that all key aspects of the weekly module and key issues were discussed	
Hou	2019	Brief name	Mobile phone-based e-health programme	No specific rehabilitation program was provided to patients randomized to the usual care control group. The relevant surgeons' usual practice was still provided, including advice to keep physically active and simple instructions to train the back muscles. Analgesia and other symptomatic treatments were also provided when necessary
		Why	Access to clinic-based rehabilitation services is often limited in areas of China. A mobile-health intervention was therefore developed to address this issue and provide rehabilitation advice to individuals who had undergone spinal surgery	
		What	Participants received access to usual care in the same way as the control group. However, they also received access to the e-health intervention. The e-health intervention contained 2 interfaces: a mobile phone–based interface for patients, and a Web-based interface for doctors. Through the mobile phone-based interface, patients were able to view the rehabilitation plans made by their physicians and conduct their rehabilitation following the video instructions. In addition, patients could receive daily reports about their exercise and alerts to prompt them to return to this system. They could also communicate with their doctors through this system. Through the Web-based interface, the doctors could adjust rehabilitation plans for patients and view reports about the patients' daily exercise. The exercise program included lumbar spine stretches and basic core stability exercises (such as bridging and extension in prone lying). Prior to being provided access to the e-health intervention, participants attended 2 sessions with the study team; one to show them how to use the intervention, and one to ensure they could undertake the recommended exercises safely	
		Who provided	It is not specified who provided the training relating to the mobile phone interface for participants. It is not specified who provided training on the rehabilitation exercises.	

		How	The 2 training sessions were attended by the participants in person. The software was then downloaded to their mobile phone 3 months after surgery	
		Where	The location of the 2 in-person sessions is not specified. Participants could access the mobile-based e-health interface from any location of their choosing	
		When and how much	The software was installed onto the patients' phones 3 months after surgery. Two meetings were held to show the patients how to use this software and how to conduct the exercises, but the timing of these sessions is not specified. Participants were required to complete at least 2 months of training. Those who completed 5 or more training sessions each week were considered to have high adherence, 3 to 5 training sessions as medium adherence, and 2 training sessions and less as low adherence.	
		Tailoring	Each participant's exercise advice was tailored by their treating clinician via the clinician-facing online interface	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	Median eHealth attendance was 5 times per week (interquartile range, IQR, 4-6) at 6 months, 5 times per week (IQR 3-6) at 12 months, and 5 times per week (IQR 4-6) at 24 months postoperatively. A total of 50, 37, and 38 patients were considered as high compliance at 6, 12, and 24 months, respectively.	
Irvine	2015	Brief name	FitBack, a web-based educational self-management intervention	The control group were only contacted to complete the nominated outcome measures at 2 months and 4 months after randomisation.
		Why	The American College of Physicians recommends multi-disciplinary team (MDT) treatment for Non-specific lower back pain (NSLBP) that lasts longer than 4 weeks, but many physicians struggle to meet these requirements due to limited rehabilitation service provision. The FitBack web-based resource was therefore developed to provide physicians with a way of providing self-management advice to their patients	
		What	The intervention uses a self-tailored cognitive-behavioural approach, based on (1) expert panel and American Pain Society (APS) recommendations	

			(2) formative research in this and previous online physical activity studies with sedentary individuals (3) the theoretical benefits of behavioural control espoused in social cognitive theory (SCT) (4) the Theory of Planned Behaviour (TPB). The FitBack user experience is designed to allow users control over the cognitive and behavioural strategies they use to impact their NLBP and to develop and support users' self-efficacy related to pain management and prevention. Using a pain and activity self-monitoring tool and 'gain-framed' text and video messages, FitBack helps users develop a self-tailored approach to manage any current NLBP and activate behaviours for prevention of future NLBP. Text articles and videos are segmented to address issues and self-care activities specific to job type: people who sit most of the day (sitters), stand most of the day (standers), drive most of the day (drivers), and do a substantial amount of lifting each day (lifters). Users receive weekly emails with gain-framed pain self-care messages and prompts to return to the FitBack program to track pain and self-care activities. At each return visit, users are encouraged to report their current level of back pain using a 10-point "pain dial". Users also track their daily pain management activities using an "activity picker" populated with pain self-care activities in four categories (rest and relief, mindfulness, general fitness, and back pain-specific stretching and strength exercises). FitBack provides users with simple 7-day and 30-day graphs to identify trends in pain level as associated with each category of self-management activity. Users have unlimited access to 30 brief (1-4 minute) videos on general aspects of pain and pain management, cognitive and behavioural strategies	

			to manage and prevent pain, and instructional videos on specific strength and stretching exercises tailored by job type.	
		Who provided	Access to the online FitBack system was emailed to participants by the study team. Participants then engaged with the FitBack online programme independently	
		How	FitBack is a web-based intervention that can be accessed via any internet-connected device	
		Where	Participants could access the FitBack web-based intervention at any location of their choosing via an internet-connected device	
		When and how much	Users of FitBack were encouraged to record their pain and activity levels daily for 8 weeks	
		Tailoring	Intervention content was tailored based on the participants' reported job type (i.e., whether they mostly sit, mostly stand, or perform frequent lifting tasks)	
		Modifications	There were no stated modifications during the study period	
		How well	No measure of treatment adherence or fidelity were reported	
Kazemi	2020	Brief name	Social media-based informational resource for nurses with occupational LBP	Comparator group 1: This group were provided the same information as the social media group, except that the information was delivered in a face-to-face format, during two 60-minute sessions (the timing of these sessions and who delivered them is not detailed). This group also received weekly text messages to encourage adherence to the recommended exercise programme.
		Why	LBP in nurses is common, however, lack of time and highly pressured clinical situations mean that providing education in an in-person format can be difficult. This intervention was designed to utilise social media to deliver LBP educational information to nurses in a convenient format	
		What	Participants in the intervention group received educational content via a social media website (the specific details of the website were not reported). An educational intervention was developed based on the PRECEDE-PROCEED model. The final programme consisted of ergonomic and correct position of the spine in daily work, stretching exercises to increase flexibility, strengthening exercises to increase muscle strength, and information about the effect of LBP on quality of life. The content of the education was uploaded to the social media site on two specific days, at a specified time. Every week a reminder message was sent through social media to encourage the participants to use the social media-based information and ask if they	

			have any questions or difficulty in understanding the content. They were also encouraged to continue the exercises regularly (flexibility and strengthening exercises)	
		Who provided	The study team uploaded informational content to the social media site. The nurse participants then accessed this information independently	
		How	The educational information was delivered via social media; however, very little detail is given about the intervention in the published paper	
		Where	Participants could access the information at a location of their choosing via an internet-connected device	Comparator group 2: Control (no intervention)
		When and how much	The information was divided into two segments that were uploaded to the social media site on two separate occasions. Weekly reminders were then sent to prompt participants to engage with the information provided. The time-period over which the information content was provided was not reported	
		Tailoring	No specific tailoring of the content is described in the published paper	
		Modifications	There were no reported modifications to the intervention during the study period	
		How well	Measures of treatment adherence and fidelity were not reported	
Krein	2013	Brief name	Web-based educational resource and uploading pedometer	Usual care participants received the uploading pedometer and monthly email reminders to upload their pedometer data in the same was as the intervention group. However, they were not set any goals and did not receive any feedback. Their access to the study website was limited to completing surveys and reporting adverse events only
		Why	This intervention was developed in an attempt to deliver relatively low-cost self-management support and advice to military veterans with chronic non-specific low back pain	
		What	The study intervention, based on the Stepping Up to Health program, consisted of three primary components: (1) the uploading pedometer that recorded and allowed transfer of step-count data to the study team (2) a website that provided automated goal setting and feedback, targeted messages, and educational materials (3) an e-community accessed via the site Participants were instructed to wear their pedometer from the time they got up in the morning until they went to bed. They then received weekly email	

			reminders to upload their pedometer data, which was used to establish weekly individualized walking goals. Each participant's goal was based on their average total step count in the prior week with a fixed number of steps (800) added to promote a gradual increase in walking for the following week. The step count goal was emailed to the participant each week and posted on the study website The study website included graphical and written feedback about progress toward walking goals and contained pain or activity-related motivational and informational messages. These messages included quick tips, which changed every other day, and weekly updates about topics in the news. Back class materials, which included handouts about topics such as body mechanics, use of cold packs, lumbar rolls, and good posture, as well as a video demonstrating specific strengthening and stretching exercises were also available on the website. The e-community (or online forum) allowed participants to post suggestions, ask questions, and share stories. Research staff participated in and monitored the forum posts as well as used the forum as a venue to generate competitions to encourage meeting walking goals.	
		Who provided	The study team provided access to the web-based resource, but participants accessed the information and entered step-count data independently. It is not clear if the tailored walking goals were decided by research study staff or whether in-built algorithms were responsible for this. Study participants with access to the website could take part in the online forum discussions	
		How	The recording of step-count data, provision of educational materials and the online discussion forum were all undertaken via the web-based intervention designed for this study	
		Where	Participants could access the website from a location of their choosing via an internet-connected device	
		When and how much	Participants were sent weekly reminders to upload their pedometer data, but they could access the site as many times as they liked during the study	

			period. Updates to the advice provided on the website were performed every 2 days. This suggests that the website was intended for frequent use, but the exact frequency that participants were advised to aim for is not reported. The intervention period was 12 months.	
		Tailoring	The step goal for each participant was tailored and was based on their recorded step count from the previous week	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	Participants logged into the website at least once per week for a median of only 20 weeks (38% of the recommended time), with approximately 20% logging in for at least 42 weeks.	
Licciardone and Pandya	2020	Brief name	Health-related quality of life report	Waiting list control
		Why	Chronic pain reduces health-related quality of life (HRQoL) and self-management interventions have been shown to improve HRQoL. This intervention aimed to provide patients with a tailored report based on the scores achieved on a validated patient-reported outcome measure of HRQoL. The aim was to improve patient's understanding of how their pain was impacting on their HRQoL so that they might then be able to address the issues highlighted independently.	
		What	Participants were provided with a graphical representation of their PROMIS-29 scores alongside a guide explaining what the results mean. The guide advised participants to share the report with their treating physician so that other approaches to treatment might be discussed. Participants completed the PROMIS-29 outcome measure using an online platform, the HRQoL report was then generated and provided to the participant. It is not clear whether this was automatically generated by the online system, or whether a staff member was required to interpret the findings and write the report. It is not reported whether participants had the choice to complete the PROMs within a clinic setting or at home, whether they had staff support or not, and whether they received a physical copy of the report or an electronic copy only. Participants had unrestricted access to usual healthcare for low back pain throughout the study period	

		Who provided	Participants completed the PROMIS-29 outcome measure using an online platform, the HRQoL report was then generated and provided to the participant. It is not reported whether they had staff support or not or whether the report was automatically generated or written by a member of the research team	
		How	HRQoL report generated using results of the PROMIS-29 online PROM. How the report was generated is not reported.	
		Where	It is reported in the methods section that all but 2 of the 52 participants randomised to the HRQoL report group received their report via online delivery. These 2 aforementioned participants received their reports 'in-person' but the location or who provided them is not reported	
		When and how much	The HRQoL report was received on one single occasion following randomisation	
		Tailoring	The HRQoL reports were tailored to each individual based on the scores they enter onto the PROMIS-29 online outcome measure	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	All 52 participants randomised to the intervention group received the HRQoL report	
Lorig	2002	Brief name	Email discussion group supplemented by a back pain information leaflet and video tape	Participants in the control group received a monthly subscription to a non-health-related magazine of their choice only
		Why	This intervention was developed to combine the benefits of detailed back pain self-management information provision alongside online social support via a closed email discussion group. Patient education and social support are acknowledged as important aspects of back pain self-management, therefore this intervention uses modes of delivery that may improve reach and require less clinical time investment	
		What	The intervention included three parts: 1) A closed email discussion group which included 2 moderators and 3 content experts (a physiotherapist, a psychologist, and a physician with expertise in back pain). The moderators acted as group leaders and if there had been no activity for several days, they would prompt interaction with the	

			group by asking a question. All group members received all emails sent by all members. The discussions were all asynchronous; there was no real-time interaction. The content experts were there to answer general medical questions posed within the group, but they were not permitted to provide specific medical advice to any individual participants. Their estimated online time commitment was 2 hours per week. 2) The back pain help book was provided to all participants in the intervention group. This was based on the principles that hurt does equal harm and provided recommendations for self-management based on the Agency for Healthcare Policy and Research guidelines. 3) All participants in the intervention group received a videotape produced by Northern California Kaiser Permanente Medical. This video included patient stories and emphasised the importance of posture and walking. It was designed to provide participants with models of good back pain self-management behaviours	
		Who provided	The email discussion group included 2 moderators and 3 content experts (a physiotherapist, a psychologist, and a physician with expertise in back pain). It is not reported whether the information book and videotape were provided via post or in-person	
		How	Email discussion group supplemented by provision of a back pain self-management advice booklet and a videotape	
		Where	Email discussions occurred online. It is not reported whether the information book and videotape were provided via post to the participants' homes, or in-person at a research facility	
		When and how much	The intervention appears to have continued for at least one year, but the intervention duration is not explicitly stated. It is not stated how frequently participants were encouraged to engage with the online discussion group	
		Tailoring	Email responses from other group members and content experts were tailored based on the questions and responses posed by others. The back pain information provided was in the form of a pre-printed booklet and was therefore not tailored to individuals' needs	

		Modifications	There were no stated modifications to the intervention during the study period	
		How well	107/202 participants in the intervention group asked to be removed from the email group due to the excessive volume of emails received	
Petrozzi	2019	Brief name	MoodGYM combined with physical treatments for low back pain	
		Why	CBT interventions have been found to improve outcomes for people with low back pain, and online CBT interventions may improve accessibility of such treatments. MoodGYM is a primary and secondary prevention internet-delivered program for preventing and managing depressive symptoms in people with troublesome but not incapacitating depressive symptoms. The aim of this combined intervention was to provide training on CBT principles to people with low back pain in order to support better pain coping and to improve pain and disability	
		What	Participants in the intervention group received a combination of physical treatment modalities and access to MoodGYM. Physical treatments included manual therapy in combination with other modalities such as advice, education and exercise. Manual therapy included spinal manipulation or mobilization and/or soft tissue massage. Advice and education consisted of reassurance and advice about symptom management and encouragement to remain active. Practitioners were instructed to provide key messages that low back pain is mostly benign and self-limiting, principles of activity pacing, along with instruction on safe manual handling, and general postural advice. Participants were also advised to remain active and avoid bedrest. Exercise therapy included a specific exercise or general conditioning regimen. Specific therapeutic exercise focused on correction of strength, mobility or motor control impairments or general conditioning exercises, prescribed at the discretion of the treating practitioner. The MoodGYM program presented a combination of written information, real-life examples and quizzes, delivered within the principles of a CBT framework. Module 1 provided information about the felt experience of troubling emotions; module 2 and 3 provided CBT-based information and behavioural	

			exercises that taught participants how to adapt healthier thoughts and behaviours in daily life; module 4 provided information about psychological distress and provided behavioural coping strategies; module 5 presented interpersonal problem-solving strategies that could be used to prevent psychological distress in personal relationships. Participants were provided with a MoodGYM user manual briefly outlining the website address and how to create a personal login to the program. No further assistance was provided above and beyond what is already available to public internet users.	
		Who provided	Physical treatments were provided by a physiotherapist or Chiropractor with at least 5 years post-qualification experience	
		How	Physical treatment delivered in a clinic setting by a registered physiotherapist or chiropractor. The MoodGYM online programme was accessed online by participants independently	
		Where	Physical treatments were delivered in a clinic setting. MoodGYM was accessed by participants online at a location of their choosing	
		When and how much	Participants were instructed to work through one module per week whilst concurrently undertaking their physical treatments. Each participant received up to 12 sessions of physical treatment, the number and frequency of sessions was determined by the treating clinician	
		Tailoring	The MoodGYM programme was the same for each participant. The physical treatment schedule was determined by the treating clinician based on each individual's needs	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	All 52 participants randomised to the intervention group completed the intervention	
Priebe	2020	Brief name	Rise-uP multimodal intervention comprising treatment support for GPs and a patient-facing smartphone app	The control group were said to receive standard care for low back in Germany. Further detail of what this entails is not reported
		Why	In Germany, treatments for low back pain rarely follow national guidance. As the aetiology of back pain is thought to be multifactorial, the approach to treatment needs to address physical and psychological aspects of a patient's	

			condition. However, access to biopsychosocial treatments are often difficult to access and resources often limited. E-health interventions may offer an alternative mode of delivery for treating back pain by both supporting GPs to make appropriate treatment decisions, and by supporting patients to manage their symptoms independently. The Rise-uP intervention was therefore developed to improve patient care by supporting patients with low back pain and the GPs who treat them	
		What	The Rise-uP intervention included several key components: 1) Participants complete the Keele STarT Back tool at the start of their treatment and are classified as low, medium, or high risk for developing chronic low back pain 2) The outcome of the patient's initial consultation is documented on an electronic case report form to allow access by other members of the research team and local pain management team 3) The GPs of high-risk patients receive a teleconsultation with a pain specialist to decide the best course of action for the patient (This could include whether referral for specialist support or further investigation is recommended) 4) The GPs of participants in the intervention group had access to a treatment algorithm; This included 'clinical investigations including red and yellow flags (STarT Back score) at baseline and revisitations depending on the risk for the development of chronic back pain and clinical progress or improvement'. 5) All participants in the intervention group receive access to the Kaia smartphone app which includes an educational program, physiotherapy advice and mindfulness exercises	
		Who provided	Participants were provided access to the Kaia app by their treating GP	
		How	Participants accessed the Kaia app on their smartphones independently. GPs accessed the electronic case report form provided by the study team. Where indicated, they also undertook a virtual meeting with the pain specialist using the online platform provided by the research team	

		Where	Participants accessed the Kaia app on their own smartphone at a location of their choosing once access had been provided by their treating GP at the GP surgery	
		When and how much	Participants were encouraged to engage with the advice and physiotherapy exercises recommended via the Kaia app as frequently as possible	
		Tailoring	The advice given to participants by the GP was tailored based on the outcome of their STarT Back screening assessment. Only GPs of high-risk participants engaged in the virtual meeting with the pain specialist	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	All participants received access to the Kaia app. 28 of the 76 patients in the intervention group who were classified as high risk for developing chronic low back pain, were discussed in a virtual meeting between the GP and a pain specialist	
Riva	2014	Brief name	The ONESELF website providing back pain education and interactive features	
		Why	Self-management interventions for low back pain are recommended, and online interventions can provide self-management advice to back pain sufferers with a high reach. Interactive features are thought to increase engagement with online interventions, and increased engagement is thought to improve the likelihood of positive outcomes. The ONESELF website with interactive features was therefore developed to provide self-management support to those experiencing low back pain in an engaging way	
		What	A modified version of the original website was created, restricting access to content on chronic low back pain only. A choice of static features including the information library, the First Aid section, and a Frequently Asked Questions (FAQ) section as well as interactive features including the Virtual Gym and the Testimonials and Commentaries sections were maintained from the ONESELF website. In addition, two interactive features were newly developed and implemented: a weekly Action Plan and a Quiz Game. The weekly Action Plan required patients to select, from a predefined list, one or more physical activities of varying intensity to be completed during the week.	

			Reminder short message service (SMS) supported patients in complying with the plan. The Quiz Game was an online examination test that allowed patients to test the information learned during navigation of the website. Patients received a multiple-choice question at the end of each visited section. For every correct answer, patients earned virtual points. The sum of these points was used to classify patients in a ranking that was available to all study participants of the intervention group so that patients could see how they scored in comparison to others.	
		Who provided	Access to the ONESELF website was provided to participants via email from a member of the research team	
		How	Participants accessed the ONESELF website independently via an internet connected device	
		Where	The website could be accessed from any location of the participants' choosing	
		When and how much	Action plans were completed weekly, but it was not reported how frequently the other website features were recommended to be used	
		Tailoring	Details of intervention tailoring is not given in the published paper	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	Measures of intervention adherence or fidelity were not reported	
Sander	2020	Brief name	e-Sano Back Care-DP, which is a Web-based self-help intervention to prevent depression and relieve symptoms in those with persistent back pain	The control group received treatment as usual only. Details of this were not documented as treatment as usual varies
		Why	Depression is a frequent comorbid condition in patients with persistent back pain and is associated with substantial adverse consequences. Shifting the focus from depression treatment to preventing depression might be a viable way to reduce the disease burden of persistent back pain	
		What	The intervention group received a guided, web-based self-help intervention plus treatment as usual. Despite national guidelines on standard treatment as usual for back pain, treatment as usual after orthopaedic care varies.	

			e-Sano Back Care-DP is a guided self-help program with 6 obligatory modules and 3 optional modules (mean [SD] completion time, 43 [32] minutes per module, that is based on cognitive behavioural therapy principles. Participants could choose to receive automated motivational text messages in addition to the online program, entailing brief exercises in daily life depending on treatment progress. During the intervention, e-coaches (trained and supervised psychologists) guided the participants by giving written feedback within 24 hours after each completed module and by answering queries. The mean (SD) guidance time was 64.8 (47) minutes per completed treatment. The intervention was password-protected and accessible on a secure platform maintained by a company that specializes in web-based interventions (Minddistrict). Intervention structure: Six weekly sessions (45-60 min.) Three optional sessions on specific issues Two booster sessions within 3 months after the last session One feedback email per session Guidance by trained and supervised e-coaches (psychologists) Daily homework assignments SMS coach: daily reinforcing text-messages Information given by text and video comments by health care professionals Audio guided exercises Mandatory content: Psychoeducational information about prevention of depression Planning for regular behavioural activation Learning and training of problem-solving skills Recognition and prevention of rumination Introduction to mindfulness and acceptance Training of self-care and relaxation skills Integration of physical activity into daily life Techniques to build robust self-esteem Optional content: Healthy sleep: sleep hygiene and stimulus control	

			Partnership and sexuality: Communication skills, physical closeness and sexuality with focus on back pain specific problems Returning to workplace: Stress-regulation, interpersonal competences and physical exercises at a workplace	
		Who provided	Trained and supervised psychologists provided written feedback to participants after completion of each online module. Participants accessed the online platform and completed the modules independently	
		How	Access to the secure online platform was provided to participants by the study team. Participants then accessed this via an internet-connected device of their choosing	
		Where	The online platform could be accessed at any location of the participants' choosing	
		When and how much	The intervention consisted of 6 obligatory and 3 optional online educational modules to be completed by participants (one module per week). The modules could be repeated as many times as desired, and the intervention period was 9 weeks	
		Tailoring	The feedback given to participants by the psychologists was tailored to each individual	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	All participants randomised to the intervention group received the intervention, but completion of the online content modules ranged from 71.8% (module 1) to 8.1% (module 9)	
Schlicker	2020	Brief name	Web- and mobile-based guided self-help intervention 'Get.Back' for patients with chronic low back pain	Participants in the control group had access to the unguided intervention after study completion (waiting list control) in addition to unrestricted access to treatment as usual
		Why	Depression is a frequent comorbid condition in patients with persistent back pain and is associated with substantial adverse consequences. Shifting the focus from depression treatment to preventing depression might be a viable way to reduce the disease burden of persistent back pain. Supporting those with chronic back pain to return to work is an important part of holistic management	

		What	The Get.Back web and mobile-based self-help intervention is adapted from eSano BackCare-D to suit people on current sick leave. In addition to unrestricted access to treatment as usual, participants in the intervention group had access to the Get.Back online intervention. The online intervention is based on cognitive behavioural therapy (CBT) and consists of 7 weekly modules lasting 45 to 60 min each. Modules include information regarding psychoeducation, behavioural activation, problem solving, cognitive restructuring, return to work, self-esteem, and relapse prevention. Get.Back differs from eSano BackCare-D mainly because of content regarding returning to work. In eSano BackCare-D, return to work was included as an optional module, whereas in Get.Back, this module was integrated into the obligatory modules and was extended and improved in content. This module specifically provides stress management strategies (coping with solvable and unsolvable problems in the workplace), psychoeducational information on how to adapt the workplace to each individual's needs (e.g., ergonomic chair and desk arrangement), and relaxation and exercise information to facilitate motion and prevent pain. The return-to-work module was introduced in the fifth intervention module. The optional modules on partnership, sexuality, and sleep habits from eSano BackCare-D were also used as optional modules in Get.Back. In addition to eSano BackCare-D, the authors also included 4 optional minimodules (15 min each) on perfectionism, social support, communication, and appreciation that could be completed after module 3, 4, 5, or 6, respectively. Get.Back also included 1 booster module 4 weeks after the completion of the intervention contrary to 2 booster modules in eSano BackCare-D. Interactive elements (e.g., emails and text messages), reminders, and exercises were used to enhance adherence to the intervention	throughout their participation.
		Who provided	Participants were guided by trained psychologists, called eCoaches, who provided semi-standardised feedback via email within 2 working days after each completed module	

		How	Access to the secure online platform was provided to participants by the study team. Participants then accessed this via an internet-connected device of their choosing. Feedback from eCoaches was provided via email	
		Where	Participants could access the intervention at any location of their choosing	
		When and how much	The intervention included 7 mandatory modules and one booster session which were to be completed at weekly intervals followed by the booster session 4 weeks after the 7th module. These were in addition to 4 mini modules and one optional module. The 4 optional minimodules (15 min each) could be completed after modules 3, 4, 5, or 6, respectively	
		Tailoring	The feedback from eCoaches was only semi-standardised, implying that some degree of tailoring was applied	
		Modifications	There were not stated modifications to the intervention during the study period	
		How well	The attrition rate was calculated by identifying the percentage of individuals who no longer utilized the intervention, as indicated in their log-in data. Participants completed on average 4.8 (SD 2.6) modules of the intervention. In total, 60% (24/40) of participants in the intervention group were identified as completers, and 55% (22/40) of participants adhered to all 7 modules. Of the 16 (16/40, 40%) participants who did not complete at least 5 modules, 1 (3%) participant never started the intervention.	
Shebib	2018	Brief name	12-week digital care programme for individuals with chronic low back pain	The control group received three digital education articles from the digital care programme. These articles discussed the importance of self-care, how to deal with setbacks in LBP, and how to manage communication and relationships when living with chronic LBP. The control group maintained access to treatment-as-usual and were
		Why	Digital technology can provide care for a large population and improve outcomes for non-invasive treatments by allowing providers to monitor adherence and activate patients to engage in their recovery. A digital therapy approach can integrate multiple conservative care channels while also tracking outcomes and providing biofeedback. Using self-regulatory tools such as biofeedback as an engagement tool in non-specific LBP rehabilitation has been shown to promote greater than 80% adherence. Biofeedback enables patients to better learn how to voluntarily control and track therapeutic exercise by converting physical movement into meaningful visual and auditory cues. This intervention therefore includes back pain self-management education alongside biofeedback assisted therapeutic exercises	

		What	Participants randomized into the treatment group received the 12-week digital care programme, consisting of: Sensor-guided exercise therapy Education articles Cognitive behavioural therapy Team discussions Activity tracking Symptom tracking 1-on-1 coaching All of the above elements were delivered via a tablet app. All participants had unrestricted access to treatment as usual throughout the study period	informed that they would be reconsidered for the program when enrolment reopened after the 12-week study.
		Who provided	Access to the tablet app and sensors was provided by the study team	
		How	Participants received a tablet computer with the DCP app installed, and two Bluetooth wearable motion-sensors with straps to be placed along the lower back and torso during the in-app exercise therapy. Participants were assigned a personal coach that provided unlimited support and accountability throughout the program and were placed in a team to provide peer support through a discussion feed within the app.	
		Where	Participants could access the intervention at any location of their choosing via the tablet computer provided by the study team	
		When and how much	Each week, participants in the DCP were instructed to complete 3 sessions of sensor-guided physical exercise, read 1 to 2 education articles, log their symptoms at least twice, perform cognitive behavioural therapy on a subset of weeks, and track a recommended 3 aerobic activities per week. The intervention period was 12 weeks	
		Tailoring	The peer discussions and advice from the personal coach were dependent upon participants' contributions and queries. It is not clear if the exercises were standardised for all group members or tailored to each individual	
		Modifications	There were no stated modifications to the intervention during the study period	

		How well	75% of intervention group participants engaged with the programme each week. 68% continued to use the sensor-guided exercise programme during weeks 9-12	
Suman	2019	Brief name	Multi-faceted e-health strategy including a mobile website, digital monthly newsletters and social media platforms	
		Why	No highly effective treatment for low back pain has yet been found. However, eHealth has shown promise with regards to its' effectiveness and cost-effectiveness in improving outcomes such as patient health, patient satisfaction, self-management and healthcare costs in patients with physical diseases. This intervention, therefore, used multiple digital strategies to deliver a self-management intervention to patients with low back pain	
		What	Patients in the cluster whose GP or PT was randomised into the intervention group received access to a multifaceted eHealth strategy that aimed to reduce patients' negative back pain beliefs and improve their knowledge and self-management of LBP. The campaign included an informative website, digital monthly newsletters, and social media platforms. The website provided comprehensive information about LBP, such as practical advice (e.g., on self-management), working and returning to work with LBP, exercise tips, and short video messages. In these videos, actors and healthcare professionals shared their experiences with LBP and provided tips on self-management, coping and working with LBP. The videos were inspired by the effective Australian mass media campaign 'Back Pain: Don't Take It Lying Down'. Social media platforms included a forum on the website, and a Facebook page where patients could contact researchers, healthcare providers and other patients. All parts of the intervention were also available in a mobile version that was adaptive to any electronic device.	
		Who provided	Access to the intervention was provided by the study team. Researchers, healthcare providers, and other study participants were involved in the social media discussions.	

		How	All aspects of the intervention (website, digital newsletter, and social media) were delivered virtually via a mobile-friendly website and the social media platform Facebook. It is not clear how the digital newsletters were delivered and whether this was via email or social media	
		Where	Participants could access the intervention in a location of their choosing via any smart device	
		When and how much	The frequency with which participants were advised to engage with the intervention is not reported	
		Tailoring	There is no specific detail on intervention tailoring in the published paper or related cited papers	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	No measure of treatment adherence or fidelity are reported in the published paper, however the associated process evaluation cited reports the following: The website user engagement log showed that a total of 302 logins were registered, belonging to 170 unique patients (55% of intervention group). The majority of patients only visited the website once or not at all. More than half of the patients (53%) did not watch any of the videos.	
Toelle	2019	Brief name	Kaia app – which is an app-based multidisciplinary treatment for back pain	In the control group participants received six individual face-to-face sessions of standard physiotherapy once a week comprising physical exercises tailored to the individual symptoms and fitness level, as well as manual therapy. The minimal duration of the physiotherapy sessions was 20 min. The physiotherapy sessions were carried out by
		Why	Multidisciplinary pain treatment (MPT) programs comprising educational, physical, and psychological interventions have shown positive treatment effects on low back pain. Nonetheless, such programs are costly and treatment opportunities are often limited to specialist centres. mHealth and other digital interventions may be a promising method to successfully support patient self-management in those experiencing low back pain. This intervention, therefore, uses an m-health platform to deliver self-management support for patients with low back pain	
		What	The Kaia App involves three therapy modules: (1) back pain-specific education (2) physiotherapy/physical exercise (3) mindfulness and relaxation techniques	

			Daily content consists of all three therapy modules. Content in the educational module covers a broad spectrum of general pain-related and back pain-specific education. There are over 30 different educational units in the Kaia App. Content is based on current international guidelines and standard textbooks in the field.	a certified physiotherapist at a local affiliated centre for physiotherapy. Furthermore, participants were encouraged to live an active lifestyle and to perform the exercises at home. Links to a selection of medically oriented websites providing online resources for education about pathophysiology, diagnoses, treatment, and self-management in LBP were also sent to control group by the clinical investigators via email weekly, along with a brief motivating message. In total, each control group participant received six emails during the trial.
		Who provided	Patients in the intervention group were provided access to Kaia App and encouraged by the clinical investigator to use the app on their smartphone or tablet	
		How	The intervention was accessed on the participants' own smartphone devices	
		Where	Participants could access the app at any location of their choosing	
		When and how much	Participants were encouraged to engage with the Kaia app at least four times a week throughout the study duration of 3 months	
		Tailoring	The content for an individual patient is compiled and updated from day to day (or upon each login) from a large background of exercises and skills archived in the Kaia App. Depending on the patient´s status of knowledge, practice, and progress this is adapted continually. The exercise regimen and content are therefore tailored to the individual patient.	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	Engagement/adherence to the Kaia app was reported as follows: after 6 weeks 62% and after 12 weeks 41% of the participants reported to have used the in-app information. Sixty-two percent after 6 weeks and 41% after 12 weeks stated they considered the content useful.	
Yang	2019	Brief name	Mobile self-management app for individuals with low back pain (Pain Care App)	
		Why	Self-management interventions have been shown to be beneficial to patients with low back pain. Digital technologies including apps have shown promise as platforms for the delivery of self-management interventions. This intervention therefore combined routine physiotherapy care with an app-based self-management intervention to try to improve outcomes in patients with low back pain	

		What	Participants in the physiotherapy plus self-management group received the following intervention: 1) Routine physiotherapy care – this may consist of manual therapy, electrophysical therapy, and traction as prescribed by the physiotherapist 2) Exercises prescribed by the treating physiotherapist to be completed in the participants' own home 4 times daily 3) Access to a smartphone app to remind participants to complete their exercises 4 times daily (participants personalise push notifications to remind them to do their prescribed exercises) and to allow recording of pain and activity levels	
		Who provided	Access to the app was provided by the study team It is not reported who carried out the physiotherapy treatment or what their credentials were	
		How	Reminders to complete the exercises and logging of pain and activity levels were provided via the app. Exercises were prescribed to the participants (and modified as needed) during the routine physiotherapy sessions.	
		Where	The location of the physiotherapy session is not specifically reported, however, participants in this study were recruited from the Rehabilitation Clinic of the Hong Kong Polytechnic University	
		When and how much	The frequency of the physiotherapy session is not reported, and this appears to vary with each individual. The therapeutic exercises were recommended to be completed four times per day	
		Tailoring	The content of the physiotherapy sessions and home exercise programme were tailored to each individual by the treating physiotherapist. Participants could tailor the reminder settings within the app using the following options: none, every hour, every 2 hours, every 4 hours, every 8 hours, or every day, or they could set a one-off alarm via the mobile phone.	
		Modifications	There were no stated modifications to the intervention during the study period	
		How well	Measure of treatment adherence or fidelity were not reported	

Table 2.5. Details of the outcome measures used and the main findings of included RCTs

Study ID	Author	Year	Outcomes and outcome measures used	Relevant numerical results Intervention Group	Relevant numerical results Control Group	Summary of key study findings (Numerical values if provided here are taken directly from the published paper)
1	Almhdawi	2020	Pain intensity today – 0-10 Visual analogue scale (VAS) Disability - Oswestry Disability Index (ODI)	Results presented as Mean (SD) Baseline: VAS 5.62 (2.06) ODI 30.95 (9.31) 6 weeks: VAS 2.3 (2.13) ODI 20.25 (13.47)	Results presented as Mean (SD) Baseline: VAS 5.10 (1.83) ODI 31.05 (10.75) 6 weeks: VAS 5.00 (1.97) ODI 30.63 (10.63)	Following six weeks of using the application, compared to control group, the intervention group demonstrated significant decrease in pain intensity (−3.45 (2.21) vs −0.11 (1.66), P<0.001), and in ODI score (−11.05 (10.40) vs −0.58 (9.0), P=0.002)
2	Amorim	2019	Pain intensity 0-10 Numerical pain rating scale (NPRS) (specific question posed to participants not reported) Activity limitation - Roland and Morris Disability Questionnaire (RMDQ)	Baseline: Mean (SD) Pain 5.3 (1.9) Activity limitation (RMDQ) 8.9 (5.4) 6 months: Mean (SD) Pain 3.8 (2.4) Activity Limitation (RMDQ) 5.7 (5.3)	Baseline: Mean (SD) Pain 5.1 (1.4) Activity limitation (RMDQ) 9.0 (6.1) 6 months: Mean (SD) Pain 4.0 (3.4) Activity Limitation (RMDQ) 6.0 (5.7)	The effect of group allocation at six months on continuous outcomes was assessed using linear regression models. There was no significant group effect on pain (P=0.635) or activity limitation (P=0.868).

3	Baumeister	2020	Pain severity – 0-10 NPRS (specific question posed to participants not reported) Pain-related disability - Oswestry Disability Index (ODI)	Baseline: Mean (SD) NPRS 1.88 (0.71) ODI 36.83 (15.86) T1: 9 weeks NPRS 1.43 (0.79) ODI 30.22 (15.64) T2: 6 months NPRS 1.62 (0.76) ODI 31.38 (16.84)	Baseline: Mean (SD) NPRS 1.78 (0.73) ODI 33.85 (14.03) T1: 9 weeks NPRS 1.63 (0.74) ODI 32.36 (15.54) T2: 6 months NPRS 1.67 (0.81) ODI 31.42 (16.32)	Standardised regression coefficient shows greater effect of intervention on pain severity (β= -0.32, 95% CI -0.57 to -0.06, P=0.013) and pain-related disability (β= -0.31, 95% CI -0.47 to -0.15, p<0.001) compared to control group at T1. No significant between group differences in pain (β= -0.14, 95% CI -0.43 to 0.15, p=0.329) or pain-related disability (β= -0.17, 95% CI -0.35 to 0.01, p=0.064) existed at T2.
4	Buhrman	2004	Pain severity – 0-100 numerical pain rating scale (NPRS) Pain diary measuring average pain intensity and highest rated pain. Impact of pain on physical function measured using the Pain and impairment relationship scale (PAIRS).	Baseline: Mean (SD) Pain diary average pain 37.4 (18.2) Pain diary highest pain 64.3 (22.2) PAIRS 55 (10.9) Post-treatment: 8 weeks Pain diary average pain 34.3 (16.8) Pain diary highest pain 54.0 (18.4) PAIRS 53.2 (10.2)	Baseline: Pain diary average pain 44.4 (14.2) Pain diary highest pain 68.5 (18.2) PAIRS 56.3 (10.8) Post-treatment: 8 weeks Pain diary average pain 39.6 (16.3) Pain diary highest pain 61.5 (19.7) PAIRS 53 (11.6)	No significant interaction between group and time for average pain intensity or highest rated pain intensity was found (i.e. there was no significant difference between the groups). For average pain intensity there was a significant main effect for time [*F*(1, 48)=6.10, p<0.05], that is average pain intensity was reduced for both groups over time. Similarly, no significant interaction effect was found for group and time for PAIRS scores. A significant effect was however found for time [*F*(1,49)=7.23, p<0.01] meaning that PAIRS

						scores improved with time regardless of group allocation.
5	Buhrman	2011	Multidimentional pain inventry (MDI). Pain and impairment relationship scale (PAIRS).	Baseline: Mean (SD)/post-treatment: Mean(SD) MPI: Pain severity 3.5 (2.5)/3.15 (2.2) Interference 3.6 (1.2)/3.2 (1.4) Life control 3.1 (1.1)/3.9 (1.0) Affective distress 2.9 (0.9)/2.8 (0.9) Support 4.0 (1.6)/4.2 (1.3) Punishing responses 1.0 (1.4)/0.7 (1.1) Solicitous responses 2.3 (1.4)/2.3 (1.2) Distracting responses: 2.5 (1.7)/2.5 (1.6) PAIRS: 53.3 (10.4)/49.1 (11.0)	Baseline: Mean (SD)/post-treatment: Mean (SD) MPI: Pain severity 3.2 (2.2)/3.35 (2.6) Interference 3.9 (1.3)/3.5 (1.2) Life control 2.7 (0.9)/3.1 (0.9) Affective distress 3.0 (0.6)/3.1 (0.6) Support 3.9 (1.5)/3.8 (1.6) Punishing responses 1.5 (1.4)/1.2 (1.3) Solicitous responses 2.1 (1.4)/1.9 (1.5) Distraction responses 2.7 (1.7)/2.5 (1.7) PAIRS: 48.3 (13.7)/46.1 (18.7)	No significant group interaction effects for MPI scores were reported, meaning that group allocation did not significantly impact on MPI scores post-treatment. A significant effect for time was found, meaning that both groups experienced a reduction in PAIRS scores regardless of group allocation [*F*(1,48)=3.9, p=0.05].
6	Carpenter	2012	Pain-related disability measured using the Roland and Morris Disability questionnaire (RMDQ) Pain rating; average pain measured using 0-10 Numerical pain rating scale (NPRS) (timeframe over which pain was recalled not reported) Pain rating; highest	Baseline Mean (SD) RMDQ 16.3 (5.3) Average pain 5.2 (1.5) Highest pain 7.2 (1.5) 3 weeks RMDQ 13.5 (5.8) Average pain 5.2 (1.5) Highest pain 7.0 (1.8)	Baseline Mean (SD) RMDQ 17.1 (4.7) Average pain 5.7 (1.7) Highest pain 7.4 (1.6) 3 weeks RMDQ 16.3 (5.2) Average pain 5.7 (1.7) Highest pain 7.3 (1.6)	A significant effect of group on RMDQ scores was found when controlling for differences at baseline p=0.01 No significant effect of group on average pain and highest pain scores was reported: p=0.507 and p=0.784 respectively

			pain measured using 0-10 NPRS (timeframe over which pain was recalled not reported)			
7	Chhabra	2018	Pain severity - Numerical pain rating scale (NPRS) (specific question posed to participants not reported) Disability - Modified version of the Oswestry Disability Index (MODI) where the question about sexual function was replaced with a question about work ability- this had been previously validated	Baseline: Mean (SD) NPRS 7.3 (1.9) MODI 52.1 (14.4) 12 weeks: NPRS 3.3 (1.7) MODI 20.2 (17.8)	Baseline: Mean (SD) NPRS 6.6 (2.1) MODI 41.4 (18.8) 12 weeks: NPRS 3.2 (2.7) MODI 29.9 (20.1)	2x2 mixed model ANOVA showed a main effect for time, however the main effect for group was non-significant [$F(1,90)=1.443$, $p=0.233$] as was the interaction effect [$F(1,90)=0.84$, $p=0.362$]. Therefore, both groups showed a decrease in pain scores at 12 weeks, but there was no significant difference between the groups. MODI scores at baseline were significantly different with the app group having a higher score - ANCOVA was therefore used; ANCOVA gave a main effect for time [$F(1,90)=4.739$, $p=0.032$] and a significant interaction effect [$F(1,90)=9.053$, $p=0.003$], meaning that although both groups recorded a improvement in MODI score from baseline, improvement in scores in the app group was significantly greater.

8	Chiauzzi	2010	Pain intensity measured via three subscales of the brief pain inventory (BPI) Physical function measured using the Oswestry Disability Index (ODI)	Baseline: Least squares Means (Standard Error), BPI worst pain subscale 7.08 (0.18) BPI Average pain subscale 5.57 (0.18) BPI pain interference subscale 5.46 (0.24) ODI 45.69 (1.77) Immediately post-intervention p value only given if pairwise post-hoc Bonferroni corrected comparison significant BPI worst pain subscale 6.53 (0.23) BPI Average pain subscale 5.13 (0.20) BPI pain interference subscale 4.70 (0.29) ODI 42.62 (1.88) 3 months BPI worst pain subscale 6.42 (0.26) BPI Average pain subscale 5.04 (0.21) BPI pain interference subscale 4.65 (0.29) ODI 43.35 (1.97) 6 months BPI worst pain subscale 6.51 (0.28) BPI Average pain subscale 4.78 (0.25)	Baseline: Least squares Means (Standard Error) BPI worst pain subscale 6.96 (0.17) BPI Average pain subscale 5.59 (0.17) BPI pain interference subscale 5.76 (0.23) ODI 46.36 (1.64) Immediately post-intervention p value only given if pairwise post-hoc Bonferroni corrected comparison significant BPI worst pain subscale 6.75 (0.21) BPI Average pain subscale 5.35 (0.19) BPI pain interference subscale 5.03 (0.26) ODI 44.09 (1.72) 3 months BPI worst pain subscale 6.82 (0.23) BPI Average pain subscale 5.44 (0.19) BPI pain interference subscale 5.00 (0.26) ODI 43.85 (0.79) 6 months BPI worst pain subscale 6.65 (0.25) BPI Average pain subscale 5.18	No statistically significant difference was seen between groups for pain intensity or physical function when the intervention group was taken as a whole. However, when the subgroup of those in the intervention group who were recruited online were compared to the control group, a significant difference in pain reduction from baseline was seen for the average pain subscale of the BPI ($t=2.71$, $p<0.05$). Also, intervention group participants saw a clinically significant reduction (defined as greater than 10%) in current pain levels from baseline: 12.3% reduction in current pain in the intervention group compared to 7% for the control group.

				BPI pain interference subscale 4.95 (0.32) ODI 44.51 (2.08)	(0.22) BPI pain interference subscale 4.78 (0.29) ODI 44.53 (1.87)	
9	Del Pozo-Cruz	2012a, 2012b	Pain-related disability measured using the Roland and Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI)	Baseline Mean (SD) Intention to treat analysis (ITT) RMDQ 12.18 (2.55) ODI 28.13 (2.23) 9/12 RMDQ 4.93 (2.59) 37% of intervention group saw an improvement in ODI scores	Baseline Mean (SD) Intention to treatment analysis (ITT) RMDQ 11.70 (2.04) ODI 28.77 (2.69) 9/12 ITT RMDQ 13.54 (2.09) 6.8% of the control group saw an improvement in ODI scores	Between group difference in change from baseline: Mean (95% CI) -8.42 (-9.76 to -7.07) Effect size -2.8 There is a statistically significantly larger reduction in RMDQ scores from baseline in the intervention group compared to the control group. Odds ratio intervention group improvements/control group improvements (95% CI) 5.42 (1.707 to 17.216), p=0.001
10	Geraghty	2018	Pain-related disability measured using the RMDQ Pain intensity - measured using three 0-10 numerical pain rating scales (NPRS) measuring the current, average, and least pain over the last 2 weeks. The mean of these three	Group 1: Internet-based intervention Baseline Mean (SD) RMDQ 6.6 (4.6) NPRS: Current pain 4.0 (2.6) NPRS: Average pain 4.5 (2.1) NPRS: Least pain 3.1 (2.1) Pain index (mean of 3 NPRS scores) 3.9 (2.0) 3 Months RMDQ 5.8 (4.5) NPRS: Current pain 3.6 (2.5) NPRS: Average pain 3.6 (2.5) NPRS: Least pain 2.3 (2.3)	Group 3: Usual care only Baseline Mean (SD) RMDQ 6.8 (4.9) NPRS: Current pain 3.6 (3.1) NPRS: Average pain 4.6 (2.0) NPRS: Least pain 3.2 (2.5) Pain index (mean of 3 NPRS scores) 3.8 (2.3) 3 Months RMDQ 6.3 (5.1) NPRS: Current pain 4.0 (2.5) NPRS: Average pain 4.1 (2.1) NPRS: Least pain 2.8 (2.1)	Between group differences for the intervention groups and control group were assessed at 3 months using linear regression models controlling for baseline values and other covariates (age, gender, marital status, employment status, income, ethnicity and the age at which the participant left education) Usual care Vs Internet-based intervention Mean (95% confidence interval)

			scores is presented as a pain index.	Pain index (mean of 3 NPRS scores) 3.2 (2.2) Group 2: Internet-based intervention plus telephone support from a physiotherapist Baseline RMDQ 7.7 (4.7) NPRS: Current pain 4.5 (2.6) NPRS: Average pain 5.2 (2.1) NPRS: Least pain 2.9 (2.7) Pain index (mean of 3 NPRS scores) 4.2 (2.2) 3 Months RMDQ 5.1 (5.1) NPRS: Current pain 3.1 (2.3) NPRS: Average pain 3.4 (1.7) NPRS: Least pain 2.3 (2.1) Pain index (mean of 3 NPRS scores) 3.1 (2.0)	Pain index (mean of 3 NPRS scores) 3.6 (2.1)	RMDQ -0.6 (-3.10 to 1.83) NPRS: Current pain -0.6 (-1.82 to 0.56) NPRS: Average pain -0.4 (-1.54 to 0.76) NPRS: Least pain -0.6 (-1.46 to 0.29) Pain index (mean of 3 NPRS scores) -0.5 (-1.47 to 0.49) Usual care Vs Internet-based intervention plus telephone support from a physiotherapist Mean (95% confidence interval) RMDQ -2.4 (-5.00 to 0.25) NPRS: Current pain -1.0 (-2.25 to 0.21) NPRS: Average pain -0.8 (-2.07 to 0.44) NPRS: Least pain 0.2 (-0.71 to 1.08) Pain index (mean of 3 NPRS scores) -0.8 (-1.78 to 0.25)
11	Heapy	2017	Average pain intensity over the past week measured using a numerical pain rating scale (NPRS) Pain-related disability measured using the	Change from baseline Mean (95% CI) NPRS 3 months -0.77 (1.29 to -0.26) 6 months -1.23 (-1.73 to -0.72) 12 months -0.51 (-1.06 to 0.04) RMDQ	Change from baseline Mean (95% CI) NPRS 3 months -0.84 (1.39 to -0.29) 6 months -1.00 (-1.52 to -0.48) 12 months -0.44 (-1.01 to 0.14) RMDQ	Difference in change from baseline between groups: interactive voice recorder (IVR) group Vs In-person control group Mean (95% CI), P value if given NPRS 3 months 0.07 (-0.67 to 0.8)

	Roland and Morris Disability Questionnaire (RMDQ) Physical function was also measured using the physical function subscale of the SF-36	3 months -2.92 (-4.16 to -1.69) 6 months -3.38 (-4.75 to -2.02) 12 months -2.63 (-3.90 to -1.35) SF-36: Physical functioning 3 months 2.20 (0.43 to 3.96) 6 months 2.05 (0.09 to 4.02) 12 months 1.50 (-0.44 to 3.45)	3 months -2.42 (-3.74 to -1.11) 6 months -1.86 (-3.25 to -0.46) 12 months -2.02 (-3.32 to -0.71) SF-36: Physical functioning 3 months 1.91 (0.01 to 3.81) 6 months 0.90 (-1.15 to 2.95) 12 months 2.09 (0.03 to 4.41)	6 months -0.23 (-0.94 to 0.49) 12 months -0.08 (-0.86 to 0.71) RMDQ 3 months -0.5 (-2.29 to 1.29), P=0.58 6 months -1.53 (-3.46 to 0.41), P=0.12 12 months -0.61 (-2.42 to 1.20, P=0.51 SF-36: Physical functioning 3 months 0.29 (-2.30 to 2.87), P=0.83 6 months 1.15 (-1.68 to 3.98), P=0.42 12 months -0.58 (-3.40 to 2.24), P=0.68 There was no significant difference between IVR and In-person CBT for any relevant outcome at any of the follow-up assessments.

12	Hou	2019	Pain severity measured using a 100mm visual analogue scale (VAS). The question posed to the participants is not stated, and the scale used is not specified. Pain-related disability measured using the Oswestry Disability Index (ODI)	Change from baseline Mean (SD) VAS: 3 months -7.02 (4.45) 6 months -17.49 (25.48) 12 months -20.55 (25.92) 24 months 29.95 (25.60) ODI 3 months -7.29 (5.31) 6 months -18.43 (23.92) 12 months -21.58 (24.64) 24 months -30.43 (23.75)	Change from baseline Mean (SD) VAS: 3 months -7.61 (5.15) 6 months -14.19 (5.11) 12 months -21.94 (5.8) 24 months -22.36 (6.90) ODI 3 months -7.90 (4.53) 6 months -14.19 (5.11) 12 months -22.07 (5.56) 24 months -23.41 (6.65)	Difference in change from baseline between groups Usual Care (UC) vs E-health Mean (SD), p value VAS: 3 months -0.63 (0.78), P=0.42 6 months 4.0 (2.83), P= 0.16 12 months -0.49 (2.98), P= 0.87 24 months 7.02 (3.18), P= 0.03 ODI 3 months -0.59 (0.76), P= 0.44 6 months 3.30 (2.96), P= 0.27 12 months -1.39 (3.13), P= 0.66 24 months 7.59 (3.42), P= 0.03 There is a statistically significant difference between the change from baseline in the VAS and ODI at 24 months favouring the E-health group.

13	Irvine	2015	Back pain: current back pain status assessed via the question - Do you have low back pain now - yes/no How bad is your back pain now? - measured using a 6 point Likert scale response In the last 2 months have you experienced back pain? - measured using a 6 point scale When you experienced back pain in the last 2 months, how intense was the pain? measured using a 7 point scale When you experienced pain in the last 2 months, how long did it usually last? - measured using a 5 point scale Function and Quality of life - measured using a 10 item scale adapted from the Multidimensional pain inventory	Baseline Mean (SD) How bad is your low back pain? 0.96 (1.26) How often have you experienced LBP? 2.86 (0.92) When you experienced LBP, on average how intense was the pain? 2.59 (1.15) When you experienced LBP, on average how long did it last? 2.52 (1.03) Functionality and QoL 3.83 (1.90) Dartmouth COOP 20.41 (5.02) T2 (2 months) Mean (SD) How bad is your low back pain? 0.82 (1.22) How often have you experienced LBP? 2.64 (1.04) When you experienced LBP, on average how intense was the pain? 2.23 (1.2) When you experienced LBP, on average how long did it last? 2.28 (1.05) Functionality and QoL	Baseline Alternative care group, Mean (SD) How bad is your low back pain? 1.22 (1.43) How often have you experienced LBP? 2.93 (0.95) When you experienced LBP, on average how intense was the pain? 2.63 (1.17) When you experienced LBP, on average how long did it last? 2.56 (1.02) Functionality and QoL 3.93 (1.97) Dartmouth COOP 20.66 (4.74) T2 (2 months) How bad is your low back pain? 1.03 (1.43) How often have you experienced LBP? 2.63 (1.02) When you experienced LBP, on average how intense was the pain? 2.26 (1.24) When you experienced LBP, on average how long did it last? 2.25 (1.03) Functionality and QoL 3.34 (1.90) Dartmouth COOP	Rates of current back pain were 42%, 46%, and 49% in the treatment, alternative care group and control group respectively at T2, P=0.37. Rates of current back pain were 29%, 41% and 41% at T3, P=0.02. There was no statistically significant difference between the groups at T2 (2 months). At T3 (4 months), current adjusted back pain status was a significant predictor of both treatment vs control (OR 1.72, 95% CI 1.11-2.68, p=.02) and treatment vs alternative care (OR 1.60, 95% CI 1.03-2.50, P=.035): Alternative care group were 1.6 times more likely than FitBack group to report back pain. Control group were 1.7 times more likely than FitBack group to report back pain. In terms of function, quality of life and wellbeing (as measured using the 10 item scale adapted from the Multidimensional pain inventory Interference scale and the interference scale of the brief pain inventory) the treatment vs

	Interference scale and the interference scale of the brief pain inventory - each question answered on a 10-point scale Physical and social function also measured using the Dartmouth Primary Care Cooperative Information Project Scale	3.27 (1.69) Dartmouth COOP 19.3 (5.18) T3 (4 months) How bad is your low back pain? 0.56 (1.00) How often have you experienced LBP? 2.16 (1.12) When you experienced LBP, on average how intense was the pain? 2.11 (1.46) When you experienced LBP, on average how long did it last? 2.03 (1.01) Functionality and QoL 3.03 (1.88) Dartmouth COOP 18.84 (5.39)	19.87 (5.16) T3 (4 months) How bad is your low back pain? 0.89 (1.30) How often have you experienced LBP? 2.39 (1.05) When you experienced LBP, on average how intense was the pain? 2.23 (1.3) When you experienced LBP, on average how long did it last? 2.12 (0.97) Functionality and QoL 3.31 (2.00) Dartmouth COOP 19.42 (5.26)	control group comparison was statistically significant at both T2 and T3 (P values not reported)

14	Kazemi	2020	Pain intensity - measured using a 0-100 VAS (the question posed to the participants was not reported, nor was the timeframe over which the pain was being recalled) Pain-related disability - measured using the Quebec back pain disability scale	Social media group: Pain, VAS Mean (SD) Baseline 5.56 (2.02) 3 months 3.54 (1.57) 6 months 3.37 (1.79) Pain-related disability, Quebec scale, Mean (SD) Baseline 31.87 (12.95) 3 months 23.03 (12.67) 6 months 19.38 (13.60)	In-person group Pain, VAS Mean (SD) Baseline 5.55 (2.33) 3 months 4.60 (1.19) 6 months 4.62 (1.65) Pain-related disability, Quebec scale, Mean (SD) Baseline 30.53 (10.17) 3 months 23.30 (14.03) 6 months 23.35 (11.21) Control group Pain, VAS, Mean (SD) Baseline 5.53 (2.06) 3 months 5.54 (1.75) 6 months 5.62 (1.67) Pain-related disability, Quebec scale, Mean (SD) Baseline 31.05 (14.56) 3 months 31.58 (13.17) 6 months 31.17 (14.52)	Pain change scores decreased significantly in both the intervention group and the in-person treatment group at 3 months but not in the control group. At 6 months the social media group showed a significant within-group change ($p<0.0001$) but the control group did not. Disability scores significantly decreased from baseline in both the intervention and in-person groups at 3 months, and in the social media group alone at 6 months ($p<0.0001$)
15	Krein	2013	Pain intensity - measured using a 0-10 Numerical pain rating scale (NPRS) but question posed to participants and recall period not specified Disability - Measured using the Roland and	Baseline Mean (SD) NPRS 6.0 (1.9) RMDQ 9.1 (6.0) MOS 48.5 (18.6) 6 months NPRS Mean scores not given RMDQ Mean scores not given MOS Mean scores not given	Baseline Mean (SD) NPRS 6.1 (1.6) RMDQ 9.8 (5.7) MOS 51.8 (16.3) 6 months NPRS Mean scores not given RMDQ Mean scores not given MOS Mean scores not given	Adjusted between group difference presented (adjusted for baseline values, and calculated as score for usual care minus the scores for the intervention group so that a positive result shows greater improvement in the intervention group) with (95% CI), P value Both all case (ITT) analysis and

			Morris Disability Questionnaire (RMDQ) Generic pain-related functional measure from the Medical Outcomes Study (MOS)	12 months NPRS Mean scores not given RMDQ Mean scores not given MOS Mean scores not given	12 months NPRS Mean scores not given RMDQ Mean scores not given MOS Mean scores not given	complete case (PP) analysis findings given NPRS 6 months ITT 0.5 (-0.03 to 0.9) 6 months PP 0.5 (-0.01 to 0.98) 12 months ITT 0.04 (-0.4 to 0.5) 12 months PP 0.1 (-0.4 to 0.5) RMDQ 6 months ITT 1.2 (-0.09 to 2.5), P=0.07 6 months PP 1.6 (0.3 - 2.8), P=0.02 12 months ITT 0.7 (-0.8 to 2.2), P=0.38 12 months PP 1.2 (-0.3 to 2.7), P=0.11 MOS 6 months ITT 2.5 (-1.5 to 6.5), P=0.23 6 months PP 3.6 (-0.51 to 7.7), P=0.09 12 months ITT -1.4 (-5.4 to 2.5), P=0.48 12 months PP 0.1 (-4.0 to 4.2), P=0.97 ITT analysis shows no significant between group differences in pain or function at 6 or 12 months
16	Licciardone	2020	SPADE cluster score from the PROMIS-29 including its 5 components	Changes in outcome measurements from baseline to 3 months, Mean (95% CI) SPADE cluster score 1.2 (0.2 to 2.2)	Changes in outcome measurements from baseline to 3 months, Mean (95% CI) SPADE cluster score 0.2 (-1.1 to 1.5)	Difference in change scores from baseline to 3 months between groups: SPADE Cluster p=0.23

			Pain severity measured using the 0-10 NPRS (average pain over the last 7 days) Back-related disability - measured using the Roland and Morris Disability Questionnaire (RMDQ)	NPRS -0.3 (-0.8 to 0.2) RMDQ 0.9 (-0.3 to 2.1)	NPRS -0.1 (-0.5 to 0.3) RMDQ -0.4 (-1.2 to 0.4)	NPRS p=0.59 RMDQ p=0.07 There were no statistically significant differences between the groups in any primary or secondary outcome.
17	Lorig	2002	Pain intensity measured using a 0-10 visual numeric scale which is described as a variant of the traditional visual analogue scale Disability measured using the Roland and Morris Disability Questionnaire (RMDQ)	Baseline: Mean (SD) Pain intensity: 3.97 (2.36) RMDQ: 10.18 (5.15) 12 months: change from baseline Mean (SD) Pain intensity: -1.50 (2.64) RMDQ: -2.77 (4.68)	Baseline: Mean (SD) Pain intensity: 3.82 (2.36) RMDQ: 9.53 (4.88) 12 months: change from baseline Mean (SD) Pain intensity: -1.02 (2.60) RMDQ: -1.51 (4.97)	Groups compared at 12 months using intention to treat analysis based on analysis of covariance controlling for demographic variables and baseline status: Pain intensity: P=0.002 RMDQ: P<0.001 Participants receiving the intervention demonstrated statistically significant improvements in pain and disability compared to the control group at 12 months

18	Petrozzi	2019	Pain-related disability measured using the RMDQ Pain intensity - measured using a 0-10 NPRS but question posed to participants and recall period not stated (e.g. current pain, pain over the last week etc)	RMDQ: Mean (SD) Baseline 9.9 (4.2) Post-intervention 5.4 (3.8) 6 months 5.1 (4.0) 12 months 4.2 (3.7) NPRS: Mean (SD) Baseline 5.1 (1.8) Post-intervention 2.8 (2.0) 6 months 3.2 (2.2) 12 months 3.0 (2.1)	RMDQ: Mean (SD) Baseline 9.9 (4.7) Post-intervention 5.8 (5.1) 6 months 5.0 (4.6) 12 months 5.3 (5.1) NPRS: Mean (SD) Baseline 4.9 (2.05) Post-intervention 2.9 (2.0) 6 months 3.2 (2.2) 12 months 4.0 (2.1)	P value for mean differences between groups (0-12 months) using linear mixed models RMDQ P=0.70 NPRS P=0.95 There is no statistically significant difference between the intervention group and the control group for pain or pain-related disability at 6 or 12 months.
19	Priebe	2020	Pain intensity for the current pain, average pain over the last 4 weeks and highest pain over the last 4 weeks were measured using a 0-10 numerical pain rating scale. A pain index was then calculated by establishing the mean of the 3 pain intensity measures	Reduction in pain intensity from baseline to 3 months of -33%	Reduction in pain intensity from baseline to 3 months of -14.3%	Pain index was lower in the RISE-up group at 3 months compared to the control group p<0.001.
20	Riva	2014	Pain burden - measured using six items from the chronic pain grading scale - 3 items measured pain intensity on a 0-10 NPRS, 3 items	Pain burden - not clear if the 6 item scales are summed and then the mean is given in the published paper; Paper states 'Mean scores' given Baseline 4.3 4 weeks 3.9 8 weeks 2.8	Pain burden - not clear if the 6 item scales are summed and then the mean is given in the published paper; Paper states 'Mean scores' given Baseline 3.8 4 weeks 3.0 8 weeks 2.1	Mean difference and significance level for pain burden when group means compared with independent samples t-test 4 weeks +0.9, p<0.10 (specific p value not given) 8 weeks +0.7, p value not given

			measured pain interference using a 0-10 scale where 0=no interference with activities, 10=Unable to carry out the activity			There is no significant difference between the groups at 4 weeks or 8 weeks in terms of pain burden, suggesting that interactive features provide no additional benefit over static content.
21	Sander	2020	Pain intensity measured using a 0-10 NPRS Pain-related disability measured using the Oswestry Disability Index (ODI)	Baseline Mean (SD) Pain intensity on a 0-10 NPRS 1.59 (0.68) ODI 27.34 (12.41) 9/52 Pain intensity on a 0-10 NPRS 1.39 (0.68) ODI 23.42 (11.72) 6 months Pain intensity on a 0-10 NPRS 1.42 (0.69) ODI 22.00 (11.28) 12 months Pain intensity on a 0-10 NPRS 1.39 (0.74) ODI 20.17 (10.62)	Baseline Mean (SD) Pain intensity on a 0-10 NPRS 1.62 (0.66) ODI 26.77 (13.14) 9/52 Pain intensity on a 0-10 NPRS 1.58 (0.72) ODI 26.03 (12.98) 6 months Pain intensity on a 0-10 NPRS 1.47 (0.7) ODI 24.29 (12.92) 12 months Pain intensity on a 0-10 NPRS 1.53 (0.68) ODI 23.60 (13.17)	Standardised and covariate adjusted regression estimate for group difference with 95% CI given below Pain intensity 9 weeks -0.25 (-0.47 to 0.02) 6 months -0.06 (-0.30 to 0.18) 12 months -0.18 (-0.45 to 0.09) ODI 9 weeks -0.24 (-0.42 to -0.05) 6 months -0.31 (-0.50 to -0.12) 12 months -0.31 (-0.5 to -0.12) These results suggest that the intervention was successful in reducing pain-related disability compared to the control intervention at all timepoints, but there was no between group difference in pain intensity.
22	Shebib	2018	Pain intensity-measured using a 0-100mm visual analogue scale (VAS)	Results of ITT analysis Mean (SD) Baseline Von Korff pain 51.1 (17.8) Von Korrf disability 34.3 (23.1)	Results of ITT analysis Mean (SD) Baseline Von Korff pain 51.4 (17.4) Von Korrf disability 40.3 (24.0)	Group difference at 12 weeks follow-up, Mean (95% CI), p value Von Korrf pain -16.4 (-22 to

	(Over the last 24 hours, how bad was your back pain) A VAS measure of pain interference was also used on a 0-100 scale - 0=no interference, 100=worst imaginable interference using the question 'Over the past 24hours, how much has your back pain interfered with your daily activities) Function/disability - Measured using the Oswestry Disability Index (ODI) Alternative pain measures - Modified Von Korff scale for pain Alternative functional measures - Modified Von Korff scale for Disability	ODI 21.7 (12.1) VAS - Pain 46.3 (20.9) VAS pain interference 38.6 (26.6) 12 weeks Von Korff pain 33.8 (21.6) Von Korff disability 21.5 (19.6) ODI 17.6 (12.0) VAS - Pain 25.8 (21.4) VAS pain interference 21.1 (20.7)	ODI 21.0 (9.66) VAS - Pain 45.4 (20.8) VAS pain interference 43.9 (25.2) 12 weeks Von Korff pain 50.5 (21.4) Von Korrf disability 40.5 (25.7) ODI 21.1 (11.2) VAS - Pain 40.8 (23.2) VAS pain interference 38.2 (26.1)	-10.9), p<0.001 Von Korff disability -13 (-19.3 to -6.7), p<0.001 ODI -4.1 (-6.5 to -1.8), p<0.001 VAS pain -16 (-22.5 to -9.4), p<0.001 VAS pain interference -11.8 (-19.3 to -4.3), p=0.002 There were significant between group differences in pain and disability favouring the intervention group.

23	Schlicker	2020	Pain intensity: Worst, least and average pain over the last week recorded on a 0-10 numerical pain rating scale. The mean of the above three pain scores were summed and the mean presented as the 'global pain rating over the last week' Pain-related disability measured using the Oswestry Disability Index (ODI)	Global pain rating over the previous week: Baseline 4.68 (1.94) 9 weeks 4.68 (1.86) 6 months 3.89 (1.60) ODI Baseline 28.5 (17.97) 9 weeks 28.26 (16.29) 6 months 25.15 (13.43)	Global pain rating over the previous week: Baseline 4.08 (1.91) 9 weeks 3.81 (1.76) 6 months 3.67 (1.80) ODI Baseline 26.11 (16.79) 9 weeks 25.56 (16.52) 6 months 24.90 (15.27)	Analysis of covariance adjusted for sex, age, and baseline symptom severity was undertaken. Results presented as mean between-group difference and 95% confidence intervals, P-value 9 weeks: Average pain 0.23 (-0.22 to 0.68), P=0.06 ODI 0.02 (-0.42 to 0.47), P=0.35 6 months: Average pain 0.21 (-0.24 to 0.66), P=0.42 ODI 0.14 (-0.30 to 0.59), P=0.36
24	Suman	2019	Pain-related disability measured using the Roland and Morris Disability Questionnaire (RMDQ)	Baseline Mean (SD) RMDQ 5.1 (4.7) 3 months RMDQ 4.4 (4.7) 6 months RMDQ 3.9 (4.3) 12 months RMDQ 3.9 (4.3)	Baseline Mean (SD) RMDQ 5.9 (5.3) 3 months RMDQ 5.2 (5.1) 6 months RMDQ 4.8 (4.8) 12 months RMDQ 4.5 (4.7)	No significant between group differences were seen for pain related disability at any timepoint.
25	Toelle	2019	Pain intensity - measured using a 0-10 numerical pain rating scale (NPRS)	Mean (SD) Pain index: Baseline 5.10 (1.07) 6 weeks 4.33 (1.11)	Mean (SD) Pain index: Baseline 5.41 (1.15) 6 weeks 4.09 (1.42)	Between group difference at 12 weeks using either 2-sided t-test or chi-square test

			(current pain, maximum pain, and average pain over the last 4 weeks) Pain index was calculated as the mean of the current, maximum, and average pain intensity Functional ability - Hannover Functional Ability Questionnaire (HFAQ) The Physical functioning subscale of the Veterans Rand-12 was also reported	12 weeks 2.70 (11.51) HFAQ Baseline 0.79 (0.14) 6 weeks 0.77 (0.17) 12 weeks 0.8 (0.12) VR-12 Physical Baseline 41.65 (8.00) 6 weeks 46.53 (9.01) 12 weeks 50.58 (6.86)	12 weeks 3.40 (1.63) HFAQ Baseline 0.76 (0.15) 6 weeks 0.74 (0.12) 12 weeks 0.75 (0.12) VR-12 Physical Baseline 40.78 (8.18) 6 weeks 45.56 (8.78) 12 weeks 48.64 (8.22)	Pain index p=0.021 HFAQ - documented as not significant - p value not specified VR-12 physical - documented as not significant - p value not specified Therefore there was a significant between-group difference at 12 weeks for pain intensity favouring the Kaia app group, but no significant difference between the groups for physical function.
26	Yang	2019	Current pain intensity measured using a 100mm Visual analogue scale (VAS) Disability - measured using the Roland and Morris Disability Questionnaire (RMDQ) Health-related quality of life was also	Baseline: Mean (SD) Current pain VAS: 5.00 (1.87) RMDQ 6.00 (3.74) SF-36 subscales: Physical function 74.00 (21.62) Bodily pain 44.00 (18.17) 2 weeks Current pain VAS: 4.00 (2.55) RMDQ 5.20 (2.78) SF-36 subscales: Physical function 80.00 (13.69) Bodily pain 34.00 (15.17)	Baseline: Mean (SD) Current pain VAS: 6.00 (1.00) RMDQ 12.00 (3.61) SF-36 subscales: Physical function 46.67 (28.87) Bodily pain 63.33 (5.77) 2 weeks Current pain VAS: 6.67 (0.58) RMDQ 12.30 (4.16) SF-36 subscales: Physical function 51.67 (15.28) Bodily pain 53.33 (5.77)	When adjusting for covariates, no significant group effects were seen for the RMDQ, P=0.16. No significant between-group difference was seen for VAS scores, P=0.24. The Freidman test was used to test for between group differences in SF-36 physical function scores. A significant between-group difference was reported for the bodily pain

	measured using the SF-36, therefore the physical function and bodily pain subscales are also reported here.	4 weeks Current pain VAS: 3.40 (2.88) RMDQ 4.40 (3.05) SF-36 subscales: Physical function 59.00 (61.89) Bodily pain 40.00 (14.14)	4 weeks Current pain VAS: 6.00 (1.73) RMDQ 11.70 (5.69) SF-36 subscales: Physical function 51.67 (18.93) Bodily pain 56.67 (5.77)	subscale of the SF-36, P=0.008, favouring the intervention group.

Interventions

A brief overview of the interventions used in the included RCTs is given in Table 2.3 (Page 60). Further details of interventions and comparators for each RCT can be found in Table 2.4 (Page 67).

There was heterogeneity in the types of interventions included across eligible RCTs. Mobile apps (Toelle et al., 2019; Yang et al., 2019; Almhdawi et al., 2020), educational websites/online platforms (Chiauzzi et al., 2010; Carpenter et al., 2012; Del Pozo-Cruz et al., 2012; Krein et al., 2013; Riva et al., 2014), social media platforms (Kazemi et al., 2021), health-related quality of life reports (Licciardone and Pandya, 2020) and multimodal interventions (Lorig et al., 2002; Buhrman et al., 2004, 2011; Irvine et al., 2015; Heapy et al., 2017; Chhabra, Sharma and Verma, 2018; Geraghty et al., 2018; Amorim et al., 2019; Hou et al., 2019; Petrozzi et al., 2019; Shebib et al., 2019; Suman et al., 2019; Priebe et al., 2020; Sander et al., 2020; Schlicker et al., 2020; Baumeister et al., 2021) were all included. Fourteen of the RCTs involving multimodal interventions included some form of input from a healthcare provider (Lorig et al., 2002; Buhrman et al., 2004, 2011; Heapy et al., 2017; Chhabra, Sharma and Verma, 2018; Geraghty et al., 2018; Amorim et al., 2019; Hou et al., 2019; Petrozzi et al., 2019; Shebib et al., 2019; Priebe et al., 2020; Sander et al., 2020; Schlicker et al., 2020; Baumeister et al., 2021).

Outcome measures

Details of the relevant outcome measures used across included RCTs can be found in Table 2.5 (Page 106).

Twenty four out of the 26 included RCTs reported pain intensity/severity as an outcome. Ten different outcome measures were recorded, demonstrating the heterogeneity across included trials.

Similarly, 24 out of the 26 included RCTs reported physical function or pain-related disability as an outcome, with 14 different outcome measures reported. The Oswestry Disability Index and the Roland and Morris Disability Questionnaire were the most common, with eight (Chiauzzi et al., 2010; del Pozo-Cruz et al., 2013; Hou et al., 2019; Shebib et al., 2019; Almhdawi et al., 2020; Sander et al., 2020; Schlicker et al., 2020; Baumeister et al., 2021) and eleven (Lorig et al., 2002; Carpenter et al., 2012; Del Pozo-Cruz et al., 2012; Krein et al., 2013; Heapy et al., 2017; Geraghty et al., 2018; Amorim et al., 2019; Petrozzi et al., 2019; Suman et al., 2019; Yang et al., 2019; Licciardone and Pandya, 2020) RCTs using these measures respectively. Chhabra et al (2018) used a modified version of the Oswestry Disability Index in which the question about sexual function was replaced with a question about work ability.

Outcomes – Pain intensity/severity

An overview of the relevant findings of included RCTs can be found in Table 2.5 (Page 106).

Of the 24 RCTs that reported pain intensity/severity as an outcome, eight reported a statistically significant effect of the digital intervention on pain compared to the control intervention at the final follow-up time-point (Lorig et al., 2002; Irvine et al., 2015; Hou et al., 2019; Shebib et al., 2019; Toelle et al., 2019; Almhdawi et al., 2020; Priebe et al., 2020; Kazemi et al., 2021). Four of these RCTS were at high risk of bias according to the Cochrane RoB-2 tool (Irvine et al., 2015; Toelle et al., 2019; Priebe et al., 2020; Kazemi et al., 2021). The RCT by Yang et al (2019) did report a significant between-group difference in the 'bodily pain' subscale of the SF-36, but not in the visual analogue pain scale which was the primary measure of pain intensity. Fifteen RCTs reported no significant between-group difference in pain intensity. The RCT by Baumeister et al (2021) did report a

between-group difference at the nine-week follow-up favouring the intervention group, however this effect was no longer detectable by six-months post randomisation. The evidence supporting the effectiveness of digital interventions for improving pain levels in individuals with low back pain is, therefore, 'conflicting' (Van Tulder et al., 2003).

Outcomes – Physical function/pain-related disability

Ten of the 24 RCTs reporting physical function/pain-related disability as an outcome reported a statistically significant effect of the digital intervention compared to the control (Lorig et al., 2002; Carpenter et al., 2012; Del Pozo-Cruz et al., 2012; del Pozo-Cruz et al., 2013; Irvine et al., 2015; Chhabra, Sharma and Verma, 2018; Hou et al., 2019; Shebib et al., 2019; Almhdawi et al., 2020; Sander et al., 2020; Kazemi et al., 2021). Three of these were at high risk of bias (Carpenter et al., 2012; Irvine et al., 2015; Kazemi et al., 2021). Fourteen RCTs reported no significant between-group difference. Once again, the RCT by Baumeister et al (Baumeister et al., 2021) demonstrated a positive effect of the intervention on pain-related disability compared to the control at the nine-week follow-up, but there was no significant between-group difference detectable at six-months post-randomisation. The evidence supporting the effectiveness of digital interventions for improving physical function/pain-related disability in individuals with low back pain is, therefore, 'conflicting' (Van Tulder et al., 2003) as inconsistent findings were reported across multiple RCTs.

In total, six RCTs reported statistically significant effects of a digital intervention on both pain and physical function/pain-related disability at the final follow-up time point (Lorig et al., 2002; Irvine et al., 2015; Hou et al., 2019; Shebib et al., 2019; Almhdawi et al., 2020; Kazemi et al., 2021). Two of these were deemed to be at high risk of bias (Irvine et al., 2015; Kazemi et al., 2021). Three of these RCTs involved use of a smartphone or tablet

app by participants (Hou et al., 2019; Shebib et al., 2019; Almhdawi et al., 2020), with two of these combining use of the app with input from a healthcare professional (Hou *et al.*, 2019; Shebib et al., 2019). Two RCTs used multimodal interventions (Lorig et al., 2002; Irvine et al., 2015) (one of which included healthcare provider input (Lorig et al., 2002)) and one used social media as a platform for information provision (Kazemi et al., 2021).

Only two of the six RCTs reporting statistically significant effects of the digital intervention on both pain and physical function/pain-related disability provided point estimates for the mean between-group differences for these outcomes (Shebib et al., 2018; Hou et al., 2019). Shebib et al. (2018) reported 95% confidence intervals that included the minimum clinically important difference (MCID) for pain (Hawker et al., 2011) but not for pain-related disability (Ostelo and de Vet, 2005). The mean between-group differences for pain and pain-related disability at 24 months reported by Hou et al. (2019) may not have been clinically meaningful (Hawker et al., 2011; Ostelo and de Vet, 2005).

The evidence supporting the effectiveness of digital interventions for improving pain and physical function/pain-related disability in individuals with low back pain is 'conflicting' (Van Tulder et al., 2003).

Behaviour change techniques

In total, 16 unique BCTs were identified across the 26 included RCTs (see Table 3). The most common were 'instructions on how to perform the behaviour', 'information about health consequences', 'prompts and cues', 'demonstration of the behaviour', 'body changes', and 'self-monitoring of the behaviour'. The median number of BCTs per digital intervention in included trials was five. The modal number of BCTs per intervention was also five. Within the six trials reporting a positive effect of the digital intervention on pain and physical function, the number of BCTs per intervention ranged from three to nine.

An overview of the BCTs employed in included trials reporting a statistically significant effect of the digital intervention on pain or physical function is shown in Figure 2.3.

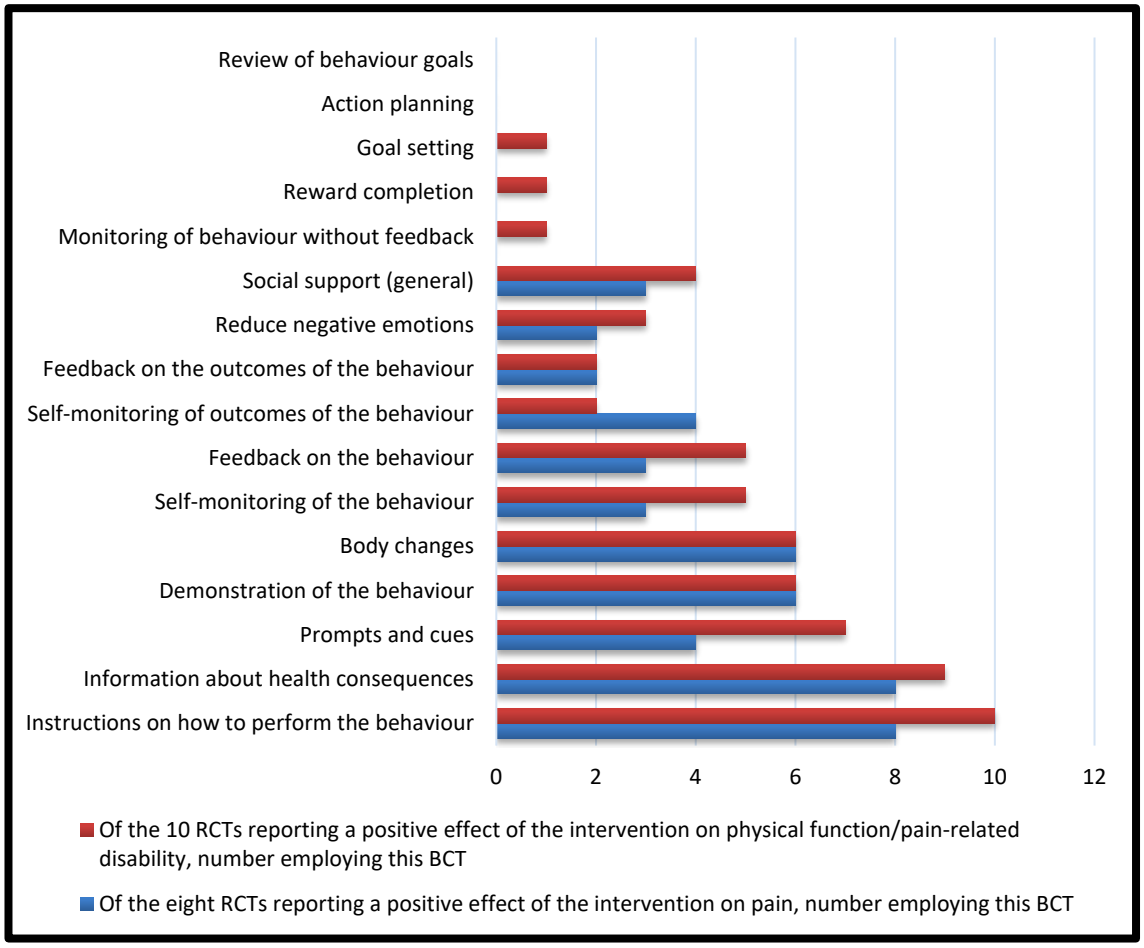


Figure 2.3. Behaviour change techniques employed in RCTs reporting a statistically significant effect of the digital intervention

2.5.3 CONTEXTUALISING THE FINDINGS OF THIS SYSTEMATISED REVIEW

This systematised review aimed to address the limitations of previous systematic reviews of the effectiveness of digital interventions for low back pain to inform this PhD study and achieve the objectives listed in section 2.5. This systematised review examined the effectiveness of digital interventions in improving pain and physical function/pain-related disability in adults with lower back pain, pelvic girdle pain and lumbopelvic pain; this was to inform the design of a digital self-management intervention for women experiencing pregnancy-related lumbopelvic pain. No RCTs could be located that explicitly reported the

inclusion of pregnant women in the study sample. Twenty-six RCTs were included in this review and the results were found to be inconsistent. Six of the included RCTs reported a statistically significant positive effect of the digital intervention on both pain and physical function/pain-related disability—three of these involved interventions that included a smartphone or tablet app. One RCT used social media to provide information, and two employed other multimodal interventions. Two of the six RCTs showing positive results were rated as 'high risk of bias' using the Cochrane ROB-2 tool; this had to be kept in mind when interpreting the findings of this review.

The inconsistent findings of this review are in keeping with those of recent systematic reviews examining the effectiveness of digital interventions for the management of chronic pain (Pfeifer et al., 2020) and musculoskeletal conditions (Hewitt et al., 2020). The inclusion of a broad range of digital interventions in this review was necessary to achieve the study aims; however, this may partly explain the reported inconsistency in the findings. Variation in intervention duration and primary endpoint selection across included studies may have also contributed.

It is noteworthy that three of the six effective digital interventions in this review used mobile phone or tablet apps as platforms for intervention delivery. None of these three RCTs were at high risk of bias, increasing the likelihood that the findings reflect the true effect of the intervention (Phillips et al., 2021). There could be many reasons for this observation, but the familiarity and convenience of smartphone technologies could be a factor. The majority of time spent online by UK adults is spent on smartphones (Ofcom, 2021). The accessibility of smartphones may promote improved levels of engagement or mean that users are more receptive to interventions delivered via these channels. Mobile technologies may therefore be a viable option for future digital intervention development, providing their use is endorsed by the target population. App-based

interventions have already shown some promise in promoting health-related behaviour change during the antenatal period (Daly et al., 2018) and are therefore worthy of consideration for delivery of a PLPP self-management intervention.

Previous systematic reviews have highlighted multiple features of digital behaviour change interventions thought to influence user engagement; these include the quality of the information provided, the degree of personalisation of intervention content, and the aesthetic appeal of the user interface (O'Connor et al., 2016; Perski et al., 2017; Szinay et al., 2020). User engagement is also viewed as a precursor to engagement in the desired behaviours (Cole-Lewis et al., 2019). However, of the six RCTs that reported the effectiveness of a digital intervention for improving pain and physical function/pain-related disability, only three explicitly reported participant adherence to the digital intervention. Interestingly, in each of these three cases, where the intervention involved a mobile or tablet app, the level of adherence reported was higher than that typically seen with medical apps (Statista, 2020). Almhdawi et al. (2020) reported the average daily usage of their app to be six minutes and forty seconds throughout the six-week intervention period, whilst Shebib et al. (2018) reported that 75% of the intervention group engaged with their tablet app each week. Shebib et al. (2018) also reported a high level of ongoing use of their Bluetooth-sensor-guided exercise program, with 68% of the intervention group demonstrating ongoing use during the final three weeks of the twelve-week intervention period. This high level of participant engagement may partly explain the positive outcomes reported (Cole-Lewis et al., 2019).

Furthermore, Hou et al. (2019) reported that 38 of the 84 participants randomised to their intervention group continued to use the app and undertake the five recommended weekly exercise sessions at the 24-month follow-up. Given that there is usually a rapid decline in app use over the first 30 days following download (Baumel et al., 2019), this

level of ongoing engagement two years after randomisation is exceptional and may have contributed to the apparent effectiveness of the intervention. It is, however, noteworthy that the intervention trialled by Hou et al. (2019) was multimodal and included healthcare professional input: HCP input is known to promote uptake and engagement with digital behaviour change interventions (O'Connor et al., 2016) and may have contributed to the high level of ongoing engagement seen in this RCT. Therefore, this type of multimodal intervention should be considered an option when developing future digital self-management interventions.

Tailoring or personalising digital intervention content has been reported to be an important facilitator of user engagement (Svendson et al., 2020). However, only one of the six RCTs in this review reporting intervention effectiveness described tailoring of informational content; Irvine et al. (2015) reported tailoring content based on the type of occupation the user undertook (i.e., whether the user reported predominantly sitting, standing, driving, or lifting during their working hours). Although this RCT reported positive findings, it was deemed to be at high risk of bias. Additionally, the three aforementioned app-based interventions incorporating static informational content resulted in positive outcomes and high levels of engagement. This questions the value of tailored information and highlights the need for an improved understanding of the factors influencing user engagement with digital interventions.

In this review, the use of the TIDieR guidance to support data extraction highlighted gaps in the reporting of several RCT interventions, including that trialled by Kazemi et al. (2021). This RCT was deemed to be at high risk of bias, but the intervention was reported to be effective in improving pain and physical function in female nurses with occupational low back pain. Consequently, in addition to the methodological issues highlighted during the risk of bias assessment, incomplete intervention reporting was also noted, further

limiting the utility of this RCT to inform this PhD study. The authors offered no information about the type of educational content included, the specific social media platforms used for information provision, or how trial participants were encouraged to engage with the educational content (i.e., whether participants were asked to read the information posted or whether 'commenting', 'liking' or 'sharing' of content was actively encouraged). This limits the utility of this RCT to inform future intervention development, as an accurate replication of the intervention would not be possible (Yamato et al., 2016).

Lorig et al. (2002) attempted to use email discussion groups to facilitate back pain self-management by providing a means of social support. This was combined with information provision via a printed booklet and videotape. This multimodal intervention effectively improved pain and disability in participants with low back pain. However, 107 of 202 intervention group participants asked to be removed from the mailing list early in the intervention period due to the overwhelming volume of email traffic (Lorig et al., 2002); this suggests that the intervention was unacceptable to over half of the intervention group. Additionally, due to the comparator chosen in this RCT, it is impossible to conclude whether the email discussion group provided any additional benefit compared to the provision of the educational information booklet. Nevertheless, this trial was published in 2002 and predates the widespread uptake of social media platforms such as Facebook and Instagram. Such platforms may provide an alternative mode of asynchronous online interaction that users may better tolerate and may, therefore, be a viable alternative for similar multimodal interventions. This review has highlighted that very few social media-based interventions have been trialled in the context of back pain self-management. Therefore, the acceptability of such platforms for intervention delivery should be explored to help inform decision-making.

The decision to include multimodal self-management interventions in this review, including those that involve non-digital components or input from a healthcare professional, may be questioned by some, owing to the resultant difficulty in understanding the true effect of the digital component (Skivington et al., 2021). This is a legitimate argument; however, the recent meta-analysis by Chen et al. (2021) highlighted that multimodal interventions comprising the addition of mobile-health interventions to usual care are more effective than usual care alone in reducing pain and disability in those with low back pain (Chen et al., 2021). As this review aimed to inform future intervention development, it was considered essential to ensure all viable options were considered. Therefore, the inclusion of relevant multimodal interventions involving both digital and non-digital components was deemed necessary.

Previous research has identified several components of lower back pain self-management interventions that are important to promote positive outcomes: condition-related education, exercise, activity planning, self-monitoring of symptoms and progress, and social support are frequently cited (Ryan and Sawin, 2009; Mann et al., 2013; Mansell et al., 2016). Only one RCT included in this review combined these key components into a single multimodal intervention (Geraghty et al., 2018). As this was a feasibility trial, it may have been underpowered to establish the effectiveness of this intervention definitively. It is, therefore, possible that a failure to adequately consider these components during the intervention design process could be responsible for the null findings reported in over half of included RCTs. Therefore, the intervention components included in any future intervention developed for women with PLPP must be carefully considered. Behaviour change theory should inform decision-making throughout the intervention development process.

A 2015 review by Keogh et al. (Keogh et al., 2015) demonstrated that non-digital self-management interventions for low back pain and arthritis in the general population include such behaviour change techniques as 'instruction on how to perform the behaviour', 'demonstration of the behaviour', and 'body changes'. In this systematised review, 'instructions on how to perform the behaviour', 'information about health consequences', 'prompts and cues' 'demonstration of the behaviour', and 'body changes' were found to be the most common. The number of BCTs included in effective interventions ranged significantly from three to nine. As yet, no definitive guidance exists as to which specific BCTs should be included in back pain self-management interventions to maximise chances of success (Armitage et al., 2021). The behaviour change intervention development process described by Michie et al. (2014) will therefore be considered when designing the self-management intervention for women with PLPP to avoid wasting valuable resources on ineffective interventions.

The heterogeneity noted in the choice of outcome measures across included RCTs in this review is unsurprising since half were published during or before 2018. This means that the influential publication by Chiarotto et al. (2018), listed on the Core Outcome Measures in Effectiveness Trials (COMET) database, would not have been available. Recently, a core outcome set for PLPP has been developed and includes pain frequency, pain intensity, physical function, health-related quality of life, and fear avoidance (Remus et al., 2021). However, no recommendations have been made about which specific outcome measures best capture these important outcomes. Therefore, careful consideration will be given to the choice of outcome measures used throughout the development and evaluation of any future digital intervention designed to support the self-management of PLPP.

Finally, although there are many similarities in the management of non-specific LBP and PLPP, some may argue that the biomechanical, hormonal, and postural changes during pregnancy make these two conditions clinically distinct. This makes the generalisability of the findings of non-specific lower back pain research to the target population challenging to establish. Ten RCTs actively excluded pregnant women in this review, and none specified whether pregnant participants were included in the final sample. In addition, the mean ages of participants in this review varied across RCTs from 35 to 60.3 years, yet the most common age range for women giving birth in England and Wales in 2019 was 30-34 years (Office for National Statistics 2020). This makes the generalisability of the findings of this review to women with PLPP questionable and highlights the need for digital self-management research in this specific population.

This review has several limitations. The screening, data extraction, risk of bias assessment, and data analysis were all undertaken by a single reviewer. Although this is common within a systematised review approach (Grant and Booth 2009), the potential for the inadvertent introduction of bias into the analysis must be considered. Additionally, McDonagh (2013) states that dual review is desirable for systematic reviews, whilst Waffenschmidt (2019) demonstrated that dual review resulted in fewer eligible studies being missed compared with a single reviewer. It is, therefore, possible that potentially eligible RCTs may have been inadvertently omitted from this review. Coding of the discernible BCTs included in trial interventions relied on the descriptions provided in the published trial reports and supplementary material. However, use of the TIDieR guidance to support data extraction highlighted gaps in the reporting of several trial interventions. It is therefore possible that additional BCTs may have been employed that could not be identified using the available information. The electronic database searches were limited to papers published in English, and the search terms used reflected the sole inclusion of

RCTs. This may have resulted in the omission of potentially relevant articles. The inclusive eligibility criteria employed in this review may have contributed to the inconsistent findings reported; however, examining the effectiveness and characteristics of a broad range of digital self-management interventions improved the utility of this review for informing future digital intervention development. The broad eligibility criteria should therefore be viewed as a strength.

Finally, when the protocol for this review was developed, it was determined that all studies with a randomised design should be included. However, four of the RCTs ultimately included (Geraghty et al., 2018; Amorim et al., 2019; Licciardone and Pandya, 2020; Schlicker et al., 2020) were feasibility trials; this means that the aim of these trials was not to establish the effectiveness of the intervention, rather to test the feasibility of the proposed study procedures (Eldridge et al., 2016). Therefore, these trials may not have been powered to detect a meaningful between-group difference in outcomes. Consequently, it cannot be concluded that the interventions used in these trials were ineffective, only that further fully powered trials are needed. Future systematic review authors may consider excluding feasibility trials to avoid this additional complexity.

2.5.4 Relevance of these findings to the current thesis

No RCTs could be located that examined the effectiveness of digital interventions for the self-management of PGP or LPP, and the available evidence relating to the effectiveness of digital interventions for the self-management of lower back pain in the general population is inconsistent. The lack of clarity regarding the recruitment of pregnant women and the age range of participants in included RCTs makes the generalisability of the findings of this review to the population of women with PLPP questionable. This review, therefore, highlights the lack of attention given to women with PLPP in digital

self-management research and underscores the need for targeted intervention development and evaluation for this specific population.

Section 2.5 addresses the first objective of this PhD study (see section 1.3) by examining the literature relating to the use of digital interventions for the management or self-management of low back pain in the general population. The information obtained from this review, including the types of digital intervention worthy of consideration and the behaviour change techniques employed in effective interventions, informed decision-making during the Phase 2 intervention development process (Chapter five).

CHAPTER THREE: STUDY OVERVIEW, PHILOSOPHY, METHODOLOGY AND ETHICAL CONSIDERATIONS

3.1 INTRODUCTION

This chapter presents a reminder of the aims and objectives of this PhD study and presents the methodological theory used to inform it. The ethical issues raised by this body of work will be briefly discussed. The regulatory approvals secured to allow this work to proceed will also be stated.

3.2 PURPOSE OF STUDY AND OVERVIEW OF STUDY DESIGN

The aim of this PhD study was to develop a feasible digital intervention to support the self-management of pregnancy-related lumbopelvic pain (PLPP). Once the literature relating to digital interventions for low back pain in the general population had been reviewed (objective number 1), the remaining objectives were to:

2. explore the PLPP-related information-seeking practises of women currently experiencing this condition
3. explore the attitudes of NHS service users and NHS-based antenatal HCPs regarding the use of digital media for the provision of PLPP-related information
4. explore the acceptability and perceived utility of the notion of a digital intervention to support the self-management of PLPP.
5. develop a prototype digital intervention based on the outcomes of objectives 1-4
6. examine how users engage with the prototype intervention to inform a preliminary judgement of its feasibility and any necessary future modifications

To achieve the remaining objectives (objectives two to six), this PhD study was divided into three sequential phases, each aiming to achieve different objectives. This is shown in figure 3.1 below.

Figure 3.1. Overview of study design.

The first phase addressed objectives two to four and included a qualitative study involving three key stakeholder groups, namely, National Health Service (NHS) service users, NHS-based midwives, and NHS-based physiotherapists. This qualitative study consisted of individual semi-structured interviews with women experiencing PLPP and focus groups with physiotherapists and midwives. The phase 1 qualitative findings directly informed subsequent study phases. The second phase addressed objective five and involved a structured process of intervention development in line with the 'Behaviour Change Wheel' approach devised by Michie et al (2014).

The third phase addressed objective six and aimed to establish how the intervention was being used in practice to inform an assessment of its feasibility: this was achieved by a retrospective quantitative analysis of user engagement data automatically collected via the online platform to which the intervention is connected.

There is much debate in the methodological literature about the delineation between 'mixed method' and 'multimethod' research (Anguera et al., 2018): 'mixed-methods' research is understood to involve the combination of both qualitative and quantitative data within the same study to provide a broader answer to a research question. However, 'multimethod research' could refer to the use of multiple qualitative methods (e.g., ethnography and individual interviews) or multiple quantitative methods (e.g., experiments and surveys) (Tashakkori and Teddlie, 2010). This PhD study, therefore, used a 'mixed methods' approach rather than a 'multimethod' (Anguera et al., 2018).

In the following sections, the philosophical underpinnings of mixed-methods research will be discussed, followed by an explanation of how the methodological literature relating to mixed-methods research has informed the design of this PhD study.

3.3 THE PHILOSOPHICAL UNDERPINNINGS OF MIXED METHODS RESEARCH

Although mixed methods research is now commonplace in health research (O'Cathain, 2009), the justification of combining methods in this way has been questioned (Denzin, 2010). This has led to the offering of pragmatism as a philosophical alternative to both positivism and constructivism that can underpin mixed methods research (MMR) and justify the combination of both qualitative and quantitative methods within a single study or program of research (Teddlie and Tashakkori, 2009).

In their early work, Lincoln and Guba (1985) described two opposing paradigms, namely positivism (which was later modified to post-positivism) and constructivism. These two paradigms differ on ontological and epistemological levels and have been seen as two opposing standpoints that are thought to underpin specific methods of research inquiry.

On a simplistic level, advocates of the post-positivist paradigm believe in a singular version of reality. The 'investigator' and 'investigated' are seen as two separate entities, whereby the researcher can study the object of the research without influencing it or being influenced by it. This is referred to as 'value-free' inquiry. Conversely, constructivists assert that there are multiple, constructed versions of reality in existence and that time and context-free generalisations are neither desirable nor possible. The researcher is seen as an active participant in the co-construction of the research findings, and it is accepted that the values and experiences of both the researcher and participant will directly influence the research outcome (Guba et al., 1994). Although it is never explicitly stated that qualitative research is solely the property of constructivists or that

quantification methods may only be used by post-positivist researchers, both the ontological and epistemological underpinnings of the constructivist paradigm advocate the employment of methods that allow interaction between the researcher and participant. Therefore, methods such as interviewing, observation and ethnography have traditionally been favoured by proponents of this paradigm (Denzin, 2010). Similarly, experimentation, the manipulation of variables, and the collection of quantitative data have traditionally been the methods of choice for the post-positivist researcher.

Throughout the 1990s, researchers began making the case that 'Pragmatism' provided an alternative paradigm that allowed the researcher to be free from the constraints imposed by the forced dichotomy between post-positivism and constructivism (Feilzer, 2010). Several defining characteristics of the classical pragmatist philosophy distinguish it from post-positivist and constructivist viewpoints. Principally, classical pragmatism asserts that an external reality exists, but we can only gain knowledge of that reality through interaction (or transaction) with it (Haack, 2004; Biesta, 2010). By interacting with the world around us, we construct our own experience of that external reality. Knowledge is therefore viewed as being both constructed and based on the reality of the world (Johnson and Onwuegbuzie, 2004; Teddlie and Tashakkori, 2009; Tashakkori et al., 2020). Therefore, the traditional dualism of realism versus relativism loses its meaning in this context, providing an alternative viewpoint more conducive to the mixing of methods (Biesta, 2010).

Researchers often state pragmatism to advocate a 'do what works in practice' approach to research methodology (Biesta, 2010). Classical pragmatism asserts that knowledge is gained through inquiry (Haack, 2004). One then makes assertions (knowledge claims) based on the outcome of that inquiry (Putnam, 1995; Hickman et al., 2009; Biesta, 2010). In this context, the type of knowledge claim one wants to make will dictate the methods

selected. For this reason, pragmatism has been described by some as the philosophical partner of MMR (Teddlie and Tashakkori, 2009) by providing a sound philosophical basis for the combination of qualitative and quantitative methods within the same study.

As a practising physiotherapist, the notion of combining patient stories (qualitative information) with clinical tests (quantitative information) to address a clinical problem was familiar to the researcher. Valuing the experiences and perceptions of patients in addition to the objective aspects of clinical assessment highlights a recognition that knowledge of the reality of a patient's condition is both subjective and objective. This mirrors some of the central tenets of pragmatism and reflects the dualistic nature of mixed-methods inquiry. Pragmatism, therefore, provided the researcher with an underpinning philosophy that is acknowledged in the methodological literature as a sound basis for mixed methods research (Teddlie and Tashakkori, 2009) and closely aligned with her prior beliefs, values, and actions.

3.4.1 MIXED METHODS RESEARCH

Several definitions of mixed methods research have been proposed in the literature over the last three decades (Creswell, 2016). A common feature of these is the combination of at least one qualitative and one qualitative method within the same project (Hesse-Biber, 2015; Hesse-Biber and Burke Johnson, 2015)). Creswell and Plano Clark (2017, page 5) suggest four core characteristics of mixed methods research to provide an all-encompassing definition that combines philosophy, methods, and research design, as follows: *'mixed methods research…*

- *'…collects and analyses both qualitative and quantitative data rigorously in response to research questions and hypotheses'*
- *'…integrates (or mixes or combines) the two forms of data and their results'*

- *'…organises these procedures into specific research designs that provide the logic and procedures for conducting the study'*
- *'…frames these procedures within theory and philosophy'*

By combining qualitative and quantitative methods in the same study, the weaknesses of each method are offset by the strengths of the other (Creswell, J. and Creswell, D., 2018). Therefore, mixed methods research can provide a deeper understanding of the phenomenon under study and may provide a more complete answer to a research question. Qualitative research can provide detailed perspectives from a small number of individuals and allow their experiences to be understood in context. However, it has limited generalisability as the research findings are viewed as context-specific (Creswell 2007). Conversely, quantitative research can draw conclusions for large numbers of people, and the findings can be generalised more widely. It can also investigate relationships within data and examine causes and effects. However, the voices of individual participants are lost when using quantitative methods, and this form of inquiry provides little understanding of context (Creswell, 2014).

According to Greene et al. (1989), there are five main reasons for choosing to combine both qualitative and quantitative research methods within the same study:

1. Triangulation: where a researcher seeks convergence or corroboration of the results gained using the two different methods

2. Complementarity: where a researcher seeks elaboration, enrichment, or clarification of the results from one method by using the results from the other method

3. Development: where a researcher intends to use the results from one method to help inform decisions made regarding the use of the other method (e.g., sampling

or measurement decisions made in a quantitative study may be informed by a preceding qualitative study)

4. Initiation: where the researcher seeks the discovery of paradox and contradiction in order to provide new perspectives

5. Expansion: where the researcher seeks to extend the breadth of inquiry by using different methods for different components of the research question

In this PhD study, the purpose of mixing methods was primarily for development. The Phase 1 qualitative study served to inform both the development of the intervention and the evaluation of its feasibility.

3.4.2 MIXED METHODS RESEARCH DESIGNS

Within the 'core design' typology of mixed methods research described by Creswell and Plano Clark (2017), there are three core research designs:

● Explanatory sequential design

● Exploratory sequential design

● Convergent design

The mixed-method design employed in the current study is the exploratory sequential design. This involves is a three-stage process:

1. Qualitative data collection and analysis.

2. The design of either a new measure, new instrument, or new intervention.

3. Evaluation of the new measure, instrument, or intervention via quantitative data collection methods (Creswell and Plano Clark, 2017).

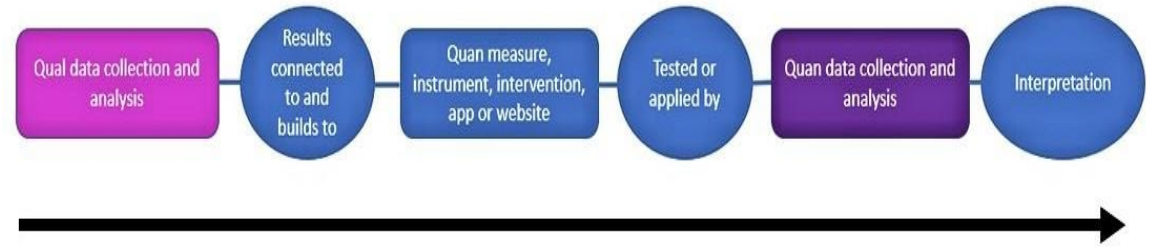


Figure 3.2. Exploratory sequential design (reproduced from Creswell and Plano Clark, 2017)

Within the exploratory sequential design, integration of the two forms of data occurs when the findings of the qualitative strand are used to inform the development of the measure, instrument, or intervention (Creswell and Plano Clark, 2017). Using this mixed-methods design ensures that the intervention is grounded in the participants' views and facilitates the evaluation of the intervention within the same program of study. This approach articulates well with the intervention development theory used in this thesis and the guidance provided in the Medical Research Council (MRC) framework for developing and evaluating complex interventions (MRC, 2008).

3.5.1 Conceptualisation of 'intervention', 'feasibility' and 'acceptability' in this thesis

Understanding objectives two to six of this PhD study demands clarity about how the terms 'intervention', 'feasibility' and 'acceptability' have been conceptualised.

In this thesis, the term 'intervention' is defined as any activity undertaken with the objective of improving the health of women with PLPP by either reducing the severity of PLPP symptoms, reducing the impact of symptoms, or improving physical function. This definition was developed from that proposed by Smith et al., (2015).

The term 'intervention feasibility' is less easily defined. Much of the methodological literature relating to 'feasibility studies' focuses on examining the practicability of large-

scale randomised controlled trials (Lancaster, 2015). In this context, assessing if an intervention can be delivered as intended is just one of many indicators of the feasibility of a future large-scale trial (Arain et al., 2010; Eldridge et al., 2016). In this thesis, the focus is not on the feasibility of a future trial, but on the feasibility of the intervention itself, therefore, Bowen's conceptualisation of intervention feasibility has been adopted (Bowen et al., 2009).

Eight potential areas of focus for intervention feasibility studies were identified (Bowen *et al.*, 2009). See Table 3.1 below.

Table 3.1. Eight potential areas of focus for feasibility studies adapted from Bowen et al 2009.

Areas of focus	Definition
Acceptability	How do intended users of the intervention react to the intervention?
Demand	Is there a demand for the intervention in practice?
Implementation	Can the intervention be delivered as planned?
Practicality	Can the intervention be delivered within the practical constraints of time or resources?
Adaptation	Can an intervention that has been shown to be effective in one setting be adapted for use in another? What adaptations need to be made and how?
Integration	Can the intervention be integrated into an existing system or infrastructure?
Expansion	Can the use of an already successful intervention be expanded to a different setting or population?
Limited efficacy	Does the intervention show some signal of efficacy when tested in a limited way?

The cells in Table 3.1 shaded in blue represent the areas of focus for this PhD study: acceptability, demand, practicality, and integration.

Within this feasibility framework, establishing the acceptability of an intervention is a crucial area of research focus. However, the temporal aspect of acceptability must also be recognised to plan appropriate data collection methods:

- Prospective acceptability describes the perception of acceptability formed before using an intervention.
- Concurrent acceptability represents the perception of acceptability constructed whilst using an intervention.
- Retrospective acceptability is the perception of acceptability constructed when an individual reflects on the entirety of their experience of using an intervention (Sekhon et al., 2017).

How a person feels about an intervention and whether the intervention fits with their value structure can be explored prior to intervention use. However, judgements about intervention coherence or perceived effectiveness may require experience of using the intervention (Sekhon et al., 2017). The qualitative study presented in this thesis will focus on the prospective acceptability of the intervention. It will also capture healthcare professionals' perceptions about the practicality of the intervention and the feasibility of its integration into current clinical practice.

3.5.2 How intervention demand, practicality, and integration were captured in this PhD study

The conceptualisation of intervention feasibility described by Bowen (2009) states that the demand for an intervention can, in part, be demonstrated by collecting data that show how an intervention is used in practice. In the context of a digital intervention, this will include measuring the level of uptake and user engagement (Lalmas et al., 2014). Engagement is, however, a multifaceted concept and has traditionally been understood differently by different academic communities: whilst the computer science community

has conceptualised engagement as a subjective experience, the behavioural science community has typically defined engagement in behavioural terms (Lalmas et al., 2014; Perski, Blandford, West, et al., 2017). In this thesis, engagement is conceptualised in behavioural terms and therefore represents the frequency, duration, and depth of interaction with the intervention (Perski, Blandford, West, et al., 2017). The retrospective quantitative analysis described in Chapter six of this thesis focussed on the level of uptake and duration of engagement with the intervention. The depth of engagement was captured by establishing which intervention features were engaged with and whether this engagement was sustained over time.

The Phase 1 qualitative exploration was undertaken to assess the prospective acceptability of the intervention from the perspective of NHS service users and clinicians. The perceived practicality of the intervention and the perceived ease of integration of the intervention into current practice was also explored. Together with the assessment of intervention demand described above, this information allowed the researcher to make a preliminary assessment of the overall feasibility of the intervention.

3.6 Ethics and governance

This PhD study involved three sequential phases and the design of Phases 2 and 3 depended on the findings of Phase 1. It was, therefore, not desirable to obtain a single ethical approval to cover the entire project; two separate submissions were made. The research involved the recruitment of NHS patients and therefore required approvals from the Research Ethics Committee (REC), the Health Research Authority (HRA), the host academic institution and the local NHS research and development (R&D) department. A submission for REC approval was made in 2015 (IRAS ID number 183127, REC reference 15/NI/0270). A substantial amendment was submitted in 2016 to request permission for

individual service user interviews to be undertaken via telephone (Substantial amendment number 1 – 15/09/2016). A second substantial amendment for change of sponsor was approved after transfer of the PhD to Manchester Metropolitan University (MMU) (Substantial amendment number 2 – 27/07/2018).

A separate submission was made for REC, HRA, MMU, and R&D approvals to cover the retrospective analysis of user engagement data (IRAS ID number 290483, REC reference 21/PR/0084). A data processing agreement between the researcher, the host NHS Trust, and the app-development company 'Living With Ltd' was constructed as part of this process. For this agreement, the researcher was named as data processor, Lewisham and Greenwich NHS Trust as the data controller, and 'Living With Ltd' as the third party clinical services provider, who hold and manage data on behalf of the data controller (the NHS Trust).

3.6.1 Ethical considerations

Phase 1

Phase 1 of this PhD study involved women in the late stages of pregnancy. Therefore, every effort was made to minimise the burden on participants. Telephone interviews were offered to minimise the burden of travel. If in-person interviews were attended, comfort breaks were ensured, and refreshments were provided. Furthermore, the majority of participants were in the last trimester of pregnancy at the time of the Phase 1 interviews. The decision was therefore made not to send transcripts for member-checking; it was felt that the request for participants to review transcripts in the final weeks of their pregnancy or the early post-partum period would significantly increase the burden of participation.

PLPP is not considered a sensitive topic. However, clinical experience showed that discussion of PLPP and the resultant movement restriction could lead to conversations about difficulties with intimate relationships. Therefore, the risk that the interview content could become sensitive had to be considered. The host Trust R&D team undertook their standard risk assessment of the Phase one study protocol and concluded that the study posed a 'low risk of harm to patients'. Nonetheless, several steps were taken to minimise the risk of distress to participants as far as possible, and to protect the emotional wellbeing of the researcher; these are described below:

- As a condition of her employment as a Research Physiotherapist within the host NHS Trust, the researcher had undertaken Good Clinical Practice (GCP) training for secondary care via the 'NIHR Learn' online platform. This ensured that the researcher was appropriately trained to gain informed consent from participants and was able to adequately explain the potential benefits and risks of the study.
- At the start of each service user interview, participants were informed that anything shared during the interview would remain confidential, except where there was a legitimate concern for the immediate safety of the participant or those around them. If the researcher was unsure of whether a concern should be reported, she had the option to discuss this with a designated member of the R&D team at the host Trust with experience of safeguarding issues. If a genuine safeguarding issue had arisen, the host Trust safeguarding team would have been contacted.
- During the service user interviews, if any participant raised issues such as low mood, anxiety, or poor pain management, but there was deemed to be no immediate risk to their personal safety, they would be advised to discuss the issue with their GP or Midwife. Participants could also be signposted to the Pelvic Pain

Partnership website for advice and support if no specific medical input was required. The Pelvic Pain Partnership are a charitable organisation that provide information, advice, and support to women with PLPP.

- As a member of staff at the host NHS Trust, the researcher had rapid access to mental health first aid services via the Trust occupational health department if any distressing issues had arisen. The researcher also had the option of discussing any distressing conversations with the supervisory team if required.

Furthermore, no funding for interpretation services meant that recruitment was limited to English-speaking women as the researcher is unilingual. This was unavoidable in this context but resulted in limited diversity amongst participants and reduced inclusivity. Evidence of the relevant regulatory approvals for Phase 1 can be found in Appendix 13.

Phase 2

Consultation with service user representatives in Phase 2 met the National Institute for Health Research definition of patient and public involvement (NIHR, 2021). Therefore, this activity did not require formal approval by the local ethics committee or the Health Research Authority. Service user representatives were compensated for their time via the provision of a £25 voucher; this is aligned with available guidance on payment for patient and public involvement (INVOLVE, 2012).

Phase 3

To gain HRA approval for Phase 3 of this PhD study, it was important to clarify how the user engagement data would be processed, and that the proposed study protocol was in line with the relevant data protection legislation.

The General Data Protection Regulation (GDPR) was introduced in May 2018 as Europe's framework for data protection law (Information Commissioner's Office (ICO), 2022). The UK left the European Union on the 31st of January 2020, however, the GDPR has been retained in UK law as the UKGDPR (ICO, 2021). As GDPR covers the processing of personal data only, it is important to distinguish between personally identifiable data, pseudonymised data, anonymised data, and anonymous data, as only the first two are subject to GDPR legislation (ICO, 2021). According to the ICO (2021), which is the UK's independent authority set up to uphold information rights in the public interest, personally identifiable data is any information relating to an identified or identifiable living individual. Pseudonymisation is the process of replacing or removing personally identifiable information from a dataset, so that individuals cannot be reidentified without access to additional information (ICO, 2021). Pseudonymised information is still considered to be personal data and therefore is still within the scope of the UKGDPR.

Anonymisation is the process of converting personal data into anonymised data by permanently removing all identifiable information. This process is irreversible and data subjects cannot be reidentified. Consequently, anonymised data falls outside the scope of UKGDPR legislation as anonymised data is no longer considered to be personal data (ICO, 2021).

The term 'anonymous' describes the status of a dataset signifying that the data were never identifiable to the accessing individual (Dove, 2019). The ICO hold that the same information can be personal data to one organisation (if access to the additional information required to reidentify the dataset is possible), but anonymous to another; the status of the data depends on the context (ICO, 2021). In Phase 3, the user engagement data provided by Living With Ltd were technically pseudonymised, as healthcare professionals at the host NHS Trust with access to physiotherapy records would have

been able to re-identify individual data subjects based on the dates that access to the app was provided. However, the dataset was anonymous to the researcher as she had no access to any of the additional information required to allow re-identification. Therefore, in this context, the Phase 3 study protocol involved accessing and analysing anonymous data only. This had important implications for the HRA approval process as there is no expectation to request retrospective participant consent for use of anonymous data (HRA, 2022a).

Under Article 6 of the GDPR, personal data can also be processed for the purposes of research without explicit consent (ICO, 2022). However, where the confidential personal data of NHS patients is involved, the preference is for consent to be gained. Where this is not practicable, additional approval by the Confidentiality Advisory Group (CAG) is usually required (HRA, 2022b). Consequently, in Phase 3, the HRA and REC approval applications highlighted the anonymous status of the data from the perspective of the researcher. This ensured that additional CAG approval was deemed unnecessary despite the data being used without explicit participant consent.

It was requested by the host Trust's Information Governance (IG) manager that a data processing agreement be drafted and considered alongside the standard data processing verbiage included in the HRA Organisational Information Document (OID). These documents can be found in Appendix 13. It was also a condition of the host NHS Trust's IG manager that the researcher's clinical collaborator act as a guarantor for the dataset. The role of the data guarantor was to ensure that all personally identifiable information had been appropriately removed by the app development company before the data could be transferred to the researcher for analysis. This detail was included in the HRA and ethical approval applications and these were subsequently approved by the HRA, the Research

Ethics Committee, the Host Trust R&D department, and the MMU ethics and governance office. The relevant approval documents can be found in Appendix 13.

3.6.2 Finance arrangements and intellectual property

The app-based self-management intervention developed and reported in this thesis was developed in collaboration with the commercial app development company 'Living With Ltd'.

This PhD was unfunded, but the app-development company agreed to collaborate on the project despite not receiving any financial compensation for their support. An informal agreement was put in place such that the researcher would undertake the content development work and provide topic-specific expertise, whilst the company would provide the necessary technical expertise. This is a model the company had successfully used with other clinical academic collaborators during the development of the NHS Squeezy app (Living With Ltd, 2021). The company benefits by expanding its portfolio of products without compensating clinicians for their time, and the clinicians/academics see their product developed without seeking funding for this work. Therefore, the researcher received no payments from the company for the development of the app content, and the company requested no payments for the technical work undertaken.

The business management team at Manchester Metropolitan University were consulted to clarify whether any intellectual property rested with the researcher or University relating to the app's development. As all app content was synthesised from publicly available sources, there was no intellectual property (IP) relating to this content. The only IP was connected to the app software and therefore rested solely with the app development company.

3.7 CHAPTER SUMMARY

This Chapter has provided an overview of this PhD study and discussed the underpinning methodology and philosophy. A description of the ethical issues raised and how these were overcome has also been provided.

In the following chapter, full details of the Phase 1 exploratory qualitative study are given, including the data collection, analysis, and findings.

CHAPTER FOUR: PHASE 1 DATA COLLECTION, DATA ANALYSIS AND FINDINGS

In this chapter, the Phase 1 exploratory qualitative study is reported. Justification of the key methodological decisions made is provided alongside a detailed description of the data collection and analysis methods. The findings of Phase 1 are then reported and discussed. Phase 1 addressed objectives two to four of this PhD study:

Objective 2	To explore the PLPP-related information-seeking practises of women currently experiencing this condition
Objective 3	To explore the attitudes of NHS service users and NHS-based antenatal HCPs regarding the use of digital media for the provision of PLPP-related information
Objective 4	To explore the acceptability and perceived utility of the notion of a digital intervention to support the self-management of PLPP.

4.1 DATA COLLECTION: PHASE 1 EXPLORATORY QUALITATIVE STUDY

Phase 1 of this PhD study involved collecting qualitative data from the three key stakeholder groups in this research: NHS service users, midwives and physiotherapists. Individual semi-structured interviews were used to gather insights from NHS service users, whilst focus groups were used with the NHS-based midwives and physiotherapists.

Figure 4.1 Demonstration of where the exploratory qualitative study fits into the overall study design

Indicators of rigour in qualitative research

Qualitative research methods are widely used in healthcare. Consequently, there is an expectation that qualitative health research will be conducted with a high degree of rigour to ensure the utility of the findings to clinical practice (Seale and Silverman, 1997). However, unlike quantitative researchers who aim to maximise internal validity or minimise bias (Lambert, 2011; Daniel, 2019), qualitative researchers accept the context-specific nature of their work and the multiple versions of reality in existence (Creswell and Poth, 2022). The assessment of qualitative research quality, therefore, requires a different approach to that employed in quantitative research. Consequently, a framework has been developed to support novice researchers in assessing the rigour of qualitative studies and supporting decision-making about qualitative research projects (Daniel, 2019). The 'TACT' framework proposes four indicators of rigour in qualitative research: trustworthiness, auditability, credibility, and transferability.

Trustworthiness represents the level of confidence a reader can have in the quality of the investigation and the outcome of the research (Daniel, 2019). Trust in the research is established through the transparent reporting of the researcher's biases, assumptions, and experiences and a systematic approach to data analysis. Verifying the research findings with participants and triangulation against other inquiry methods are also helpful (Daniel, 2019). However, this is somewhat challenged by Barbour (2001), who argues that member-checking may represent an unnecessary burden on participants and may risk prioritisation of the individual participant's concerns over the researcher's broad overview of multiple perspectives (Barbour, 2001).

Auditability in qualitative research requires a systematic approach to collecting, analysing, and interpreting qualitative data (Daniel, 2019). Field notes and research diaries can

facilitate the auditability of qualitative research, as can the use of a structured and transparent approach to data analysis, such as the framework method (Ritchie and Spencer, 1994; Daniel, 2019). Thorough reporting of the data collection and analysis process via the use of relevant reporting guidance (e.g., the Consolidated criteria for reporting qualitative research checklist) can also enhance auditability (De Jong et al., 2021). Such practices are in line with the open research agenda currently promoted in UK higher education institutions (UK Research and Innovation, 2022).

Credibility in qualitative research reflects the degree to which the findings can be considered dependable, relevant, and congruent (Daniel, 2019). Strategies to improve the credibility of qualitative research include the coding of data by multiple team members or, where this is not practicable, reflexive discussions with the research team about the codes and themes developed; this ensures that alternative interpretations are considered during the analysis (Barbour, 2001; Daniel, 2019). It is also recommended that verbatim quotations are used in qualitative research reports; this is to demonstrate that the researcher's interpretations are grounded in participants' accounts (Daniel, 2019).

Lastly, the transferability of qualitative research findings reflects the extent to which the insights gained in a particular context can offer valuable lessons in other settings (Daniel, 2019). Consequently, establishing the transferability of qualitative research findings relies on the transparent reporting of information about the study sample, the research context, the researcher, and the relationship between the researcher and participants (Lincoln and Guba, 1994; Daniel, 2019). Once again, the use of relevant reporting guidance can facilitate this process.

Throughout this chapter, the steps taken by the researcher to maximise rigour will be described. The COREQ checklist has been used to facilitate transparent reporting of the

data collection, analysis, and findings. A copy of the completed COREQ checklist can be found in Appendix 3.

4.1.1 NHS SERVICE USER INTERVIEWS: JUSTIFICATION OF KEY METHODOLOGICAL DECISIONS

To maximise the chances of developing an intervention deemed acceptable to service users, the views of this group took priority. Initially, focus groups had been considered to collect data from each of the three stakeholder groups in a time-efficient manner. However, it was decided that individual interviews with service users would be more appropriate to ensure the individual voices of this priority group could be heard without suppression (Barbour and Kitzinger, 1998). Additionally, as service users were discussing personal experiences related to their health, the relative privacy afforded by individual interviews was felt to be appropriate (Sim and Waterfield, 2019).

The original version of the study protocol approved by the REC stated that data collection would be undertaken in an in-person format to allow greater opportunity to build rapport and access non-verbal communication cues (Agar et al., 2003). However, it was later considered that the time commitment and burden of travel associated with in-person data collection may limit recruitment. Therefore, the substantial amendment made to the study protocol (approved by the research ethics committee, see section 3.7) allowed individual semi-structured interviews with service users to be undertaken by telephone if preferred by the participant. As this research was undertaken in the pre-pandemic period when video-conferencing platforms were not widely used, these were not considered as an option.

Each participant was offered the opportunity to participate in a single interview, either in-person or via telephone. A commonly held view among qualitative researchers is that in-person interviews are superior to telephone interviews as they provide a better

opportunity to build a rapport with participants (Novick, 2008). In-person interviews also allow the researcher to pick up on non-verbal cues to prompt further questioning or give a deeper understanding of the participants' feelings (Novick, 2008). Despite this, research suggests that data collected via telephone interviews are comparable to those collected via in-person interviews (Drabble et al., 2016). In addition, the relative anonymity the participant experiences when the researcher cannot see them may encourage them to disclose controversial views and allow a more open conversation (Agar et al., 2003). Therefore, undertaking the interviews via telephone was not seen as a weakness of the study or detrimental to rigour.

A semi-structured interview format was used as this allowed the researcher to ensure that key topics were covered with each participant but provided sufficient flexibility to explore new insights and probe for additional information where required (Green and Thorogood, 2004; Barbour, 2013; Hall and Roussel, 2020).

Due to the study's exploratory nature, the notion of data saturation was not the sole determinant of sample size (Braun and Clarke, 2021). The sample size was primarily influenced by the richness of the data generated across interviews and focus groups. Pragmatic considerations, such as the availability of participants and the timeframe for recruitment, also had to be recognised.

4.1.2 NHS SERVICE USER INTERVIEWS: DETAILS OF RECRUITMENT AND DATA COLLECTION

For the phase 1 qualitative exploration, a sample of NHS service users were recruited when they attended a routine antenatal visit to Wrightington, Wigan and Leigh NHS Trust. Attempts were made to ensure that participants at various stages of pregnancy and with varying symptom severity were represented within the sample. However, participants

were not purposively sampled according to demographic or socioeconomic characteristics.

Service users reporting PLPP to their midwife were informed about the study by their treating clinician. They were provided with a participant information leaflet (PIL) and invited to discuss the study further with the researcher who was present in the clinic. The inclusion and exclusion criteria employed are detailed in Table 4.1.

Table 4.1. Qualitative study service user inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
Otherwise healthy pregnant women	Known pregnancy-related complications
Aged 18 years or older	Multiple pregnancies
Currently experiencing PLPP	Inadequate understanding of written or spoken English

Those who requested to discuss the study further were given a detailed verbal explanation and offered the opportunity to ask questions. If they had read the PIL and were confident they wished to participate, they were asked to sign a consent form. If more time was required to consider their decision, potential participants could take up to two weeks to decide. In these cases, service users were given a consent form and stamped addressed envelope to take home. If they later decided to participate, they completed the consent form and returned it to the researcher by post. Service users were advised to contact the researcher directly by email if they had further queries. If potential participants made no contact within two weeks, it was assumed they did not wish to take part, and no further contact was made.

The topic guide used for the service user interviews can be found in Appendix 4. This topic guide was developed with support from the supervisory team and was piloted with two patient representatives from the researcher's personal network.

All interviews were led by the researcher (MM) and lasted between 20 and 60 minutes. Only one interview was conducted in person; this took place in a private room within the antenatal department of the host NHS Trust at the participant's request. All other interviews were conducted via telephone. During two of the telephone interviews, participants declared that a family member was present with them. To the researcher's knowledge, during the remaining interviews, only the researcher and participant were present. The researcher had no existing relationship with participants and the only contact made prior to the interview was during the initial recruitment conversation.

During the interviews, each participant was made aware that the researcher was a physiotherapist employed by their treating NHS Trust with a keen interest in improving the care of women with PLPP. It was, however, made clear that nothing disclosed during the interview would be shared with their treating clinician or impact the healthcare they received.

All semi-structured interviews with NHS service users were digitally audio-recorded. The researcher also took reflexive notes immediately after each interview. These notes were retained and used to support data analysis. The researcher transcribed the interview audio-recordings in an intelligent verbatim format; that is, the words used by participants were transcribed exactly as they were spoken, except that 'fillers' such as 'erm', 'ahh' and 'hmm' were omitted as they were not seen to add to or change meaning (McLellan et al., 2003). Transcripts were not returned to participants for member-checking.

4.1.3 Focus groups with NHS-based midwives and physiotherapists: justification of key methodological decisions

Focus groups were an appropriate method to gather qualitative data from NHS-based midwives and physiotherapists in a time-efficient manner. For these clinicians, the

opportunity for interaction between group members and in-depth discussion afforded by the focus group method was something the researcher was keen to exploit. Focus groups allow participants to share their views and listen to those of others. This allows individuals to reflect on their perceptions and shape their views in response to the contributions of other group members (Barbour and Kitzinger, 1998). The opportunity for group members to challenge each other's views may allow access to insights that would not be available during an individual interview (Barbour and Kitzinger, 1998). In the Phase 1 study, each participant in the focus groups was a qualified clinician with significant experience managing pregnant women with PLPP. Therefore, the risk that dominant individuals would overshadow other group members was felt to be manageable by the researcher. Separate focus groups for each professional group (one for the group of midwives and one for the group of physiotherapists) were planned, as literature suggests that shared experience and shared culture can facilitate the open exchange of dialogue (Morgan, 1997; Barbour and Kitzinger, 1998). It is acknowledged that in some circumstances bringing together individuals from different backgrounds can introduce group members to different perspectives and challenge their thinking (Barbour and Kitzinger, 1998; Freeman, 2006). However, it was felt that interprofessional differences might hamper open and honest conversation.

The physiotherapist participants were all known to each other, although they were not direct work colleagues. The midwives who participated in the focus group worked within the same team. The literature suggests that including pre-existing groups (or a collection of individuals familiar with each other) in focus group discussions can increase the likelihood that at least some of the conversation reflects naturally occurring talk (Freeman, 2006). Therefore, the benefits this afforded were seen to outweigh the increased range of perspectives that could be offered if additional participants were

invited to join the group. The topic guide used for these focus groups can be found in Appendix 5.

4.1.4 Focus groups with NHS-based midwives and physiotherapists: details of recruitment and data collection

NHS-based midwives and physiotherapists were invited to join the study via an invitation email which their line managers disseminated. The email included a copy of the PIL and instructions to contact the researcher directly by email if they wished to take part. This approach to clinician recruitment meant the researcher was reliant on the line managers to disseminate invitation emails to the appropriate staff members, according to the inclusion criteria listed in Table 4.2.

Consent forms were signed on the day of the focus group before data collection.

The topic guides used for the focus groups can be found in Appendix 5. These topic guides were developed with support from the supervisory team. These were piloted with two ex-colleagues of the researcher who were musculoskeletal physiotherapists working for an NHS Trust in the Merseyside region.

Table 4.2 Inclusion criteria used for the focus groups with clinicians

Inclusion criteria for physiotherapy focus group participants	**Inclusion criteria for midwifery focus group participants**
Qualified HCPC registered physiotherapist	Qualified NMC registered midwives
Minimum 5 years post-qualification experience	Experience of working in a community or antenatal setting
Experience of managing women with PLPP	Experience of managing women with PLPP

All focus groups were facilitated by the researcher (MM). The recruited physiotherapists were known to the researcher before the start of the study, but they were not direct

work colleagues. There was no pre-existing relationship between the researcher and the midwives recruited. Before starting each focus group, participants were informed of the researcher's professional background and interest in the management of PLPP. For both groups of clinicians, focus groups were held in private rooms familiar to participants within the host NHS Trust. It was hoped that this would facilitate the open sharing of ideas (Breen, 2006; Freeman, 2006). An assistant, who was a colleague of the researcher and worked as a research assistant in the NHS, made brief notes throughout the focus groups to document any significant conversation points and subtle non-verbal cues that the researcher might have otherwise missed. The researcher and assistant discussed the immediate interpretation of the ideas raised during the focus group. The researcher then took brief reflexive notes. These notes were used to inform the data analysis process. Focus groups lasted around 90 minutes each. They were audio-recorded and transcribed by the researcher in an intelligent verbatim format. Transcripts were not returned to participants for member-checking.

4.1.5 Researcher positionality and reflexivity

At the time of the Phase 1 data collection, the researcher was employed by the NHS as a research physiotherapist and worked part-time in the private sector as a senior musculoskeletal physiotherapist. The researcher held a Master of Research degree in Health Sciences and had undertaken external training in qualitative data collection. The researcher had previously supported colleagues with focus group moderation. However, the Phase 1 participant interviews were the researcher's first experience independently conducting individual interviews.

The researcher is a white, heterosexual, cisgender female from a working-class background with two dependent children. At the time of Phase 1 data collection, the

researcher had over 13 years' experience working as a musculoskeletal physiotherapist within the NHS and around seven years' experience managing women with PLPP. The researcher's interest in the topic of this thesis was driven by personal experience in clinical practice. This experience suggested that potential improvements could be made to patient care by improving PLPP-related information provision. The researcher, therefore, approached this PhD study with the perspective that improved condition-related information provision was needed for women with PLPP and that improved self-management support would be a positive development. At the outset of the PhD study, the researcher also believed that digital technology might be a useful platform for delivering a PLPP self-management intervention. This was primarily driven by the researcher's experience of undertaking a previous pilot project concerning PLPP-related information provision (Moffatt and Flynn, 2014).

4.2 Data analysis: Phase 1 exploratory qualitative study

Analysis was undertaken using the framework method (Ritchie and Spencer, 1994). The framework method provides a structured and traceable qualitative data analysis method (Furber, 2010). It relies heavily on the researcher's interpretations as other methods of qualitative data analysis do, but the process can be reviewed and audited by others to demonstrate how analytical decisions were made (Ritchie and Spencer, 1994). The framework method was designed to be used when the aims of the analysis are clear at the outset and when the research needs to be appropriately targeted to illuminate specific predetermined issues (Ritchie and Spencer, 1994). Therefore, this method helps ensure that research objectives are met but allows sufficient flexibility to enable unexpected insights that emerge to be incorporated into the analysis.

The framework method (Ritchie and Spencer, 1994) involves the following five stages:

- Familiarisation
- Identifying a thematic framework
- Indexing
- Charting
- Mapping and interpretation

Data were analysed by the researcher (MM) with direct support from the second supervisor at every stage.

4.2.1 Familiarisation

Familiarisation is about becoming familiar with the range and diversity of the data (Ritchie and Spencer, 1994; Ritchie et al., 2013). During Phase 1, this involved repeatedly reading interview and focus group transcripts and making notes on any key ideas that became apparent. These notes were compared to the reflexive notes taken immediately after each interview or focus group to ensure that the researcher's ideas were grounded in participants' accounts. This process resulted in a list of key ideas emergent from the data deemed important to participants and relevant to addressing the research objectives. This thought process was documented manually, as no specific qualitative data management software was used to support the analysis. A photo of the hand-written list constructed is, therefore, given on the next page. This list was reviewed with the second supervisor, and advice on how to streamline this list was offered.

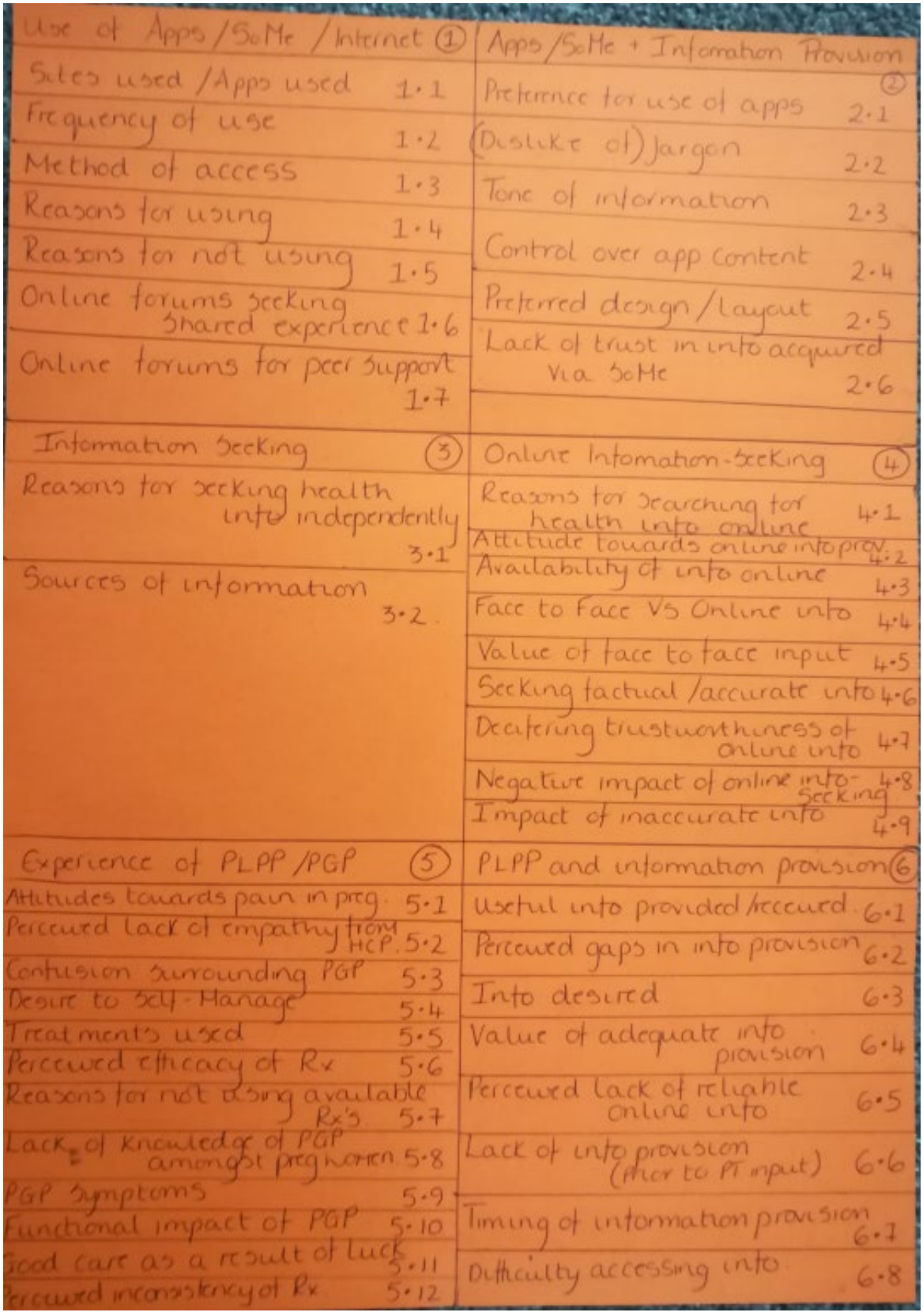


Figure 4.2. Photo of initial ideas for recurrent themes and key issues

4.2.2 IDENTIFYING A THEMATIC FRAMEWORK

This involves reviewing the list of key ideas collated during the familiarisation stage and identifying a set of key themes according to which the data can be sorted (Ritchie and Spencer, 1994; Ritchie *et al.*, 2013).

To develop a thematic framework for service user data, the researcher reviewed the *a priori* issues informed by the research objectives (see section 1.3), the issues raised by participants during data collection, and the recurrent patterns of perceptions or experiences observed within the transcripts. This process was then repeated for the physiotherapy and midwifery focus groups to produce three thematic frameworks - one for each of the key stakeholder groups. These can be found in Appendix 6.

These three thematic frameworks were then consolidated into one framework that could be used to sort the entire dataset. Any themes relating to the same phenomenon across the three thematic frameworks were grouped, and any direct duplicates removed. Where very similar concepts were alluded to, but these had been labelled differently across the three frameworks, these were renamed to ensure the chosen terms appropriately captured the meaning intended by each group. The final framework consisted of four main themes; each theme encompassed four or five subthemes. The final version of the consolidated thematic framework can be found in Table 4.3 below.

Table 4.3. Consolidated coding framework used to sort the entire dataset

Consolidated coding framework for entire dataset Name of theme/subtheme	Numerical code
Information seeking and information provision in the context of PLPP	1
Online health information-seeking behaviours	1.1
Online vs face-to-face information provision	1.2
Deciphering trustworthiness of online health information	1.3
Current trends in information provision in the NHS	1.4
Desired content and layout of PLPP information	1.5
Attitudes towards mobile phone apps and social media platforms for information provision	2
Apps and social media as platforms for information provision	2.1
Barriers to use of a social media or app-based intervention in current practice	2.2
Facilitators to use of a social media or app-based intervention in current practice	2.3
Suggested use and function of a social media or app-based intervention in current practice	2.4
PLPP management in the context of the NHS	3
Barriers to optimal PLPP management	3.1
Facilitators to optimal PLPP management	3.2
Lack of standardisation of pare pathway for patients with PLPP	3.3
Interprofessional relationships and boundaries in the context of PLPP management	3.4
Perceived importance of adequate PLPP management	3.5
Attitudes towards PLPP and its management	4
Attitudes towards PLPP as a problem	4.1
Myths and confusion surrounding PLPP	4.2
Attitudes towards self-management	4.3
Facilitators to successful self-management	4.4
Patient expectations of PLPP treatment	4.5

4.2.3 Indexing

Indexing is the process of systematically applying the thematic framework to the entire dataset. Each passage of each transcript was re-read and annotated according to the thematic framework and the appropriate label applied.

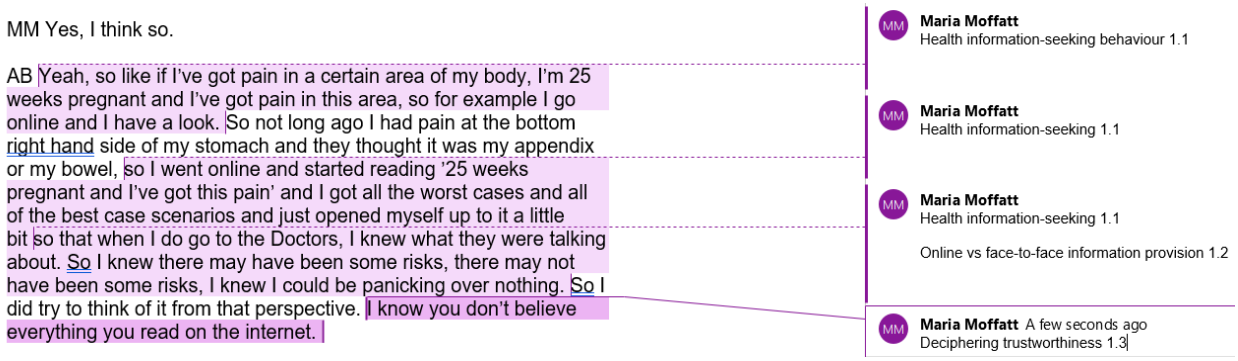


Figure 4.3 Screenshot of a section of labelled text demonstrating the labelling process undertaken

4.2.4 Charting

Charting allows all sections of data given the same label to be viewed together (Ritchie and Spencer, 1994). Charts were drawn up for each theme, and entries were made for several respondents on the same chart.

The thematic chart allowed the researcher to see which participants discussed key themes and what was said. If a participant had not generated any data relating to a particular theme or subtheme, the empty cell in the thematic chart was annotated with the code 'ND' to indicate that this concept was 'not discussed'.

Four thematic charts were constructed in Microsoft Excel, one for each key theme identified in the consolidated thematic framework (see Table 4.3). It is advised that the thematic chart should be populated with distilled summaries of data rather than verbatim chunks of text (Ritchie and Spencer, 1994). Large quantities of textual data can then be

converted into a manageable format. However, the volume of data in this study was not excessively large. Therefore, it was considered acceptable to transfer the relevant verbatim text into the appropriate cell of the thematic chart (alongside a reference for its position within the transcript) and add a short passage summarising the meaning as interpreted by the researcher within the same cell. The summary passages were highlighted and boldened for increased visibility. This allowed the researcher constant access to sections of data deemed relevant to the research question and the ability to quickly scan for similarities across the data from different participants. Figure 4.4 below shows a small section of the thematic chart to demonstrate how the researcher entered the data.

	Theme 4: Attitudes towards PLPP and it's management		
Participant ID	4.1: Attitudes towards PLPP as a problem	4.2: Myths and confusion surrounding PLPP	4.3: Attitudes towards self-management
Service user 1	*Well like I said, this is my 4th pregnancy, so in my first pregnancy it was just that my leg kept giving way and it was just an achey back, and to be honest, at that point in my life I didn't think anything of it and I just thought it was part and parcel of being pregnant and I would just lose sensation in my leg and my bum cheek and I would fall quite a lot because I would lose sensation in my leg……Erm and then when I had my second, I ended up with the same thing but it was worse. That's when I ended up going to the Doctors' 'I thought this is just, I just thought that this was normal. You know I was 26 years old, first baby, I didn't really understand it. I just assumed that when you're pregnant, you would just get a bad back, and you just had to deal with it.'* Page 5, line 27. ***Reports that in her first pregnancy, she assumed that pain was normal part of pregnancy and therefore did not seek treatment** *'Yeah, I wasn't referred over for my back at all even though I told them about the pain and I told them the history, I still wasn't*	*And it's only now in this pregnancy since I've got to see [the physiotherapist- name removed for anonymity]…she's kind of explained it a lot more and explained it properly so I understand it a lot better.'* Page 6, line 18. ***States that until she saw the physio, she was not clear about what caused PLPP**	*I try not to go and see the Doctor if I can help it. Like I will see the Doctor a lot more quickly if it's my children with the problem, but where I'm concerned, I hold off a little bit and see if I can manage it myself. So I do check the internet to see if it is something that I should be worried about.'* Page 4, line 27. ***States a preference for self-management of all medical conditions if possible** *'Yeah unless I have to. If I'm really concerned or if it's pain I really can't bear, (laughs) you know?'* Page 5, line 5. *** Would only choose to self medical help if pain is severe or if she is worried and feels intervention is required**

Figure 4.4. Portion of thematic chart for demonstration

4.2.5 MAPPING AND INTERPRETATION OF THE DATA

The 'mapping and interpretation' phase is when the researcher compares and contrasts the perceptions and experiences of each participant and attempts to identify patterns, connections, or explanations (Ritchie and Spencer, 1994).

During this analysis stage, the researcher examined the data charted under each sub-theme and looked for commonalities in the participants' responses. Any commonalities were listed in a separate table in Microsoft word. These lists were then distilled down to identify any patterns within participants' responses that should be presented in the results section. This process also allowed the researcher to ensure the names given to themes and subthemes were wholly appropriate and to make minor modifications where required. Additionally, if it became clear that there was significant overlap between subthemes, these were collapsed and renamed for simplicity. Table 4.4 below shows how the key ideas presented in the results section were identified from the charted data.

Table 4.4. Identification of key ideas in participants' responses

Theme 1. Information seeking and information provision in the context of PLPP		
Subtheme name	**Commonalities identified in participants' accounts**	**Key concepts identified for presentation under each subtheme**
1.1 Online health information-seeking behaviours	● Seeking reassurance from online information ● Use of online information to inform decision-making ● Arming self with knowledge before consultation with health care professional (HCP) ● Attempting to alter power dynamic between patient and HCP by gaining information online ● Reducing need for HCP input by gaining knowledge online ● Online information so vast and easily accessible ● Searching for factually accurate information ● Clinician perspective that online information seeking amongst patients is widespread ● Difficulty accessing information elsewhere leads to online information seeking	● Reassurance through information acquisition ● Increased independence and power through knowledge acquisition ● Vast amounts of information easily accessible ● Service user versus clinician perception of drivers for information-seeking

This was repeated for each theme and subtheme.

Upon completion of the analysis, the themes were re-ordered to reflect a more logical sequence for presentation, as shown below.

Theme 1: Attitudes towards PLPP and its management

- Subtheme 1.1: Attitudes towards PLPP as a problem
- Subtheme 1.2: Myths and confusion surrounding PLPP
- Subtheme 1.3: Attitudes towards self-management

Theme 2: PLPP management in the context of the NHS

- Subtheme 2.1: The barriers to optimal PLPP management
- Subtheme 2.2: The facilitators to optimal PLPP management
- Subtheme 2.3: Interprofessional relationships and boundaries
- Subtheme 2.4: The perceived importance of adequate PLPP management

Theme 3: Information seeking and information provision in the context of PLPP

- Subtheme 3.1: Online health information-seeking behaviours
- Subtheme 3.2: Online versus face-to-face information provision
- Subtheme 3.3: Deciphering trustworthiness of online health information
- Subtheme 3.4: Current trends in information provision in the NHS

Theme 4: Attitudes towards digital media as platforms for information provision

- Subtheme 4.1: Apps and social media as platforms for information provision
- Subtheme 4.2: Barriers to the use of a social media or app-based intervention for the management of PLPP in current clinical practice
- Subtheme 4.3: Facilitators to the use of a social media or app-based intervention for the management of PLPP in current clinical practice
- Subtheme 4.4: The suggested use and function of a social-media or app-based intervention for the management of PLPP in current clinical practice

Three of the seven service users recruited to Phase 1 had consented to receive a lay summary of the findings by email once data analysis was complete. Participants were

informed they were welcome to comment on the study findings by responding to the email received. However, no responses were returned.

4.3 Findings of the Phase 1 exploratory qualitative study

Each theme and associated sub-theme will be discussed in detail in the following sections. This will provide an overview of the range of opinions identified across the three stakeholder groups and highlight where similarities and differences occur both within and between these three groups.

Table 4.5 below provides an overview of participant characteristics; Phase 1 participants included seven service users, six midwives, and four physiotherapists. Three service users approached for recruitment declined to participate; two stated they had no interest in the study whilst one was planning to return to her native country several days later.

Given the limited sample size, it cannot be definitively claimed that data saturation was achieved (Braun and Clarke, 2021). However, rich data were generated from all three stakeholder groups that were deemed sufficient to fulfil the aims of this phase of the PhD study.

Table 4.5 Qualitative study participant characteristics

Characteristics of service users n=7	
Age range	21–36
Number of service users who were primiparous	3
Number of service users who were multiparous	4
Number of service users who hold a university degree	4
Number of service users who had experienced PLPP in a previous pregnancy	3
Characteristics of midwives n=6	
Number of midwives working in antenatal setting	6
Number of midwives with 5–10 years clinical experience	0
Number of midwives with >10 years clinical experience	6
Characteristics of physiotherapists n=4	
Number of physiotherapists working in a musculoskeletal setting	2
Number of physiotherapists working in a women's health setting	2
Number of physiotherapists with 5–10 years clinical experience	2
Number of physiotherapists with >10 years clinical experience	2

Figure 4.5 below visually displays the relationship between themes and subthemes.

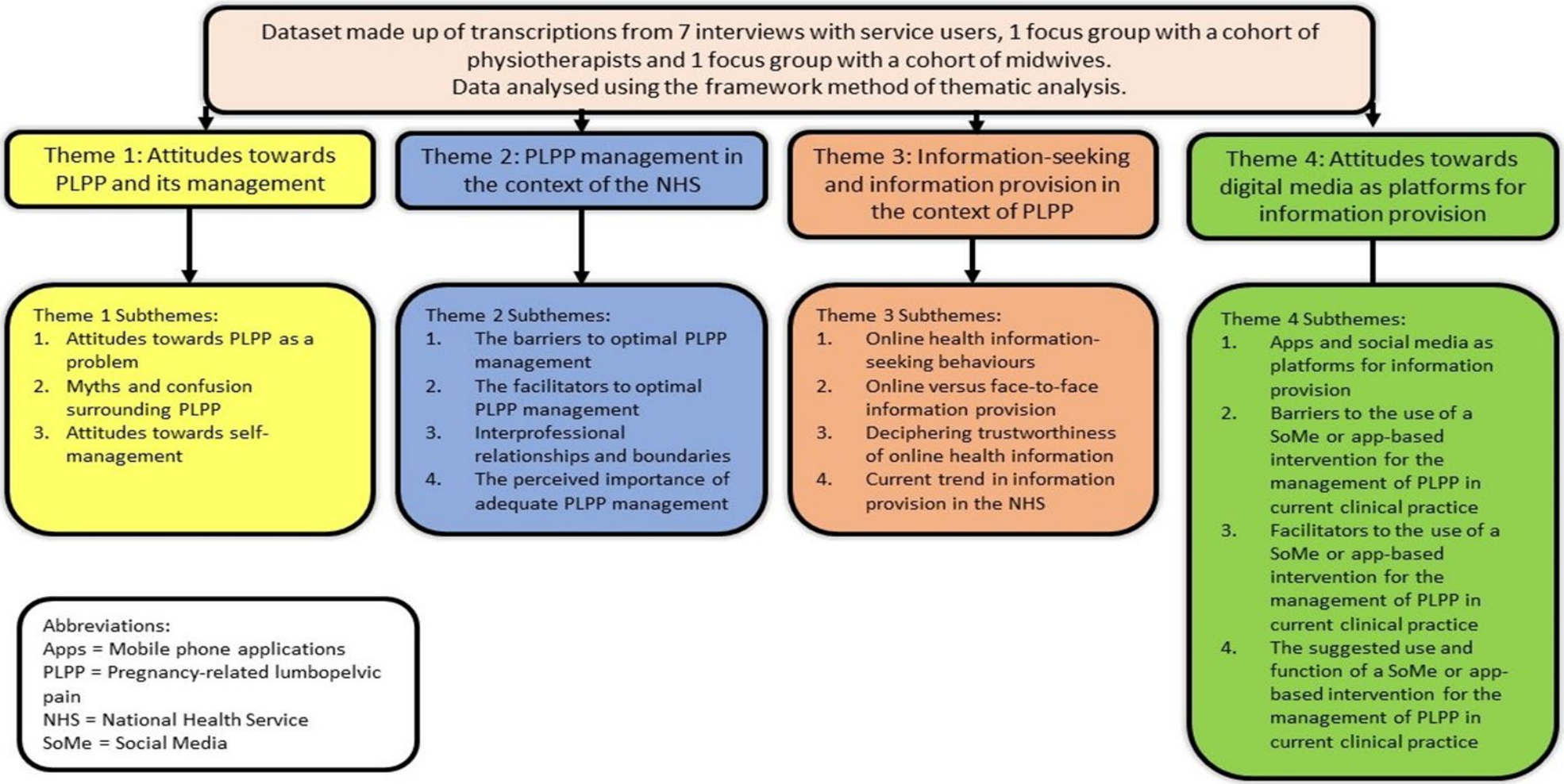
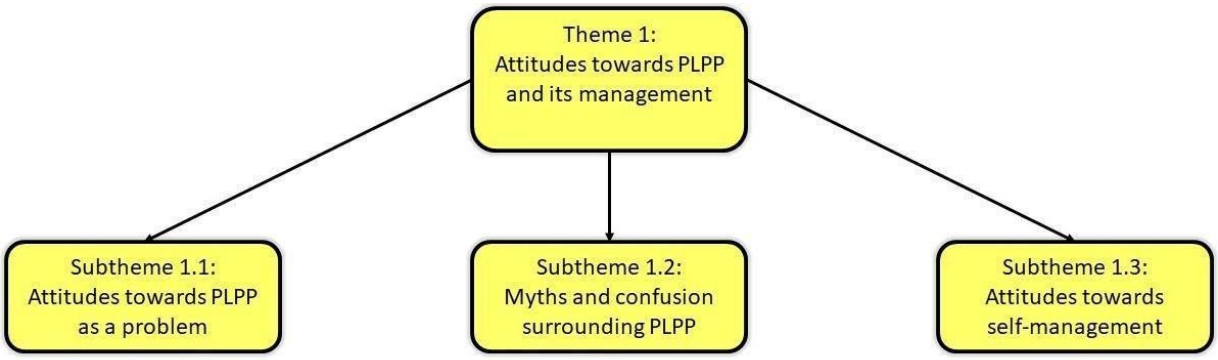


Figure 4.5. Relationship of themes to sub themes

4.3.1 Theme 1: Attitudes towards PLPP and its management

Figure 4.6 Theme 1



4.3.1.1 Subtheme: Attitudes towards PLPP as a problem

Each of the three stakeholder groups discussed their attitudes towards PLPP as a problem, and there were many similarities between the insights provided by the three groups. There was agreement across the entire dataset that PLPP can cause significant disability to the sufferer.

> *''I said I'm in quite a lot of pain. The sciatica's kicked in as well and I'm literally walking on crutches. I'm having to be assisted to the toilet, my mum has had to come and stay with me, I'm sleeping downstairs''* Service user 5, page 1, line 23

The physiotherapists did however go further and state that for them, the defining feature of PLPP, and what delineates it from the so-called '*normal*' pain '*expected*' during pregnancy is the level of disability experienced.

> *''…one [service user with PLPP] might only have a bit of normal back ache, you know, just a bit of pain that she can cope with that is quite manageable, and it's not debilitating or interfering with her life. Whereas the other one, she's got pelvic girdle pain, and it's debilitating, and it is affecting her work and life''* Physiotherapist 2, page 37, line 15

There was some debate amongst the midwives about how they viewed the condition; One group member stated that it was her perception that some midwives do appear to

have a 'flippant attitude' towards PLPP. This however appeared to be at odds with the views of others participating in the focus group who strongly disagreed with this idea.

> Midwife 6: *''I mean, as midwives we just take pelvic girdle pain very much as, oh, it's a part of pregnancy, kind of get on with it really. Sometimes you, as a midwife, don't appreciate how debilitating it is.''*
>
> Midwife 1: *''I don't feel like that when I see them.''*
>
> Midwife 6: *''No. I don't either, but I know that talking to women, that it does get kind of pushed as, well, it's just a part of pregnancy. And it is part of pregnancy but it's a big debilitating part of pregnancy potentially.''* page 10, line 1.

This dissenting view was however supported by two service users who stated that when they reported the onset of PLPP symptoms to their own antenatal healthcare provider, this was met with a dismissive attitude, and very little empathy.

> ''*The first thing the midwife said was 'it's ligament pain' and I said to them, this is my 4th pregnancy, this isn't ligament pain, this is something else and I felt like I was kind of being brushed off a little bit.''* Service user 1, page 5, line 1.

Six of the seven service users were keen to express the view that prior to a diagnosis of PLPP being made by their midwife or physiotherapist, they had no awareness of the existence of PLPP as a condition. They stated that unlike other common pregnancy-related issues such as morning sickness, PLPP is not openly discussed amongst pregnant women.

> *''…all of these other symptoms, people know to expect them don't they, like morning sickness or needing the toilet all the time. Like that's just a given, even when you've never been pregnant, you just know that these symptoms, because they've kind of been round for years haven't they, and we all talk about them. Well like this pain has been too, but no one really talks about it do they? They don't bring it to anyone's attention…'' service user 3, page 7, line 19*

Two service users reported that it was only after discussing their PLPP symptoms with peers or family members that they realised their pain was not a normal part of pregnancy, and that this new knowledge was the driver for them to seek advice.

> *''..and that's the only reason I went [to the doctor] was because my mum was like 'you've got a kidney infection or something, get to the doctors tomorrow' so I did, well that was because I was told to go because I'd spoken to somebody about it.*

> *Well, she, to be honest, she saw how much pain I was in and told me to get to the doctors''* Service user 7, page 11, line 6.

The physiotherapists stated that they were concerned that PLPP was not given the attention it deserves amongst other HCP groups, and that it should be granted the same consideration as other common women's health issues such as urinary incontinence.

> Physiotherapist 3: "*All the information is about the baby, about the screening and health and everything from that point of view. So although you get told about blood pressure and itching and ankle swelling and all of these things, that's because they're all more life threatening"*
>
> Physiotherapist 1: "*and they can affect the baby*"
>
> Physiotherapist 3: *''But then again you get a leaflet about pelvic floor exercises [when the service user visits the midwife for the first visit], but I'm sure that not everyone gets pelvic floor dysfunction, but they're all told immediately that you need to do these exercises. So what's the difference between having an information sheet about pelvic girdle pain and pelvic floor exercises?''* Page 32, line 17

The impact of the general lack of awareness of PLPP on those experiencing severe symptoms was also discussed. One service user and the group of physiotherapists held the view that it is common for most pregnant women to experience some form of transient, mild lower back pain at some point during their pregnancy. Therefore, when women experience severe PLPP symptoms, it may be assumed by friends, colleagues and family members that what they are actually experiencing is the '*normal*' or '*expected*' level of pain, and that they are merely reacting in a dramatic fashion, or over exaggerating their symptoms.

> *''I think it's because there's the myth attached to it that it's just all part and parcel of pregnancy and so they should just get on with it? I do…I do, I think it's a very bad myth because everybody gets a bit of back ache in pregnancy, people think it's all the same type of pain… I think there's no recognition that they're, you know there's no distinction between the two. I don't think they see that black and white, they just think it's all one thing and therefore the one who's in really bad pain, just looks really pathetic and dramatic.''* Physiotherapist 2, page 37, line 13

The aforementioned service user described a pressure to be seen to '*cope*' with PLPP symptoms to avoid appearing '*soft*' or dramatic.

> *''But as well you know, you don't want to be soft, you know, you don't want to be one of those women who's like 'Oh my God I can't cope with this', you know because so many women go through it that you don't want to be one of those people''* Service user 3, page 4, line 6

The physiotherapists perceived the potential impact of this pressure to cope with PLPP symptoms to be increased anxiety or a feeling of inadequacy.

> *''I had one lady, it was heart-breaking, there was her, her sister-in-law, and her best friend all pregnant at the same time as her, and they were waltzing through their pregnancies and she could barely walk…and she'd been told before she got to me that this was all just part and parcel of pregnancy and that she had to just get on with it. So she thought that everyone else thought she was really pathetic, because everyone else around her was so fine.''* Physiotherapist 3, page 30, line 8.

The final issue raised by the physiotherapists regarding their attitude towards PLPP as a condition, was the overwhelming view that PLPP is, for the majority of pregnant women, a transient condition with a largely positive prognosis. It was the view of the group that in their collective clinical experience, only women with pre-existing, related musculoskeletal conditions, continue to experience significant symptoms in the extended postpartum period.

> Physiotherapist 3: "*...There's always that assumption that it's going to go away, but what about the ones where it doesn't?*
>
> Physiotherapist 2: *"I think for the vast majority it does. You get the ones who've had the acute on chronic pain, and it does take that bit longer to settle…"*
>
> Physiotherapist 1: "*Or they've had some underlying problem*"
>
> Physiotherapist 2: "*Yeah, that's right. The only ones who come back to me…are the ones who were struggling with pelvic, or their back pre-pregnancy and the pregnancy has exacerbated it…*"
>
> Physiotherapist 1: "*But they had a problem anyway*"
>
> Physiotherapist 2: *''Yeah, oh yeah. It's very rare that someone without an underlying problem it persists. It's very rare, there's usually something that was established before''* page 39, line 1

4.3.1.2 Sub Theme: Myths and confusion surrounding PLPP

When discussing PLPP, members of each of the three stakeholder groups referred to a number of myths and some confusion surrounding the condition. Six of the seven service users spoke of either the confusion surrounding the perceived causes of PLPP, or the treatment options available to them. Each of the service users expressed a difficulty in deciphering the degree to which pain is considered a normal part of pregnancy and alluded to the confusion this can cause.

> *''When it came to my back pain, at first, I was going 'I'm in pain because I'm pregnant, that's why'...There's no point going to the doctors because they're gonna turn to me and say 'Umm, you know you've got a human growing inside of you?' and I'll be like 'Yeah, that's why I've got back pain, I'm really sorry [for bothering you]!''* Service user 7, page 10, line 35

In a similar manner, the physiotherapists commented on the pervasive nature of the myth that PLPP is a normal part of pregnancy.

> *''I mean, it's like we said before, that knowledge [about PLPP] isn't out there and how many people get fobbed off with 'it's normal'.* Physiotherapist 2, page 30, line 7

The physiotherapists perceived there to be significant confusion regarding the correct terminology for PLPP amongst other HCP groups.

> Physiotherapist 3: *''I think as well, there's still a lot of confu…like it still gets called SPD [symphysis pubis dysfunction]. So like a lot of women I see, they don't realise that they've got PGP [pelvic girdle pain] because they'll say, 'I've not got SPD, I've got pain in my back, or pain in my buttock' or something…So then I have to explain, well SPD was the old term but we got rid of it because it didn't really describe [it]...''*
>
> Physiotherapist 1: "*Well this is again where the education with the midwives comes in. It all comes back to discussion and education. They probably don't even know it's [the name for SPD] been changed"* Page 33, line 9

This observation was also noted by one service user, who complained that her midwife had referred to PLPP as 'symphysis pubis dysfunction' or 'SPD', which she felt highlighted the confusion present surrounding the terminology used for this condition.

> *''But I know with the pelvic girdle pain, did it used to be called SPD?...So I think there's a lot of confusion there and I'm not sure if midwives have updated in terms of the new name''* Service user 2, page 3, line 1

This same service user later explained that she also found the term pelvic girdle pain (PGP) confusing, as the pain she was experiencing was specifically located in her lower back, and she therefore felt that that the term pelvic girdle pain misrepresented her symptoms.

> *''…and that's when I went to the physio and that's when pelvic girdle pain was mentioned, which I would never have thought it was that, because you don't associate your back with your pelvis really do you? I mean, I know it's around the same area, but…So it has been a bit confusing in that sense.''* Service user 2, 5 line 28.

4.3.1.3 Subtheme: Attitudes towards self-management

Across the entire dataset, there was evidence of an overwhelmingly positive attitude towards the self-management of PLPP amongst all three stakeholder groups. Two service users stated a definite preference for non-pharmacological management of pregnancy-related pain, and there was a clear willingness amongst each of the service users interviewed to put any self-management advice available to them into practice.

> *''And even before they referred me to physio, because they said it could be 4-6 weeks before you go, and they said it sounds a bit like sciatic pain, I did look online then at exercises and stretches to help with the sciatic pain, to try to help with the pain''* service user 4, page 4, line 1.

Both clinician groups noted that their prior clinical experience had led them to believe that most patients with PLPP are keen to be given the tools to self-manage the condition. However, two of the physiotherapists also held the view that some of their patients expect to have access to 'hands on' treatments including manual therapy and acupuncture.

> *''Most choose to go down the acupuncture route because they'll have spoken about it with friends and someone has said 'yeah I had acupuncture and it was*

> *helpful' or something, and I think they just like to do whatever they think is going to help don't they?''* Physiotherapist 3, page 31, line 15

These same two physiotherapists felt that although most patients are willing and able to self-manage PLPP with the appropriate advice, some expect the provision of frequent face-to-face support in order to help them manage the condition.

> *''I think you don't get any that are like really in between. You get your ones who are really on the ball with it, really motivated, and they want to self-manage and you get your others who are like catastrophizing, and just need, well they're just very precious shall we say''* Physiotherapist 2, page 29, line 4.

The midwives expressed the view that self-management advice allows patients to feel less reliant on clinicians and can provide a sense of control over their condition. They viewed self-management as a form of patient empowerment and agreed that this should be enabled wherever possible.

> *I know we want women to be independent and have some self, sort of, some sense of agency when they're pregnant so they can feel not so dependent on us. We want them to take responsibility for their health and wellbeing as well, don't we?* Midwife 2, page 27, line 7

Each of the service users interviewed and both clinician groups agreed that early provision of advice and adequate information provision were key facilitators to successful self-management of PLPP. All service users made some suggestions about the information they felt necessary for reassurance and adequate condition-management. Numerous factors were cited including: the pathophysiology of PLPP, the treatment options available (including complementary therapies), the self-management strategies available, medication safety information, and advice regarding labour and delivery.

When discussing self-management, the physiotherapists once again stated their perception of the importance of reassurance and information provision. One physiotherapist used the interesting metaphor of likening PLPP to the common cold. This was not an attempt to be flippant, but rather the mechanism she used to convey the notion that although the symptoms of PLPP can be significantly debilitating, if the patient

is aware of the cause of the symptoms, they understand that the level of discomfort is commensurate with the suspected underlying pathology, and they know that in all likelihood the symptoms will resolve within a relatively predictable timeframe, then they will be more willing and better able to self-manage the condition.

> *''But you all know yourselves, that although you wouldn't go to the GP, you can have a really, really, bad cold and feel absolutely awful, and you actually start to think 'oh my god is this normal'. But then because you know that it eventually will get better, you convince yourself that you can cope with it and you just get on with it. I think it's like that.''* Physiotherapist 4, page 38, line 7

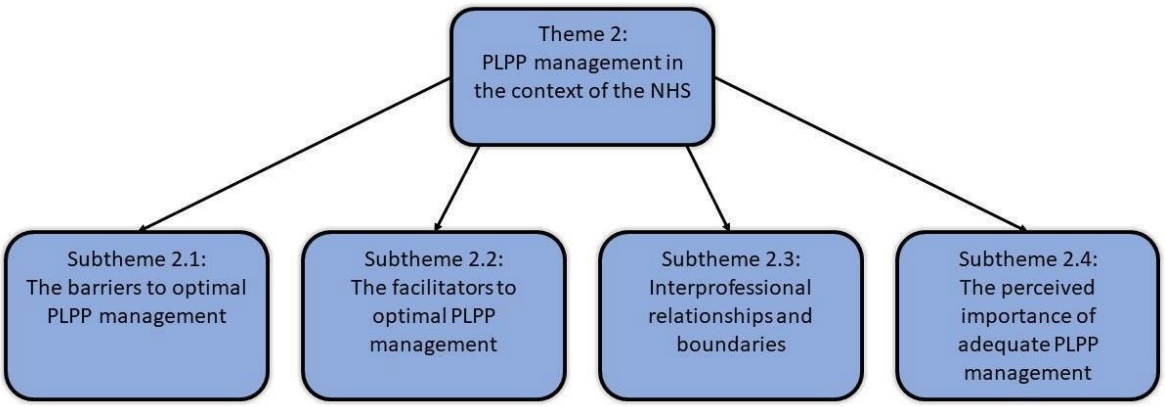
This perception described above was in keeping with the views expressed by four of the service users who stated that their ability and willingness to self-manage PLPP was facilitated by the understanding of the benign nature of the condition and its positive prognosis.

> *''So my physio explained that it's about the hormones that you release during pregnancy and things and for me, that was like Oh God yeah, that makes sense and that's how it feels…So for me I thought that all that information was really useful.''* Service user 6, page 7, line 17.

The data presented within this theme demonstrate that each of the three stakeholder groups shared the view that PLPP is a debilitating condition with the potential to cause significant pain and impact on an individual's level of function. There was a prior lack of awareness of PLPP demonstrated amongst the service users interviewed, and the pervasive nature of the belief that PLPP is a normal part of pregnancy was visible in the data. The overriding attitude to self-management was positive across the entire dataset, and the importance both service users and clinicians placed on the provision of condition-related information for successful self-management was clearly evident.

4.3.2 THEME 2: PLPP MANAGEMENT IN THE CONTEXT OF THE NHS

Figure 4.7 Theme 2



4.3.2.1 SUBTHEME: THE BARRIERS TO OPTIMAL PLPP MANAGEMENT

The provision of conflicting information from different HCPs was identified by three of the service users as a potential barrier to optimal management. These concerns were also shared by the midwives who believed that not all HCPs had equal knowledge and training regarding the management of PLPP and that this could potentially lead to mixed messages being given to service users

> *''They'll say [patients will say], oh, but my GP said this. Well, with all due respect, they're not the expert in pregnancy''* Midwife 6, page 19, line 6

The physiotherapists also perceived that the approach to PLPP management varied between professional groups, between individual HCPs, and between different NHS Trusts; this was felt to be a barrier to optimal outcomes. The following quote highlights that even within their own NHS Trust the physiotherapists felt that different settings provided different levels of service.

> *''So I've explained to them [the patients] that they can go to [another NHS treatment centre within the host NHS Trust] if they like, but it wouldn't be a women's health physio as such, like it wouldn't be as much of a thorough*

assessment, that it'll just be more MSK-based [musculoskeletal MSK]'' Physiotherapist 2, page 26, line 20

Four service users cited a lack of time with their clinician or feeling rushed during their consultation, as potential barriers to optimal treatment.

''So [physiotherapist name] kind of went through everything, but they're very limited with the time they have with you. I know your first appointment is a bit longer, but she did kind of whizz through everything'' Service user 4, page 3, line 23

Interestingly, time constraints were not discussed by the Physiotherapists, but were of significant concern to the midwives who emphasised a paucity of time in clinic and considerable clinical time-pressures as potential barriers to optimal management. The conversation extract to follow demonstrates this opinion and shows the frustration experienced by the midwives as a result.

Midwife 1: *''…but you're still under pressure. If you really got into a conversation about a woman with pelvic girdle pain, it would take you beyond that allocated amount of time that you've been given to see that woman. I'm just being honest.''*

Midwife 3: *''You're given about 5 minute appointments now, that's it. And we used to get 15 minutes didn't we? To do blood pressures, urine check…''*

Midwife 1: *''To feel rushed like that. As a professional to feel rushed like that, when you can see somebody in front of you that needs that support, it's so frustrating that all you can think of is that I've got 7, 8, 9, 10 more people to see yet. It's an awful feeling because you're doing, you're not giving them the service that they need''*

All midwives nodding in agreement

Midwife 3: *''I mean, it tends now to be, you know, rather than giving them those kind of advices as a preventative, we're only giving that advice if they come in saying, I think I've got some pelvic girdle pain''* page 11, line 17

Two service users proposed that variable waiting times for physiotherapy treatment could be a potential barrier to optimal treatment. The midwives also held the view that prolonged waiting times for physiotherapy treatment could be a barrier in some settings. The physiotherapists however prided themselves on a well-managed waiting list for PLPP patients, that never exceeded three weeks. Local variation in physiotherapy service

provision may have influenced these perceptions and may set differing expectations for both service users and clinicians.

The perceived inequity of access to physiotherapy treatment was raised during the midwifery focus group, as several midwives commented that patients of a higher socio-economic status may have better and faster access to physiotherapy treatment via the private healthcare sector.

> Midwife 2: *''Because I know a lot of people have 'Simply Health' now don't they? And they have access to these resources [physiotherapy treatment] elsewhere either through their partner's health insurance or…''*
>
> Midwife 1: *''But that's only a certain demographic''*
>
> Midwife 6: *''It's not universal, it's not equitable''*
>
> Midwife 2: *''I'm not saying it's fair, I'm just saying it's there!'' page 13, line 1*

The midwives also raised the issue of limited NHS resources as a barrier to PLPP management; they explained that community-based, midwifery-led exercise classes that included education on the self-management of PLPP, had to be halted due to insufficient resources.

> Midwife 2: *'…when I was a community midwife, we used to run aqua-natal classes and we did post-natal exercise, and it was based on Pilates exercises. So we used to spend a lot of time talking about posture and pelvic floor and about over-abducting your hips, how to get in and out of bed, how to get off a sofa…'*
>
> Midwife 6: *'In and out of a car'*
>
> Midwife 2: *'How to get in and out of a car with plastic bags on the seats sliding, feet together. We used to do all of that. But that was part of the exercise classes and just good basic general information about looking after yourself.'*
>
> Researcher: '*So does that not happen anymore here?*'
>
> Midwife 2: *'It all got cut!'*
>
> Researcher: *'So it came down to funding?'*
>
> Midwife 6: *'Yeah!'*
>
> Midwife 1: *'Funding and resources and staffing.'*

4.3.2.2 SUBTHEME: FACILITATORS TO OPTIMAL PLPP MANAGEMENT

Adequate information provision and early access to information were important facilitators to optimal PLPP management cited by both groups of clinicians and each of the service users interviewed. Collectively, the service users put forward several suggestions regarding the content and format of information they felt necessary to facilitate the management of the PLPP and to reduce condition-related anxiety. Service users wanted to be provided with the full available range of treatment options and advised on how these should be accessed. In addition, service users expected to be given information regarding the cause of the pain as it is currently understood, the prognosis for recovery in the postpartum period and how PLPP might impact on labour and birthing options. One service user also stated that if she was provided with a home exercise program, she should be given an understanding of how this might help her in order to encourage adherence.

> *''And you know they are exercises that you tend to get anyway [those prescribed by her treating physiotherapist], you know, I've got the 'what to expect when you're expecting' book, and some of the exercises are in there, but it's knowing the benefits and having someone to talk through the benefits of them is more helpful''* Service user 6, page 5, line 19

The provision of reassurance was identified by the majority of the physiotherapists as the most important facilitator to optimal PLPP management; this reflected the opinions of four of the service users, who stated that the search for reassurance had been a significant driver to seek treatment for their PLPP symptoms.

> *''So I asked friends who'd been pregnant and they'd not had the same symptoms [symptoms of PLPP] so then you think 'Oh God, what's wrong?'…that's when I thought oh maybe I'd better address this before it gets worse''* Service user 3, page 3, line 17

For the midwives, the presence of passionate and caring NHS staff was perceived to be a facilitator to PLPP management, as was the adoption of a holistic approach to

management, taking account of the psychological and emotional components of the patients' pain experience. The midwives also valued the contribution of other health professionals in facilitating more efficient management of PLPP. One example presented was that of access to medication safety advice via a community-based pharmacist to avoid the need for patients to wait for a consultation with their GP or midwife.

> *''You don't have to contact a midwife or a GP [for medication advice], you can signpost to like a pharmacist and speak to the pharmacist over the counter. They may have easier access to that.''* Midwife 5, page 21, line 15

4.3.2.3 Sub Theme: Interprofessional relationships and boundaries

Both the physiotherapists and midwives discussed the impact of interprofessional relationships and boundaries in the context of PLPP management. Both groups stated a mutual reliance on the other to optimise patient outcomes: the physiotherapists felt that timely referral and appropriate provision of advice by the midwives were essential for optimal management, whereas the midwives stated that the provision of advice and referral for physiotherapy treatment were the mainstay of their PLPP management approach.

Despite acknowledging the importance of both professional groups in optimising the management of PLPP, the physiotherapists shared the perception that an interprofessional division exists between themselves and the midwives. They felt this had the potential to negatively impact patient experience and preclude interprofessional collaboration.

> Physiotherapist 1: "*Right, so they should be referring those patients [women with PLPP] on to us shouldn't they?"*
>
> Physiotherapist 2: *''Yeah but do you not think there's a bit of us and them attitude? I sadly find that there's a them and us divide [between physiotherapists and midwives], that I don't think they really think very much of us…I think that old-*

> *school midwives think there's not much we can do bar give some crutches and a belt.* page 25, line 1

There was some discussion amongst both groups of clinicians about different professionals' roles in the management of PLPP. The physiotherapists discussed the possibility that PLPP, as a musculoskeletal condition, may be perceived by the midwives to fall outside of their scope of practice.

> *''I guess from their point of view [midwives], it's probably outside of their remit isn't it [PLPP]? Or they might feel like it is…Like for us, if someone asks us, like if they are pregnant and they ask about other aspects of pregnancy, or about the development of the baby, I'd be like 'Oh God, I'm not quite sure, ask your midwife' so I think there's an element of that. Maybe they think that they're not happy to be physically assessing something that's outside of their remit and seeing and giving advice about this.''* Physiotherapist 3, page 41, line 1

The midwives themselves however implied that they viewed their role in the management of PLPP to be that of diagnosis, information provision and onward referral, rather than involvement with long-term management or monitoring.

> *''It can take time to go through things systematically, finding out what the pain is, where it is…getting to the crux of the problem can take time, then signposting them to physio or just, you know, life management [advice] around the house et cetera''* Midwife 2, page 6, line 16

When discussing professional boundaries, one member of each professional group raised the issue that when asked to provide advice to patients on a topic outside of their core professional training, they felt forced to rely on lived experience to inform the advice they offered. Undergraduate midwifery training involves very little coverage of pregnancy-related musculoskeletal conditions within many higher education institutions (see University of Manchester course description as an example (University of Manchester, 2022), therefore a lack of lived experience of PLPP was perceived by one member of the midwifery group to be a limiting factor to the provision of adequate self-management advice.

> *''If you've lived with that experience and you can [call upon that experience to inform your advice], but if you've not, and you're still that healthcare professional*

that somebody's asking your advice on, then that can become difficult, can't it, for you as a professional when someone's in front of you'' Midwife 1, page 9, line 20

Similarly, undergraduate physiotherapy education may not provide specific training on the management of 'women's health' conditions unless a practice placement in this area is undertaken. Specific knowledge of such issues may therefore require additional postgraduate study. (For an example of an undergraduate Physiotherapy program handbook, see the Manchester Metropolitan University's 2018-2021 version (Manchester Metropolitan University, 2017)). One member of the physiotherapy group who was from a musculoskeletal background therefore felt that she was unable to give advice regarding alternative birthing positions for women with PLPP as she had received no formal training on the topic and had no personal experience to draw upon.

''I feel that because I've not had kids, that I'm not in a position to, you know they'll ask me questions and I'll be like, erm, it probably would've helped to have had a baby, but there's nothing I can do about that for the time being…that's just my personal opinion that it's hard to advise on the birthing side if you haven't been through it'' Physiotherapist 4, page 29, line 12

4.3.2.4 Subtheme: The perceived importance of adequate PLPP management

The perceived importance of adequate PLPP management or the possible consequences of poor management, were discussed by every member of every stakeholder group. The potential for the progression of symptoms was discussed by both groups of clinicians and was mentioned explicitly in three service user interviews.

''…well yeah, knowing what they could've done to help, or what I could have done to avoid worse pain that I've gone through, or anything. Nobody seemed to mention that.'' Service user 5, page 3, line 1

Four of the seven service users stated that until they were given adequate information about PLPP from their healthcare providers, they had harboured significant concerns about the nature of the pain they were experiencing, how the condition might impact

upon their pregnancy, and whether the condition would affect their ability to care for their baby.

> *''When I first started with it, I was worried, what is this? Is it going to affect me forever? You know, what is it?'' Service user 6, page 7, line 17*

The physiotherapists also stated that a poor understanding of PLPP can lead to increased condition-related anxiety and reiterated the need for adequate information provision and reassurance.

> *''I open it up with like, kind of, reassurance that it's not anything they've done wrong, that the baby is fine in there, it's you that's suffering…and you can see them physically deflate as the anxiety just reduces.''* Physiotherapist 2, page 29, line 18

The idea that poor PLPP management may lead to increased future healthcare costs was discussed by both professional groups. It was however interesting to note that it was the midwives who highlighted the potential for future chronic lower back pain, as demonstrated in the quote below.

> *''It's public health isn't it? Public health information, because in 40 years when these pregnant women who are suffering [with PLPP] are older, they're going to be struggling again aren't they?''* Midwife 6, page 11, line 6

Conversely, the physiotherapists, discussed the potential reduction in the need for early induction of labour or elective caesarean section in late pregnancy, if PLPP is appropriately managed.

> *''I feel like the worse they get, they're going back asking to be induced early or to be considered for a section, and all these things when actually, if, you know, they could be, I don't know, just managed a bit better earlier on, that would better all round''* Physiotherapist 3, page 36, line 15.

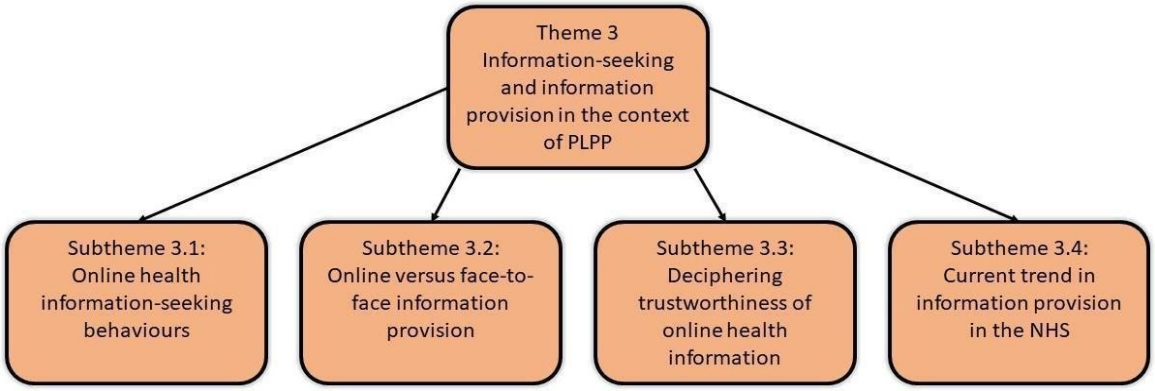
The impact of delayed referral for physiotherapy treatment was discussed by the physiotherapists. The consensus view amongst the group was that if the patient was not referred for assessment until the very late stages of pregnancy, their treatment options might be more limited.

> *''But that's the thing though isn't it, getting them early makes such a difference. It makes everyone's life easier. It makes your life easier [directed to the other physiotherapists] because you can treat them. It certainly makes the patient's life easier, and ultimately the midwife''* Physiotherapist 2, page 36, line 13

In summary, the data presented within this second theme has highlighted the perception that inconsistent or conflicting information provision; lack of time in clinic; relevant training, knowledge, and experience; available resources; and the current variability in service provision, may be barriers to optimal PLPP management. Conversely, early intervention and the provision of adequate information have been proposed as facilitators to successful PLPP management. The perceived potential consequences of poor PLPP management have been presented, and these were said to include progression of symptoms, increased condition-related anxiety, and increased future healthcare costs. Once again, this information suggests that an intervention that provides a broad range of evidence-based, condition-related information, that is deemed to be in line with current clinical practice, would be welcomed by each of the three stakeholder groups.

4.3.3 Theme 3: Information seeking and information provision in the context of PLPP

Figure 4.8 Theme 3



4.3.3.1 Sub Theme: Online health information-seeking behaviours

Across the interviews and focus groups, the perceived drivers for independent online health information seeking were discussed by each of the three stakeholder groups. There was however some discord between the perceived reasons cited by the two groups of clinicians compared to the accounts provided by the service-users. The clinicians perceived the reasons for their patients to independently seek information online to be rather simplistic; either to clarify information gathered directly from a healthcare professional (HCP), or as a substitute for face-to-face information provision when access to a HCP was not possible.

> *''I think it's difficult with the NHS, the way it is, is that resources are so stretched and so that healthcare professionals aren't that easily accessible, so people are much more media savvy, tech savvy''* (Midwife 6, page 5, line 23)

However, data analysis demonstrated that the reasons for seeking information online described by service users were much more complex. The search for reassurance featured prominently in the narratives of five of the seven service users; either to reassure themselves of the benign nature of the health issue they were experiencing, or to inform their own decision-making regarding the need for further intervention.

> *''So I do check the internet to see if it's something that I should be worried about. Now if everybody on the forums is saying that this is a concern then, or are they saying that, no…you're not in early labour. Your baby is not about to pop out. I do tend to then cross reference with the NHS [website]...''* Service user 1, page 4, line 29

Additionally, some of the service users described how online information-seeking helped to provide a means to modify the power dynamic between themselves and their HCPs; suggesting a possible desire in some individuals to shift away from the traditional, hierarchical relationship between medical professionals and their patients. One service user spoke of using online health information to 'arm' herself with knowledge prior to

consultation with her healthcare professional (HCP), in order to allow her to ask appropriate questions and to critically appraise the information they provided to her.

> *''I like to have that knowledge before I go in to talk to someone. I don't like going in blind. I like to go in armed with a little bit of something otherwise you can't ask questions and you're totally reliant on what they say''* (Service user 1, page 3, line 16)

4.3.3.2 Sub Theme: Online versus face-to-face information provision

This second subtheme was discussed at great length by each group and highlighted the internal conflict both service users and HCPs felt regarding the relative benefits and drawbacks of online information provision. Several concerns regarding online health information were common to all three stakeholder groups, highlighting the potential negative consequences of online health information provision.

The risk that information obtained online may be misinterpreted or misunderstood, was a recurring thread in the conversations between both groups of HCPs and was also specifically discussed by two of the service users.

> *''Because you don't know how an individual perceives information. What one person reads into something, somebody else could interpret in a completely different way.'' (all midwives nodding in agreement)* Midwife 1, page 5, line 14

Both groups of HCPs discussed the perceived potential for online information to cause unnecessary panic or distress. This was also highlighted by three of the seven service users when discussing their search for PLPP-related information.

> *''…because you do google it and you hear horror stories about like 'my pelvis was shifted' or 'I had to go on crutches' or 'I was in a wheelchair' so then you think oh God!''* Service User 3, page 4, line 5

Three of the seven service users described the overwhelming volume of online material and the difficulty faced when attempting to filter out the factually accurate information desired.

> *''I googled everything which is a massive mistake isn't it because the information you get is just ridiculous, there's so much and you don't know what to believe''* Service user 3, page 2, line 1

This concern was echoed in the discussions that took place within the physiotherapy focus group.

Both the physiotherapists and the midwives shared the concern that seeking information solely from online sources in place of an in-person consultation with a HCP would deny pregnant women the opportunity to ask questions if the information they obtain is unclear.

> *''Plus then [when using google to search for online information], they've nobody to ask questions to have they?...Yeah, and I do think they [service users] like to ask questions. So that face-to-face is important.''* (P1) Physiotherapists 1, page 20, line 19.

The benefit of having the opportunity to ask questions when receiving face-to-face information from a HCP was also discussed specifically by two service users.

> *''It's just good [when information is provided face-to-face by the HCP], you can ask questions and she [the physiotherapist] can go through any bits you don't understand''* Service user 3, page 8, line 10.

There was a range of opinions amongst the service users on asking questions of HCPs. Three of the service users stated their belief that the information provided by a HCP provided more reassurance than that acquired online and was often deemed to be more factually accurate. Conversely, two other service users held the view that not all HCPs are willing to answer questions about PLPP, and that this may create a barrier to information exchange between the patient and the professional.

> ''*I feel like you're sort of just rushed out of there [from the midwifery appointment] like they're not interested in what you're wanting to ask them..''* Service user 5, page 2 lines 17.

During the midwifery focus group, it was highlighted that if different professionals provide conflicting information to their patients, the trust in future information provision, or even the relationship with the patient, may be undermined.

> Midwife 6: *''…because you get a lot of conflict or a lot of wrong information being given out by one professional…and then then another professional…comes in and contradicts it or say, no, that's not right, then the woman gets confused or loses faith in it.''*
>
> Midwife 5: "*That's when they end up not saying anything then isn't it?"* page 18, line 23

In addition, both the Midwives and Physiotherapists detailed the perceived negative consequences of their patients independently seeking information online. For both groups of clinicians, the risk of a missed differential diagnosis was of significant concern; particularly that symptoms indicative of serious pathology may inadvertently be overlooked. The fear amongst the clinicians was that patients may falsely reassure themselves using online information and therefore fail to seek the required intervention or monitoring.

> *''How do they know it's pelvic girdle pain and not anything more serious?''* Midwife 4, page 26, line 8

The accuracy of the information available online was another issue raised by both groups of professionals. The midwives were concerned about the lack of control professionals have over what is posted online, and the impact of inaccurate information on their patients.

> *''I think it's important that the information is out there but being able to police it being the right information is key. Because we know we haven't got any control over that have we, as healthcare professionals [directs rhetorical question to the group] … the problem is if they're just googling'' (multiple speakers express agreement at the same time)* Midwife 1 page 7, line 15.

The physiotherapists were also concerned that independent online information-seeking may lead their patients to engage with online forums rather than trusted online information resources. The subsequent concern was that forums may expose patients to

both inaccurate information, and what the clinicians referred to as '*horror stories*', that they defined as recollections of negative experiences of health conditions posted online. A shared opinion amongst the physiotherapists was that this may lead to unnecessary condition-related anxiety.

> *''…it's all just horror stories, especially, going back to the forum thing, say like a lot of my patients who have surgery for stress incontinence for example, I tend to find that people will only put horror stories on there [on online forums]…They go away and they read about it and they're adamant they don't want it [surgery for stress incontinence] whereas actually, we've got a really good success rate here, and it's a very successful operation in general anyway. But they'll come back and they'll say it's all going to go wrong, everyone who has this done has problems and it never works!''* Physiotherapists 1, page 16, lines 8-17.

Another concern amongst the midwives was that a shift to online resources within their NHS Trust may have resulted in a loss of '*the personal touch*' (midwife 1, page 8, line 15) from their clinical practice. They saw this as an undesirable development, as prior experience had informed the perception that face-to-face contact remains highly valued by patients, despite the availability of online resources.

> '*…we live in a virtual digital world, but still I think the feedback that you get is that the contact with the midwife is still really, really, really beneficial*" Midwife 6, page 8, line 1.

4.3.3.3 Sub Theme: Deciphering trustworthiness of online health information

The concept of 'trustworthiness' of online health information was a concern highlighted across all three stakeholder groups. The implied meaning of 'trustworthiness' in this context was the degree to which the participants deemed the information acquired online to be factually accurate, in line with current evidence or reflective of best practice recommendations. A number of individuals in both clinician groups described a perception that their patients may struggle to delineate high quality, trustworthy information from inaccurate information or hearsay. Directing patients to trustworthy

information sources was therefore deemed essential, as the following conversation extract demonstrates.

> Midwife 6: *''I think if you google stuff, then it causes more panic that it actually resolves''*
>
> Midwife 2: *''Doctor Google''*
>
> Midwife 6: *''Midwife google! So, what you do is you just make sure that, especially for pregnant women, that it's only the NHS website [that they use to search information]''*
>
> Researcher: "*So you prefer to advise them [service users] to use certain websites?*
>
> Midwife 6: "*Yeah, yeah*"
>
> Midwife 5: "*And make sure it's trusted information basically*" page 4, line 23 onwards

Two service users echoed this concern and described the difficulty they experienced in deciphering the inherent trustworthiness of health information obtained online.

> *''I'm always searching something [online]. I think it's great in terms of the volume of information, but in regard to what is trusted information, that could be more helpful''* service user 6, page 1, line 15

However, six of the seven service users also described the methods they had devised to ensure that they accessed information that they considered to be 'trustworthy' and accurate. These cited methods included seeking information from a predefined list of trusted resources (such as the NHS website, 'BabyCenter' and 'Tommy's midwives'), and placing greater trust in resources recommended to them by their antenatal healthcare providers or trusted peers (e.g., friends with previous experience of pregnancy). A recurring theme across the dataset was that the NHS website appeared to be trusted above all other online resources. This implicit trust was owing to the belief that the information presented on the NHS website would be vetted prior to publication and would meet the same high standards expected of all NHS healthcare provision.

> *''Well if it's on the NHS one [NHS website] then that should be right shouldn't it? I don't think they'd be allowed to put anything on there that's not true''* Service user 3, page 2, line 20

> "*The NHS [website] I always go with because you know they've got the facts"* Service user 4, page 2, line 6

4.3.3.4 Subtheme: Current trends in information provision in the NHS

Within this subtheme service users expressed a range of experiences regarding the volume, quality, and format of PLPP-related information provided to them from their antenatal healthcare providers. Some of the service users described being provided with verbal information alone; some had been given written information in the form of a leaflet; whereas for some, the complete lack of information provision had led to significant frustration.

> *''And like with my midwife, I wasn't offered any information on pelvic girdle pain or sciatica and I was made to feel like, just get on with it really.''* Service user 2, page 2, line 12

When questioned regarding the use of written or digital information resources to supplement verbal information provision, the physiotherapists described the use and distribution of a group of paper-based leaflets published by the Pelvic Obstetric and Gynaecological Physiotherapist group (POGP). Interestingly, in a similar way to the patients having an implicit trust in the information on the NHS website, the Physiotherapists displayed confidence in the publications produced by the POGP. There was a clear assumption that the information produced by their special interest group would be accurate, relevant and in line with best practice. One physiotherapist stated that she will occasionally direct patients towards trusted online resources, such as the pelvic partnership's website, however the group as a whole described a current reliance on paper-based resources.

> *''…but if I'm going to recommend something [online resources], then I tend to only recommend the websites that are in the booklets we give out, the POGP PGP leaflet. I've never really looked at them I'll be honest, but I just assume, well they must be alright because they've been written in the booklet''* Physiotherapist 4, page 18, line 16.

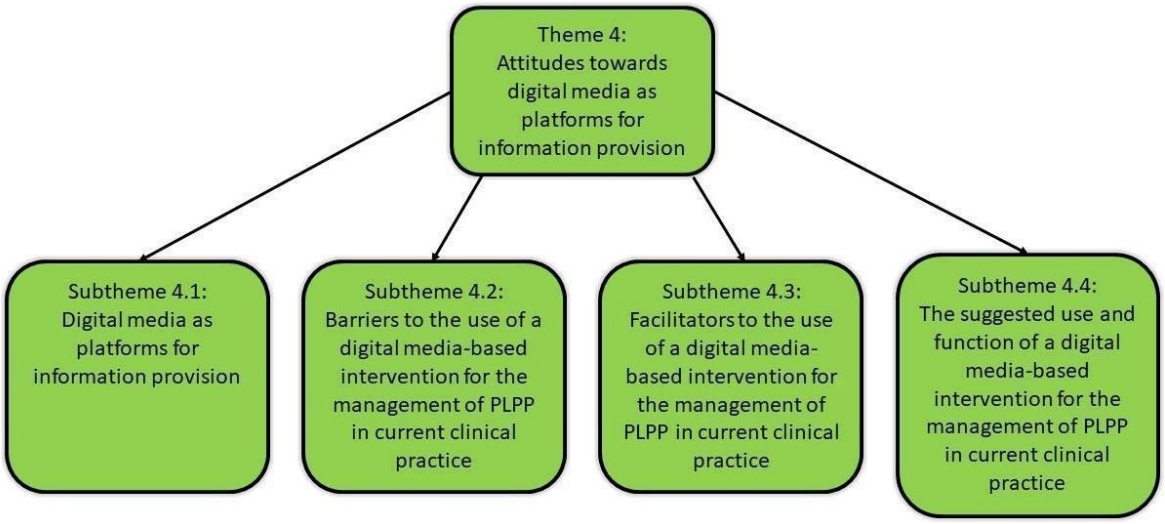
Conversely, the midwives described an institution-wide shift towards the use of online resources in an attempt to reduce costs and save time. Online information resources were reported to be used in place of paper-based leaflets. Virtual tours of the midwifery unit, and virtual antenatal education classes were also described.

> *''I mean now, for neonatal for us, we signpost and send electronic leaflets now don't we? They don't get the paper version. I think it was more of a cost related thing for the Trust.''* Midwife 1, page 3, line 23.

In summary, this theme has highlighted the range of drivers for online information seeking as perceived by each of the three stakeholder groups. The perceived benefits and risks of searching for information in this way have been highlighted, in addition to the ongoing value placed on face-to-face information provision. The difficulties presented by the need to filter vast volumes of online information has been acknowledged, in addition to the problem of delineating trusted, accurate information from opinion and hearsay. Finally, the variation in the volume, quantity, and format of information provided to patients has been demonstrated, and the shift towards online resources ongoing within NHS institutions sampled has been recognised. Therefore, despite the value placed on face-to-face information provision, this data suggests that a digital intervention that provides current, evidence-based, condition-related information to patients could address some of these issues.

4.3.4 Theme 4: Attitudes towards mobile phone apps and social media as platforms for information provision.

Figure 4.9 Theme 4



4.3.4.1 Sub Theme: Apps and social media as platforms for information provision

Each of the stakeholder groups discussed their attitudes towards the use of mobile phone apps and social media for the provision of general health-related information. All groups perceived mobile phone apps to be useful for the provision of information as they were seen as convenient sources of information, specific to the topic of interest. Four of the seven service users reported the use of pregnancy-related apps during their current pregnancy, supporting the familiarity of mobile phone apps to this group.

> *''...and I've got an app that I use quite a lot called 'Sprout'...Well it's like looking at the development of the baby, and my kids use it as well so they can see what the baby will be like and where it will be up to''* Service user 1, page 2, line 10

Two members of the physiotherapist group and three of the midwives reported some experience of using mobile phone apps to support clinical practice. Both physiotherapists described the use of an app to remind their patients to do their prescribed pelvic floor muscle exercises, whilst the midwives had been involved with a clinical trial exploring the use of a mobile phone app for the remote monitoring of blood pressure. Both groups of

clinicians commented on the accessibility and familiarity of mobile phone apps and acknowledged their subsequent potential as a platform for information provision.

> *''I think a lot of them [pregnant patients] like the idea of an app don't they? You go through a load of different stuff and then you mention an app and it's like 'ooh an app, I'll have a look at that''* Physiotherapist 2, page 24, 8

Interestingly, when discussing the use of social media for information provision, the physiotherapist group discussed how their own recent declining use of platforms such as Facebook had caused them to question the wisdom of attempting to use these as a means of providing PLPP-related information to patients. The group members agreed that if patients are not accessing social media platforms regularly, or if enthusiasm for these platforms is generally waning, then any attempt to use these to convey PLPP-related information to patients may prove futile.

> *''I don't know if this is just me, but since hating Facebook and retracting [my own] use, now it's an effort to go on it. So that's the only thing I was thinking in terms of…use for healthcare…I used to go on it all the time…whereas now…I don't go on it for days…that would defeat the object of it being like an open channel [for information provision]''* Physiotherapist 4, page 8, line 3

Four of the seven service users stated a definite preference for mobile phone apps over social media for information provision and cited a lack of trust in information acquired via social media as the principal reason for this.

> *''Well personally, I think an app would be far more useful. I download apps all the time but like I said, I don't use Facebook any more or anything like that and I wouldn't use social media to look for information. I use it more just to see what other people are up to…that is what I use social media for. I wouldn't trust information on there if I didn't know where it was from. Whereas if I've got an app, I've got it for a specific reason. So that would be, for me personally, I think that would be much more useful.''* Service user 6, page 6, line 4

4.3.4.2 Sub Theme: Barriers to the use of a social media or app-based intervention for the management of PLPP in current clinical practice

A range of barriers to the use of apps and social media were identified across the three groups of participants, however there were subtle differences in the specific issues raised.

For the service users, if the content or layout of an app was not seen as engaging, or if the volume of information was deemed to be overwhelming, these were perceived to be significant barriers to use.

> *''...because it's got to look appealing…and not be too much like, not too wordy and make you think 'ohh, bore off!' Like…I think it needs to look appealing and sound appealing…it's hard to get that balance''* Service user 7, page 21, line 27

The cost of mobile phone apps was also identified as a factor determining use. Two of the three service users who explicitly discussed cost stated that the price of an app could be overlooked if the content was seen to justify the cost.

> *''I mean nobody like paying for an app and it depends on the reviews it gets to be honest…They're kind of negligible costs but if they're not working you really do begrudge paying £2 for something.''* Service user 6, page 6, line 12

For one service user however, cost was said to be a definite barrier that she could not overcome.

> *''So I think well instead of paying for it [an app] I'll just google it or ask the midwife or GP. It's an expensive time as it is, so you're not going to pay for an app''* Service user 2, page 7, line 11.

Although the potential for online forums to provide peer support was acknowledged by two of the service users, the possibility for social media platforms to become vehicles for misinformation was a significant concern for the physiotherapists.

> *''But I think that's the thing about Facebook isn't it, that it's become a bit of a free-for-all, a bit of a forum doesn't it turn into? And I know everyone will put their own opinion on, so like I've got friends who will put like 'I've got this problem, what does everyone think?' So, like 'you need to do this'… or like 'I think you need to try this' [posted in reply], like medication suggestions and all sorts and I'm like just go and see your Doctor!''* Physiotherapist 3, page 9, line 11.

The need to supply large amounts of personal data in order to access an app-based or social media-based intervention was another barrier highlighted by one service user. If the request for personal information was seen to be excessive or was not deemed to be

relevant to the potential benefit of having access to the intervention, this would present an insurmountable barrier to uptake.

> *''For me it would be the information you are taking from me and where you are using it. So it's what I would need to give in order for you to, in order for me to get an app. You know, I try to keep my personal information as personal as possible, which I know is not doable in this day and age, but it would depend on what you were asking from me.''* Service user 6, page 6, line 30

The protection of personal data was a concern echoed by the midwives. The notion implicit in their discussion was that both clinicians and patients would need to feel reassured of the safety of any personal data entered into the app for uptake of the intervention to be encouraged.

> *''As long as there was none of that spyware attached or all the other ways that they collect your data that you don't even know about''* Midwife 2, page 22, line 12

When discussing barriers to digital interventions for the management of PLPP, the physiotherapists' discussion centred around social media. These barriers to the implementation of a social media-based intervention into clinical practice included the lack of access to technology within different NHS Trusts, the idea that social media platforms are often blocked by NHS IT servers, and a gradually reducing personal level of engagement with social media. The physiotherapists also raised their concerns about the idea of using platforms such as Facebook for the provision of information to their patients and highlighted the potential for such platforms to be converted into '*forums*' for negative experiences, with the subsequent risk of exposing patients to inaccurate information.

> *''Like I think that's the danger with Facebook is that it becomes like a bit of a 'Mumsnet' [existing online forum for expectant and new mothers] with everyone just having their own opinion on there'' Physiotherapist 3, page 10, line 12*

Finally, the midwives proposed inappropriate commercial advertising as a potential barrier to the use of an app-based or social media-based intervention into their own

clinical practice. They were strongly opposed to any advertising by commercial companies that either produce or distribute formula milk for babies, presumably because this would be at odds with the current public health campaign to promote breast-feeding. One midwife referred to the priming effect of subtle advertising. She used 'Nestle' as an example of a company that one would usually associate with the manufacture of confectionary, but is actually also a global producer of baby milk products. The following is an extract from the conversation on commercial advertising.

> Midwife 2: *''As long as there was no commercial interest, with pops and …''*
>
> Midwife 1: *''Yeah. Formula milk companies or selling artificial things''*
>
> Midwife 2: *''Obviously they can be quite subtle as well [adverts from manufacturers of formula milk], like Nestle, you'd kind of relate that to chocolate, but actually…[sentence not completed as all midwives nodding in agreement]''* Page 22, line 3 onwards

4.3.4.3 Sub Theme: Facilitators to the use of a social media or app-based intervention for the management of PLPP in current clinical practice

When discussing the facilitators to the use of a social media or app-based intervention in clinical practice, both the midwives and physiotherapists agreed that ease of use for the treating clinician was a significant factor determining uptake.

> *''…to have an app in the App store, pull it up, download it and then you can just say you can delete it later if you want, but it's there if you need to use it''* Midwife 1, page 24, line 21

One note of caution amongst the midwives was that a social media or app-based intervention would need to contain clear warnings about red flag signs in order for them to endorse it. In addition to this, the physiotherapists wanted reassurance that the information included in the content would be consistent with current guidance and therefore in line with their own clinical practice. The physiotherapists also suggested that if this was the case, then patient use of such an intervention could potentially allow them

to make more efficient use of their clinical time. The following conversation extract between physiotherapists 1 and 2 illustrates this point.

> Physiotherapist 2: ‘’*It would help I think* [having a social media or app-based intervention to support practice]’’
>
> Physiotherapist 1: ‘’*Especially if it’s the same information you’d give out anyway*’’
>
> Physiotherapist 2: ‘’*You could actually use the first session to get started with some proper treatment instead of just talking through the advice*’’
>
> Physiotherapist 1: ‘’*As long as the information is consistent and doesn’t contradict anything that we’d tell them, then it’d help*’’ page 43, line 1.

Each of the seven service users described features of the proposed intervention that would facilitate uptake. An intervention containing a broad range of condition-related information and clear self-management advice would be more likely to be adopted.

> *‘’Well it would have been nice to be given all the information under that umbrella if you will, all of the information to help me. I’ve had to finish work early because of this, so just as much information as possible about the whole thing and what I could’ve done to help myself’’* Service user 2, page 4, line 11

4.3.4.4 Sub theme: The suggested use and function of a social media or app-based intervention for the management of PLPP in current clinical practice

One clear idea that emerged from the data collected from both clinician focus groups was that any digital intervention for the management of PLPP should be distributed by a HCP, to allow the opportunity to screen for potential differential diagnoses.

> *‘’I was talking about when they come in with pain and you want to get to the heart of it, exactly what kind of pain. Because if it’s pelvic girdle pain, it could be masking a UTI or…You do need to have a discussion about it to make sure that you get a proper diagnosis’’* Midwife 2, page 26, line 13

Both professional groups discussed this issue. The physiotherapists suggested that the midwives were best placed to distribute the intervention as they have more frequent contact with antenatal service users and would therefore likely be the first professionals to whom the symptoms of PLPP are reported.

> *''If the women could be given an app at the first appointment that they mention it [PLPP] to the midwife, and told this is a good app, it's all approved and if you need to we can refer you to physio''* Physiotherapist 2, page 39, line 15

The ideal time to provide access to the intervention was also discussed by all clinicians and all but one service user. There was agreement amongst all three stakeholder groups that early access to such an intervention would be preferable to prevent the deterioration of symptoms and to avoid unnecessary condition-related anxiety. This could be considered a form of safety-netting. There was however some disagreement as to precisely how early this should occur to have the most beneficial effect. One midwife suggested that the intervention could be distributed to every pregnant woman in the early stages of pregnancy as a preventative measure. This suggestion was not contested by the other midwives.

> *''I'd like to give it [app-based intervention for PLPP] to every woman at first point of contact and just say, look, this is something that might affect you in your pregnancy, it might not, but you download the app and if you feel you need it, have a read through it and if you do feel like you need it for further support, then you've got it''* Midwife 1, page 16, line 13

This notion was echoed by four of the seven service users.

> *''…by the time it gets that bad there isn't really a lot they can do for you, so I think that at the first appointment or in the first couple of appointments, they gave you a leaflet about it and said, you know, 'look out for these symptoms' or 'look out for these types of pains and if you have it, at your midwife appointment, bring it to their attention'''* Service user 3, page 5, line 27

One physiotherapist also shared the view expressed above, however this was contested by other members of the group who felt that the intervention would be most beneficial to those who had reported symptoms of PLPP to their midwife. The physiotherapists therefore formed the consensus view that the intervention has the potential to bridge the gap in the care pathway between reporting symptoms to the midwife and being assessed by a physiotherapist.

> *''They [the midwives] could say like 'you will be referred to physio, everything will be alright, but in the meantime here's an app, have a look on there'. Everybody knows how to download an app''* Physiotherapist 4, page 23, line 10.

The wisdom of providing access to a social-media or app-based intervention prior to the onset of PLPP symptoms was also questioned by one service user, who explained that she would have had little interest in such information until it became pertinent to her at the point that she developed symptoms.

> *''I think it would have been useful [to have received information earlier in the pregnancy], but until you start having the pain, it's not really something you kind of take on board or look into. Well I don't anyway. But you know when you are suffering from something and things start going a bit pear-shaped, you know until then, I'd scan over it but not really take it in.''* Service user 4, page 4, line 23.

The data presented under this theme demonstrated a widespread acceptance of the use of mobile phone apps for the provision of PLPP-related information, and a definite preference for the use of apps over social media for this purpose. Multiple barriers to the implementation of a social media or app-based intervention were presented, however each of the three stakeholder groups also provided several suggested facilitators to increase uptake and promote successful implementation. Early access to such an intervention was deemed to be preferable by all stakeholder groups however there was some debate, both within and between stakeholder groups, over the ideal timing of information provision.

4.4 PHASE 1 DISCUSSION

Summary of key findings

Analysis of the data collected during Phase 1 resulted in the generation of four main themes (see Figure 4.5, page 183).

Theme 1: Attitudes toward PLPP and its management

There was agreement across the dataset that PLPP is a debilitating condition but is not given the same attention as other common pregnancy-related issues. Physiotherapists highlighted the pervasive myth that PLPP is a normal part of pregnancy. Confusion about the extent to which PLPP should be accepted as a normal part of pregnancy was also reported.

Theme 2: PLPP management in the context of the NHS

Self-management was viewed positively by all three stakeholder groups, and early provision of condition-related advice was seen as beneficial. Understanding the benign nature of the condition and the positive prognosis were believed to facilitate of self-management. Service users also wanted a broad range of information to be provided, including advice about self-management, medication safety, and birthing.

Conflicting PLPP-related information was identified as a barrier to optimal management by all stakeholder groups. Lack of clinical time was also a concern for service users and midwives. The perceived consequences of poor PLPP management included the symptom progression and increased future care costs.

Theme 3: Information seeking and information provision in the context of PLPP

Each service user engaged in online information-seeking, yet all stakeholder groups highlighted concerns about web-based information. Service users were concerned about the trustworthiness and overwhelming volume of online content. Clinicians worried about the lack of control over online information, the potential for misinterpretation, and the risk of exposure to misinformation. Clinicians, therefore, preferred to direct women to trusted online resources, whilst service users preferentially accessed sources recommended by clinicians and peers.

Theme 4: Attitudes towards digital media as platforms for information provision

All stakeholder groups viewed mobile apps as acceptable platforms for PLPP-related information provision. Use of social media for this purpose was viewed less favourably. The proposed facilitators for adopting a digital self-management intervention for PLPP included the safety of personal data, ease of use for clinicians, use of engaging content and minimalistic layout, and distribution of the intervention by healthcare professionals to avoid the risk of misdiagnosis.

Perceived barriers to use included commercial advertising, and cost.

Clinicians were willing to integrate a digital PLPP self-management intervention into their practice and both the physiotherapists and midwives suggested how they perceived this might be best achieved.

Implications

Phase 1 highlighted a preference for using mobile apps for information provision and provided insight into service users' information needs and aesthetic preferences. This directly informed the design of the app developed in Phase 2, as reported in Chapter 5. The willingness of clinicians to integrate such an intervention into their practice and the perceived practicality of doing so, support the notion of intervention feasibility.

Phase 1 data also highlight the debilitating nature of PLPP and the need to support self-management in women with this condition. Clinicians should reassure patients about the benign nature of PLPP and highlight the positive prognosis. Early intervention may reduce condition-related anxiety and facilitate self-management. Adequate information provision may also reduce the need for independent online information-seeking, thus reducing the risk of exposure to misinformation.

Nonetheless, online information-seeking is widespread amongst pregnant women (Sayakhot and Carolan-Olah, 2016), and patients are often reluctant to discuss online

information with their clinicians (Tan and Goonawardene, 2017). HCPs should, therefore, openly enquire about condition-related information accessed online, thus creating the opportunity to correct misinformation and provide reassurance.

Strengths and limitations

Strengths

The use of the Framework method to increase the transparency of the data analysis and the thorough reporting of the findings using the COREQ checklist.

Limitations

The transcriptions of interviews and focus groups were not returned to participants for member-checking, and initial data coding was undertaken by a single researcher (MM). Efforts were made to offset the impact of these decisions through reflexive discussions with the supervisory team and the recording of detailed reflexive notes throughout the analysis process.

White middle-class women were over-represented amongst the sample of service users; the lack of a formalised purposive sampling strategy and a demographically homogenous sampling frame (Office for National Statistics, 2022) may have contributed to the limited diversity within the study sample.

4.5 Reflection on the need for a purposive sampling strategy in future research

After reflecting on the lack of diversity within the Phase 1 study sample, it is accepted that any future qualitative work related to this PhD study, undertaken to inform intervention development or modification, would benefit from using a purposive sampling technique (Sharma, 2017). Several factors influence the uptake and engagement with digital behaviour change interventions; these include health literacy, digital literacy, age, educational level, employment status, and ethnicity (Perski et al., 2017). It would, therefore, be valuable to consider these factors as part of a purposive sampling strategy

for future related research (Benoot et al., 2016). Additionally, as discussed in section 7.5 of this thesis, there may also be several condition-specific factors that might influence uptake and engagement with PLPP self-management interventions. These could feasibly include parity, pregnancy stage, and symptom severity. It would, therefore, also be helpful to consider these factors during recruitment for future intervention development work. This approach would ensure the recruitment of a sample with maximum variability (Palinkas et al., 2015) and the representation of a wide range of perspectives; this would, in turn, increase the likelihood of generating transferable research findings (Benoot et al., 2016; Sharma, 2017) and may serve to facilitate uptake and engagement with the intervention developed.

In the next chapter, the intervention development process informed by the Phase 1 qualitative findings will be described in full. It will be explained how the barriers and facilitators to PLPP self-management identified in the data were used to inform the design of an app-based intervention in collaboration with a commercial app-development company and a key clinical collaborator. The theory underpinning the intervention development process will also be presented.

CHAPTER FIVE: PHASE 2 DEVELOPMENT OF AN APP-BASED SELF-MANAGEMENT INTERVENTION FOR WOMEN WITH PLPP USING THE BEHAVIOUR CHANGE WHEEL APPROACH

This chapter reports Phase 2 of this PhD study; it describes how the findings from the Phase 1 qualitative study were used to inform the development of a mobile app-based intervention to support the self-management of PLPP. The chapter closes with a summary of the strengths and limitations of the Phase 2 methods and the implications for ongoing intervention development.

Phase 2 addressed objective five of this PhD study.

Objective 5	To develop a prototype digital intervention based on the outcomes of objectives 1-4

The Behaviour Change Wheel approach to intervention development, which incorporates the Capability, Opportunity, and Motivation model of behaviour (COM-B) (Michie et al., 2014), was used to inform this PhD study. Therefore, the following section will describe the theory underpinning this approach; full detail of its application during the Phase 2 intervention development process will then be provided in subsequent sections.

Figure 5.1 Demonstration of where the intervention development process fits into the overall study design

5.1 Theoretical underpinnings of the Phase 2 intervention development process

The COM-B model of behaviour is centred on the idea that a given behaviour will only be enacted if the individual has the capability and opportunity to enact the behaviour and if their motivation to do so is greater than their motivation to engage in any alternative behaviours (Michie et al., 2011). Capability to perform a behaviour is subdivided into physical and psychological components. Physical capability relates directly to the individual's physical functioning, such as strength, balance, and coordination. Whilst psychological capability relates to the individual's mental functioning, such as understanding and memory (Michie et al., 2011; Timlin et al., 2020). Opportunity is also subdivided into both physical and social components. Physical opportunity refers to the opportunities afforded by the physical environment, such as the availability of adequate equipment, resources, finances, and time. Whilst social opportunity involves other people, for instance, certain behaviours may be facilitated by expectations and practises within a particular culture or set of social norms. Motivation involves both automatic and reflective components. Automatic motivation relates to instinct, drive, habit, and affective processes. However, reflective motivation involves conscious thought, such as planning and evaluation (Michie et al., 2011).

Capability, opportunity, and motivation are all interlinked and can all influence behaviour. However, the relationship between these model components is not unidirectional, as enacting a behaviour can influence capability and motivation to repeat the behaviour (Michie et al., 2011). Figure 5.2 below depicts the bidirectional relationship between capability, opportunity, and motivation with behaviour.

In the context of PLPP, self-management could involve several changes to behaviour, such as taking over the counter pain relief, modifying everyday activities, or undertaking a structured home exercise programme (POGP, 2015). Multiple factors could plausibly impact one's ability to enact those behaviours; including understanding the behaviours that may improve symptoms (psychological capability), having time to undertake those behaviours (physical opportunity), having access to equipment (physical opportunity), being supported by family members/friends (social opportunity), and believing that certain behaviours may be capable of reducing symptoms (reflective motivation).

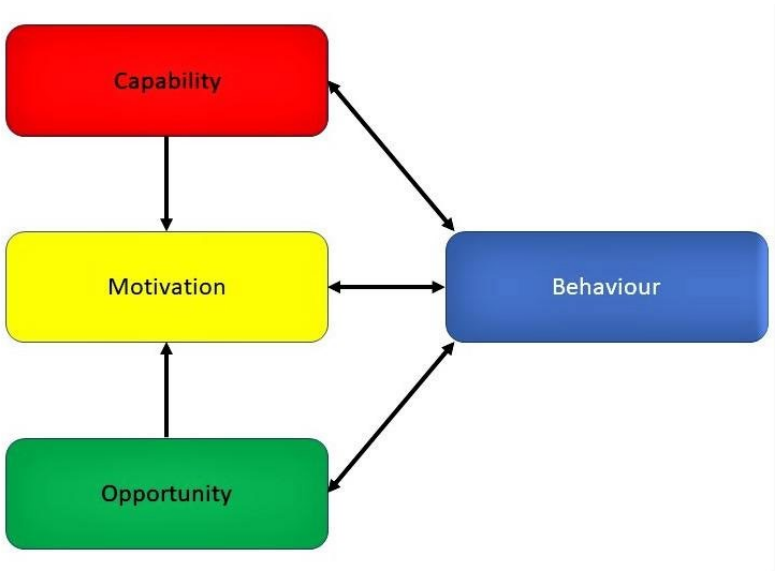


Figure 5.2. The COM-B model of behaviour (Reproduced from Michie et al., 2011)

The COM-B model of behaviour sits at the centre of the 'behaviour change wheel' (BCW) developed by Michie et al. (2011). Figure 5.3 below shows the BCW in its entirety. The wheel's hub is the COM-B model of behaviour and its six components. The middle layer of the wheel includes nine possible ways an intervention might influence behaviour, known as intervention functions. Finally, the outermost layer of the wheel provides seven possible types of policy that might be used to support implementation. For definitions of the interventions and policy categories included in the BCW, please see Table 5.1.

Figure 5.3. The behaviour change wheel (Michie et al 2011, creative communications licence allows reproduction)

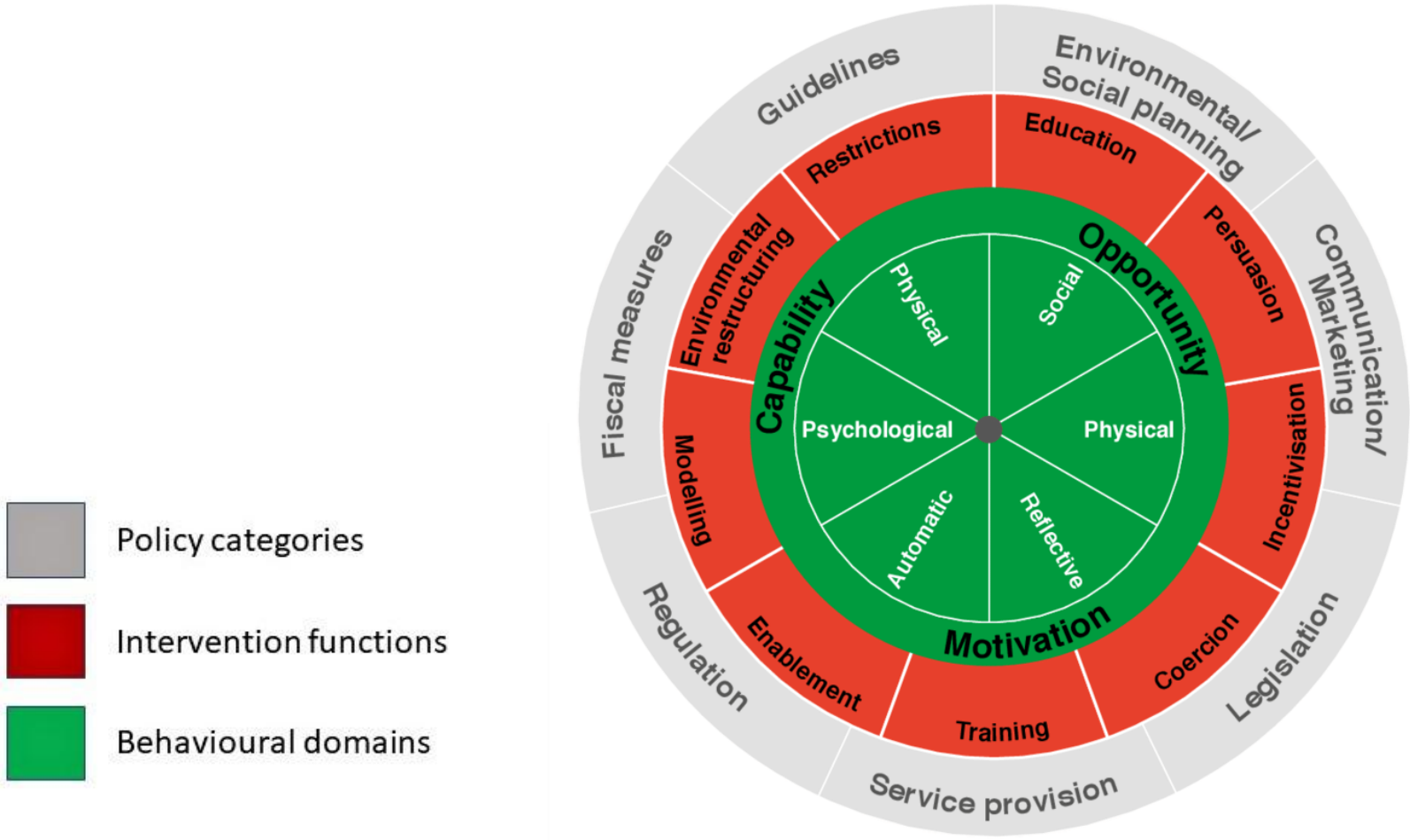


Table 5.1. Definitions of BCW intervention functions and policy categories (Michie et al., 2011; Michie et al., 2014, pages 111 and 135)

Intervention function	Definition
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings or stimulate action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the target behaviour (or to increase the target behaviour by reducing the opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Providing an example for people to aspire to or imitate
Enablement	Increasing means/reducing barriers to increase capability (beyond education and training) or opportunity (beyond environmental restructuring)
Policy categories	Definition
Communication/marketing	Using print, electronic, telephonic, or broadcast media
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision
Fiscal measures	Using the tax system to reduce or increase the financial cost
Regulation	Establishing rules or principles of behaviour or practice
Legislation	Making or changing laws
Environmental/social planning	Designing and/or controlling the physical or social environment
Service provision	Delivering a service

In 2014, Michie et al. published a text describing a systematic approach to intervention development using the BCW as an underpinning framework. The BCW approach is not specific to digital interventions but applies to any intervention aiming to change behaviour (Michie et al., 2014); it has been successfully applied to the development of both digital and non-digital interventions (Barker *et al.*, 2016; Vasiliou *et al.*, 2021). Therefore, this approach was adopted in this PhD study to inform the development of a prototype mobile app-based intervention to support the self-management of PLPP. Full details of how the BCW was used in this PhD study can be found in the following sections.

5.2 Application of the Behaviour Change Wheel approach to intervention development in this PhD study

There are three key stages to the Behaviour Change Wheel approach to intervention development, and each stage has several sequential steps. Figure 5.4 below summarises the process.

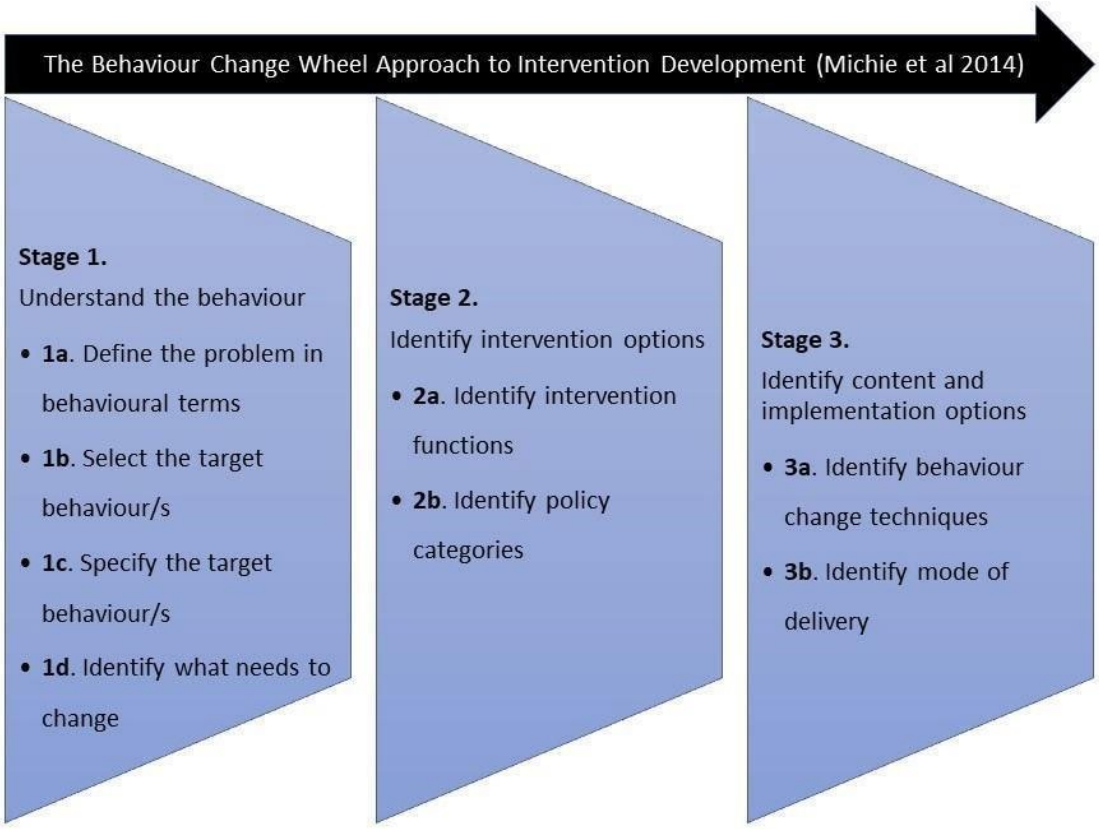
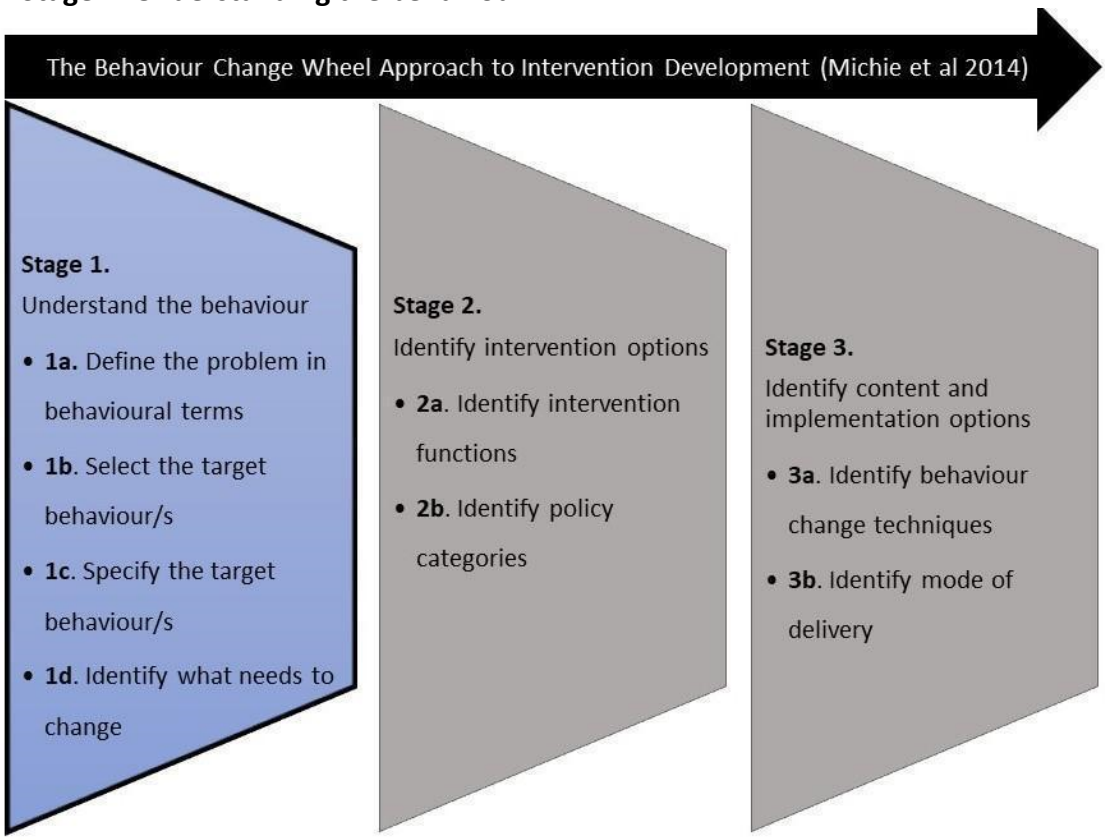


Figure 5.4. The Behaviour Change Wheel process of intervention development

The following sections present a description of how each stage of this intervention development process was followed during Phase 2 of this PhD study.

5.2 Stage 1. Understanding the behaviour



5.2.1 Define the problem in behavioural terms (step 1a)

This PhD study addressed the need to increase the uptake of self-management behaviours amongst women with PLPP.

5.2.2 Select the target behaviours (step 1b)

Michie et al. (2014) recommend keeping the number of target behaviours to a minimum. However, PLPP self-management involves a collection of behaviours to help manage symptoms and optimise physical function (POGP 2015). Therefore, a review of current clinical guidance was first undertaken to establish the recommended behaviours for PLPP self-management.

Three electronic academic databases (SCOPUS, MEDLINE and CINAHL) were searched for clinical guidelines and systematic reviews relating to the management of PLPP. Additional searches via Google were undertaken for clinical guidelines not published in academic journals. Known clinical advisory group websites were also searched. These are listed below:

- The Pelvic Obstetric and Gynaecological Physiotherapy group
- The American Physical Therapy Association
- The Royal College of Obstetricians and Gynaecologists
- The British Society for Rheumatology
- The European Federation of National Associations of Orthopaedics and Traumatology
- The British Orthopaedic Association

Documents were screened by title, abstract, and year of publication to find relevant literature published between 2013 and 2018. Searches were limited to the last five years to ensure the information was current when this review was completed. Important publications (such as the European guidelines for the diagnosis and management of pelvic girdle pain (Vleeming et al., 2008)) would have been omitted using this search strategy. However, this was accepted as more recent clinical guidance superseded these documents.

Full-text documents were retrieved and read in full (For a list of the relevant publications selected for use, please see Appendix 7). Relevant systematic reviews and guidelines were used to establish a list of self-management behaviours recommended for women with PLPP. This list is shown in Table 5.2 below. Each

recommended self-management behaviour was allocated a category to help the researcher more easily conceptualise the range of behaviours highlighted.

Table 5.2. Self-management behaviours identified from current clinical guidance and relevant systematic reviews advised for women with PLPP

	Recommended self-management behaviour	Category of behaviour	Where is the behaviour performed
1	Seek medical input when significant deterioration in condition occurs or when symptoms cause suspicion of a potential complication	Appropriate help-seeking	Individuals own home and/or workplace, antenatal clinic, GP clinic, physiotherapy clinic as appropriate
2	Remain active within the limits of pain	Activity modification	Individuals own home and/or workplace
3	Reduce or avoid activities that aggravate the pain		
4	Modify activities of daily living to minimise unilateral movement of the pelvis and heavy lifting		
5	Modify posture to avoid excessive lumbar lordosis or prolonged static postures		
6	Sleep on one side with a pillow between the knees		
7	Rest when needed		
8	Non-pharmacological pain management – heat application	Pain management	Individuals own home and/or workplace
9	Non-pharmacological pain management – cold application		
10	Non-pharmacological pain management – relaxation/mindfulness		
11	Home exercises – pelvic floor exercises	Exercise	Individuals own home and/or workplace
12	Home exercises – stability exercises for the abdominal and gluteal muscles		
13	Home exercises – general aerobic exercise		
14	Home exercises – general strengthening exercises		

5.2.3 SPECIFYING THE TARGET BEHAVIOURS (STEP 1C)

To help conceptualise PLPP self-management as part of a broader behavioural system, a basic conceptual map was constructed using pre-existing qualitative research, the findings of Phase 1, and the researcher's own experience in clinical practice (see Figure 5.5 below). This conceptual map identifies some of the outside influences that may impact an individual's ability to enact PLPP self-management behaviours and highlights the complexity of the context in which a self-management intervention would be required to operate. Within the conceptual map, knowledge of the recommended self-management behaviours by service users was viewed as an essential precursor to enactment of the behaviour. Therefore, access to PLPP self-management information was highlighted as a potential target for intervention development at an early stage.

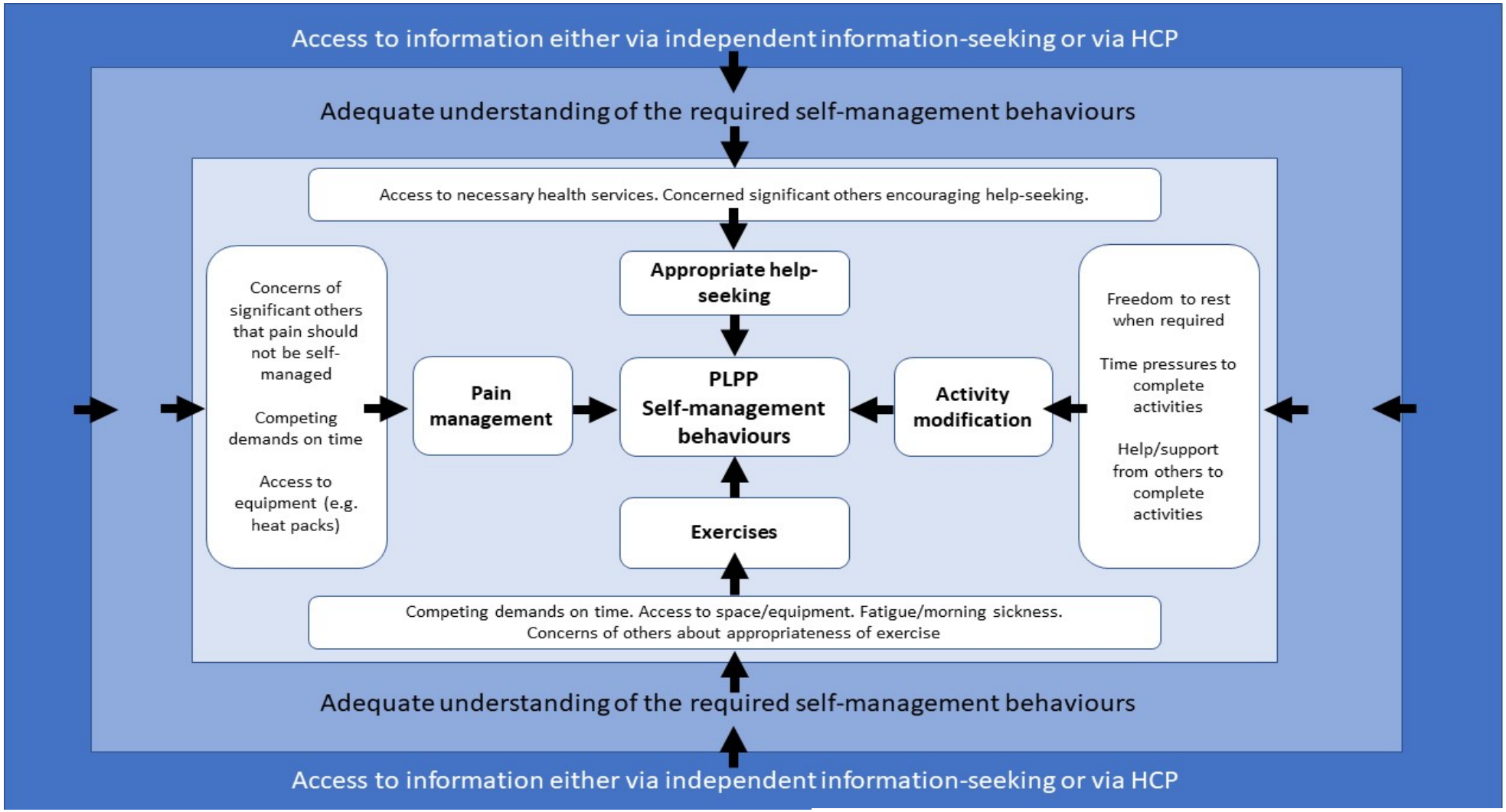


Figure 5.5 Conceptual map of PLPP self-management behaviours

Successful HCP-delivered self-management programs for low back pain in the general population do not focus on one single self-management behaviour such as exercise, but rather view self-management as a collection of complementary behaviours (Oliveira *et al.*, 2012; Keogh et al., 2015; Du et al., 2017). Consequently, the researcher did not prioritise any single self-management behaviour as the primary intervention target without any evidence on which to base this decision. Therefore, the self-management behaviours listed in Table 1 were all considered necessary intervention targets (Oliveira et al., 2012; Keogh et al., 2015; Du et al., 2017).

5.2.4 Identifying what needs to change (step 1d)

Barriers and facilitators to PLPP self-management highlighted by the three stakeholder groups in Phase 1 (predominantly sections 4.3.1 and 4.3.2) were revisited to establish what needed to change. These were then mapped to the COM-B model of behaviour to establish whether it was the capability, opportunity, or motivation to enact the behaviour that needed to be addressed. This allowed the intervention to be appropriately targeted (see Table 5.3 below).

Once potential targets for change were identified, a second table was constructed. Table 5.4 below (pages 157-158) shows each COM-B model component, what needs to happen to allow the desired behaviour, and whether change relating to that component needs to occur based on the data gathered in Phase 1.

Table 5.3. Categorisation of stakeholder perceptions of the barriers to PLPP self-management according to the COM-B model of behaviour

Stakeholder group	Capability	Opportunity	Motivation
Service users	● Lack of awareness of PLPP ● Lack of knowledge of PLPP self-management behaviours ● Difficulty filtering factually accurate trusted information from available online resources	● Lack of access to required information resources ● Delayed access to information/referral from HCP ● Lack of trusted online information readily accessible/easily locatable	● Belief that PLPP is a normal part of pregnancy and therefore should not require specific management might reduce motivation to undertake self-management behaviours ● Belief that the pain of PLPP may be from a sinister cause might increase motivation for help-seeking due to pain-related anxiety and reduce motivation for self-management behaviours
Midwives	● Lack of training on PLPP/lack of personal experience to draw upon to provide advice in some cases ● Reliance on signposting to physiotherapy services	● Lack of time available in clinic to adequately assess and diagnose PLPP then provide adequate advice ● Lack of funding for antenatal education classes, therefore, reduced opportunity to provide information about PLPP	
Physiotherapists	● Some feel unable to advise about labour and birthing due to lack of training and/or personal experience	● Often do not see women with PLPP until the late stages of pregnancy or until the symptoms are severe ● No opportunity for early contact or information provision prior to physiotherapy referral ● Support for self-management limited by waiting lists/resources	

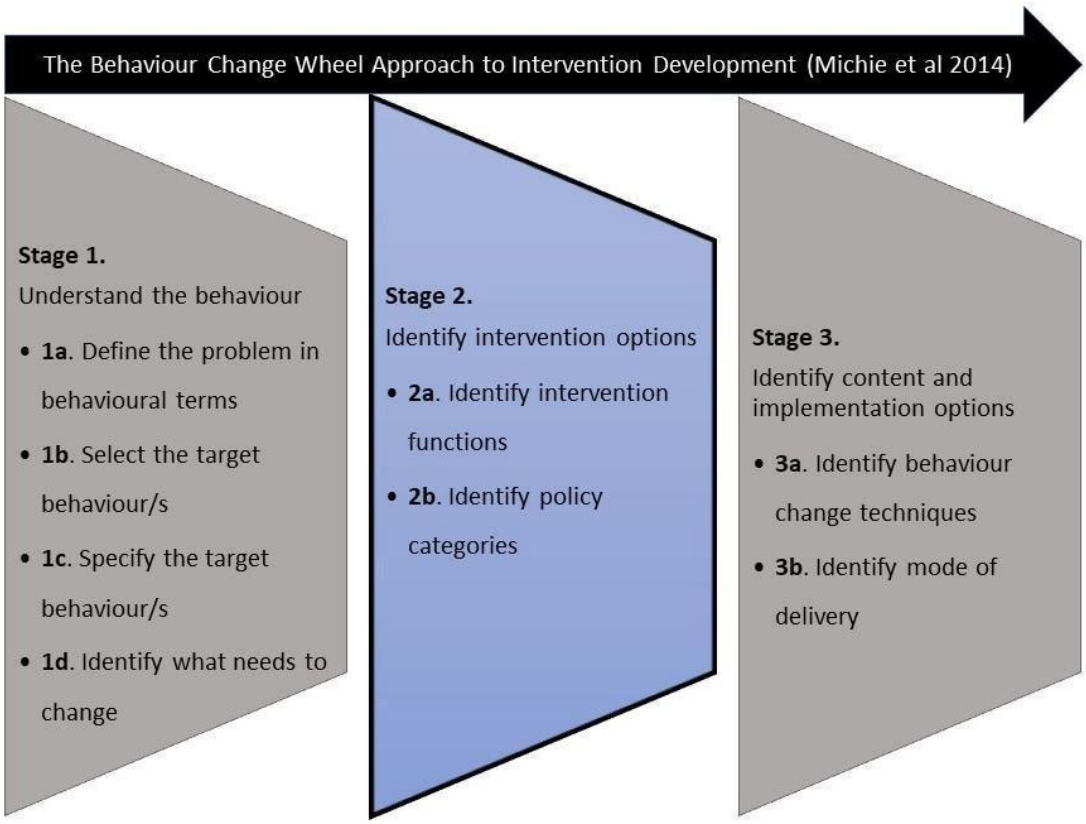
Table 5.4. Identification of required changes to facilitate PLPP self-management

COM-B component	What needs to happen for the desired self-management behaviours to occur	Based on data gathered from stakeholders, is there a need for change?
Physical capability	Individuals with PLPP require the physical skills to carry out the activity modifications, pain management techniques, and home exercise program.	No change is required based on qualitative data collected.
	Healthcare providers need the physical capability to communicate the required self-management information.	No change is required based on qualitative data collected.
Psychological capability	Individuals with PLPP require the knowledge and understanding of the recommended self-management behaviours.	Yes. Data indicates that knowledge of recommended self-management behaviours may be lacking.
	Healthcare providers need adequate knowledge and understanding of the recommended self-management behaviours in order to communicate this information to their patients.	Yes. Data indicates that there may be some gaps in knowledge on behalf of the healthcare providers in some cases.
Physical opportunity	Individuals with PLPP must have the time, equipment, and resources to carry out the recommended self-management behaviours.	Yes. Data indicates there is a lack of access to trusted information resources; this limits the ability to develop psychological capability.
	The healthcare providers must have the time required to communicate the information and must have access to patient-friendly information resources to support this process.	Yes. Midwives highlighted a limited amount of time in the clinic that may hamper PLPP-related information provision.
Social opportunity	Individuals with PLPP must have social support to allow self-management behaviours to occur. Self-management behaviours must also be seen to be socially acceptable.	No change is required based on qualitative data.

	Healthcare provider information provision practices must fit with local departmental culture and practice.	No change is required based on qualitative data. There is no indication that PLPP-related information provision would be deemed socially unacceptable or would be inconsistent with departmental culture.
Reflective motivation	Individuals with PLPP must hold the belief that self-management behaviours will improve symptoms.	Yes. Data indicates there is a lack of knowledge of PLPP self-management behaviours and a lack of understanding about the nature of the condition.
Reflective motivation	Healthcare providers must hold the belief that PLPP is a condition that can be debilitating for pregnant women and that it requires adequate management.	Possibly. Data indicate that although those sampled agree PLPP can be debilitating and requires adequate management, participant responses suggest this belief may not be held by all healthcare providers across the organisations from which participants were recruited. Previous qualitative data also suggests that these beliefs may not be held widely across the relevant professional specialities (see Chapter 2).
Automatic motivation	Individuals with PLPP must have established routines and habits for the recommended self-management behaviours.	Yes. A change could help to establish habits and routines for self-management behaviours.
	Healthcare providers must have established routines and habits for providing information relating to PLPP self-management.	Yes. A change could help establish routines for information provision to ensure consistency.

In Table 5.4, psychological capability, physical opportunity, and reflective and automatic motivation are possible targets to facilitate PLPP self-management behaviours. Michie et al. (2014) refer to this as the 'behavioural diagnosis'. Data from Phase 1 suggest that change needs to be targeted not just at individuals experiencing PLPP but also at their antenatal healthcare providers.

5.3 Stage 2. Identifying intervention options



5.3.1 Identifying the intervention function (step 2a)

For each component of the COM-B identified as a possible target for change, Michie et al. (2014) recommend a list of possible intervention functions deemed most likely to bring about the desired change to behaviour. Table 5.5 lists the intervention functions considered for this thesis (Michie et al., 2014).

Table 5.5. Possible intervention functions to be targeted in this study

	Intervention function	Description of intervention function
1	Education	Increasing knowledge or understanding
2	Training	Imparting skills
3	Environmental restructuring	Changing the physical or social context to facilitate engagement in the desired behaviour
4	Enablement	Increasing access to the means needed to perform a behaviour or reducing barriers to the desired behaviour
5	Restriction	Using rules to reduce the opportunity to engage in competing behaviours
6	Modelling	Providing an example for people to aspire to in relation to the desired behaviour
7	Persuasion	Using communication to induce either positive or negative feelings, or to stimulate action towards the desired behaviour
8	Incentivisation	Creating an expectation of a reward for enacting the desired behaviours
9	Coercion	Creating an expectation of punishment or cost of either not enacting the desired behaviours or engaging in competing behaviours

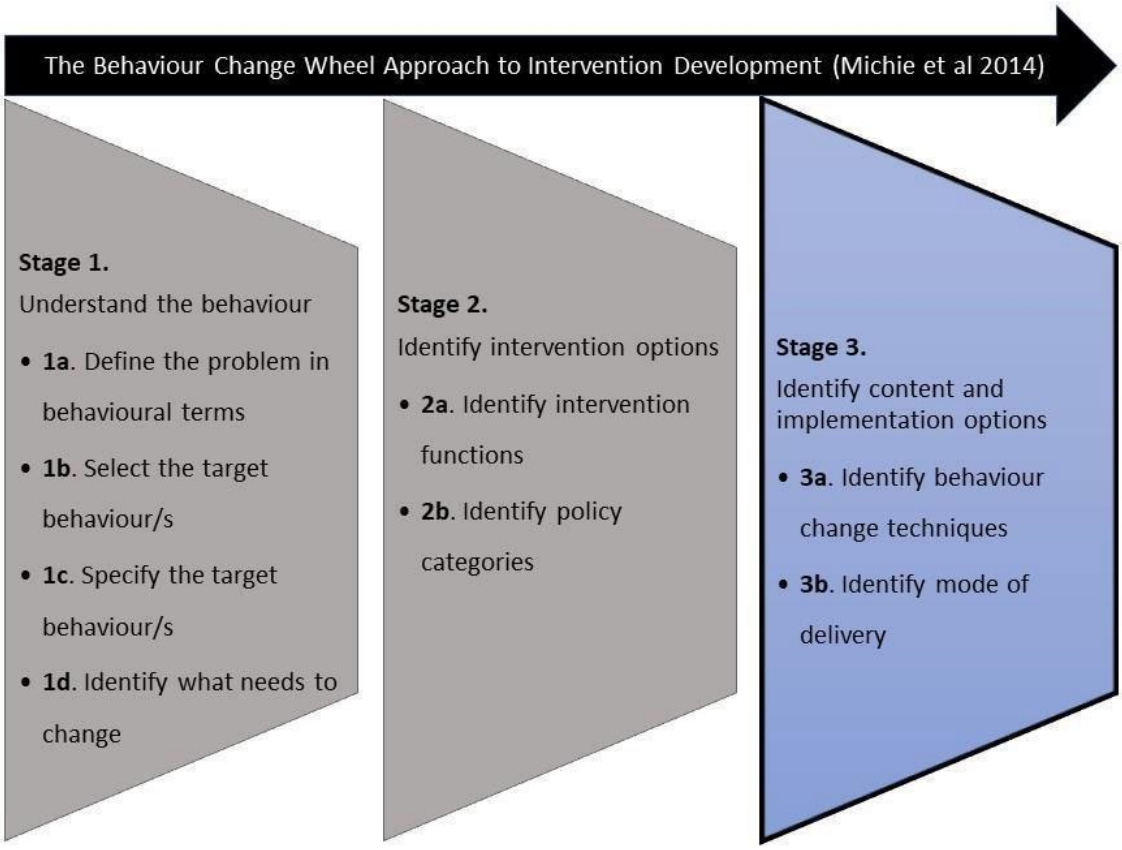
The intervention functions highlighted in blue were deemed most appropriate to address the issues highlighted in Table 5.4. Provision of condition-related information (such as why PLPP occurs and details of the likely prognosis) and information about recommended self-management behaviours (including instructions on how to perform the behaviours and why those behaviours may be helpful) are forms of education and training. Highlighting the potential benefits of PLPP self-management behaviours may improve reflective motivation to enact the behaviours; this is a form of persuasion. Providing antenatal healthcare providers with a trusted information resource to offer their patients would reduce the time

demand associated with oral information delivery and may fill any existing gaps in healthcare provider knowledge. This is, therefore, a form of enablement.

5.3.2 Identify policy categories (step 2b)

Once the intervention functions have been determined, Michie et al. (2014) recommend establishing which type of policy may be used to support the implementation of the intervention (see Table 5.1 on page 147 for a description of the different policy categories recommended). Nonetheless, mandating the use of a prototype intervention via policy would seem inappropriate until the development process is complete, and effectiveness has been convincingly established. Step 2b of the BCW process has therefore been omitted in this thesis. However, once development and evaluation of the intervention are complete, clinical guidelines may be the most appropriate policy category to support implementation.

5.4 STAGE 3. IDENTIFY CONTENT AND IMPLEMENTATION OPTIONS



Once the intervention functions had been decided (see Table 5.5), the next step was to select the specific behaviour change techniques (BCTs) to facilitate the desired behaviours (Step 3a) (Michie et al, 2014). Please note that as a mobile phone app had already been identified as the mode of intervention delivery preferred by most service users participating in the Phase 1 exploratory qualitative study (section 4.3.4.1), step 3b will not be further discussed.

5.4.1 IDENTIFY APPROPRIATE BEHAVIOUR CHANGE TECHNIQUES (STEP 3A)

Ninety-three BCTs are included in the internationally agreed behaviour change taxonomy (version 1) published by Michie et al. in 2013 (Michie et al., 2013; Michie et al., 2014). This taxonomy was developed to facilitate accuracy and consistency

when reporting behaviour change interventions (Armitage *et al.*, 2021). The 93 BCTs included in the taxonomy are organised into 16 categories, and each has a thorough definition to allow consistency across studies.

The BCTs most frequently used to support the intervention functions 'education', 'enablement', 'training' and 'persuasion' are listed in Table 5.6 below (Michie et al., 2014). Michie et al. (2014) recommend considering these frequently used BCTs when deciding which to include in the intervention.

The options listed in Table 5.6 were narrowed down based on the following considerations:

- Affordability, practicability, effectiveness, acceptability, safety, and equity – the APEASE criteria (Michie et al., 2014).
- The BCTs identified in successful digital interventions for back pain self-management (as presented in Chapter 2 section 2.5.2)
- The BCTs identified in non-digital self-management interventions (Keogh *et al.*, 2015).
- The core components of self-management interventions highlighted in section 1.2.3 (Lorig and Holman, 2003).
- What was deliverable in the context of a mobile phone app

Table 5.6. Behaviour change techniques for the selected intervention functions

Intervention functions selected from Table 5.5	Most frequently used BCTs to support selected intervention function (Michie et al., 2014)
Education	Information about social or environmental consequences Information about health consequences Feedback on behaviour Feedback on outcomes of the behaviour Prompts/cues Self-monitoring of behaviour
Persuasion	Credible source Information about social consequences Information about health consequences Feedback on behaviour Feedback on outcomes of the behaviour
Training	Demonstration of the behaviour Instructions on how to perform the behaviour Feedback on the behaviour Feedback on outcomes of the behaviour Self-monitoring of the behaviour Behavioural practice/rehearsal
Enablement	Social support unspecified Social support practical Goal setting (behaviour) Goal setting (outcome) Adding objects to the environment Problem solving Action planning Self-monitoring of the behaviour Restructuring of the physical environment Review behaviour goals Review outcome goals

5.4.2 Involvement of the app-development company in decision-making about app content and features

The decisions regarding which BCTs were deliverable via an app-based intervention involved in-depth discussion with the app development company 'Living With Ltd' to establish the technical limitations.

As no financial compensation was being paid to the company for their work, it was agreed at the outset that additional technical development work would be kept to a minimum, and where possible, existing technologies would be used. Extensive discussion between the researcher and the app development company clarified that technology had already been developed to support the provision of textual and visual information, the use of a goal-setting function, the configuration of multiple-choice patient-reported outcome measures, and two-way communication between the clinician (via the pre-existing online platform) and app user (through a patient-facing mobile phone app).

It was agreed that the app developed for this PhD study would be included as an additional ‘module’ to a pre-existing online platform developed by the app-development company known as the ‘Living With Pelvic Health Platform’ (Living with Ltd, 2022), which is already in use in the NHS. This online platform is used by clinicians and links to a collection of user-facing mobile phone apps developed by ‘Living With Ltd’ in collaboration with expert clinicians. Service users at subscribing NHS Trusts can be provided with access to apps linked to the platform to support their ongoing care. Clinicians send an invitation link to service users’ nominated email addresses via the online platform. The link received is then used to download

the app software for free to the user's mobile phone. Other condition-related apps linked to the platform include those targeting overactive bladder, faecal incontinence, and pelvic organ prolapse (Living With Ltd, 2022).

5.4.3 Refined list of BCTs selected for inclusion in the app

Delivery of the BCTs shown in Table 5.7 below was therefore feasible.

Table 5.7. Refined list of BCTs deemed deliverable via the app-based intervention

Intervention functions selected	BCT deemed deliverable within the constraints of existing technology	Details of how the BCT will be delivered
Education	Information about health consequences	An explanation of why PLPP self-management behaviours may be of benefit would be included in the information provided
Persuasion	Credible source	NHS service users would be receiving evidence-based information collated by researchers and clinicians
Training	Instructions on how to perform the behaviour	Information about the recommended self-management behaviours and how these should be undertaken would be provided
Training	Demonstration of the behaviour	External links to publicly available videos published by charitable organisations and special interest groups demonstrating self-management behaviours would be made available
Enablement	Social support (unspecified)	Service users would be able to seek advice from their clinician via the app if desired, therefore fulfilling the description of 'Advise on, arrange or provide social support e.g., from friends, relatives, colleagues, buddies or staff' Michie et al (2013)
Enablement	Goal setting	Service users would be able to set their own personal goals relating to PLPP self-management behaviours
Enablement	Self-monitoring of the outcome of the behaviour	Patient reported outcome measures capturing levels of pain and functional restriction could be included to monitor the outcome of self-management behaviours.

Once the definitive list of relevant BCTs that could be delivered via an app-based intervention had been determined, the specific content for the intervention was then developed.

5.5 Determining specific content for the app to deliver the selected BCTs (step 3a continued)

5.5.1 Instructions on how to perform the behaviour, information about health consequences, and demonstration of the behaviour

Current clinical guidance and evidence relating to the management of PLPP had to be synthesised to ensure the information needs of women with PLPP were met and selected BCTs could be delivered. Relevant systematic reviews and guidelines identified via the search described in section 5.2.2 were used to inform the intervention content by following a structured information extraction process. The key information needs identified by the stakeholders were considered (see sections 4.3.1.3 and 4.3.2.2), and a bespoke framework for information extraction was developed. Five key categories were identified:

1. The proposed underlying pathological mechanisms of PLPP
2. Risk factors and prognosis
3. Treatment options
4. Self-management strategies
5. Labour and birthing

Figure 5.6 below demonstrates the layout of the data extraction table used.

Title of Paper First author Source Year of publication	Proposed underlying pathological mechanism	Risk factors and Prognosis	Treatment options	Self-management strategies	Labour and birthing
Pelvic girdle pain and pregnancy. Information for you Royal College of Obstetricians and Gynaecologists 2015	PGP is usually caused by the joints moving unevenly, which can lead to the pelvic girdle becoming less stable and therefore painful. Extra weight and the change in the way you sit or stand will put more strain on your pelvis.	You are more likely to have PGP if you have had a back problem or have injured your pelvis in the past or have hypermobility syndrome, a condition in which your joints stretch more than normal.	Advice Exercises to strengthen your abdominal and pelvic floor muscles to improve your balance and posture and make your spine more stable. Manual therapy Hydrotherapy Acupuncture Support belt or crutches Paracetemol Walking aids	keeping active but also getting plenty of rest • standing tall with your bump and bottom tucked in a little • changing your position frequently – try not to sit for more than 30 minutes at a time • sitting to get dressed and undressed • putting equal weight on each leg when you stand • trying to keep your legs together when getting in and out of the car • lying on the less painful side while sleeping • keeping your knees together when turning over in bed • using a pillow under your bump and between your legs for extra support in bed	Most women with pelvic pain in pregnancy can have a normal vaginal birth. Make sure the team looking after you in labour know you have PGP. They will ensure your legs are supported, help you to change position and help you to move around You may find a birthing pool helps to take the weight off your joints All types of pain relief are possible, including an epidural. A caesarean section will not normally be needed for PGP. There is no evidence

Figure 5.6. Excerpt from information extraction table used to synthesise current advice for women with PLPP

Once the data extraction table was populated, the relevant information collated for each topic area was reworded using appropriate accessible language. Where required, additional details were sought from papers cited in selected guidance documents. (For a complete list of references used to write the app content, please see Appendix 8.)

For the BCT 'demonstration of the behaviour', relevant external links to trustworthy, publicly available video content were included in the app content. Once written, the app content was passed to the app-development team for checking and coding. An early copy of the app's textual content is included in Appendix 9 for demonstration. Figure 5.7 below shows how the content was presented in the app based on the suggestions of service users during the Phase 1 qualitative study. The layout is minimalistic, and the text was presented in small, manageable sections to allow easier reading.

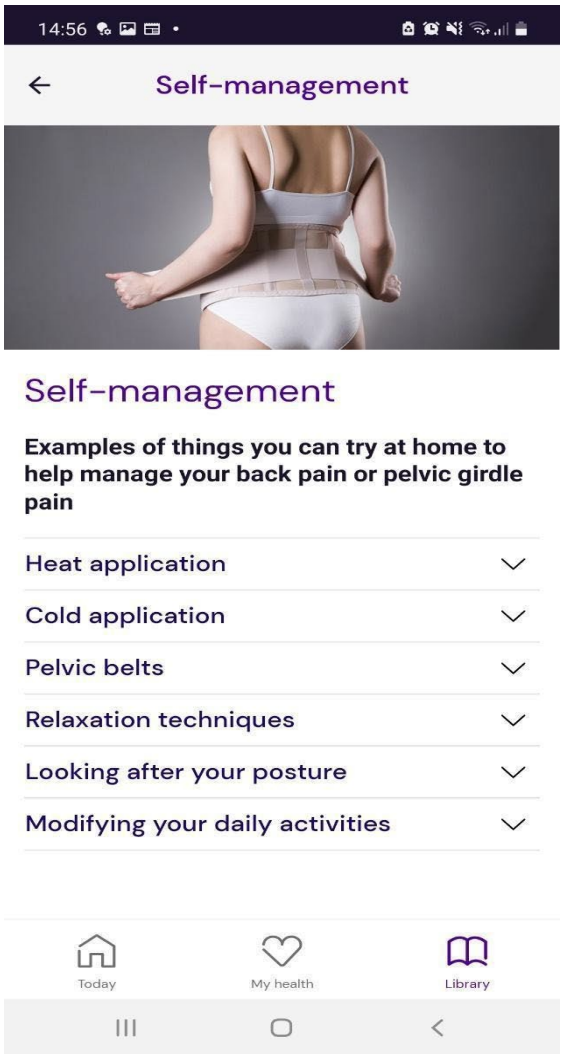


Figure 5.7. In-app content – Instructions on how to perform the behaviours

5.5.2 EXERCISES

There is clear evidence that exercise may be of benefit to women experiencing PLPP (van Benten et al., 2014; Davenport et al., 2019). However, there is little agreement about the most beneficial exercise or the optimum dosage. A previous systematic review highlighted the benefit of 'stability' exercises for women with PLPP (van Benten et al., 2014), although this has recently come under criticism (Stuge, 2019). Symptom aggravation has also been reported after specific types of 'stability' exercise (Mens et al., 2000). Despite this, a UK-based survey of practice reported

that such exercises are commonly used to manage PLPP (Bishop et al., 2016). Therefore, including such exercises in the app was deemed acceptable and in keeping with clinical practice. The pragmatic decision was made to keep the number of exercises to a minimum and to include only those deemed suitable for women with severe PLPP: This represented a trade-off between the potential for some clinical benefit and the risk of adverse effects.

Four physiotherapy colleagues of the researcher with experience of managing women with PLPP were consulted between May and June 2019 to seek their opinions regarding suitable exercises. This was a clinical consultation exercise, not a primary research activity (HRA 2021). These discussions did not involve formal data collection and were therefore not the subject of ethical review.

Details of included exercises can be found in Appendix 10.

5.5.3 SELF-MONITORING

A relevant outcome measure had to be selected to deliver the BCT 'self-monitoring of the outcome of the behaviour' (see Table 5.7). In 2021, Remus et al. published a core outcome set for pregnancy-related pelvic girdle pain (a subset of PLPP). This core outcome set (COS) included five outcomes under the domain entitled '*life impact*'. These were: pain frequency, pain severity, activity limitation, health-related quality of life and fear avoidance. However, this information was not available at the time of intervention development; a pragmatic decision was therefore made regarding the most appropriate way for app users to track their progress. This decision was informed in three ways:

1. Consideration of the patient-reported outcome measures used in clinical practice at that time
2. The desire to minimise the burden associated with the completion of multiple outcome measures
3. The literature relating to appropriate outcome measures for PLPP available at the time

Informal email consultation via the Pelvic, Obstetric and Gynaecological Physiotherapy (POGP) group was undertaken to explore the outcome measures commonly used in clinical practice. Responding POGP committee members stated that they frequently used the Pelvic Girdle Questionnaire (PGQ) themselves and that use of this measure was widespread in clinical practice. The PGQ is a condition-specific measure developed for use with women with PPGP to capture levels of activity restriction and bodily symptoms (Stuge et al., 2011). The PGQ has also been used with a mixed population of women with PLBP, PPGP, and PLPP and has shown good responsiveness to change in this population (Ogollah et al., 2019). The PGQ has 20 items relating to activity restriction and five related to bodily symptoms; each scored on a 4-point Likert scale. Each scale is scored from 0 to 3, where '0' represents no pain or activity restriction, and '3' represents the worst pain or activity restriction. The scores are then summed to give a total out of 75. This is then converted to a score out of 100, where higher scores represent worse pain and functional restriction. The minimal important change (MIC) for the total PGQ score was found to be 11.0 (Ogollah et al., 2019). It is accepted that Likert scales with an even number of response options may be seen to force a response in a particular

direction as they do not allow for neutrality (Croasmun and Ostrom, 2011; Warmbrod and Warmbrod, 2014). However, as the PGQ is widely used and validated, it was deemed an appropriate choice.

The app-development company confirmed that the PGQ could be converted into digital format using existing technology and that reminders to complete it could be included if desired. The PGQ was therefore confirmed as the sole outcome measure to be included in the app, and users could enable reminders to complete it monthly if they wished. This timeframe was chosen because monthly completion was in line with clinical practice at the host NHS Trust: to date, there are no clear recommendations about how frequently core outcomes should be measured in women with PLPP (Remus et al., 2021). However, as PLPP tends to increase gradually as the pregnancy progresses (Morino et al., 2017), monthly PGQ completion was deemed appropriate to allow timely detection of meaningful changes in the users' condition (Stuge et al., 2017; Ogollah et al., 2019).

Figure 5.8 below shows how the PGQ appears to users of the app.

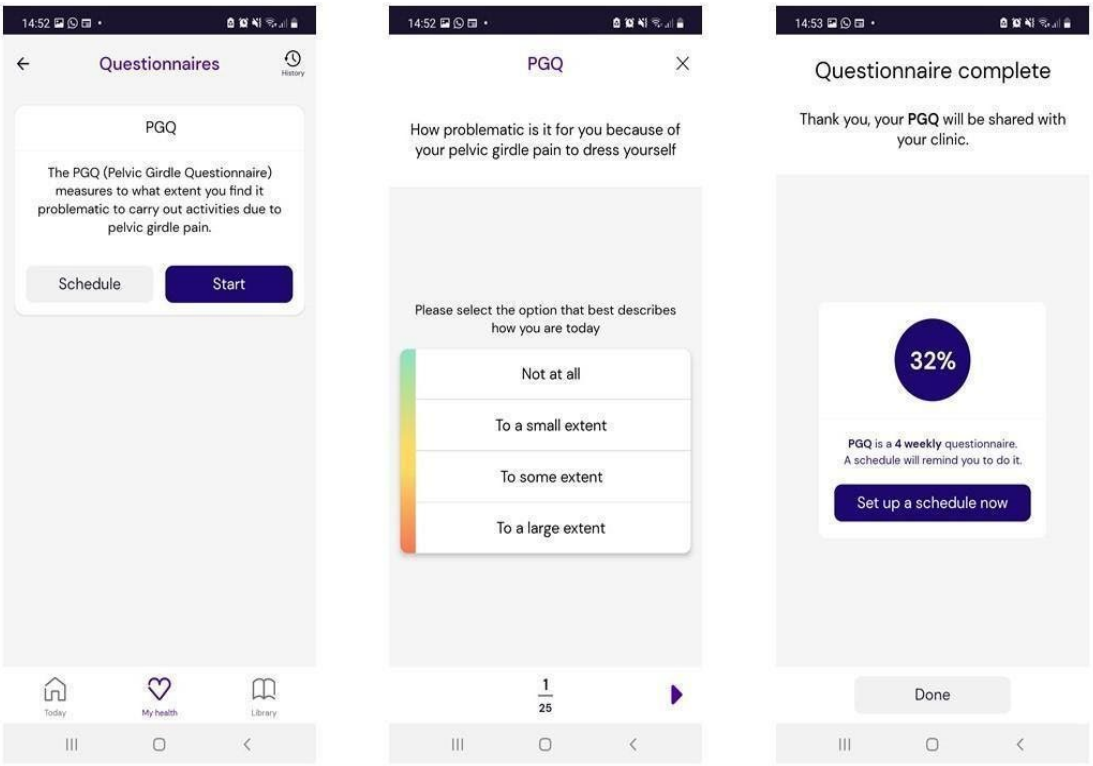


Figure 5.8. In-app features – The Pelvic Girdle Questionnaire

5.5.4 GOAL SETTING

Suitable technology existed to allow an in-app goal-setting function to be included. The advice on goal setting included in the app was purposely generic to prevent users from inferring that specific activity-related goals were preferred. Figure 5.9 below shows how the goal-setting function was presented in the app following feedback from the service user representative group (discussed below in section 5.6).

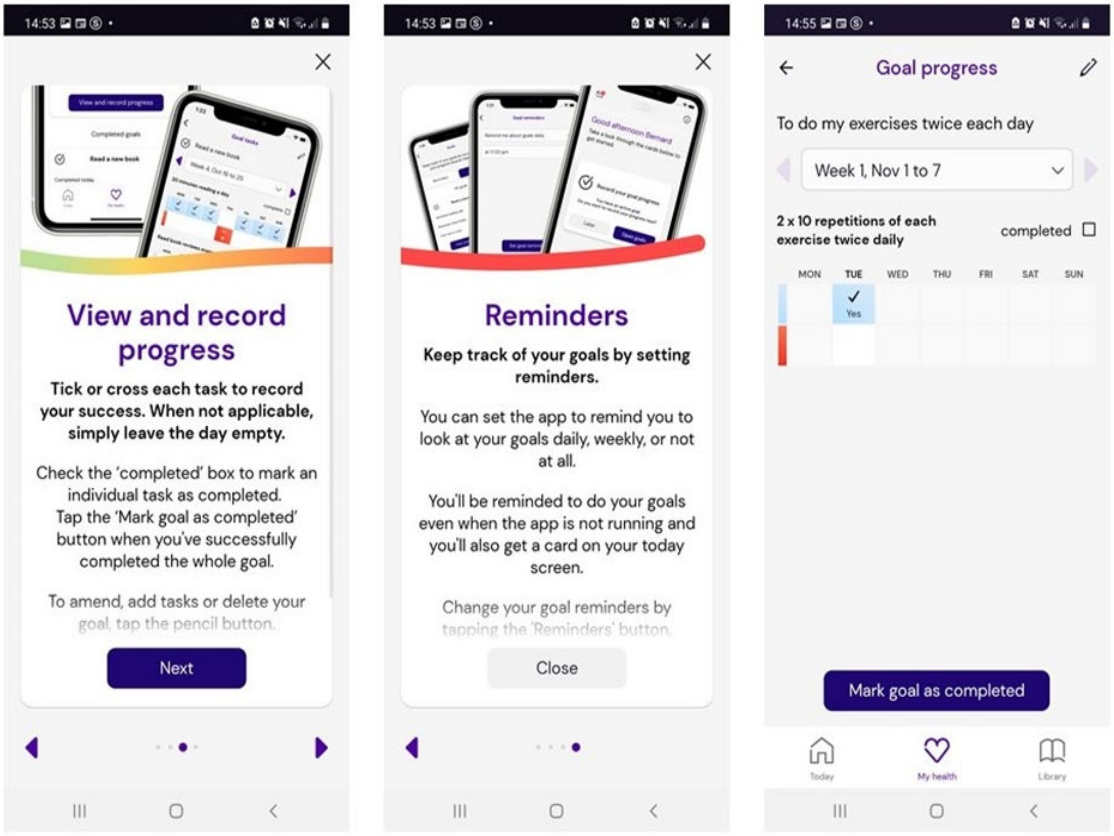


Figure 5.9. In-app features - Goal setting function

5.5.5 Social support (unspecified)

To allow the BCT 'social support (unspecified)' (See Table 5.7) to be delivered via the app, two-way messaging between the treating clinician and app-user was included as a feature.

Figure 5.10 below shows how the in-app messaging feature appeared to users of the intervention.

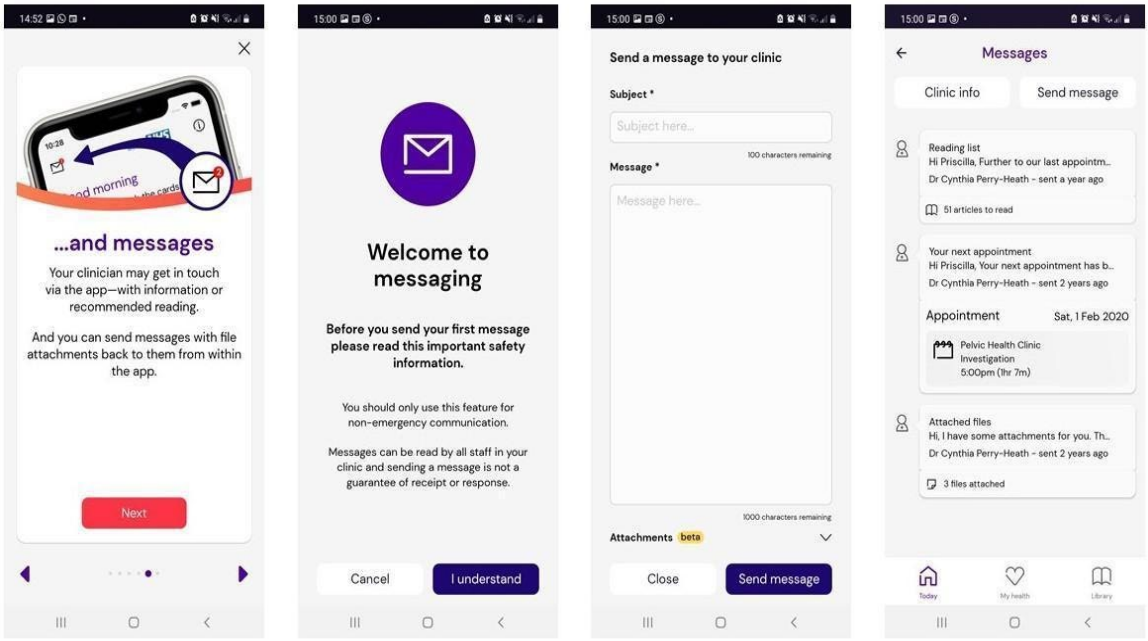


Figure 5.10. In-app features – Two-way messaging

Once the working prototype had been constructed, this completed the recommended steps in the BCW approach to intervention development. However, intervention development is an iterative process, and necessary modifications are often identified once the intervention is used (Craig et al., 2008; Medical Research Council, 2008; Skivington et al., 2021). Therefore, a group of service user representatives reviewed the prototype app before any plans for further feasibility testing were made.

5.6 Service user representative feedback and modifications to the initial prototype app

5.6.1 Service user representatives

Once a working prototype of the app had been developed, four women were contacted through the researcher's network to provide feedback on its content,

appearance, and functionality. This type of patient and public involvement (PPI) does not require HRA or ethical approval (National Institute for Health Research, 2021). Each patient representative had given birth to a baby within the last three years, but only one had personal experience of PLPP that was sufficiently severe to seek medical help. The group was not fully representative of the broader population of pregnant women; they were all white, aged 30-35, and all but one identified as middle-class. Each representative met with the researcher independently between 1st June 2019 and 30th July 2019, and each session lasted between 60 and 90 minutes. A £25 voucher was offered to compensate representatives for their time, in line with PPI payment guidance available at the time (INVOLVE, 2012).

5.6.2 Structure of patient representative consultation sessions

Patient representatives were shown a demonstration of the app's functions on the researcher's android device and were asked to comment on the app's layout, information presentation, and ease of use. They were given time to read the content of the advice pages and asked to comment on the language, tone, and layout of the written text.

5.6.3 Feedback on aesthetics and functionality

Each patient representative was satisfied with the minimalistic layout and presentation. Interestingly, two commented that the white background made the app look more 'clinical' – this was viewed positively and was felt to give the app more credibility. Each representative could navigate the app features with relative ease and reported that the navigation tabs were a helpful addition.

5.6.4 Feedback on information clarity

Each representative commented on the lack of clarity regarding the goal-setting function in the original prototype; the issue was the lack of explanation about how to select an appropriate goal. The researcher and clinical collaborator subsequently developed some basic guidance which was included in more recent iterations.

5.6.5 Feedback on the language and tone of the content

Two representatives commented on the language used to describe the exercises and the section on postural advice. The description of the exercises was deemed to overstate the potential benefits, which the representatives felt was inappropriate. Minor modifications to the language were therefore made. See Appendix 10.

The advice given in the section on posture and activity modification was deemed to have an excessively negative and authoritative tone. The representatives, therefore, suggested several modifications. These were subsequently included and can be found in Appendix 11.

Each representative raised concerns about using the term 'hip abduction' as this is not commonly understood. However, there were no suggested alternatives despite lengthy discussions; therefore, this term has remained unchanged in the app.

Once all recommended changes had been made, the app was ready for further feasibility testing in the third phase of this study. The Phase 3 data collection, analysis, and findings are reported in Chapter 6.

5.7 PHASE 2 DISCUSSION

Use of the BCW to inform the development of an M-health intervention is in keeping with recommendations in the M-health intervention development literature (West and Michie, 2016; Davies and Mueller, 2020). Additionally, evidence supports the notion that interventions developed using the BCW are more effective than those developed using informal or intuitive approaches (Kolodko et al., 2021). Use of the BCW to inform Phase 2 of this PhD study is, therefore, justified.

The informal collaboration agreement with the app development company described in this thesis mandated the use of pre-existing technology and the minimisation of additional development work. This meant the opportunity to develop additional app features and modify app aesthetics was limited. Consequently, the use of formal co-production methods (where app features and aesthetics are directly informed by service users' needs and preferences (Davies and Mueller, 2020)) was not feasible in this context. The inability to adopt this approach in Phase 2 of this PhD study may have negatively impacted the uptake of and engagement with the app in Phase 3. Formal co-production methods will, therefore, be considered during any future funded app-development work.

Once a prototype app has been developed, feedback from potential users is essential to assess functionality and establish the acceptability of the content, layout, and design (Breakey et al., 2013). Within this PhD study, this was achieved by convening a small group of service user representatives who were asked to navigate the app and provide feedback on its content and functionality. This approach constituted a service user consultation exercise. Minor modifications to

the wording of the app content were made following this. However, overall, the app was perceived to be usable and acceptable by all members of the group.

The four service user representatives consulted were all white women, aged 30-35 years, all of whom had engaged with further education, and all but one identified as middle-class. Therefore, this group did not adequately reflect the socioeconomic or ethnic diversity that exists within the wider population of women in the UK (Office for National Statistics, 2021). Perceptions of M-health intervention usability and acceptability may be influenced by multiple factors including digital literacy, health literacy, social identity, and cultural norms (Perski et al., 2017). Therefore, insufficient input from service users from a wide range of backgrounds may have led to a failure to identify issues relating to the cultural relevance, comprehensibility, or accessibility of the app content. The potential impact of this on the uptake of and engagement with the app in Phase 3 is further discussed in Chapter 7. Consultation with a more culturally and socioeconomically diverse service user representative group will be a priority as app development continues in the post-doctoral period.

In the next chapter, Phase 3 of this PhD study is reported in full, including the data collection, data analysis, findings, and implications.

CHAPTER SIX: PHASE 3 DATA COLLECTION, DATA ANALYSIS AND FINDINGS

This Chapter reports Phase 3 of this PhD study. Phase 3 addressed objective six of this PhD study by examining how service users engaged with the intervention described in Chapter five.

Objective 6	To examine how users engage with the prototype intervention to inform a preliminary judgement of its feasibility and any necessary future modifications

In the following sections, the Phase 3 data collection and analysis methods are described. The findings of the retrospective quantitative analysis of app user engagement data are then presented and discussed.

Figure 6.1 Demonstration of where the retrospective quantitative analysis of user engagement data fits into the overall study design

6.1 DATA COLLECTION: PHASE 3 RETROSPECTIVE QUANTITATIVE ANALYSIS OF USER ENGAGEMENT DATA

During the COVID-19 pandemic, many non-essential outpatient services were temporarily halted, including musculoskeletal and pelvic health physiotherapy outpatient services. Therefore, the researcher's clinical collaborator decided to implement the prototype app-based intervention developed during Phase 2 of this

PhD study within her own Pelvic Health Physiotherapy service in March 2020. The app was initially implemented to support the care of women referred to the service for the management of PLPP whilst in-person care was unavailable. The app-based intervention is linked to an existing online platform controlled by the app-development company (Living With Ltd). Please see Chapter five, section 5.4.2 for details. User engagement data is continuously collected by the platform and used for monitoring and auditing by the company. The dates that access to the app is granted, the specific app features accessed (and dates of access), the dates that patient-reported outcome measures are completed, and outcome measure scores are all available for extraction and review. Data from NHS service users given access to the intervention since the app was implemented had therefore been automatically collected via the platform throughout this period. Therefore, user engagement data collected in this way provided an accurate reflection of how the intervention had been used by NHS service users in a 'real-world' setting. Following Health Research Authority approval, access to a pseudonymised version of the available database was obtained and subjected to retrospective descriptive analysis. This was deemed an efficient way to access user engagement data without needing an additional period of prospective data collection. The database was considered pseudonymised rather than anonymised because it was theoretically possible for clinicians at the host NHS Trust (with access to physiotherapy treatment records) to identify app users by the date they were granted access to the app. It was, however, acknowledged that this would be impossible for the researcher to do and therefore ethically sound.

The regulatory approvals gained to allow the researcher to access this data are described in section 3.7. The app-development company prepared the pseudonymised user engagement data in the form of a protected Microsoft Excel file. This was first sent to the researcher's clinical collaborator to check that all identifiable patient data had been removed. This was in line with the data processing agreement set-up as part of the HRA approval process. The database was then sent to the researcher via secure encrypted email and stored on the Manchester Metropolitan University secure research data storage platform ready for analysis.

It was hoped that data relating to engagement with specific sections of informational content would be available for analysis. However, the extraction of relevant data and transformation into a usable format requires technical expertise and is a time-consuming process. Due to the COVID-19 pandemic, staffing issues at the app-development company meant that sufficient resources to undertake this process were not available. Therefore, the level of engagement with other app features, namely the in-app messaging, goal setting, and self-monitoring, had to be used to indicate the overall level of engagement with the app. Additionally, data provided for analysis were pseudonymised, and it was a condition of the data controller that re-identification should be made as difficult as possible. For this reason, specific demographic details for the service users such as age, ethnic background, and stage of pregnancy could not be accessed. The impact of these limitations is discussed in Chapter eight.

6.2 Data analysis: Phase 3 retrospective quantitative analysis of user engagement data

There are multiple ways to measure user engagement with mobile apps (Lalmas et al., 2014). The method adopted in this PhD study, which involves a description of the app features engaged with and the frequency of engagement, is in line with common practice in m-health research (Pham et al., 2019). Details of the analysis undertaken in Phase 3 of this PhD study are given below.

Pseudonymised data provided by the app-development company for retrospective analysis included:

1. The number of service users invited to use the app by their treating clinician and the dates that this access was provided to each
2. The number who downloaded the software and registered to use the app after access was granted and the dates that registration took place for each
3. The number completing the pelvic girdle questionnaire (PGQ), the number of times each user completed this and the scores at each completion
4. The number who used the in-app messaging function, when messages were sent, and the word count of the messages where applicable
5. The number who engaged with the goal-setting function at any point after access to the app was granted, the number of goals set by each user and the date these goals were set
6. The number of messages sent from treating clinicians to service users, when these messages were sent, and the word count of the messages where applicable, was also provided.

Data were condensed by the researcher so that for each app user a single row of data existed that included:

- study identification number
- uptake status (i.e., not registered, registered but not engaging, or engaging)
- date invited to use the app
- date registered to use the app
- number of days from invitation to registration
- date discharged
- time from invitation to discharge in days
- duration of exposure to the intervention
- which app features were engaged with
- the dates that these engagements occurred
- Pelvic Girdle Questionnaire scores

The number of service users who registered to use the app was calculated as a proportion of the total number invited by their treating clinician. This was to indicate the rate of conversion from potential user to user. The mean length of time between invitation and the point of registration is also reported.

The proportion of those accessing the app who completed the PGQ at least once was calculated. The number of those who completed the PGQ at least once who then completed a second time is also given. The mean PGQ scores at each completion are reported to provide insight into the levels of pain and functional restriction experienced by those choosing to engage with the app.

The number and proportion of service users accessing the app who engaged with the in-app messaging function is reported, alongside the mean/median number of messages sent per patient and the mean/median word count of these messages where applicable. The number and proportion of patients who received at least one message from their treating clinician is reported alongside the mean/median word count of these messages where applicable.

The number of patients who accessed the app who then engaged with the goal-setting function at least once is presented. The proportion of those accessing the app who engaged with all three app functions (self-monitoring via the PGQ, in-app messaging, and goal setting) is also presented.

6.3 Findings of the Phase 3 retrospective quantitative analysis of user engagement data

The anonymised retrospective app user engagement data provided by the data controller at Lewisham and Greenwich NHS Trust covered approximately 20 months from the 27th of March 2020 to the 10th of November 2021. During this period, 167 NHS service users had been invited to use the app by their treating clinician as part of their routine physiotherapy care for PLPP.

6.3.1 Initial app uptake

Of the 167 service users invited to use the app, 106 (63.5%) downloaded the app and registered their personal details. Figure 6.2 below shows the number of service users invited to use the app during each month of the study period and the number registering to use the app each month. For context, the periods of COVID-19 national lockdown have been highlighted using black arrows. It is interesting to note

that all women referred to the women's health physiotherapy team for treatment of PLPP are offered access to the app as part of routine care. The decline in the number of invitations to use the app over time therefore appears to indicate a decline in referral rates during the study period.

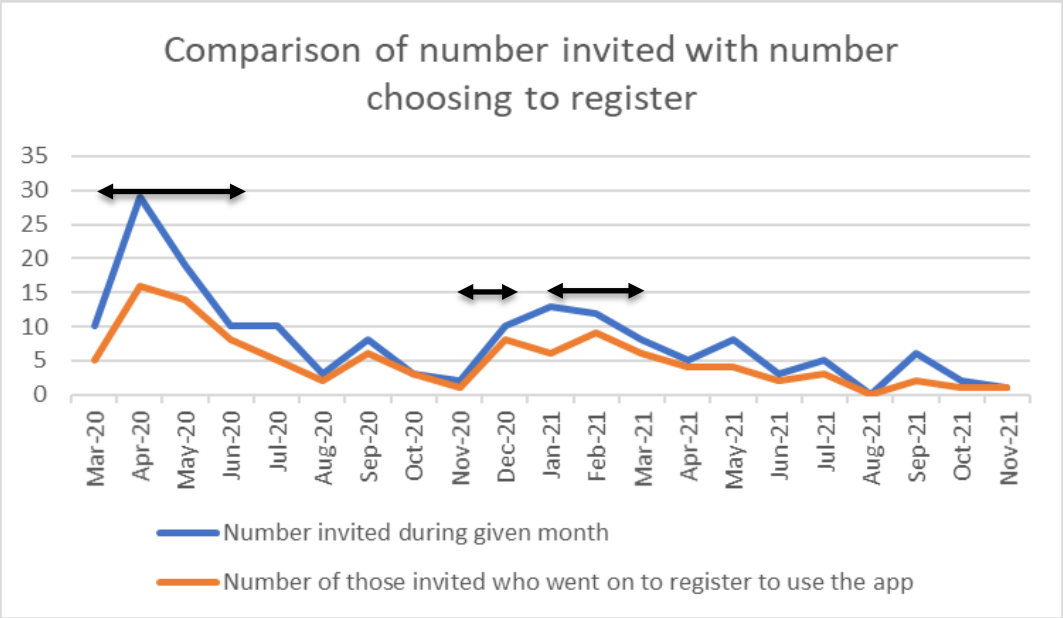


Figure 6.2. Number of service users invited to use app compared to the number choosing to register for access

For those that chose to register for access to the app, the mean number of days from invitation to registration was 8.63 (standard deviation 16.83). The data were however positively skewed, therefore the median number of days from invitation to registration was 2.0 (range 0-99). The modal number of days from invitation to registration was 0.

6.3.2 Engagement with app features

The three app features for which user engagement data were available for analysis were the Pelvic Girdle Questionnaire (PGQ) (which represents the 'self-monitoring'

feature of the app), the in-app messaging service (which allows interaction between the healthcare professional and the service user), and the goal-setting function (which represents the activity planning function of the app). Of the 106 service users who registered to use the app, 35 actively engaged with at least one key app feature (33%), 2 actively engaged with two or more app features (1.9%), but no service users chose to engage with all three key app features (0%). 23 of the 106 service users (21.7%) who registered to use the app engaged on the day of download. Only four of the 106 (3.8%) recorded an engagement episode 30 days or more after the date of download.

6.3.3 Engagement with the Pelvic Girdle Questionnaire

All 35 service users who engaged with at least one app feature, attempted to complete the PGQ at least once. The PGQ is scored from 0-100, where '0' represents no pain or functional restriction and '100' represents the worst possible pain and functional restriction. For context, a recent multinational cross-sectional study found that a cohort of UK women with PLPP who reported a mean pain rating score of seven on a '0 to 10' numerical pain rating scale, reported a mean PGQ score of 53 (Gutke et al., 2018). One service user chose not to complete the PGQ question relating to sporting activities therefore a total score had not been generated by the online platform. The mean PGQ score at first completion for the remaining 34 participants was 56.09 (standard deviation 17.52). The median PGQ score was 59.5 (range 13-87). The mean number of days from registering to use the app to completing the PGQ for the first time was five (standard deviation 19.3). The data were positively skewed; the median number of days from registration to first

PGQ completion was 0 (range 0-112). The modal number of days from registration to first PGQ completion was also 0.

Five of the 35 service users (14.3%) who engaged with the PGQ chose to complete this for a second time. The mean PGQ score increased at second completion to 57.6 (standard deviation 20.2). The median PGQ score at second completion decreased to 55 (range 37-89). The mean number of days between the first and second PGQ completions was 46.4 (standard deviation 25.9, median 57, range 9-72). Table 6.1 below shows the number of service users choosing to complete the PGQ for a second time in relation to the distribution of PGQ scores at the first completion.

Table 6.1. Number choosing to complete PGQ for a second time and distribution of PGQ scores at first completion.

PGQ score at first completion	Number choosing **not** to complete PGQ for a second time	Number choosing to complete PGQ for a second time	Total
0-30	3	1	4
31-60	15	2	17
61-90	12	2	14
90+	0	0	0
Total	30	5	35

Footnote: One service user did not complete the question on sporting activities and therefore a PGQ score had not been calculated. However, the responses to the other questions would have generated a total score below 30 regardless of the response to the sporting activities question. This service user has therefore been counted in the 0-30 category.

6.3.4 Engagement with the goal setting feature

Two of the 35 service users (5.8%) who engaged with the PGQ also engaged with the goal-setting function. For each of the two service users who engaged with the goal-setting function, one goal was set on one single occasion. For one of these two

service users, the goal was set on the same day that the user registered to use the app. For the other, the goal was set one day after registration.

6.3.5 Engagement with the in-app messaging feature

None of the 106 service users registered to use the app sent any in-app messages to their clinician. No in-app messages were received by any service user from their treating clinician. All clinicians were trained on how to use the online platform to send messages to service users, but it is not known whether service users were actively encouraged to utilise the messaging feature of the app.

It is noteworthy that users with the highest overall level of app engagement registered to use the app on the same day the invitation was received, completed the PGQ on the day of registration, and set a goal within 24 hours.

6.3.6 Service users who did not engage

Many of the service users who were invited to use the app but chose not to register (n=61) were discharged from the online system by their clinician, meaning that access to the app was withdrawn. 52 of the 61 service users choosing not to register (85.2%) were discharged in this manner. The mean number of days from invitation to discharge was 220 (standard deviation 95, median 209, range 52-333). To the researcher's knowledge, no reminders were sent by the clinician to encourage registration after the initial invitation was sent.

6.3.7 Service users discharged off the system

Of the 106 service users who registered to use the app, only six (5.7%) were discharged from the system by their treating clinician. This meant that for these six

users, access to the app content would still be available, but the in-app messaging feature allowing interaction with the clinician would be disabled. The mean number of days from invitation to discharge for these six service users was 404 (standard deviation 167.4, median 457, range 205-548).

6.3.8 Length of access to the app content

For the remaining 100 service users who had registered to use the app and had not been discharged from the system, the mean number of days of access to the app, up to the point of data extraction on the 10th of November 2021, was 390.8 days (standard deviation 163.7).

6.4 Reflection on the categorisation of Phase 3 as a retrospective analysis of user engagement data rather than a service evaluation

Original research often involves testing novel interventions that somehow differ from current standard care. Conversely, service evaluations are undertaken solely to establish whether current healthcare services achieve their desired aims (Twycross and Shorten, 2014). Phase 3 is described in this thesis as a retrospective quantitative analysis of user engagement data. However, the app under investigation in Phase 3 represented standard care within the host Trust at the time the study was undertaken. It, therefore, had to be considered whether Phase 3 could legitimately be classified as a service evaluation to determine whether full ethical and Health Research Authority approvals were required.

The intended aim of any healthcare service offered for the management of PLPP would be to improve the clinical outcomes of service users with this condition. A service evaluation in this context would, therefore, aim to establish if this aim was

achieved or whether service users were satisfied with the service provided. However, the stated aim of Phase 3 was not to examine the clinical outcomes of app users; rather, the aim was to extend our understanding of the feasibility of a digital self-management intervention for this population by examining user engagement statistics. Therefore, the aim was not to evaluate the service.

A further distinction between original research and service evaluation lies in the type of data collected for each. Research studies often require the collection of data beyond those needed to support clinical care (Chen et al., 2019). Conversely, service evaluations often utilise data routinely collected to inform clinical practice (Chen et al., 2019). The data of primary interest in Phase 3 was the rate of uptake of and engagement with the app, not the change in clinical outcomes of app users. Although user engagement data are routinely collected via the online platform to which the app is connected, they have limited direct clinical utility. Therefore, focusing on these data does not align with the intended purpose of a service evaluation. Discussing the above with the supervisory team led to the decision that Phase 3 could not be categorised as a service evaluation. Rather, it was best described as a retrospective analysis of user engagement data and that full ethical and HRA approvals were required.

6.5 PHASE 3 DISCUSSION

Summary of key findings

Descriptive analysis of app user engagement data revealed that 106 of the 167 service users offered access to the app downloaded the software and registered their details with the online system. 33% of the 106 service users who registered to

use the app engaged with at least one key app feature. Less than 2% of registered users engaged with two or more key app features, and none engaged with all three. 21.7% of registered users engaged with the app on the day of download, whilst just 3.8% logged a period of engagement after 30 days.

For the 35 users who engaged with the Pelvic Girdle Questionnaire (PGQ), the median PGQ score at first completion was 59.5 out of 100. Five users completed the PGQ on two occasions; the median PGQ score at second completion reduced to 55. The number of invitations to use the app steadily declined throughout the study period.

Implications

Phase 3 of this PhD study was undertaken to inform a judgement about the demand for the app in line with the intervention feasibility framework proposed by Bowen et al. (2009). To the researcher's knowledge, there is no defined cut-off for intervention uptake that demonstrates a sufficient demand for an intervention. However, a similar app-based intervention designed to support pain self-management has been deemed feasible with a similar rate of uptake to that observed in this study (Slepian et al., 2020): the 'Manage My Pain' app was offered to a cohort of patients when they attended a transitional pain service in Toronto. The rate of app uptake was 61%; this was interpreted by study authors to indicate that users considered the app to be a feasible and acceptable treatment adjunct (Slepian et al., 2020). It is, therefore, reasonable to suggest that the level of the demand for the intervention observed in this study is sufficient to support the notion of feasibility. However, further research is needed to understand why some

potential users chose not to engage and the factors that may have influenced this decision.

The low level of *ongoing* app engagement reported was aligned with expectations (Baumel et al., 2019; Statista, 2020). However, without access to demographic detail or insights about app users' experiences, the researcher can only speculate reasons for the engagement patterns observed. Further research is needed to explore the factors that may have influenced engagement with the app. A proposal of how this might be achieved is presented in Chapter 8.

Furthermore, there is an assumption that increased engagement with behaviour change interventions will result in improved outcomes (Cole-Lewis et al., 2019). However, in the context of a newly developed app-based self-management intervention, the desired level of engagement to achieve the optimal clinical outcome is unknown (O'Brien, 2020). Once the intervention development process is complete, future research should explore the relationship between engagement and outcomes to inform appropriate implementation.

Section 6.3.3 reported that median PGQ scores improved at the second completion, suggesting an early signal of potential benefit of the intervention. However, the number of users engaging with the PGQ for a second time was significantly limited. This finding may, therefore, simply represent natural variability within the data (Netz et al., 2019).

Strengths and limitations

Analysis of online behavioural data automatically recorded by the secure online platform ensured accurate data capture and a true reflection of app use in a real-world setting. However, lack of access to behavioural data relating to the use of the

in-app information meant that the level of users' engagement with such content remains unknown. Questions about the perceived utility of in-app information articles also remain unanswered. Furthermore, the lack of access to users' demographic information precluded an assessment of the association between demographics and app engagement. These issues are further discussed in Chapters 7 and 8.

6.6 Summary of the key findings of this PhD study and the implications

This PhD study aimed to explore the feasibility of a digital self-management intervention for women with PLPP. The areas of intervention feasibility explored during Phases 1 and 3 were acceptability, demand, practicality, and integration. Phase 1 was designed to capture the perceived acceptability, practicality, and ease of integration of a digital self-management intervention for PLPP and gather sufficient information to inform intervention development in Phase 2. Phase 3 involved assessing the demand for the app-based intervention developed.

The Phase 1 exploratory qualitative study suggested the notion of an app-based self-management intervention for PLPP was acceptable to both NHS service users and clinicians. The midwives and physiotherapists were willing to integrate such an intervention into their practice, provided this did not involve significant additional time or effort. Both groups of clinicians also suggested how a digital self-management intervention might be incorporated into the current care pathway. Implementing such an intervention for PLPP was perceived to be practical in an NHS setting, with potential utility in bridging the gap between reporting symptoms and commencing physiotherapy treatment.

The findings of Phase 1 directly informed the development of an app-based self-management intervention in Phase 2. Use of the behaviour change wheel supported this process. The usability and acceptability of the app's content and features were then informally tested by a group of service user representatives. This service user consultation resulted in minor changes to the wording of the app content; however, overall, the app was deemed usable and acceptable.

The app was successfully implemented as an emergency measure during the COVID-19 national lockdown. This confirmed the ability and willingness of clinicians to integrate the app into practice and that an app-based self-management intervention for PLPP is practical to deliver in an NHS context. The rate of app uptake was 63.5% which was in line with expectations (Slepian et al., 2020; Statista, 2020) and suggested an acceptable level of demand for the intervention. Ongoing engagement with the app, as indicated by the degree of interaction with in-app features, was in line with that typically seen with medical apps downloaded from publicly available app stores (Statista, 2020). However, further work is needed to understand the factors influencing uptake and engagement and whether the in-app information met users' needs. The findings of this work will determine whether the app can be sufficiently modified to address the issues raised, and if so, the nature of the modifications required.

Based on the findings reported in Chapters four to six of this thesis, the app developed shows some promise as a feasible intervention to support the self-management of women with PLPP. However, further research is required to inform the ongoing development of the app and optimise its utility for clinical practice. The

lack of diversity within the sample of service users during Phases 1 and 2 may have resulted in the development of an intervention equipped to meet only the needs of a specific subset of the population. Addressing this concern will be a priority during future related research.

In the next chapter, the findings of this PhD study will be contextualised in relation to the wider literature relating to women's experiences of PLPP and what is known about the uptake of and engagement with digital interventions in other populations. A broader discussion of the app's feasibility for supporting PLPP self-management will also be presented.

CHAPTER SEVEN: DISCUSSION

7.1 CHAPTER INTRODUCTION

This chapter will discuss the main findings of the systematised review, the Phase 1 qualitative exploration and the Phase 3 retrospective quantitative analysis. Reflections on the Phase 2 app development process will also be offered. The findings of Phase 1 will be discussed with reference to the wider body of qualitative literature relating to women's experiences of PLPP. A brief discussion of what the Phase 1 findings convey about the prospective acceptability of the app will also be given. The findings of Phase 3 will be contextualised within the wider body of literature on the uptake of and engagement with mobile healthcare apps. The choice of BCTs included in the app and the context in which the app was implemented will be discussed in relation to the reported engagement levels. Finally, based on the findings reported in this thesis, a discussion of the app's feasibility for supporting PLPP self-management will be presented.

This mixed-methods PhD study was undertaken to develop a digital intervention for women experiencing PLPP and explore its feasibility. The qualitative phase explored the needs and preferences of NHS service users and clinicians in relation to such an intervention and the perceived barriers to PLPP self-management. The intervention development process progressed in line with the Behaviour Change Wheel approach, informed by the Phase 1 qualitative study findings and the available self-management literature. The prototype app-based intervention was then refined in response to the feedback of a small service user representative group. The app was

subsequently implemented within a single NHS Trust in the UK in response to the COVID-19 pandemic. A retrospective analysis of pseudonymised user engagement data was undertaken in Phase 3; these data were automatically collected via the online platform to which the app is connected.

7.2 Discussion of how the findings of the systematised review informed this PhD study

The systematised review findings aligned with previous systematic reviews examining the effectiveness of digital interventions for managing musculoskeletal pain (Hewitt et al., 2020) and other chronic pain conditions (Pfeifer et al., 2020). In this systematised review, intervention duration and content varied hugely between trials; this could have contributed to the inconsistent findings. Further, the primary endpoints selected across included trials varied from just three weeks (Carpenter et al., 2012) to two years (Hou et al., 2019). This, too, may have contributed to the inconsistent findings reported (McLeod et al., 2019).

Despite the inconsistent findings, the systematised review reported in Chapter two provided valuable insights that informed decision-making during Phases 1 and 2 of this PhD study. The findings of the review showed that three of the six interventions shown to be effective in improving pain and physical function/pain-related disability in individuals with LBP used either a mobile or tablet app as part of the intervention. Combined with evidence from previous systematic reviews demonstrating the potential utility of m-health technologies in promoting antenatal behaviour change, this suggested that mobile apps were worthy of consideration in Phase 2.

Only two RCTs included in the systematised review examined interventions that included a social-media-based component (Suman et al., 2019; Kazemi et al., 2021). This was surprising given the widespread uptake of social media and its increasing use for information provision in order fields of healthcare (Jamnadass et al., 2019). Kazemi et al. (2021) reported positive effects of a social media-based intervention, but the trial was at high risk of bias. Gaps in the reporting of the intervention were also noted, limiting the utility of this RCT to inform future intervention development. The systematised review did, however, highlight that social media platforms may be underutilised for intervention delivery in the field of back pain self-management. Given pregnant women's widespread use of social media (Sayakhot and Carolan-Olah 2016) and the unexplored potential of such platforms for intervention delivery, it was deemed important to explore stakeholders' perceptions of this topic during Phase 1 of this PhD study.

The systematised review also showed that half of the effective interventions were multimodal and incorporated some form of input from a healthcare professional (Lorig et al., 2002; Hou et al., 2019; Shebib et al., 2019). This aligned with the findings of the systematic review by Chen et al. (2021), showing that m-health interventions combined with usual care were more effective than usual care alone. Therefore, during the Phase 1 exploratory qualitative study, stakeholders' perceptions of how digital interventions might best support current PLPP management were sought. This was, in part, to establish the nature and intensity of healthcare professional input deemed feasible and desirable by stakeholders.

The systematised review found that the number of BCTs included in effective interventions ranged from three to nine, with the most common being 'instructions

on how to perform the behaviour' and 'information about health consequences'. These observations suggested that information about the desired self-management behaviours and *why* these might be helpful should take priority when developing the intervention content in Phase 2. This notion aligns with evidence from the self-management literature that promotes patient education as the core of self-management interventions (May, 2010). The findings of the systematised review also suggest that the *number* of BCTs is not the sole determinant of intervention effectiveness. This insight supported the perceived importance of using a structured intervention development process to guide the selection of BCTs during the Phase 2 intervention development.

Finally, the systematised review highlighted a significant gap in the digital intervention literature relating to women with PLPP and underscored the need for targeted intervention development and evaluation for this population. This supports the value of this PhD study and highlights the unique contribution to knowledge made by this thesis.

7.3 Discussion of the Phase 1 exploratory qualitative findings

The findings of Phase 1 aligned with the extant evidence demonstrating the limited awareness amongst pregnant women about PLPP as a condition (Sadr et al., 2012; Elden et al., 2014; Clarkson and Adams, 2018). The personal impact of PLPP on service users also mirrored previous research (Mackenzie et al., 2018). The service users in Phase 1 of the study highlighted the benefits of information provision for reducing condition-related anxiety and facilitating self-management. However, the experiences of a minority of service users indicated that the information needs of

this group are not always met. This finding highlighted the ongoing need for improved information provision practices for women with PLPP and reflected the lack of condition-specific information provision.

Data presented in Chapter four shows that some clinicians may still view PLPP as a normal part of pregnancy, and they, therefore, view specific condition-related management as unnecessary. These findings are in accord with earlier research discussed in Chapter two. This approach to PLPP is unhelpful given the potential consequences of the condition in terms of work absence and decreased function (Gutke et al., 2018). Recent publications in the midwifery and General Practice literature suggest that a positive shift in attitude toward the management of PLPP may already be underway within facets of the clinical community (Fishburn et al., 2015; Walters et al., 2018). However, data presented in this thesis highlight that more might need to be done to raise clinicians' awareness of the personal (Mackenzie et al 2018), social (Persson et al., 2013) and economic impact of PLPP (Truong et al., 2017) and the need for appropriate management strategies.

The condition-specific information needs of service users were highlighted and included an explanation of the causes of PLPP as they are currently understood; information about the prognosis of PLPP; the management and self-management options for PLPP; and information about how PLPP might impact labour and birthing. This information was used to inform the development of the app content during Phase 2 of this PhD study to ensure that the intervention developed directly addressed the needs of stakeholders. The value of this approach has been repeatedly highlighted in the literature (Yardley, Morrison et al., 2015; Morrison et

al., 2018; Muller et al., 2019) to maximise the chances of intervention effectiveness and successful future implementation.

Specific knowledge gaps and conflicting information provision from different professional groups were identified as barriers to PLPP management by the clinicians participating in Phase 1. This was unsurprising given that conflicting information is known to be detrimental (Hämeen-Anttila et al., 2014; Marshall et al., 2019) and unmet information needs are associated with increased anxiety in other healthcare contexts (Faller et al., 2016; Møller et al., 2020). All three stakeholder groups therefore welcomed an evidence-based information resource to support PLPP self-management.

The use of a digital intervention to deliver PLPP-related information was acceptable to all stakeholder groups; however, there was a preference for the use of apps over social media among most service users. A lack of trust in information obtained via social media was the most common reason for this opinion. This finding was unexpected given that pregnant women are often highly engaged with social media (Dekker et al., 2016; Lupton et al. 2016; Zhu et al. 2019; Skouteris and Savaglio, 2021) and view the information obtained via these platforms as valued (Moon et al., 2019) and trusted (Larsson 2009). The conflict between the findings of Phase 1 and those of previous work concerning social media could be due to demographic differences in the study populations sampled, the different research contexts in which the studies were undertaken, or the fact that service users in Phase 1 were describing the search for condition-specific information rather than generic pregnancy-related information.

Each stakeholder group identified several barriers to using a digital intervention to manage PLPP in an NHS setting: cost, data security, commercial advertising, excessive information, clinical time pressures and limited resources were all proposed by participants. These were largely in keeping with barriers to implementing app-based interventions identified in other areas of healthcare (Dehzad et al., 2014; Gagnon et al., 2016; Velu et al., 2017; Petersen et al., 2020) and had to be carefully considered during the intervention development phase of this PhD study.

Clinicians expressed a willingness to implement a digital intervention to support the management of PLPP, providing the content was consistent with best practice and delivery did not require a significant commitment of clinical time. This finding aligned with literature from the field of implementation science suggesting that multiple clinician-related factors can influence intervention implementation, including available time, resources, training, and current working practices (Geerligs et al., 2018; Cowie et al 2020; Seckler et al., 2020; Rogers et al., 2021). Given the potential influence of clinician input on app uptake and engagement proposed in later sections of this chapter, the challenge of balancing clinician burden with service user training needs must be carefully considered to optimise outcomes.

In summary, the findings of Phase 1 demonstrate that the notion of a digital intervention to support the self-management of PLPP was acceptable to all stakeholder groups. The use of a mobile phone app for this purpose was also acceptable. Clinicians were willing to integrate such an intervention into their

practice providing the content was reflective of best practice, and implementation did not require a significant commitment of clinical time.

7.4 Rate of uptake of the app reported in this thesis

The Phase 3 retrospective quantitative analysis found that 63.5% of the NHS service users given access to the app proceeded to download the software and complete the app registration process. This figure would appear to be comparable to other healthcare apps designed for pain management (Slepian et al., 2020). However, contextualising this finding is difficult for several reasons: A recent scoping review undertaken to inform the design of the NHS test and trace app found that reported rates of uptake for generic healthcare apps range from 1% to 100% (Thorneloe et al., 2020) depending on the type of app under investigation and the study design employed. Much of the work relating to the uptake of healthcare apps has involved an assessment of the number of downloads from publicly available app stores (Goyal et al., 2016; Carlo et al., 2019; Fleming et al., 2020; Aydin and Silahtaroglu, 2021). As the mode of distribution of the app in the current study was via a healthcare professional as part of routine care, direct comparison with much of this previous work seems inappropriate. Furthermore, several studies have commented on the uptake of healthcare apps in the context of a prospective clinical trial (Ben-Zeev et al., 2018; Edney et al., 2019; Mohr et al., 2019; Kenny et al., 2020). However, research participants' behaviour is known to be influenced due to the knowledge that they are being observed, via the Hawthorne effect (McCambridge et al., 2014). Therefore, direct comparison to the findings reported in this thesis, where app distribution was part of routine practice, is not possible.

Whilst there is a wealth of literature relating to engagement with healthcare apps, there is much less relating to initial uptake. There are however several issues known to specifically influence uptake of healthcare apps. These include factors relating directly to the app itself, such as the look and design of the app; factors relating to the potential user, such as whether they perceive the app to be easy to use and useful to them; social factors, such as whether the app is congruent with the individual's perceived identity; and the credibility of the app or the level of trust the user has in the app's developer (Venkatesh and Davis, 2000; Perski, Blandford, Ubhi, et al., 2017; Russell et al., 2018; Thorneloe et al., 2020; Borghouts et al., 2021; Szinay, Perski, et al., 2021). These factors will be discussed in more detail below.

7.4.1 Influence of aesthetics, content, and ease of use on rates of app uptake

Within this PhD study, the look and design of the app were influenced by the app-development company's distinctive presentation style, and the service user representative group endorsed this following the development of the initial prototype. Therefore, it was hoped that the app's aesthetic appeal would not have been a significant barrier to uptake. Comparing the rate of uptake of the app developed in this PhD study with that of the company's other products may have provided further insight into the role of aesthetics; however, ethical approval to access such information was not secured. Service user representatives deemed the design of the app to be 'simple' and 'clinical', which was reflective of suggestions in the literature that simple designs are favoured (Vaghefi and Tulu, 2019; Szinay, Perski, et al., 2021). Nonetheless, it must be acknowledged that preferences for app design and colour scheme are inconsistent and vary across user groups (Perski,

Blandford, Ubhi, et al., 2017); therefore, the endorsement of just four individuals cannot guarantee wider acceptability.

The service user representative group felt that the app functionality was acceptable, and they were able to navigate the app without difficulty. However, the perceived ease of use of an app is impacted by users' prior experience with similar technology (Nunes et al., 2019), their level of digital literacy (Kuek and Hakkennes, 2020) and their level of health literacy (Mackert et al., 2016). The service user representative group in this study was demographically similar to the sample of service users included in the exploratory qualitative study that informed the app development. These groups were made up of white, predominantly middle-class women, most of whom were educated to undergraduate level. This is not reflective of the broader demographic of women treated for PLPP across the NHS. Digital literacy is linked to age, sociodemographic status (Rosalina et al., 2021), educational level, and digital skills training (Bejaković and Mrnjavac, 2020). Therefore, the service user representative group may be expected to have a high level of digital literacy and hence be more likely to perceive the app as easy to use. However, this group may not fully reflect the population in which the app was implemented. Lewisham has an overall index of multiple deprivation score of 28.59, putting it in the 20% most deprived local authorities in England (Lewisham Council, 2019). Lower educational attainment and high levels of social deprivation are known to be associated (Department for Education, 2015), and both these factors are known barriers to digital inclusion (NHS Digital, 2021). It is, therefore, possible that some app users in Phase 3 of this PhD study could have constructed a different perception of the app's ease of use compared to the service user representative group, owing

to differing levels of digital literacy. This may have presented a barrier to uptake. Additionally, 46% of people in Lewisham are from a non-white background (Care Quality Commission, 2019), and 22.1% of the local population state a language other than English as their first language (Census Information Scheme GLA Intelligence Unit, 2013). It is, therefore, possible that the app, which is only available in English, was not sufficiently equipped to serve the local population.

Finally, app access was paid for by the host NHS Trust via its pre-existing subscription to Living With Ltd. The app was free for service users to download and equity of access to all service users owning a smartphone was therefore ensured. This may have been a potential facilitator to app uptake in the context of this PhD study, given the level of deprivation reported in the local area (Lewisham Council, 2019).

7.4.2 The influence of credibility, perceived usefulness, and choice on the rate of app uptake

Whether an individual perceives an app to be useful will affect their decision regarding uptake (Szinay et al., 2020; Szinay, Perski, et al., 2021). However, to construct their perception of the app's usefulness, service users in Phase 3 may have considered multiple diverse factors: Endorsement of the app by healthcare professionals may have increased the app's credibility, which may have facilitated uptake (Russell et al., 2018). This is aligned with the search for trustworthy information previously reported. However, the altered therapeutic relationship between service users and healthcare professionals (due to lack of access to in-person care during the COVID-19 national lockdown) may have reduced the impact

of this endorsement (Brun-Cottan et al., 2020) and reduced motivation to use the app. Service users' beliefs about the potential for self-management behaviours to improve symptom management (i.e., the individual's reflective motivation to use the app) may have also been an important determinant of app uptake in line with the COM-B model of behaviour (Michie et al. 2011).

App use in this study initially replaced in-person treatment as part of an emergency response to the COVID-19 pandemic. Therefore, service users' beliefs about the ability of the app to provide an adequate replacement for routine care may have informed their construction of perceived usefulness and impacted their decision to download and use the app (Fulton et al., 2018; Vegheti and Tulu 2019). Furthermore, self-determination theory would suggest that any given behaviour is more likely to be enacted out of a sense of choice rather than a result of external pressure (Deci and Ryan, 2012). Therefore, it is possible that if service users felt obliged to engage with the app due to the lack of alternative treatment options during the pandemic, this may have negatively impacted their motivation for uptake. Finally, it is noteworthy that one study reported that the requirement to create an account to use an app would deter some users from proceeding to engage (Perski, Blandford, Ubhi, et al., 2017). It is, therefore, possible that the requirement to register for app use in this PhD study may have been off-putting to users. This is in accord with data presented in section 4.4.2 suggesting the need to supply personal data is a barrier to uptake.

7.4.3 The influence of social factors on levels of app uptake

Pregnant women are acknowledged as mass users of digital media (O'Higgins et al., 2014), and pregnancy-related apps are popular with this group (Hughson et al., 2018). Therefore, it is reasonable to believe that the app developed in Phase 2 would be perceived as congruent with the social identity of women with PLPP. Nonetheless, as noted above, the women sampled to inform the app's development may have been systematically different from the population of women using the app in Phase 3 (Krausova and Vargas-Silva, 2013; Bloomfield and Chapman, 2018). Consequently, app users from different socioeconomic or ethnic backgrounds may have perceived the app content as less relevant to them and may have been less motivated to engage with it. This issue may however have been more likely to influence engagement than initial uptake, as decisions about the relevance of the app's content could not be made until the app had been downloaded and viewed.

7.4.4 App uptake as an indicator of demand for the intervention

To the researcher’s knowledge, there is no defined cut-off for intervention uptake that would indicate adequate demand for a healthcare intervention and support the notion of intervention feasibility. The rate of uptake of the app developed in this PhD study for women with PLPP is comparable to other apps designed to support pain management (Slepian et al., 2020), suggesting an acceptable level of demand for the intervention. Nonetheless, uptake needs to be maximised for the app to have the most substantial impact on NHS service users with PLPP. Convening a more representative service user group for future consultation may be a straightforward way of ensuring the app is deemed appealing, culturally

appropriate, and usable by women from various backgrounds (Staniszewska et al., 2018; Witham et al., 2020; Treweek et al., 2021).

7.5 App engagement in Phase 3 of this PhD study

Lee et al. (2018) found that engagement with in-app self-monitoring features influenced overall engagement. Therefore, in relation to this PhD study, engagement with the PGQ may be the best indicator of overall engagement. However, it is acknowledged that if app users accessed in-app informational resources without interacting with other in-app features (self-monitoring, goal setting, and in-app messaging), then the levels of engagement reported in this thesis may be significantly underestimated.

There is a general assumption that increased engagement with a behaviour change app is more likely to change the desired behaviour (Cole-Lewis et al., 2019). However, it is acknowledged that the relationship between levels of engagement and outcomes may be non-linear and that the precise 'dose' of an intervention required to bring about the desired behavioural changes is often unknown (O'Brien et al., 2020). In some instances, one single period of engagement with a digital behaviour change intervention may be sufficient to facilitate the new behaviour or to formulate a new habit (Michie et al., 2017). For example, if a user's reason for engaging with an intervention is to increase knowledge of the desired behaviour, a single period of engagement, where the information can be read and absorbed, may be all that is required. Once this need has been met, the user will disengage as the intervention has already served its purpose (Wrosch et al., 2003).

Evidence shows that healthcare app engagement is highest immediately after download but declines rapidly within the first 30 days (Baumel et al., 2019). A report by the online company Statista showed that only 20% of users engaged with medical apps on the same day the apps were downloaded. Just 7% engaged after seven days, and 3.5% remained engaged after 30 days (Statista, 2020). These figures align with the findings presented in Chapter six, which reported that 21.7% of users engaged with the app on the day of download and 3.8% engaged after 30 days. Lack of ongoing engagement with healthcare apps also appears to be problematic in clinical trials, with a similar pattern of declining engagement seen in studies designed to examine healthcare app efficacy (Druce et al., 2019). Therefore, understanding the optimal level of engagement through further inquiry is essential.

Furthermore, users of healthcare apps reportedly decide whether to engage within 50-500 milliseconds of exposure to the app content (Lindgaard et al., 2006). This suggests that rapid, intuitive decision-making may influence mobile app engagement (Kahneman and Frederick 2005). Understanding the factors informing these intuitive decisions would be helpful to inform future app development.

7.5.1 Factors influencing levels of app engagement

To better understand the potential barriers to app engagement in this PhD study, a broader view of how the app fits into the PLPP care pathway was considered. App engagement is a discrete behaviour; therefore, app users need sufficient capability, opportunity, and motivation to enact this behaviour in the same way they do to enact PLPP self-management behaviours. Figures 7.1 and 7.2 below demonstrate the difference between the pre-pandemic PLPP physiotherapy care pathway and

the pathway implemented in this PhD study. These figures also highlight how the altered service user experience and associated treatment burden in the context of this PhD study might have influenced engagement with the app.

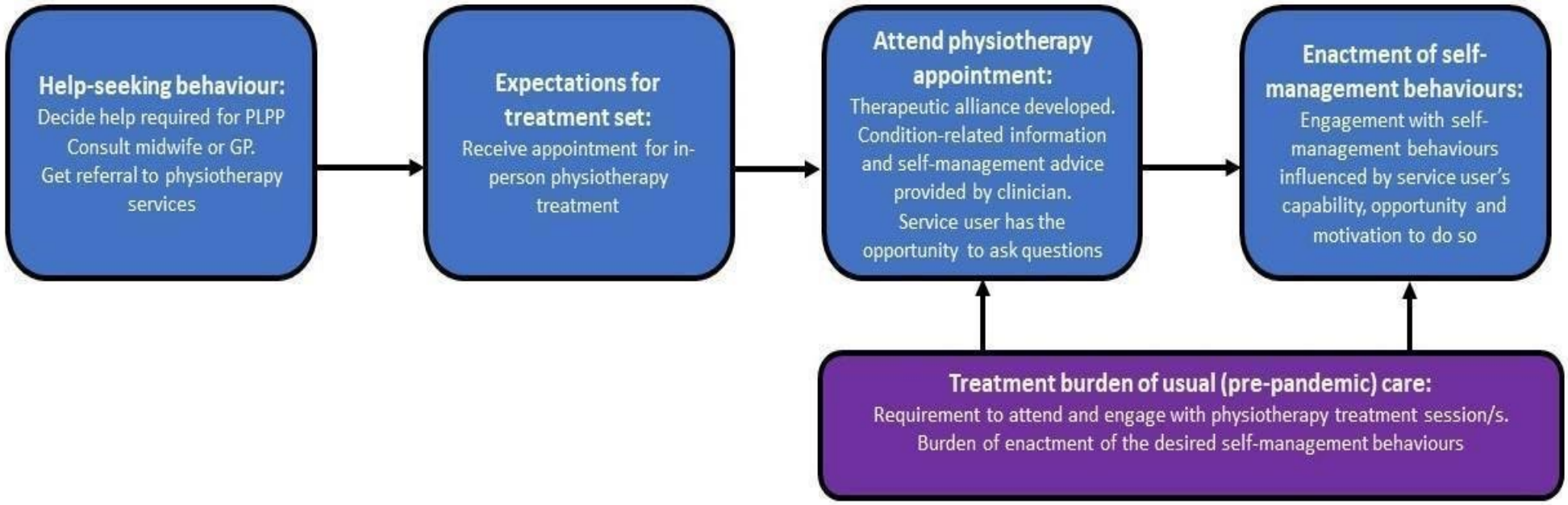


Figure 7.1. Pre-pandemic care pathway for women with PLPP at the host NHS Trust

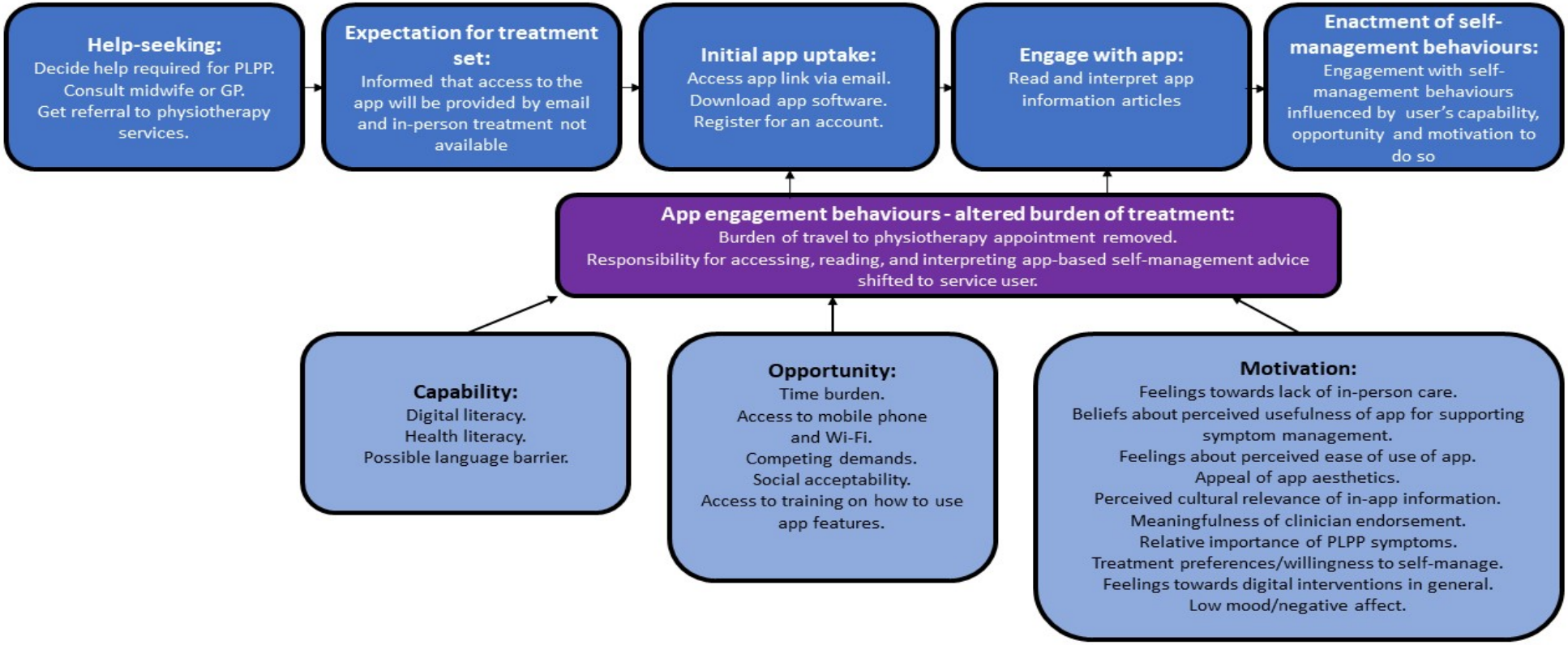


Figure 7.2. Mid-pandemic care pathway for women with PLPP at the host NHS Trust

7.5.2 The influence of treatment goals on the levels of app engagement

Service users who sought help for PLPP symptoms at the host Trust during the study period were provided access to the app in place of in-person care. This was due to reduced physiotherapy services as part of the national response to the COVID-19 pandemic. Motivation to engage with the app will therefore have been dependent upon what the service user hoped to gain from seeking treatment (i.e. their treatment goal), how important that goal was to them at the outset (i.e. the salience of the treatment goal), and the perception of whether the app was capable of facilitating the achievement of that goal (Flaherty et al., 2019). Their willingness to self-manage the condition or take an active role in their treatment will also have influenced their decision to engage (Svendsen et al., 2020), as individuals desiring passive or in-person treatment may have believed that use of the app was incongruent with their wishes and incapable of meeting expectations.

7.5.3 The influence of personal traits on levels of app engagement

Personal traits may influence a user's decision to engage with a healthcare app. It is thought that extroverts prefer in-person healthcare delivery and may be deterred from engaging with digital interventions (Borghouts et al., 2021). Additionally, psychological factors such as low mood, depression, and fatigue are also known barriers to engagement with healthcare apps (Borghouts et al., 2021). The exact reasons for this are unclear from the available literature, but the association between depression, anxiety, and motivation (Dickson and MacLeod, 2004) may contribute. Data from the pre-pandemic period shows that around 20% of pregnant women experience psychological symptoms (such as depression and

anxiety) (Fawcett et al., 2019). It is, therefore, possible that psychological factors could have contributed to the low levels of engagement reported in this thesis. This is further discussed in relation to the pandemic in section 7.10.

7.5.4 The influence of pregnancy stage on levels of ongoing app engagement

An important consideration about the level of ongoing engagement in this study is that, in most cases, PLPP is a transient condition (Gausel et al., 2020). The most common time to experience PLPP is between the 24th and 36th week of pregnancy, with symptoms being more common in the later stages (Vermani et al., 2010), and usually resolving quickly in the postpartum period (Gausel et al., 2020). It is likely that many women seeking treatment for their condition and subsequently being provided access to the app would require its use for a relatively short time. Therefore, it may not be reasonable to expect prolonged engagement in this context. As the researcher did not have access to demographic data due to ethical considerations, it is not possible to assess whether the stage of pregnancy at the point of app uptake influenced ongoing engagement. This should be considered in future work.

7.6 Engagement with app features: In-app messaging

Chapter Six reported no engagement with the in-app messaging function and no messages sent from clinicians to service users during the study period. This was surprising given that a significant body of published evidence suggests that digital interventions that enable communication between user and healthcare provider are viewed favourably by potential users (Anderson et al., 2016; Adu *et al.*, 2018;

Svendsen et al., 2020; Szinay et al., 2020; Borghouts et al., 2021; König et al., 2021; Szinay, Perski, et al., 2021). The formation of a patient-healthcare provider partnership is a key component of any successful self-management intervention (Du et al., 2017). Similarly, feedback on progress has been reported as an important feature of digital health interventions for low back pain in the general population (Svendsen et al., 2020). Therefore, providing a means of healthcare provider-service user communication was deemed an essential inclusion at the app development phase based on the existing self-management and behaviour change literature. The finding that this feature was not used as anticipated was unexpected; the reasons for this should be explored in future research. Possible influences on the level of engagement with the in-app messaging feature are discussed in the following sections.

7.6.1 Lack of engagement with in-app messaging feature: possible role of therapeutic alliance

To make sense of the lack of engagement with the in-app messaging feature, it must be considered that this app was developed to facilitate self-management in women receiving routine care for PLPP. Evidence suggests that behaviour change interventions that include a combination of in-person and digital components may be more effective at producing the desired behaviour changes than standalone digital interventions (Santarossa et al., 2018). However, at the start of Phase 3, the app was used to replace routine care that could not be provided due to the COVID-19 national lockdown. The app was therefore initially implemented as a standalone digital intervention to support the self-management of PLPP. Access to the app was provided remotely; service users and clinicians were therefore denied the

opportunity to build a rapport or develop a therapeutic relationship before the app became part of the care pathway.

The 'therapeutic alliance' or working relationship between healthcare providers and service users affects outcomes in various healthcare contexts (D'Alfonso et al., 2020; Lederman and D'Alfonso, 2021). Debate exists about whether such an alliance can be developed via digital interventions, with blended forms of clinical care (using a combination of in-person and digital interventions) seen as potentially more conducive (Valentine et al., 2020; Williams et al., 2021). It could be argued that simply providing an in-app messaging feature is insufficient to stimulate a relationship between service users and healthcare providers where one does not already exist (Morrison, 2015). Considering this, it may be less surprising that the in-app messaging feature was not used as intended. Additionally, the model of supportive accountability (Mohr et al., 2011) would suggest that providing a means of communication between service users and healthcare providers could create a sense of accountability on the part of the service user to engage with the app and undertake the self-management behaviours recommended. However, according to this model, the sense of accountability to the treating clinician relies on the perception that the clinician is trustworthy, benevolent, and expert (Santarossa et al., 2018). In the absence of a strong therapeutic relationship, this sense of accountability may have been lost; the potential influence over service user behaviour will therefore also have been lost. Furthermore, the patient-healthcare provider relationship has been shown to influence adherence to the use of a prescribed healthcare app in patients with multimorbidity (Tahsin et al., 2021). If the healthcare provider-service user relationship has the same influence over

engagement in the current context, the lack of clinician contact and altered therapeutic relationship in Phase 3 may have been problematic.

7.6.2 Lack of engagement with in-app messaging feature: possible influence of lack of clinician involvement

Social support is an important means of facilitating health behaviour change and influences chronic pain self-management (Dorflinger et al., 2013). However, it is acknowledged that digital interventions may be an insufficient means of providing social support to users who have a strong need for connectedness outside of the app context (Morrison, 2015). Therefore, even service users who may ordinarily wish to discuss their condition with a healthcare provider may have felt demotivated to use the in-app messaging feature for this purpose.

Not all service users received training on the use of relevant app features, as government guidance precluded in-person treatment for much of the Phase 3 study period. As evidence suggests that such training and guidance is a facilitator to engagement (Michie et al., 2017; Borghouts *et al.*, 2021), this could plausibly have impacted engagement with the in-app messaging function from the perspective of the service users.

In addition to providing a means of service user-healthcare provider communication and social interaction, the second purpose of the in-app messaging feature was to provide feedback on the outcomes of PROMs completed within the app. Feedback on progress is an important feature of self-management interventions (Bandura, 1998a; 2004). The ability to provide such feedback was therefore deemed a valuable feature. However, as discussed in Chapter six,

engagement with The Pelvic Girdle Questionnaire was lower than expected. Therefore, the opportunity to provide feedback on progress relating to PROMs could not be fully exploited by clinicians. Additionally, clinicians could not use the in-app messaging feature to give feedback on any goals set by users, as details about goals and goal attainment are not currently visible to clinicians via the online platform. As discussed in section 7.7, goal setting is an important feature of self-management interventions. Therefore, the perceived value of using the in-app messaging feature to give and receive feedback on goals/goal attainment should be explored further with stakeholders. If this functionality is perceived as valuable, the additional development work and associated costs might be justified.

7.6.3 Summary of issues related to engagement with the in-app messaging feature

In summary, the in-app messaging function was not used by service users or clinicians and would therefore appear to be of limited value in the current context. It is possible that if the app had been implemented as a means of supporting routine clinical care rather than as a replacement for it, the therapeutic relationship between the service user and their treating clinician might have facilitated engagement with this feature. The in-app messaging feature could be further exploited to provide and receive feedback on goal setting and goal attainment. However, for this to be possible, the app's functionality would have to be improved so that details of goals and goal progress are visible via the online clinician interface. As this would require additional work and expense for the app development company, the potential value to clinicians and service users would need to be explored in further stakeholder consultation exercises.

7.7 Engagement with in-app features: Goal setting

Goal setting is seen as an essential component of physical rehabilitation (Wade, 2009) and is a crucial component of effective behaviour change interventions in other fields of antenatal health research (Brown et al., 2012). Therefore, a goal-setting feature was deemed valuable for the app developed in this PhD study. Nonetheless, the retrospective quantitative analysis presented in Chapter Six shows that only two of the 106 service users who registered to use the app engaged with the goal-setting function. Each of these users only created one goal on one single occasion. This suggests that either service users could not see the potential value of this feature to support their self-management or that the functionality of the goal-setting feature presented a potential barrier to engagement (Paige et al., 2018).

When reviewing the initial app prototype, the service user representative group highlighted that although they could navigate the goal-setting feature without issue, they would have had significant difficulty choosing a relevant goal. Guidance information was therefore drafted in response to this feedback and included in the updated version of the app. However, it is possible that this guidance may have been insufficient to meet users' needs. Difficulty selecting a salient goal may therefore have presented a significant barrier to engagement with the app's goal-setting function in Phase 3 (Morrison, 2015). It must also be acknowledged that poor engagement with the goal-setting feature will have led to the loss of the benefits of 'goal-setting' for encouraging behaviour change (Michie et al., 2017; Cole-Lewis et al., 2019).

Interestingly, previous studies have reported that in-app goal-setting features would be viewed positively by potential users and that the inclusion of a goal-setting function may be a facilitator to healthcare app uptake and engagement (Perski, Blandford, Ubhi, et al., 2017; Szinay et al., 2020; Szinay, Perski, et al., 2021). Digital interventions to promote physical activity that include a goal-setting function have also been shown to be more efficacious than those that do not (Schoeppe et al., 2016). Therefore, it is essential to consider other factors that may have influenced engagement with the in-app goal-setting feature to direct future intervention modification and development. These are discussed below.

7.7.1 Low level of engagement with goal setting feature: potential influence of mode of delivery

A meta-analysis published in 2016 (McEwan et al., 2016) demonstrated that goal setting was equally as effective at promoting physical activity behaviour change regardless of whether the intervention was delivered in-person, using digital means, or via a combination of both. However, more recently, a large systematic review and meta-analysis by Epton et al. (2017) examined the effectiveness of goal setting interventions across all types of behaviour change intervention. This review reported that goal setting might be more effective as a behaviour change technique when delivered 'face-to-face'.

Goal setting in the context of physiotherapy treatment is often considered a shared activity between patient and clinician (Stevens et al., 2017). Interventions that include education on setting relevant goals and providing feedback on goal progress are effective in managing chronic lower back pain in the non-pregnant

population (Gardner et al., 2019). Therefore, difficulty choosing a salient goal, difficulty verbalising that goal, or difficulty developing an appropriate plan of how that goal will be implemented (i.e., action planning) in the absence of training from their treating clinician may have presented a significant barrier to utilisation of the in-app goal-setting feature in this PhD study. One potential solution to this problem is for users to be allowed to select from a standardised list of goals, thus removing the burden of goal selection (Morrison, 2015). However, this reduces the user's control over their experience and may constrain the degree of personalisation available in the app. As personalisation is a desirable feature of healthcare apps (Perski, Blandford, Ubhi, et al., 2017; Paige et al., 2018; Bol et al., 2019; Svendsen et al., 2020; Thorneloe et al., 2020), this balance would need to be carefully considered.

7.7.2 Low level of engagement with goal setting feature: potential influence of lack of clinician feedback

The app developed in this PhD study did not provide the facility for clinicians to provide feedback on the goals set by service users or the progress made with those goals. This might have reduced the likelihood of the in-app goal-setting feature being effective as a behaviour change technique even if engagement levels were higher, as combining goal setting with feedback on goal progress might be more effective than using goal setting in isolation (Latham and Locke, 1991; McEwan *et al.*, 2016; Bailey, 2019). This premise was challenged by Epton et al. (2017), who found no significant additional benefit of feedback compared to goal setting alone. However, this review (Epton et al. 2017) highlighted that monitoring of the behaviour or outcome by others improved the effectiveness of goal setting

interventions. Therefore, modifying the app to allow clinicians to monitor and give feedback on goal progress would seem worthy of consideration. Furthermore, if clinician input is proven to facilitate app engagement in future stakeholder consultation exercises, this would need to be considered in future cost-effectiveness evaluations. This is because digital interventions are often assumed to reduce the clinical time burden and, therefore, the cost of service delivery. However, if the clinical time required to introduce the app, provide training on app functionality, and provide feedback to service users is considerable, potential improvements in clinical efficiency may be negated. This must be considered as the programme of app development and evaluation continues.

7.7.3 Summary of issues relating to engagement with the goal setting feature

The goal-setting feature of the app developed in this PhD study was not used as expected. The lack of clinician support to select a salient goal or monitor goal progress, and the lack of opportunity to demonstrate app functionality to users, may have contributed to the low level of engagement seen. Offering app users a predefined list of goals to choose from and developing the app's functionality so that clinicians may provide feedback on goal progress may be worthy of consideration in future app iterations.

7.8 Engagement with in-app features: The pelvic girdle questionnaire

Self-monitoring of symptoms (or self-monitoring of the outcomes of self-management behaviour) is seen as a key feature of successful self-management interventions for musculoskeletal pain (Hutting et al., 2019). Self-monitoring is also

a common feature of self-management apps for those with chronic pain (Devan et al., 2019). The opportunity for clinicians to view the progress made by app users in relation to their symptoms is also reported to be viewed positively in the digital intervention literature (Anderson et al., 2016; Santarossa et al., 2018; Svendsen et al., 2020; König et al., 2021). For these reasons, the inclusion of a self-monitoring feature was deemed important in this study. Nevertheless, Lazard et al. (2021) found that sharing health data with a healthcare professional was deemed an important feature of healthcare apps by just 74 out of 462 individuals included in their survey. Therefore, the conclusions reached about the value of in-app patient-reported outcome measures at the time of intervention development may have been unwarranted.

In Phase 3, the responses to the patient-reported outcome measure (The Pelvic Girdle Questionnaire, PGQ) submitted by users were visible to clinicians via the online clinician interface. At the app-development phase, it was envisaged that this would provide the opportunity for clinicians to identify service users deteriorating unexpectedly or those struggling with daily activities so that additional support may be provided. Therefore, the inclusion of the PGQ within the app - providing users with the opportunity to monitor their symptoms and clinicians the ability to monitor users' progress - was expected to be a feature with a high level of engagement.

7.8.1 Low level of ongoing engagement with the pelvic girdle questionnaire: potential influence of service user burden

Data analysis demonstrated that 35 of the 106 service users who downloaded the app chose to engage with the PGQ self-monitoring feature; just five of the 35 service users who engaged completed the PGQ on more than one occasion.

There could be several possible reasons for this. Firstly, the PGQ has 25 questions and, therefore, may have been perceived by users as too time-consuming to complete. Excessive perceived effort is a known barrier to engagement with digital interventions (Torous et al., 2018; Wei et al., 2020), as is excessive time consumption (Adu et al., 2018; Szinay et al., 2020; Szinay, Cameron et al., 2021; Szinay, Perski, et al., 2021). Increased cognitive load (or mental effort) is also known to be a barrier to ongoing engagement (Szinay et al., 2020; Szinay et al. 2021). Additionally, Bakker et al. (2016) highlight that manual data entry may not be viewed positively by busy individuals and that app users may be more likely to engage with self-monitoring features when part of the data entry is automated (e.g. via the use of wearable technologies). Further, although Böhm et al. (2020) found that uptake of app 'modules' (i.e., sections of app content) involving data entry was relatively high, ongoing engagement with these modules was comparatively low. As the use of automated data entry was not an option in this study due to technical limitations, the requirement to enter responses to each of the 25 questions on the PGQ and the time burden of doing so may have been off-putting to users.

7.8.2 Low level of ongoing engagement with the pelvic girdle questionnaire: potential influence of the chosen outcome measure

The core outcome set for PLPP includes pain and physical activity restriction (Remus et al., 2021), and these outcomes appear to be of importance to women experiencing this condition (Elden et al., 2014; Close et al., 2016; Mackenzie et al., 2018). Data collected via electronic outcome measures are also known to be comparable to those collected via paper forms (Gwaltney et al., 2008; Yu et al., 2021). It was therefore deemed reasonable to include a validated patient-reported outcome measure that records pain levels and degree of functional restriction (Stuge et al., 2017) within the app. However, the acceptability of the PGQ was not explicitly explored in Phase 1, and the functionality was not commented on during the service user representative consultations. It is, therefore, possible that when converted to digital format, the PGQ may not have been acceptable to service users. Further, the core outcome set for PLPP also includes health-related quality of life and fear-avoidance domains (Remus et al. 2021). The decision to measure pain and physical function alone may have resulted in failure to capture domains deemed meaningful to users. This may have presented an additional barrier to engagement (Haywood, 2007).

7.8.3 Low level of ongoing engagement with the pelvic girdle questionnaire: potential influence of lack of clinician involvement

Monitoring of patient-reported outcome measures is deemed an important part of physiotherapy practice (Rasmussen-Barr et al., 2021) and forms part of routine care for service users receiving physiotherapy treatment (Chartered Society of Physiotherapy, 2012). However, in the context of routine physiotherapy care, the

clinician would discuss the value of such measures with service users and explain how responses might be used to optimise management (Meerhoff et al., 2021). It is, therefore, possible that when delivered as a standalone digital intervention in Phase 3, the app developed in this PhD study may not have adequately conveyed the value of PGQ completion to users. Additionally, the lack of formal training for service users about in-app features may have presented an additional barrier (Borghouts et al., 2021). Lastly, during the COVID-19 national lockdown, service users would have been aware that clinicians were powerless to offer additional support should a deterioration in their outcome scores be seen, as in-person treatment was not available. Therefore, it is possible that this knowledge influenced their motivation to engage with the PGQ and presented a potential barrier to engagement.

7.8.4 Summary of issues relating to engagement with the pelvic girdle questionnaire

The available literature regarding the utility of self-monitoring as a behaviour change technique would suggest that the decision to include a method of self-monitoring is defensible (Michie et al., 2013; Michie et al., 2014). However, the acceptability of the PGQ as the chosen outcome measure, the adequacy of the in-app information about the PGQ, and the role of clinician input in facilitating self-monitoring all need to be explored during future stakeholder engagement exercises.

7.9 Engagement with in-app information

Based on the available data, no inference can be made about how frequently the in-app information was accessed or whether this met users' needs. Low levels of ongoing engagement could simply indicate that only a short period of interaction is required to meet the stated aims rather than reflect poor acceptability (Michie et al., 2017; O'Brien et al., 2020). It is, however, possible that the volume of information (Szinay et al., 2020; Szinay, Perski, et al., 2021), the tone with which the information was conveyed (Fulton et al., 2018; Paige et al., 2018), the inability to tailor the information to individual users (Adu et al., 2018; König et al., 2021; Shabir et al., 2022), or a perceived lack of cultural relevance (Borghouts et al., 2021; Shabir et al., 2022) could all have presented potential barriers to engagement. Further, disengagement from healthcare apps can occur for additional reasons such as boredom (Thorneloe et al., 2020), lack of novelty (Szinay, Perski, et al., 2021) and a failure of an app to meet expectations (Lazard et al., 2021). It is therefore important to explore the views of users in further stakeholder consultation to understand how the in-app information was received and whether any further modifications to the content are required.

7.10 Declining use of the app during the Phase 3 study period (from March 2020 to November 2021)

The retrospective quantitative analysis showed that the number of women invited to use the app each month during the Phase 3 study period steadily declined over time (see section 6.3.1). It was clarified verbally with the clinical collaborator at the host NHS Trust that access to the app was still being offered to all women referred

to the women's health physiotherapy service for the management of PLPP at the time of writing. Yet, the number of monthly invitations dropped significantly. This suggests a potential decline in the number of referrals to physiotherapy services for women with PLPP.

A recent systematic review suggests that utilisation of healthcare services has significantly reduced for 'less severe' illnesses during the COVID-19 pandemic compared to the pre-pandemic figures (Moynihan et al., 2021). Evidence also suggests that pandemic-related anxiety is common amongst pregnant women: Many women have expressed concerns about contracting COVID-19 (Hillyard et al., 2021) and about the potential impact of the virus on them and their unborn babies (Atmuri et al., 2021). It is, therefore, possible that women with PLPP may be less likely to seek help for their condition during the ongoing pandemic due to altered personal health priorities (Onchonga et al., 2021). The relative importance of competing priorities in the context of the pandemic may also be an important determinant of app uptake and engagement (Morrison, 2015).

Furthermore, evidence suggests that although pregnant women may be willing to accept virtual healthcare as an alternative to in-person care delivery during the pandemic, this is not the preferred option (Atmuri et al., 2021; Liu et al., 2021). Many women have expressed dissatisfaction with virtual care (Ahlers-Schmidt et al., 2020), and levels of dissatisfaction appear to have increased as the pandemic has progressed (Liu et al., 2021). It is possible that an awareness that in-person care was precluded might have reduced the motivation for help-seeking amongst women during the Phase 3 study period. This may be due to the perception that

the care offered will not meet expectations or align with personal preference. Moreover, reduced capacity within primary care services during the COVID-19 pandemic may have reduced access to physiotherapy services for some women with PLPP (National Health Service, 2021).

Finally, the COVID-19 pandemic has had a negative effect on mental health globally (Kumar and Nayar, 2020; Xiong et al., 2020; Knolle, Ronan, and Murray, 2021), and the impact on pregnant women has been widely acknowledged (Ahlers-Schmidt et al., 2020; Ceulemans et al., 2020; Lebel et al., 2020). Evidence suggests that pregnant women's mental health has been disproportionately affected during the pandemic, with levels of anxiety and depression increasing more in pregnant women than in their non-pregnant counterparts (López-Morales et al., 2021). Lebel et al. (2020) found that 37% of the 1987 pregnant women surveyed had experienced clinically relevant symptoms of depression, whilst 57% had experienced clinically relevant symptoms of anxiety. As negative emotions may influence motivation (Michie et al. 2011), it is also possible that a deterioration in psychological status may have influenced motivation to seek help for PLPP.

7.11 Reflections on the Phase 2 app development process and possible influence on outcomes

7.11.1 Reflections on the use of the Behaviour Change Wheel

At the early stage of the PhD study, the researcher's understanding of the Behaviour Change Wheel (BCW) was still developing. As a result, it is possible that the framework may not have been used to its full potential. Use of the BCW framework was appropriately planned to guide the qualitative data analysis and

inform decision-making relating to the intervention. However, the BCW was not fully utilised to inform the development of the topic guides for the stakeholder interviews and focus groups. The impact of this cannot be known, and valuable information emerged from the data collection regardless. Nonetheless, it must be accepted that using the BCW throughout the entire process may have influenced the qualitative findings generated.

Further, when findings from the qualitative study were mapped to the COM-B model of behaviour, the researcher considered whether to sub-categorise these using the Theoretical Domains Framework (TDF). This is an optional step in the BCW process of intervention development stated to provide additional granular detail about the changes required to allow enactment of the desired behaviours (Michie et al., 2014). The TDF is a synthesis of 33 behaviour/behaviour change theories clustered into 14 domains of cognitive, affective, social, and environmental influences on behaviour (Michie et al., 2005; Cane et al., 2012). The 14 domains of the TDF map directly to the six domains of the COM-B (Michie et al., 2014).

Table 7.1 below is an excerpt from a table in the text by Michie et al. (2014), showing the links between the COM-B, the TDF, and intervention functions. Table 7.1 shows that the recommended intervention functions vary minimally within a single area of the COM-B, regardless of the TDF domain selected. Therefore, mapping from the COM-B to the TDF appeared to constitute an additional layer of complexity that would have little influence on the outcome. This optional step was therefore omitted. Whilst this was considered appropriate given the constraints of a PhD study, it must be acknowledged that the additional detail provided by the

TDF may have influenced decision-making relating to app content during the later stages of the development process.

Table 7.1. The links between the COM-B, the TDF, and intervention functions, excerpt taken from Michie et al (2014: page 113-114)

COM-B	TDF	Intervention functions
Physical capability	Physical skills	Training Enablement
Psychological capability	Knowledge	Education
	Cognitive and interpersonal skills	Training
	Memory, attention, and decision processes	Training Environmental restructuring Enablement
	Behavioural regulation	Education Training Modelling Enablement
Reflective motivation	Professional/social role identity	Education Persuasion Modelling
	Beliefs about capabilities	Education Persuasion Modelling Enablement
	Optimism	Education Persuasion Modelling Enablement
	Beliefs about consequences	Education Persuasion Modelling
	Intentions	Education Persuasion Incentivisation Coercion Modelling
	Goals	Education Persuasion Incentivisation Coercion Modelling Enablement

7.11.2 Additional reflections on the choice of behaviour change techniques and mode of delivery

To date, there is no firm guidance regarding which of the 93 unique behaviour change techniques (BCTs) (Michie et al., 2013) work best for whom and under which circumstances. Research into this area is ongoing (Armitage et al., 2021). However, the importance of attending to the choice of BCTs in mobile healthcare apps has been reported (Cucciniello et al., 2021). Decisions about the choice of BCTs in Phase 2 of this PhD study were based on consideration of data from Phase 1, digital self-management literature presented in Chapter two, the behaviour change intervention development literature, and the practicability of the delivery of selected techniques within the technical constraints imposed by the app development company. Given this somewhat pragmatic decision-making process, it must be accepted that selecting a different set of behaviour change techniques may have had a different impact on app engagement levels. This may potentially have had a stronger influence on engagement with the desired self-management behaviours (Cole-Lewis et al., 2019).

7.11.3 Reflections on the presentation of in-app information

External links to appropriate video and audio content were provided within the app; however, the main mode of information provision was via written text within the app articles. Therefore, the behaviour change technique 'instruction on how to perform the behaviour' could have been delivered in a more user-friendly/accessible format had the required technology been readily available. Implementation of alternative modes of information provision via visual and audio

means may have also helped to ensure that the information contained within the app was accessible to a wider range of users (UK Government, 2021).

7.11.4 Reflections on the type of self-monitoring feature selected

The decision to include a self-monitoring feature was in line with recommendations in the self-management literature (Oliveira et al., 2012). In this case, 'self-monitoring of the outcomes of behaviour' was the behaviour change technique chosen and was in keeping with suggestions by Michie et al. (2014). However, the proportion of those registered to use the app that engaged with this feature was just 33%. It is possible that self-monitoring of the behaviour itself, such as the use of in-app exercise diaries or activity logs, may have been viewed more positively by users: monitoring of pain and activity restriction via the PGQ may have focussed users' attention on their symptoms rather than the positive steps taken to help manage their condition. This might have triggered negative emotions, which in turn could have negatively impacted levels of engagement (Bakker et al., 2016; Michie et al., 2011). Alternative modes of self-monitoring such as activity logs and exercise diaries should be considered during future stakeholder consultation exercises to direct future iterations of the app. The method of data entry and the associated effort required from users would have to be carefully considered.

7.11.5 Reflections on the type of in-app social support selected

The in-app messaging function aimed to deliver the behaviour change technique entitled ‘social support (unspecified)’. This feature provided a direct method of contact between service users and clinicians; however, as reported in section 7.4, it was not used as expected. Previous authors have suggested that harnessing the

power of virtual communities (either by creating app-specific online communities or by linking apps to existing social media platforms) may increase engagement both with the app itself (Paige et al., 2018) and with the desired health behaviours (Petersen et al., 2020). This does, however, appear to be somewhat contentious amongst app users, dependent upon the type of app under investigation and the healthcare issue the app was designed to tackle (Perski, Blandford, Ubhi, et al., 2017; Tong and Laranjo, 2018). As pregnant women are known to be mass users of social media (Sarker et al., 2017; Zhu et al., 2019), an in-app virtual community is worthy of consideration in future design iterations, but the views of service users in relation to this would need to be explored. It is important to be mindful of the inaccurate and conflicting advice often circulated via social media platforms (Swire-Thompson and Lazer, 2020) and the potential impact that this might have (Carpenter et al., 2016). This would need to be appropriately managed should an online community be deemed desirable.

7.11.6 Reflections on the use of reminders and prompts within the app

The only type of 'reminder' built into the app was to prompt users to create a schedule for completion of the PGQ. Notifications would also be 'pushed' to app users if messages were received from their clinicians. Therefore, the behaviour change technique 'prompts and cues' was not utilised. Controversy exists about the utility of push notifications (e.g. reminders, push messages, etc.) in healthcare apps; some authors have highlighted the potential benefits of using such features (Muench and Baumel, 2017; Bidargaddi et al., 2018; Hernandez-Reyes et al., 2020), whilst others have reported that the influence of frequent push

messages reduces over time (Freyne et al., 2017). This suggests that some form of 'notification fatigue' may exist. Evidence from qualitative studies also shows that app users prefer to have control over the frequency of push messages for them to be deemed acceptable (Perski, Blandford, Ubhi, et al., 2017) and that some users find push messages annoying (Szinay, Perski, et al., 2021). The optimal frequency, content, and purpose of push messages are currently unknown in the context of PLPP. In-depth exploration of this topic would therefore be required during future stakeholder consultations before the behaviour change technique 'prompts and cues' could be meaningfully implemented.

7.12 The feasibility of the app in its current form and the need for further work

As discussed in section 3.5, there were four facets of feasibility being explored in this study: prospective acceptability, demand, practicality, and integration (Bowen *et al.*, 2009; Sekhon et al., 2017). The Phase 1 study findings presented in Chapter four demonstrated that the notion of an app-based self-management intervention for women with PLPP was acceptable to stakeholders. It is, however, acknowledged that there is often a discord between the way potential users of an intervention say they will interact with it and the way they actually do (Yardley, Morrison et al., 2015). Clinicians were willing to integrate a PLPP self-management intervention into their practice. The level of uptake and overall engagement with the app, as reported in Chapter six, also demonstrated a reasonable level of demand for the intervention. The implementation of the app as part of the response to the COVID-19 pandemic demonstrated that the

intervention was practical to deliver in an NHS setting. The feasibility of the app developed for supporting PLPP self-management, therefore, looks promising.

The level of uptake and engagement with the app aligned with expectations based on the available evidence (Slepian et al., 2020; Statista, 2020). However, more needs to be done to explore service users' experiences of using the app. This is important because the optimal level of engagement with the app is unknown at present (O'Brien et al., 2020). Additionally, the way users interacted with the information provided cannot be known from the data collected and reported in this thesis. An understanding of whether the in-app information met users' needs and the factors influencing uptake and engagement is essential to inform ongoing app development and maximise future clinical utility. Therefore, in the next chapter, a program of further work is suggested to address these remaining questions.

CHAPTER EIGHT: CONCLUSIONS, IMPLICATIONS OF THE FINDINGS, AND PROPOSED FUTURE WORK

This chapter provides closing thoughts on this thesis, beginning with the conclusions and future areas for research. A reflexive scrutiny of the strengths and challenges of this PhD study are outlined to finish.

8.1 CONCLUSIONS

This study began with an interest in developing a digital intervention to support women with PLPP to self-manage their condition and improve their quality of life. This remains an important area that requires future research; the personal, social, and economic consequences of PLPP demand the ongoing pursuit of management strategies that will empower pregnant women to take control of their health.

This PhD study was underpinned by a systematised literature review examining the effectiveness of digital interventions for the management and self-management of LBP, PGP, and LPP. No RCTs could be located that examined the use of digital interventions in individuals with PGP or LPP, and no RCT explicitly stated the inclusion of pregnant women in the sample. The effectiveness of digital interventions for the management and self-management of LBP in the general population was also found to be inconsistent. This review, therefore, highlighted a significant gap in the literature and underscored the need for targeted digital intervention development and evaluation for women with PLPP.

The Phase 1 qualitative study facilitated the development of a digital intervention to address key stakeholders' priorities, preferences, and concerns. This served to

maximise the chances of future uptake, engagement, and effectiveness (Skivington et al., 2021). Phase 2 employed a recognised behaviour change intervention development theory linked to a coherent model of behaviour to produce an app-based self-management intervention for women with PLPP. This approach served to improve the likelihood of the app having the desired effect on self-management behaviours. Phase 3 then used retrospective user engagement data to assess how women with PLPP used the app during the COVID-19 pandemic. This thesis, therefore, represents the first stage in an ongoing programme of digital intervention development research that is in line with the MRC framework for the development and evaluation of complex interventions (MRC, 2008).

The use of a mixed-methods approach framed this research and ensured the findings of the Phase 1 qualitative study directly informed the app's development and the assessment of its feasibility (Creswell and Plano Clark, 2017). The exploratory sequential mixed-methods design provided a logical framework for this PhD study and was in keeping with both the intervention development literature and the pragmatic philosophical underpinnings.

In previous chapters, the data reported in this thesis have been contextualised and possible explanations for the reported findings proposed. In this section, the framework of intervention feasibility described by Bowen et al (2009) will be used to inform conclusions about whether the app developed in this PhD study is feasible to support the self-management of PLPP. As discussed in Chapter 3, the areas of feasibility examined in this thesis were acceptability, demand, practicality, and integration.

Phase 1 data demonstrated that using an app-based intervention for the management of PLPP was acceptable to NHS service users and clinicians. Service users conveyed the need for improved PLPP-related information provision and stated a willingness to engage with a digital self-management intervention. Clinicians were willing to integrate digital self-management resources into their practice and perceived the potential clinical benefit of doing so. Service users and clinicians viewed the notion of app-based interventions positively, and many had prior experience using apps in their daily lives or to support clinical practice. Therefore, the perceived acceptability and ease of integration of the intervention highlighted in Phase 1 support the notion that a digital intervention for the management of PLPP may be feasible.

The rate of app uptake reported in Chapter 6 indicated a reasonable level of demand for the intervention, with 63.5% of those given access to the app taking the opportunity to download the software and register to use it. This reflects the level of uptake of other app-based pain management interventions deemed feasible by previous researchers (Slepian et al., 2020). Implementation of the app as an emergency measure during the COVID-19 pandemic evidenced the willingness of clinicians to integrate the app into current practice and the practicality of implementation in the host NHS setting. Therefore, the level of demand for the intervention and the practicality of implementation demonstrated in Phase 3 also support the notion that the app may be a feasible self-management intervention for women with PLPP.

Nevertheless, it is acknowledged that the data available for analysis in Phase 3 may have significantly underestimated the actual level of app engagement due to the inaccessibility of data relating to engagement with in-app information articles. Additionally, data reflecting the experiences of app users and the reasons for non-engagement given by those who chose not to download the app were not collected in this PhD study; this means that the retrospective acceptability of the app and the factors influencing uptake remain unknown. The app, therefore, shows some promise as a feasible adjunct to routine care for women with PLPP. However, further work is needed to understand the factors influencing app uptake and engagement in women from a broad range of socioeconomic and ethnic backgrounds. Whether or not the in-app information met users' needs must also be explored. These additional insights will inform future development of the app and optimise its utility for clinical practice.

The iterative approach to app development described above reflects the cyclical nature of intervention development and evaluation described by the MRC (MRC, 2008). Findings of the preliminary feasibility testing undertaken in this PhD study suggest a continued focus on intervention development is needed to optimise potential clinical value. The further work described in section 8.6 will inform decisions about whether the app in its current form can be sufficiently modified to address issues raised or whether the development of a new prototype may be required.

8.2 Implications of the findings for women with PLPP

PLPP is a common condition, and this thesis has highlighted the myths and confusion surrounding it. Pregnant women should report lumbopelvic pain symptoms to their antenatal healthcare provider to ensure an accurate diagnosis and appropriate advice are received. If information needs cannot be met during a clinical consultation, women should ask to be signposted to trustworthy online resources to avoid the negative impact of inaccurate or anxiety-provoking online content.

8.3 Implications of the findings for clinical practice

This study has highlighted the lack of condition-related information available to women with PLPP and the barriers to adequate PLPP self-management. Clinicians caring for these women should review their current information provision practices and consider offering condition-related information as soon as symptoms are reported. Awareness of the anxiety caused by a lack of understanding of PLPP is essential for clinicians, and the value of reassurance regarding the favourable prognosis should not be underestimated. Clinicians should also be aware that independent online information-seeking is common among women with PLPP. Open discussion with patients about the information they find online may help them identify trustworthy resources and limit the negative impact of misinformation.

8.4 Implications of the findings for clinical advisory groups

The NHS long term plan sets out a strategy to increase the integration of digital resources into clinical practice. This thesis adds to the rapidly growing body of literature relating to the feasibility and acceptability of digital interventions. Given the ubiquity of smartphone technologies and their wide uptake among pregnant women, professional bodies such as the Pelvic Obstetric and Gynaecological Physiotherapy group and the Royal College of Midwives should consider guiding members about trustworthy digital resources. As the NHS app library was decommissioned in December 2021, advice from clinical advisory groups would support clinicians in understanding the resources available for pregnancy-related conditions that meet the Digital Technology Assessment Criteria for Health and Social Care (DTAC) that could be safely integrated into practice (see section 8.5 for further details on the DTAC). Training could also address the relevant safety considerations relating to digital interventions. This would inform clinicians' evaluation of publicly available digital resources to support patient care.

8.5 Implications of the findings for app developers

Many publicly available apps for the management of low back pain have been criticised for being under-theorised or lacking a solid evidence base (Escriche-Escuder et al., 2020). However, this thesis provides one example of how interdisciplinary cooperation can address this issue. Collaboration between developers, academics, service users and clinicians can ensure that healthcare apps address the needs of stakeholders, are based on the best available evidence, and can be implemented into clinical practice. This will raise the standards of

healthcare apps and increase the likelihood of future clinician endorsement. This approach is in keeping with recommendations in the intervention development literature (see Skivington et al., 2021 for one example) and should therefore be considered by future app developers.

In a UK NHS setting, digital health solutions are often checked against multiple quality standards before being endorsed and funded by commissioners (NHSX, 2022). In 2021, the Digital Technology Assessment Criteria (DTAC) for Health and Social Care was introduced by NHSX, the UK Government unit responsible for establishing policy and best practice for the use of digital technology and data in the NHS (NHSX, 2022). The DTAC was designed to be used by NHS organisations at the point of procurement to ensure that digital technologies meet the minimum baseline standards for safety, security, operability, and usability (NHSX, 2021). In addition to the DTAC, the National Institute for Health and Care Excellence have published an 'Evidence standards framework for digital health technologies' designed to ensure that all digital technologies implemented in an NHS setting are supported by appropriate evidence of effectiveness (NICE, 2018). As app developers have multiple standards to adhere to, global companies such as ORCHA exist that provide extensive baseline assessments of digital technologies encompassing all requisite national standards (ORCHA, 2020). Therefore, following a robust, collaborative app development process, such as that employed in this PhD study, would support app developers to produce digital solutions with the highest chance of effectiveness (Michie et al., 2017) and to plan their evaluation strategies in line with the NICE evidence standards framework (NICE, 2018). This

would enable app developers to meet many of the requisite standards set out by ORCHA, and thus facilitate successful implementation of their products.

8.6 Implications for future research

This thesis reports the first stage of an ongoing programme of digital intervention development research addressing the needs of women with PLPP. The app developed in this PhD study has demonstrated promise as a feasible intervention to support the self-management of PLPP; however, further work is required. This section describes the proposed future research to optimise the app's utility for supporting clinical practice.

Previous research shows that the context in which an app user is situated will influence levels of engagement (Flaherty et al., 2019) and that multiple demographic and personal factors may impact a user's decision to take up and use an app (Szinay et al., 2020; Thorneloe et al., 2020; König et al., 2021). As this is the first app specifically aimed at women with PLPP, it is not yet known whether pregnancy stage or parity influence engagement with the app. However, it is known that nulliparous women are more likely to seek pregnancy-related information than multiparous women (Sayakhot and Carolan-Olah, 2016). Further, women with experience of PLPP in a previous pregnancy may de-prioritise engagement with treatment due to experience of symptom resolution in the postpartum period. Conversely, previous negative experiences with PLPP may increase the motivation for help-seeking and increase engagement with the app (Michie et al., 2011). For this reason, detailed demographic and pregnancy-related information must be prospectively collected alongside app usage data so

that potential associations can be examined. Factors such as age, parity, pregnancy stage, ethnic origin, socioeconomic background, digital literacy, health literacy, and level of anxiety or depression should all be considered.

Nevertheless, the prospective quantitative study described above will not show whether the information provided within the app meets users' needs; a second qualitative study with app users would be required for this purpose (Yardley, Ainsworth, et al., 2015; Yardley, Morrison, et al., 2015). It will be essential to purposively sample app users from various ethnic and socioeconomic backgrounds to ensure a sufficiently broad range of perspectives are represented. This will address the lack of diversity in the exploratory qualitative study and service user representative consultations conducted to date. This approach is also in line with the National Institute for Health Research INCLUDE framework (NIHR, 2020): this guidance urges researchers to actively promote the inclusion of participants from underserved populations to ensure that research samples are representative of the wider population. This helps ensure that research findings are more generalisable to the real-world (NIHR, 2020).

The aim of this second qualitative study would be to explore the experiences of app users, and any suggestions for future modifications to the app's content or functionality. Specific objectives of this qualitative study are detailed in Table 8.1 below.

Table 8.1. Objectives of future qualitative study to be undertaken in the post-doctoral period

1	To explore the drivers to download the app and the intended goals of use
2	To explore whether in-app information is currently acceptable to users and any required modifications
3	To explore the barriers and facilitators to app engagement
4	To explore reasons for lack of engagement or disengagement with the app
5	To explore users' perceptions of the usability, acceptability, and value of the three key in-app features

Completion of the above work would contribute to the knowledge on the factors influencing engagement with the app and help to direct future design iterations. The outputs from this work would also add to the growing body of literature relating to the use of healthcare apps for pregnant women.

8.7 Strengths and limitations of this PhD study

The strengths of this PhD study include an intervention development process underpinned by an in-depth understanding of the use of digital interventions in the management of low back pain in the general population. The voices of women experiencing PLPP (NHS service users) and clinicians were also central to the design of the intervention. The app was developed following a robust process aligned with the behaviour change wheel approach to intervention development (Michie et al., 2014). Service user representatives were also consulted to refine the design and content of the app following the initial prototype development, in line with recommendations in the literature (Yardley et al., 2015; Skivington et al., 2021). The app usage data retrospectively analysed was captured automatically via the

online platform to which the app is connected. This meant that the data reflected real-world usage of the app during the COVID-19 pandemic (Milne-Ives et al., 2020). As these data were captured in real-time from NHS service users not enrolled in a clinical trial, they cannot have been impacted by the Hawthorne effect (McCambridge et al., 2014) as the users would not have been aware that they were being monitored. Additionally, the research did not rely on self-reported data; therefore, the potential influence of social desirability bias was eliminated (Deshields et al., 1995). Furthermore, many issues often associated with retrospective research, such as incomplete data collection or changes to data collection methods during the study period (Tofthagen, 2012), did not affect this PhD study, as data were consistently collected via the online platform throughout Phase 3.

There are several limitations to this PhD study that must be acknowledged. The lack of dual screening, data extraction, and risk of bias assessment, all increase the risk of inadvertent omissions and errors in the systematised review (McDonagh, 2013; Waffenschmidt et al., 2019). The inclusion of feasibility trials also increased the likelihood of inconsistent findings, as feasibility trials are less likely to be adequately powered to detect a true between-group difference in outcomes (Sim, 2019).

The representativeness of the sample for the exploratory qualitative phase and the service user representative consultations is also a limitation. As discussed in the previous sections, the over-representation of white middle-class women may have meant that the content and functionality of the app may not adequately reflect the

needs and wishes of women from different backgrounds. This may have influenced levels of engagement with the app and must therefore be addressed in future app development work.

The app development process for this study was undertaken in the pre-pandemic period. The aim was to develop an intervention designed to supplement in-person routine care and facilitate self-management of PLPP. This means that the qualitative study findings reflect the perspectives of stakeholders prior to the drastic societal and technological changes that have occurred since early 2020. The findings of qualitative studies are context-specific (Korstjens and Moser, 2017); it is therefore possible that the qualitative data collected in the pre-pandemic phase may not have been sufficient to direct the design of an intervention ultimately implemented during the pandemic, where information needs, treatment expectations, mental wellbeing, and access to healthcare services are all likely to have changed (Coxon et al., 2020; Liu et al., 2021; McBride et al., 2021).

It is known that the positionality of the researcher in relation to the research participants may influence the findings of qualitative research (Holmes, 2020). During the recruitment of NHS service users, potential participants were informed of the researcher's background and the aims of the Phase 1 study. The knowledge that the researcher was a physiotherapist with an interest in developing an intervention to support the self-management of PLPP could feasibly have influenced the responses given to the questions posed. Additionally, during the physiotherapists' focus group, the researcher was a relative insider due to a background working in antenatal and musculoskeletal physiotherapy (Chavez,

2015). Conversely, during the midwifery focus group, the researcher was a relative outsider due to a lack of insight into midwifery professional practice (Dwyer and Buckle, 2009). This insider-outsider position of the researcher during different parts of the research process may have had differing influences on the conversations that occurred and, ultimately, on the findings produced (Chavez, 2015; Dwyer and Buckle, 2009). The reflexive discussions and journaling undertaken throughout the Phase 1 data collection and analysis aimed to minimise the potential influence of positionality.

During the midwifery focus group, two of the group members (midwives 3 and 4) contributed relatively less to the discussion than the rest, despite repeated attempts by the researcher to seek additional input. These two group members remained engaged throughout the session and their body language suggested agreement with the sentiments expressed by others. However, it is recognised that in a group interview or focus group, dominant group members can overshadow or even silence more reserved individuals, resulting in the perceptions of these individuals being hidden from the researcher. In addition, within a group setting, there is a possibility that those with dissenting views can be reluctant to share these due to fears over how they might be received by other group members (Barbour and Kitzinger, 1998). Therefore, the possibility that midwives 3 and 4 avoided sharing their views due to fear of conflict with other group members, or concerns about social desirability, cannot be ignored.

Access to app usage data reflecting users' interactions with condition-related information articles was not available. Therefore, no comment could be made

about the number of times information articles were accessed or the length of time users spent engaging with the information provided. Engagement with in-app features was used as an indicator of overall app engagement. If the app was used as an information resource alone, engagement with in-app features (goal setting, messaging, and self-monitoring) might have underestimated the overall engagement levels; users could plausibly have read the information without engaging with the additional in-app features. Nonetheless, many authors have called for the measurement of user engagement to move beyond simply counting the number of interactions, as the optimal number to achieve the desired outcomes is unknown (Lalmas et al., 2014; O'Brien et al., 2020). It is, therefore, likely that the proposed future qualitative study described in section 8.6 would provide a more valuable insight into the utility of the in-app information than a simple count of user interactions (Yardley, Morrison, et al., 2015; O'Brien et al., 2020). Completion of this further work is therefore much needed.

Finally, the prototype app developed and reported in this thesis was not assessed using a formal app rating scale; this may be viewed by some as a limitation. There are at least 25 published quality rating scales for healthcare apps in existence (Azad-Khaneghah et al., 2021; Hensher et al., 2021). These cover multiple domains including perceived usefulness, perceived ease of use, functionality, acceptability, inclusion of BCTs, and user satisfaction (Azad-Khaneghah et al., 2021). However, there is little agreement about which assessment domains are most important, leading to ongoing uncertainty about how best to evaluate healthcare apps (Hensher et al., 2021). The distinction between assessment domains is also unclear (Nouri et al., 2018). Additionally, assessment scales are often designed for use by

professionals rather than end users (Azad-Khaneghah et al., 2021). This is problematic if the priorities of end users are not considered in the design of these scales, as high-scoring apps may still experience low levels of user engagement. For these reasons, the decision not to use a published rating scale to assess the app developed in this PhD study was not considered a limitation. However, once the app has been modified in response to the further work recommended in section 8.6, formal assessment against the DTAC baseline standards can be completed to facilitate rollout of the app across multiple NHS Trusts.

CHAPTER NINE: REFLECTIVE STATEMENT

This final chapter provides closing thoughts on the thesis, beginning with a reflexive scrutiny of the decision-making, and finishing with a summary of my current thinking on the self-management of PLPP.

9.1 WHAT WAS MY ROLE IN THE RESEARCH?

When I began to write this final chapter, I reflected in depth upon my research journey and thus my development and progress over the last seven years. I have undertaken multiple professional roles during this PhD study: clinician, student researcher, and now lecturer.

When enrolling on the part-time PhD programme, I had just begun working in a 'research physiotherapist' role in the NHS after spending much of my career working in a musculoskeletal outpatient setting. The latter years of my outpatient role had involved caring for women with pregnancy-related musculoskeletal conditions, including PLPP. At the outset of this PhD, I, therefore, felt that my previous experience had given me a good understanding of the needs of women with PLPP. Hence, I may have unknowingly approached this PhD study with preconceived ideas about what needed to change, perhaps creating a form of unconscious bias and, in some ways, perpetuating the paternalistic model of healthcare provision (Taylor, 2009). I have reflected on how this perspective might have influenced decision-making throughout the PhD study; I have also considered the potential impact on the interpretation of research findings (Dodgson, 2019).

I entered the part-time PhD programme with some previous research methods training after completing a Master of Research degree via the NIHR Integrated Clinical Academic training pathway in 2013. My research training has subsequently continued through the PhD and my research role within the NHS. This put me in the privileged position of developing my understanding of research both from an academic perspective and in terms of the practicalities of research delivery in an NHS context. This has allowed me to reflect on the decisions made during the PhD study from a broader perspective.

My current role as a lecturer has allowed me to share the experience gained throughout my clinical career and part-time PhD. Reflexive discussions with colleagues and students have also allowed me to consider my decision-making throughout the PhD study and challenge many of my prior assumptions.

9.2 Reflections on the use of the MRC guidance on developing and evaluating complex interventions to inform this PhD study

The MRC guidance on developing and evaluating complex interventions (MRC, 2008) was used to inform the design of this PhD study. This guidance has received criticism for adopting an overly simplistic conceptualisation of complexity and failing to acknowledge that complex interventions often evolve significantly during implementation (Craig and Petticrew, 2013). Nonetheless, this guidance provided an overarching framework for the design by recommending key development activities and highlighting important considerations. According to the 2008 MRC guidance, complex intervention development comprises three key activities: identifying the evidence base, identifying or developing appropriate theory, and modelling processes and outcomes (MRC, 2008). Therefore, this thesis began with

a systematised review of relevant literature to identify the evidence base and establish the generalisability of this evidence to the population of women with PLPP. However, little detail was offered in the MRC guidance about how theory should be applied during the development process, and little attention was paid to the value of stakeholder input. This, therefore, necessitated engagement with the broader intervention development literature to inform the design of this PhD study.

Additionally, in the 2008 MRC guidance, the boundaries between 'modelling processes and outcomes' (part of the intervention development process) and 'testing procedures' (part of feasibility and pilot testing) appear somewhat blurred. Therefore, research planning required consultation with the methodological literature to gain conceptual clarity regarding 'intervention feasibility'. This, in turn, enabled the selection of appropriate data collection methods (Bowen et al., 2009). The 2021 updated MRC guidance on developing and evaluating complex interventions (Skivington et al., 2021) addresses the above issues; this updated guidance places stakeholder consultation at the core of all stages of development and evaluation and provides additional clarity about how both the feasibility of the intervention and the feasibility of a future evaluation of effectiveness should be conceptualised and established (Skivington et al., 2021).

9.3 Reflections on other methodological decisions

Considering the needs and views of women with PLPP and the clinicians who treat them was central to the design of this PhD study. This approach was in line with recommendations in the intervention development literature (Yardley, Morrison, *et*

al., 2015). The Phase 1 qualitative data and the views of service user representatives were integral to the app's design. However, the utilisation of defined co-production methods, where service users are actively involved in all decision-making, may have resulted in the development of an app more aligned to service user needs (Hawkins et al., 2017; Kayser et al., 2018). As my understanding of co-production methods has developed since embarking on this PhD project, I would now consider employing such methods for any future intervention development endeavours.

Furthermore, whilst data collection for the Phase 1 qualitative exploration was ongoing, I had not given due consideration to the representativeness of the sample of service users recruited. Moreover, it was not until the Phase 3 user engagement data was analysed that I truly reflected on the impact this oversight may have had. The introduction of the NIHR INCLUDE framework facilitated this thinking and contributed to my current appreciation of the need for representative research samples in the production of widely applicable research findings (NIHR, 2021).

9.4 Reflections on the role of self-management in PLPP

The most significant change in my thinking as I have developed over the course of this PhD has been in relation to the role of self-management in PLPP. This change has developed during both data collection and analysis, and my thinking continues to develop. At the outset of this PhD study, the main driver for developing an intervention to support self-management was the belief that self-management is a form of patient empowerment (Bravo et al., 2015) that might reduce unnecessary healthcare resource utilisation (Jiang et al., 2019). This notion is in line with the

dominant narrative in the literature (Pulvirenti et al., 2014; Bravo et al., 2015). Self-management, therefore, fits with the ethos of the NHS, where efficient use of resources is actively encouraged. The Phase 1 exploratory qualitative findings aligned with existing evidence suggesting that women with PLPP view self-management positively, and the level of uptake of the app developed in this PhD study supports a reasonable demand for such an intervention. However, evidence suggests that although self-management interventions for individuals with low back pain in the general population are more effective than no treatment, the effect size is moderate at best (Du et al., 2017).

My prior belief about the nature of self-management and my interpretation of self-management theory had previously led me to conclude that those who fail to successfully self-manage their condition may lack sufficient self-efficacy (Prior and Bond, 2004; Marks et al., 2005; Degerstedt et al., 2020) or the self-management skills required (Kongsted et al., 2021). More recently, however, after considering the low level of ongoing engagement with the app developed in this PhD study (and indeed with all healthcare apps (Statista, 2020)), I have started to re-conceptualise self-management in terms of the burden placed on the service user. 'Burden of Treatment Theory' (May et al., 2014) reframes self-management as a way of shifting the burden of care away from the healthcare provider onto the patient, as opposed to an act of empowerment. According to this theory, how well a service user can engage with self-management depends on their understanding of what is being asked of them, the resources available to them, and the social networks they connect to that can support self-management activities (May et al., 2014). When conceptualised in this way, facilitation of self-management would

require much more than simply increasing the knowledge and skills of the individual service user. Instead, interventions would also aim to ensure that the necessary resources and social support are in place to allow engagement with the desired behaviours. Using the behavioural theoretical language used throughout this thesis, this would involve focusing on the psychological capability and both the physical and social opportunity to enact the behaviours, something a digital intervention is not equipped to do. For this reason, completing the further work described in Chapter eight and gaining a deeper understanding of the factors influencing app engagement, is essential. This work will shed light on whether the barriers to app engagement in this PhD study were related to the app itself - and therefore more readily amenable to change - or whether outside influences were more important. If the latter proves to be the case, a deeper consideration of how to overcome these additional barriers would be needed. This is because bolstering personal resources and facilitating the development of social networks is currently beyond the scope of NHS physiotherapy services.

I am, however, conscious that my reflections on data collected during the Covid-19 pandemic will continue to develop in the post-pandemic period: Provision of NHS services, including physiotherapy, changed dramatically during the pandemic, with virtual consultations and remote service delivery becoming the norm (Rawlinson and Connell, 2021). Therefore, the move towards digitising healthcare services set out in the NHS Long-term plan (NHS, 2019) was undoubtedly expedited. However, the development and implementation of digital healthcare solutions across the NHS will continue to progress to help meet the nation's demands and attempt to reduce the pressure on clinical staff and services (NHS, 2019). Understanding how

to support patient engagement with digital healthcare solutions may therefore become a vital area of research focus.

Whilst considering the potential impact of contextual factors on engagement with self-management interventions (May et al., 2014), I also began to consider the implications of this for evaluating the effectiveness of healthcare apps. If multiple contextual factors can impact app engagement (Tarricone et al., 2021), the importance of undertaking a process evaluation alongside any examination of an app's effectiveness cannot be underestimated (Moore et al., 2015). The MRC offers guidance on the process evaluation of complex interventions to help uncover contextual factors that might mediate outcomes (MRC, 2015). This facilitates an understanding not only of whether an intervention works, but also for whom and under what circumstances (Fletcher et al., 2016). The further research described in section 8.6 will go some way to highlighting factors influencing app engagement in the context of this PhD study. The output from this work may help inform any future process evaluation undertaken alongside an assessment of the app's effectiveness once development work is complete (MRC, 2015).

9.5 Summary of reflections

In summary, owing to my developing reconceptualisation of self-management, I have begun to take a broader view of the role of digital self-management interventions in the lives of women with PLPP. I have therefore begun to question what more might need to be done to support self-management behaviours beyond the delivery of behaviour change techniques commonly used in previous back pain self-management interventions. I have reflected on the choices made regarding the

methods employed; I accept that opportunities to increase the amount and quality of service user involvement were not taken. I also acknowledge that my position as a clinician may have influenced my approach to the research design, the data analysis, and the proposition of the thesis. Reflecting on the learning undertaken and the challenges overcome has allowed me to appreciate the transformative nature of this PhD journey and has reaffirmed my enthusiasm to continue developing as an academic.

REFERENCES

Abraham, C., Wood, C.E., Johnston, M., Francis, J., Hardeman, W., Richardson, M. And Michie, S. (2015), "Reliability Of Identification Of Behavior Change Techniques In Intervention Descriptions", *Annals Of Behavioral Medicine: A Publication Of The Society Of Behavioral Medicine*, Academic.Oup.Com, 49(6), Pp. 885–900.

Adu, M.D., Malabu, U.H., Malau-Aduli, A.E.O. And Malau-Aduli, B.S. (2018), "Users' Preferences And Design Recommendations To Promote Engagements With Mobile Apps For Diabetes Self-Management: Multi-National Perspectives", *Plos One*, 13 (12) Pp. E0208942. [Online] [Accessed October 2021] Available at: DOI: 10.1371/journal.pone.0208942

Agar, C. S. Aneshensel, R. R. Fredrichs, V. A. Clark, P. A. Yokopenic, W. S. Aquilino, W. S. Aquilino, L. A. Losciuto, R. Brown, D. Cahalan, A. V. Cicourel, J. M. Conley, W. M. O'barr, J. R. Corsi, T. L. Hurley, J. R. Corsi, T. L. Hurley, J. R. Corsi, L. B. Rosenfeld, G. D. Fowler, K. E. Newcomer, D. C. Niekerk, J. D. (2003), "In-Person Versus Telephone Interviewing", In Gubrium, H.A. (Ed.), Inside Interviews: New Lenses, New Concerns, London. Sage Publications, Pp. 174–193.

Ahlers-Schmidt, C.R. et al. (2020) 'Concerns of women regarding pregnancy and childbirth during the COVID-19 pandemic', Patient education and counselling [Preprint]. doi:10.1016/j.pec.2020.09.031.

Albert, H., Godskesen, M. And Westergaard, J. (2001), "Prognosis In Four Syndromes Of Pregnancy-Related Pelvic Pain", *Acta Obstetricia Et Gynecologica Scandinavica*, 80 (6) Pp. 505–510.

All Party Parliamentary Groups on Global Health (2014) *Patient Empowerment - For Better Quality, More Sustainable Health Services Globally*. APPG. London. Available at: https://globalhealth.inparliament.uk/news/patient-empowerment-better-quality-more-sustainable-health-services-globally (accessed 15 December 2021).

Almhdawi, K.A., Obeidat, D.S., Kanaan, S.F., Oteir, A.O., Mansour, Z.M. And Alrabbaei, H. (2020), "Efficacy Of An Innovative Smartphone Application For Office Workers With Chronic Non-Specific Low Back Pain: A Pilot Randomized Controlled Trial", *Clinical Rehabilitation*, 34 (10) P. 1282-1291.

Al-Sayegh, N.A., Salem, M., Dashti, L.F., Al-Sharrah, S., Kalakh, S. And Al-Rashidi, R. (2012), "Pregnancy-Related Lumbopelvic Pain: Prevalence, Risk Factors, And Profile In Kuwait", *Pain Medicine* , 13 (8) Pp. 1081–1087.

Amorim, A.B., Pappas, E., Simic, M., Ferreira, M.L., Jennings, M., Tiedemann, A., Carvalho-E-Silva, A.P., *Et Al.* (2019), "Integrating Mobile-Health, Health Coaching, And Physical Activity To Reduce The Burden Of Chronic Low Back Pain Trial

(Impact): A Pilot Randomised Controlled Trial", *BMC Musculoskeletal Disorders*, 20(1), Pp. 71.

Anderson, K., Burford, O. And Emmerton, L. (2016), "Mobile Health Apps To Facilitate Self-Care: A Qualitative Study Of User Experiences", *Plos One*, 11 (5), Pp. E0156164. [Online] [Accessed October 2021] Available at: DOI: 10.1371/journal.pone.0156164

Anderson, R.M. and Funnell, M.M. (2005) 'Patient empowerment: reflections on the challenge of fostering the adoption of a new paradigm', *Patient education and counselling*, 57(2), pp. 153–157. doi:10.1016/j.pec.2004.05.008.

Anderson, R.M. and Funnell, M.M. (2010) 'Patient empowerment: myths and misconceptions', *Patient education and counselling*, 79(3), pp. 277–282. doi:10.1016/j.pec.2009.07.025.

Anguera, M.T. *et al.* (2018) 'Revisiting the difference between mixed methods and multimethods: Is it all in the name?', *Quality & quantity*, 52(6), pp. 2757–2770. doi:10.1007/s11135-018-0700-2.

Arain, M. *et al.* (2010) 'What is a pilot or feasibility study? A review of current practice and editorial policy', *BMC medical research methodology*, 10, p. 67. doi:10.1186/1471-2288-10-67.

Armitage, C.J., Conner, M., Prestwich, A., De Bruin, M., Johnston, M., Sniehotta, F. And Epton, T. (2021), "Investigating Which Behaviour Change Techniques Work For Whom In Which Contexts Delivered By What Means: Proposal For An International Collaboratory Of Centres For Understanding Behaviour Change (Cubic)", *British Journal Of Health Psychology*, Wiley, 26(1), Pp. 1–14.

Atmuri, K. *et al.* (2021) 'Perspectives of pregnant women during the COVID-19 pandemic: A qualitative study', *Women and birth: journal of the Australian College of Midwives* [Preprint]. doi:10.1016/j.wombi.2021.03.008.

Aydin, G. And Silahtaroglu, G. (2021), "Insights Into Mobile Health Application Market Via A Content Analysis Of Marketplace Data With Machine Learning", *Plos One*, 16 (1), Pp. E0244302. [Online] [Accessed January 2022] Available at: DOI: 10.1371/journal.pone.0244302

Azad-Khaneghah, P., Neubauer, N., Miguel Cruz, A. and Liu, L. (2021), "Mobile health app usability and quality rating scales: a systematic review", *Disability and Rehabilitation. Assistive Technology*, Taylor & Francis, 16(7), pp. 712–721.

Backhausen, M., Damm, P., Bendix, J., Tabor, A. And Hegaard, H. (2018), "The Prevalence Of Sick Leave: Reasons And Associated Predictors – A Survey Among Employed Pregnant Women", *Sexual & Reproductive Healthcare: Official Journal Of The Swedish Association Of Midwives*, 15, Pp. 54–61.

Bailey, R.R. (2019), “Goal Setting And Action Planning For Health Behavior Change”, *American Journal Of Lifestyle Medicine*, 13 (6), Pp. 615–618.

Bakker, D., Kazantzis, N., Rickwood, D. And Rickard, N. (2016), “Mental Health Smartphone Apps: Review And Evidence-Based Recommendations For Future Developments”, *JMIR Mental Health*, 3(1), Pp. E7. [Online] [Accessed November 2021] Available at: DOI: 10.2196/mental.4984

Bakker, E.C., Van Nimwegen-Matzinger, C.W., Ekkel-Van Der Voorden, W., Nijkamp, M.D. And Völlink, T. (2013), “Psychological Determinants Of Pregnancy-Related Lumbopelvic Pain: A Prospective Cohort Study”, *Acta Obstetricia Et Gynecologica Scandinavica*, 92(7), Pp. 797–803.

Bandura, A. (1998a), “Health Promotion From The Perspective Of Social Cognitive Theory”, *Psychology & Health*, Routledge, 13(4), Pp. 623–649.

Bandura, A. (1998b), “Personal And Collective Efficacy In Human Adaptation And Change”, *Advances In Psychological Science*, 1(1), Pp. 51–71.

Bandura, A. (2001), “Social Cognitive Theory: An Agentic”, *Annual Review Of Psychology*, 52, Pp. 1–26.

Bandura, A. (2004), “Health Promotion By Social Cognitive Means”, *Health Education & Behavior: The Official Publication Of The Society For Public Health Education*, 31(2), Pp. 143–164.

Bandura, A. (2005), “The Evolution Of Social Cognitive Theory”, In: *Great Minds In Management*, Oxford. Oxford University Press. Pp. 9–35.

Barbour, R. S. (2001). Checklists for improving rigour in qualitative research: a case of the tail wagging the dog? *BMJ* , 322 (7294), pp.1115–1117. [Online]. Available at: doi:10.1136/bmj.322.7294.1115.

Barbour, R. (2013), *Introducing Qualitative Research: A Student’s Guide*. London. SAGE

Barbour, R. And Kitzinger, J. (1998), *Developing Focus Group Research: Politics, Theory And Practice*, Edited By Barbour, R.S. And Kitzinger, J., California. Sage Publications.

Barker, F., Atkins, L. And De Lusignan, S. (2016), “Applying The Com-B Behaviour Model And Behaviour Change Wheel To Develop An Intervention To Improve Hearing-Aid Use In Adult Auditory Rehabilitation”, *International Journal Of Audiology*, Taylor & Francis, 55(3), Pp. S90–8.

Baumeister, H., Paganini, S., Sander, L.B., Lin, J., Schlicker, S., Terhorst, Y., Moshagen, M., *Et Al.* (2021), “Effectiveness Of A Guided Internet- And Mobile-Based Intervention For Patients With Chronic Back Pain And Depression (Ward-Bp): A Multicenter, Pragmatic Randomized Controlled Trial”, *Psychotherapy And Psychosomatics*, 90(4), Pp. 255–268.

Baumel, A., Muench, F., Edan, S. And Kane, J.M. (2019), "Objective User Engagement With Mental Health Apps: Systematic Search And Panel-Based Usage Analysis", *Journal Of Medical Internet Research*, JMIR Publications Inc., 21(9), Pp. E14567. [Online] [Accessed December 2021] Available at: DOI: 10.2196/14567

Beales, D.J., O'sullivan, P.B. And Briffa, N.K. (2009), "Motor Control Patterns During An Active Straight Leg Raise In Chronic Pelvic Girdle Pain Subjects", *Spine*, 34(9), Pp. 861–870.

Beatty, L. And Lambert, S. (2013), "A Systematic Review Of Internet-Based Self-Help Therapeutic Interventions To Improve Distress And Disease-Control Among Adults With Chronic Health Conditions", *Clinical Psychology Review*, Vol. 33(4), Pp. 609–622.

Beauchamp, M.R., Crawford, K.L. And Jackson, B. (2019), "Social Cognitive Theory And Physical Activity: Mechanisms Of Behavior Change, Critique, And Legacy", *Psychology Of Sport And Exercise*, 2, Pp. 110–117.

Bejaković, P. And Mrnjavac, Ž. (2020), "The Importance Of Digital Literacy On The Labour Market", *Employee Relations: The International Journal*, Emerald Publishing Limited, 42(4), Pp. 921–932.

Benoot, C., Hannes, K. and Bilsen, J. (2016). The use of purposeful sampling in a qualitative evidence synthesis: A worked example on sexual adjustment to a cancer trajectory. *BMC medical research methodology*, 16, p.21. [Online]. Available at: doi:10.1186/s12874-016-0114-6.

Ben-Zeev, D., Brian, R.M., Jonathan, G., Razzano, L., Pashka, N., Carpenter-Song, E., Drake, R.E., *Et Al.* (2018), "Mobile Health (Mhealth) Versus Clinic-Based Group Intervention For People With Serious Mental Illness: A Randomized Controlled Trial", *Psychiatric Services* , 69(9), Pp. 978–985.

Bernardelli G, Vigna L, Nava C, et al. (2020) Physical Activity in Healthcare Workers With Low Back Pain: Effects of the Back-FIT Randomized Trial. *Journal of occupational and environmental medicine / American College of Occupational and Environmental Medicine* 62(6): e245–e249. DOI: 10.1097/JOM.0000000000001844.

Bidargaddi, N., Pituch, T., Maaieh, H., Short, C. And Strecher, V. (2018), "Predicting Which Type Of Push Notification Content Motivates Users To Engage In A Self-Monitoring App", *Preventive Medicine Reports*, 11, Pp. 267–273.

Biesta, G. (2010), "Pragmatism And The Philosophical Foundations Of Mixed Methods Research", *Sage Handbook Of Mixed Methods In Social And Behavioral Research*, California. SAGE publications. 2nd Edition, Pp. 95–118.

Bishop, A., Holden, M.A., Ogollah, R.O., Foster, N.E. And Ease Back Study Team. (2016), "Current Management Of Pregnancy-Related Low Back Pain: A National Cross-Sectional Survey Of U.K. Physiotherapists", *Physiotherapy*, 102(1), Pp. 78–85.

Biviá-Roig, G., Lisón, J.F. And Sánchez-Zuriaga, D. (2019), "Effects Of Pregnancy On Lumbar Motion Patterns And Muscle Responses", *The Spine Journal: Official Journal Of The North American Spine Society*, 19(2), Pp. 364–371.

Bloomfield, J. And Chapman, P. (2018), "Diversity Policy And Intercultural Change In The Borough Of Lewisham", In White, B.W. (Ed.), *Intercultural Cities: Policy And Practice For A New Era*, New York. Springer International Publishing. Pp. 215–250.

Böhm, A.-K., Jensen, M.L., Sørensen, M.R. And Stargardt, T. (2020), "Real-World Evidence Of User Engagement With Mobile Health For Diabetes Management: Longitudinal Observational Study", *JMIR Mhealth And Uhealth*, Vol. 8 No. 11, P. E22212. [Online] [Accessed November 2021] Available at: DOI: 10.2196/22212

Bol, N., Høie, N.M., Nguyen, M.H. And Smit, E.S. (2019), "Customization In Mobile Health Apps: Explaining Effects On Physical Activity Intentions By The Need For Autonomy", *Digital Health*, 5, Pp. 2055207619888074. [Online] [Accessed October 2021] Available at: doi: 10.1177/2055207619888074

Borghouts, J., Eikey, E., Mark, G., De Leon, C., Schueller, S.M., Schneider, M., Stadnick, N., *Et Al.* (2021), "Barriers To And Facilitators Of User Engagement With Digital Mental Health Interventions: Systematic Review", *Journal Of Medical Internet Research*, 23(3), Pp. E24387. [Online] [Accessed December 2021] Available at: DOI: 10.2196/24387

Bowen, D.J., Kreuter, M., Spring, B., Cofta-Woerpel, L., Linnan, L., Weiner, D., Bakken, S., *Et Al.* (2009), "How We Design Feasibility Studies", *American Journal Of Preventive Medicine*, 36(5), Pp. 452–457.

Brady, T. (2012), "Strategies To Support Self-Management In Osteoarthritis: Five Categories Of Interventions, Including Education", *Orthopaedic Nursing / National Association Of Orthopaedic Nurses*, 31(2), Pp. 124–130.

Braun, V. And Clarke, V. (2021), "To Saturate Or Not To Saturate? Questioning Data Saturation As A Useful Concept For Thematic Analysis And Sample-Size Rationales", *Qualitative Research In Sport, Exercise And Health*, Routledge, 13(2), Pp. 201–216.

Bravo, P., Edwards, A., Barr, P.J., Scholl, I., Elwyn, G., Mcallister, M. And Cochrane Healthcare Quality Research Group, Cardiff University. (2015), "Conceptualising Patient Empowerment: A Mixed Methods Study", *Bmc Health Services Research*, 15, Pp. 252.

Breakey, V. R. et al. (2013). The value of usability testing for Internet-based adolescent self-management interventions: 'Managing Hemophilia Online'. *BMC medical informatics and decision making*, 13 (1), p.113. [Online]. Available at: doi:10.1186/1472-6947-13-113

Breen, R.L. (2006), "A Practical Guide To Focus-Group Research", *Journal Of Geography In Higher Education*, Routledge, 30(3), Pp. 463–475.

Brown, M.J., Sinclair, M., Liddle, D., Hill, A.J., Madden, E. And Stockdale, J. (2012), "A Systematic Review Investigating Healthy Lifestyle Interventions Incorporating Goal Setting Strategies For Preventing Excess Gestational Weight Gain", *Plos One*, 7(7), Pp. E39503. [Online] [Accessed January 2022] Available at: DOI: 10.1371/journal.pone.0039503

Brun-Cottan, N., Dpt, Mcmillian, D., Pt, Dsc, Ocs And Hastings, J., Pt, Phd, Ncs. (2020), "Defending The Art Of Physical Therapy: Expanding Inquiry And Crafting Culture In Support Of Therapeutic Alliance", *Physiotherapy Theory And Practice*, 36 (6), Pp. 669–678.

Buhrman, M., Fältenhag, S., Ström, L. And Andersson, G. (2004), "Controlled Trial Of Internet-Based Treatment With Telephone Support For Chronic Back Pain", *Pain*, 111(3), Pp. 368–377.

Buhrman, M., Nilsson-Ihrfeldt, E., Jannert, M., Ström, L. And Andersson, G. (2011), "Guided Internet-Based Cognitive Behavioural Treatment For Chronic Back Pain Reduces Pain Catastrophizing: A Randomized Controlled Trial", *Journal Of Rehabilitation Medicine: Official Journal Of The Uems European Board Of Physical And Rehabilitation Medicine*, 43(6), Pp. 500–505.

Burns, P.B., Rohrich, R.J. And Chung, K.C. (2011), "The Levels Of Evidence And Their Role In Evidence-Based Medicine", *Plastic And Reconstructive Surgery*, Ovid Technologies (Wolters Kluwer Health), 128 (1), Pp. 305–310.

Burton, A.K., Kim Burton, A., Waddell, G., Malcolm Tillotson, K. And Summerton, N. (1999), "Information And Advice To Patients With Back Pain Can Have A Positive Effect", *Spine*. 24(3) Pp2484

Butzner, M. And Cuffee, Y. (2021), "Telehealth Interventions And Outcomes Across Rural Communities In The United States: Narrative Review", *Journal Of Medical Internet Research*, 23(8), P. E29575.

Calguneri, M., Bird, H.A. and Wright, V. (1982) 'Changes in joint laxity occurring during pregnancy', *Annals of the rheumatic diseases*, 41(2), pp. 126–128. doi:10.1136/ard.41.2.126.

Camacho-Morell, F. And Esparcia, J. (2020), "Influence And Use Of Information Sources About Childbearing Among Spanish Pregnant Women", *Women And Birth: Journal Of The Australian College Of Midwives*, 33(4), Pp. 367–376.

Cane, J., O'Connor, D., & Michie, S. (2012). Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implementation science: IS*, *7*(37) Pp. 7-37. Available from: https://doi.org/10.1186/1748-5908-7-37

Care Quality Commission. (2019), *Lewisham And Greenwich Nhs Trust Evidence Appendix*, 2019, London. CQC, Available At:

Https://Www.Cqc.Org.Uk/Sites/Default/Files/Lewisham_And_Greenwich_Nhs_Trust_Evidence_Appendix_Published_11_January_2019.Pdf.

Carlo, A.D., Hosseini Ghomi, R., Renn, B.N. And Areán, P.A. (2019), "By The Numbers: Ratings And Utilization Of Behavioral Health Mobile Applications", *NPJ Digital Medicine*, 2, Pp. 54.

Carpenter, D.M., Geryk, L.L., Chen, A.T., Nagler, R.H., Dieckmann, N.F. And Han, P.K.J. (2016), "Conflicting Health Information: A Critical Research Need", *Health Expectations: An International Journal Of Public Participation In Health Care And Health Policy*, 19(6), Pp. 1173–1182.

Carpenter, K.M., Stoner, S.A., Mundt, J.M. And Stoelb, B. (2012), "An Online Self-Help Cbt Intervention For Chronic Lower Back Pain", *The Clinical Journal Of Pain*, 28 (1), Pp. 14–22.

Carter, J., Sandall, J., Shennan, A.H. And Tribe, R.M. (2019), "Mobile Phone Apps For Clinical Decision Support In Pregnancy: A Scoping Review", *Bmc Medical Informatics And Decision Making*, 19(1), Pp. 219.

Census Information Scheme Gla Intelligence Unit. (2013), *2011 Census Snapshot: Main Language*, No. Cis2013-01, London. Census Information Scheme Gla Intelligence. Available At: Https://Londondatastore-Upload.S3.Amazonaws.Com/Pcu%3d2011-Census-Snapshot-Main-Language.Pdf.

Ceulemans, M., Hompes, T. And Foulon, V. (2020), "Mental Health Status Of Pregnant And Breastfeeding Women During The Covid-19 Pandemic: A Call For Action", *International Journal Of Gynaecology And Obstetrics: The Official Organ Of The International Federation Of Gynaecology And Obstetrics*, 151(1), Pp. 146–147.

Chang, H.-Y., Jensen, M.P., Yang, Y.-L., Lee, C.-N. And Lai, Y.-H. (2012), "Risk Factors Of Pregnancy-Related Lumbopelvic Pain: A Biopsychosocial Approach", *Journal Of Clinical Nursing*, 21(9-10), Pp. 1274–1283.

Chan, K.L. And Chen, M. (2019), "Effects Of Social Media And Mobile Health Apps On Pregnancy Care: Meta-Analysis", *Jmir Mhealth And Uhealth*, 7(1), P. E11836. [Online] [Accessed October 2021] Available at: doi: 10.2196/11836

Chartered Society Of Physiotherapy (Great Britain). (2012), *Quality Assurance Standards For Physiotherapy Service Delivery*, Edited By Chartered Society Of Physiotherapy. London. CSP, Available At: Https://Play.Google.Com/Store/Books/Details?Id=Uj1daqaacaaj.

Chavez, C. (2015), "Conceptualizing From The Inside: Advantages, Complications, And Demands On Insider Positionality", *The Qualitative Report* 13, Pp. 474-494, Available at: Https://Doi.Org/10.46743/2160-3715/2008.1589.

Chen, L.-Y. A. and Fawcett, T. N. (2019). Service evaluation: A grey area of research? *Nursing ethics*, 26 (4), pp.1172–1185. [Online]. Available at: doi:10.1177/0969733017742961.

Chen, M., Wu, T., Lv, M., Chen, C., Fang, Z., Zeng, Z., Qian, J., *Et Al.* (2021), "Efficacy Of Mobile Health In Patients With Low Back Pain: Systematic Review And Meta-Analysis Of Randomized Controlled Trials", *Jmir Mhealth And Uhealth*, 9(6), P. E26095. [Online] [Accessed December 2021] Available at: DOI: 10.2196/26095

Cherni, Y., Desseauve, D., Decatoire, A., Veit-Rubinc, N., Begon, M., Pierre, F. And Fradet, L. (2019), "Evaluation Of Ligament Laxity During Pregnancy", *Journal Of Gynecology Obstetrics And Human Reproduction*, 48(5), Pp. 351–357.

Cherryholmes, C.H. (1992), "Notes On Pragmatism And Scientific Realism", *Educational Researcher* , American Educational Research Association, 21(6), Pp. 13–17.

Chhabra, H.S., Sharma, S. and Verma, S. (2018) 'Smartphone app in self-management of chronic low back pain: a randomized controlled trial', European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society, 27(11), pp. 2862–2874. doi:10.1007/s00586-018-5788-5.

Chiarotto, A., Boers, M., Deyo, R.A., Buchbinder, R., Corbin, T.P., Costa, L.O.P., Foster, N.E., *Et Al.* (2018), "Core Outcome Measurement Instruments For Clinical Trials In Nonspecific Low Back Pain", *Pain*, 159(3), Pp. 481–495.

Chiauzzi, E., Pujol, L.A., Wood, M., Bond, K., Black, R., Yiu, E. And Zacharoff, K. (2010), "Painaction-Back Pain: A Self-Management Website For People With Chronic Back Pain", *Pain Medicine* , 11(7), Pp. 1044–1058.

Chu, J.T., Wang, M.P., Shen, C., Viswanath, K., Lam, T.H. And Chan, S.S.C. (2017), "How, When And Why People Seek Health Information Online: Qualitative Study In Hong Kong", *Interactive Journal Of Medical Research*, 6(2), P. E24. [Online] [Accessed September 2019] Available at: doi: 10.2196/ijmr.7000

Clarkson, C.E. And Adams, N. (2018), "A Qualitative Exploration Of The Views And Experiences Of Women With Pregnancy Related Pelvic Girdle Pain", *Physiotherapy*, 104(3), Pp. 338–346.

Close, C., Sinclair, M., Liddle, D., Mc Cullough, J. And Hughes, C. (2016), "Women's Experience Of Low Back And/Or Pelvic Pain (Lbpp) During Pregnancy", *Midwifery*, 37, Pp. 1–8.

Cole-Lewis, H., Ezeanochie, N. And Turgiss, J. (2019), "Understanding Health Behavior Technology Engagement: Pathway To Measuring Digital Behavior Change Interventions", *Jmir Formative Research*, 3(4), P. E14052. [Online] [Accessed November 2021] Available at: doi: 10.2196/14052

Collins, C. and Rochfort, A. (2016) 'Promoting Self-Management and Patient Empowerment in Primary Care', in Capelli, O. (ed.) *Primary Care in Practice - Integration is Needed*. London: IntechOpen, pp. 27–42. doi:10.5772/62763.

Corps, D. (2020), "Births In England And Wales - Office For National Statistics", Hampshire. Office For National Statistics, 21 July, Available At: Https://Www.Ons.Gov.Uk/Peoplepopulationandcommunity/Birthsdeathsandmarriages/Livebirths/Bulletins/Birthsummarytablesenglandandwales/2019 (Accessed 14 September 2021).

Cowie, J., Nicoll, A., Dimova, E. D., Campbell, P., & Duncan, E. A. (2020). The barriers and facilitators influencing the sustainability of hospital-based interventions: a systematic review. *BMC Health Services Research*, *20*(1), Pp588. https://doi.org/10.1186/s12913-020-05434-9

Coxon, K., Turienzo, C.F., Kweekel, L., Goodarzi, B., Brigante, L., Simon, A. And Lanau, M.M. (2020), "The Impact Of The Coronavirus (Covid-19) Pandemic On Maternity Care In Europe", *Midwifery*, 88(102779), P. 102779. [Online] [Accessed January 2022] Available at: doi: 10.1016/j.midw.2020.102779

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., Petticrew, M. And Medical Research Council Guidance. (2008), "Developing And Evaluating Complex Interventions: The New Medical Research Council Guidance", *BMJ* , 337, P. A1655. [Online] [Accessed January 2019] doi: https://doi.org/10.1136/bmj.a1655

Craig, P. and Petticrew, M. (2013) 'Developing and evaluating complex interventions: reflections on the 2008 MRC guidance', International journal of nursing studies, 50(5), pp. 585–587. doi:10.1016/j.ijnurstu.2012.09.009.

Creswell, J. W. (2016) 'Reflections on the MMIRA The Future of Mixed Methods Task Force Report', *Journal of Mixed Methods Research*, 10(3), pp. 215–219. doi: 10.1177/1558689816650298.

Creswell, J.W. (2007), *Qualitative Inquiry And Research Design: Choosing Among Five Approaches*. London. SAGE Publications

Creswell, J.W. (2014), *Qualitative, Quantitative And Mixed Methods Approaches*. London. Sage Publications. Available At: Http://155.0.32.9:8080/Jspui/Bitstream/123456789/1091/1/Qualitative%2c%20quantitative%2c%20and%20mixed%20methods%20approaches%20%28%20pdfdrive%20%29-1.Pdf.

Creswell, J.W. (2021), *A Concise Introduction To Mixed Methods Research*, London. Sage Publications, Available At: Https://Pdfs.Semanticscholar.Org/B5d5/3119476db7c9336038ef760715946f7b5b2f.Pdf.

Creswell, J.W. And Clark, V.L.P. (2017), *Designing And Conducting Mixed Methods Research*, London. Sage Publications, Available At: Https://Doc1.Bibliothek.Li/Acd/Flmf050277.Pdf.

Creswell, J.W. And David Creswell, J. (2018), *Research Design: Qualitative, Quantitative, And Mixed Methods Approaches*. London. Sage Publications.

Creswell, J.W. And Plano Clark, V.L. (2017), *Designing And Conducting Mixed Methods Research*. London. Sage Publications.

Creswell, J.W., Plano Clark, V.L., Gutmann, M.L. And Hanson, W.E. (2003), "An Expanded Typology For Classifying Mixed Methods Research Into Designs", In: *Tashakkori, A.Teddlie, Y.C. Handbook Of Mixed Methods In Social And Behavioral Research*, Pp. 209–240.

Creswell, J. W. and Poth, C. N. (2022). *Qualitative Inquiry and Research Design*. [Online]. Available at: https://us.sagepub.com/en-us/nam/qualitative-inquiry-and-research-design/book246896 [Accessed 19 August 2022].

Croasmun, J.T.O. (2011) 'Using Likert-Type Scales in the Social Sciences', Journal of Adult Education; Brigham City volume, pp. 19–22. Available at: https://www.proquest.com/docview/1018567864.

Cucciniello, M., Petracca, F., Ciani, O., & Tarricone, R. (2021). Development features and study characteristics of mobile health apps in the management of chronic conditions: a systematic review of randomised trials. *NPJ Digital Medicine*, *4*(1), Pp. 144. https://doi.org/10.1038/s41746-021-00517-1

D'alfonso, S., Lederman, R., Bucci, S. And Berry, K. (2020), "The Digital Therapeutic Alliance And Human-Computer Interaction", *JMIR Mental Health*, 7(12), Pp. E21895. [Online] [Accessed December 2021] doi: 10.2196/21895

Daly, L.M., Horey, D., Middleton, P.F., Boyle, F.M. And Flenady, V. (2018), "The Effect Of Mobile App Interventions On Influencing Healthy Maternal Behavior And Improving Perinatal Health Outcomes: Systematic Review", *JMIR Mhealth And Uhealth*, 6(8), P. E10012. [Online] [Accessed October 2021] DOI: 10.2196/10012

Damen, L., Buyruk, H.M., Güler-Uysal, F., Lotgering, F.K., Snijders, C.J. And Stam, H.J. (2001), "Pelvic Pain During Pregnancy Is Associated With Asymmetric Laxity Of The Sacroiliac Joints", *Acta Obstetricia Et Gynecologica Scandinavica*, 80(11), Pp. 1019–1024.

Daneau, C. *et al.* (2021) 'Mechanisms Underlying Lumbopelvic Pain During Pregnancy: A Proposed Model', *Frontiers in pain research (Lausanne, Switzerland)*, 2, p. 773988. doi:10.3389/fpain.2021.773988.

Daniel, B. K. (2019). Using the TACT Framework to Learn the Principles of Rigour in Qualitative Research. *Electronic Journal of Business Research Methods*, 17 (3),

pp.118-129–pp118-129. [Online]. Available at: doi:10.34190/JBRM.17.3.002 [Accessed 20 August 2022]

Davenport, M.H., Marchand, A.-A., Mottola, M.F., Poitras, V.J., Gray, C.E., Jaramillo Garcia, A., Barrowman, N., *Et Al.* (2019), "Exercise For The Prevention And Treatment Of Low Back, Pelvic Girdle And Lumbopelvic Pain During Pregnancy: A Systematic Review And Meta-Analysis", *British Journal Of Sports Medicine*, Bmj Publishing Group, England, 53(2), Pp. 90–98.

Davies, A. and Mueller, J. *Developing Medical Apps and mHealth Interventions*. Springer International Publishing. [Online]. Available at: doi:10.1007/978-3-030-47499-7 [Accessed 22 September 2022].

Deci, E.L. And Ryan, R.M. (2012), "Self-Determination Theory", In Higgins, E. (Ed.), *Handbook Of Theories Of Social Psychology,* Washington. Psycnet.Apa.Org, Pp. 416–436.

Daniel, B. K. (2019). Using the TACT Framework to Learn the Principles of Rigour in Qualitative Research. *Electronic Journal of Business Research Methods*, 17 (3), pp.118-129–pp118-129. [Online]. Available at: doi:10.34190/JBRM.17.3.002 [Accessed 20 August 2022].

Degerstedt, Å., Alinaghizadeh, H., Thorstensson, C.A. And Olsson, C.B. (2020), "High Self-Efficacy - A Predictor Of Reduced Pain And Higher Levels Of Physical Activity Among Patients With Osteoarthritis: An Observational Study", *Bmc Musculoskeletal Disorders*, 21(1), Pp. 380.

Dehzad, F. , Hilhorst, C. , de Bie, C. and Claassen, E. (2014) Adopting Health Apps, What's Hindering Doctors and Patients?. *Health*, 6, Pp2204-2217. doi: 10.4236/health.2014.616256.

de Jong, Y., van der Willik, EM., Milders, J., Voorend, CGN., Morton, RL., Dekker, FW., Mueleman, Y., and van Diepen, M. (2021). A meta-review demonstrates improved reporting quality of qualitative reviews following the publication of COREQ- and ENTREQ-checklists, regardless of modest uptake. *BMC medical research methodology*, 21 (1), p.184. [Online]. Available at: doi:10.1186/s12874-021-01363-1.

Dekker, R. L., King, S., & Lester, K. (2016). Social Media and Evidence-Based Maternity Care: A Cross-Sectional Survey Study. *The Journal of Perinatal Education*, *25*(2), Pp105–115. https://doi.org/10.1891/1058-1243.25.2.105

Del Pozo-Cruz, B., Adsuar, J.C., Parraca, J., Del Pozo-Cruz, J., Moreno, A. And Gusi, N. (2012), "A Web-Based Intervention To Improve And Prevent Low Back Pain Among Office Workers: A Randomized Controlled Trial", *The Journal Of Orthopaedic And Sports Physical Therapy*, 42(10), Pp. 831–841.

Denzin, N.K. (2010), "Moments, Mixed Methods, And Paradigm Dialogs", *Qualitative Inquiry: Qi*, 16(6), Pp. 419–427.

Department For Education. (2015), *Supporting The Attainment Of Disadvantaged Pupils: Articulating Success And Good Practice Research Brief*, No. 2015, London. Department For Education, Available At: Https://Assets.Publishing.Service.Gov.Uk/Government/Uploads/System/Uploads/Attachment_Data/File/473975/Dfe-Rb411_Supporting_The_Attainment_Of_Disadvantaged_Pupils_Brief.Pdf.

Deshields, T.L., Tait, R.C., Gfeller, J.D. And Chibnall, J.T. (1995), "Relationship Between Social Desirability And Self-Report", *The Clinical Journal Of Pain*, 11(11), Pp. 189–193.

Devan, H., Farmery, D., Peebles, L. And Grainger, R. (2019), "Evaluation Of Self-Management Support Functions In Apps For People With Persistent Pain: Systematic Review", *Jmir Mhealth And Uhealth*, 7(2), P. E13080. [Online] [Accessed November 2021] doi: 10.2196/13080

Dickson, G. and McDonough, S.M. (2019) *Section 10, chapter 3: Self-management of Low back pain*, *Wheeless' Textbook of Orthopaedics [Online]*. Available at: https://www.wheelessonline.com/issls/section-10-chapter-3-self-management-of-low-back-pain/ (Accessed: 27 February 2022).

Dickson, J. And Macleod, A. (2004), "Brief Report Anxiety, Depression And Approach And Avoidance Goals", *Cognition And Emotion*, 18(3), Pp. 423–430.

Dodgson, J. E. (2019) 'Reflexivity in Qualitative Research', *Journal of Human Lactation*, 35(2), pp. 220–222. doi: 10.1177/0890334419830990.

Doğru, H.Y., Özsoy, F., Doğru, S., Karaman, T., Şahin, A., Özsoy, A.Z., Çakmak, B., *Et Al.* (2018), "Catastrophizing, Depression And Anxiety During Pregnancy: Relation Between Lumbopelvic Pain And Physical/Social Functioning", *Journal Of Rational-Emotive And Cognitive-Behavior Therapy: Ret*, 36(2), Pp. 119–136.

Dorflinger, L., Kerns, R.D. And Auerbach, S.M. (2013), "Providers' Roles In Enhancing Patients' Adherence To Pain Self Management", *Translational Behavioral Medicine*, 3(1), Pp. 39–46.

Dove, E. and Laurie, G. (2019) 'Response to: Anonymising and sharing individual patient data' *BMJ* 350, Pp H1139 [Online] Available from: https://www.bmj.com/content/350/bmj.h1139/rr

Drabble, L., Trocki, K.F., Salcedo, B., Walker, P.C. And Korcha, R.A. (2016), "Conducting Qualitative Interviews By Telephone: Lessons Learned From A Study Of Alcohol Use Among Sexual Minority And Heterosexual Women", *Qualitative Social Work : Qsw : Research And Practice*, 15(1), Pp. 118–133.

Druce, K.L., Dixon, W.G. And Mcbeth, J. (2019), "Maximizing Engagement In Mobile Health Studies: Lessons Learned And Future Directions", *Rheumatic Diseases Clinics Of North America*, 45(2), Pp. 159–172.

Du, S., Hu, L., Dong, J., Xu, G., Chen, X., Jin, S., Zhang, H., *Et Al.* (2017), "Self-Management Program For Chronic Low Back Pain: A Systematic Review And Meta-Analysis", *Patient Education And Counseling*, 100(1), Pp. 37–49.

Du, S., Liu, W., Cai, S., Hu, Y. And Dong, J. (2020), "The Efficacy Of E-Health In The Self-Management Of Chronic Low Back Pain: A Meta Analysis", *International Journal Of Nursing Studies*, 106, Pp. 103507. [Online] [Accessed September 2021] DOI: 10.1016/j.ijnurstu.2019.103507

Dwyer, S.C. And Buckle, J.L. (2009), "The Space Between: On Being An Insider-Outsider In Qualitative Research", *International Journal Of Qualitative Methods*, 8(1), Pp. 54–63.

East Sussex NHS Trust. (2021), *Pelvic Health Physiotherapy Antenatal Advice For Women Experiencing Back Or Pelvic Pain*, East Sussex. East Sussex NHS Trust, Available At: Https://Www.Esht.Nhs.Uk/Wp-Content/Uploads/2020/07/0832.Pdf.

Edney, S., Ryan, J.C., Olds, T., Monroe, C., Fraysse, F., Vandelanotte, C., Plotnikoff, R., *Et Al.* (2019), "User Engagement And Attrition In An App-Based Physical Activity Intervention: Secondary Analysis Of A Randomized Controlled Trial", *Journal Of Medical Internet Research*, 21(11), Pp. E14645. [Online] [Accessed September 2020] doi: 10.2196/14645

Elden, H., Gutke, A., Kjellby-Wendt, G., Fagevik-Olsen, M. And Ostgaard, H.-C. (2016), "Predictors And Consequences Of Long-Term Pregnancy-Related Pelvic Girdle Pain: A Longitudinal Follow-Up Study", *BMC Musculoskeletal Disorders*, 17, Pp. 276.

Elden, H., Lundgren, I. And Robertson, E. (2014), "The Pelvic Ring Of Pain: Pregnant Women's Experiences Of Severe Pelvic Girdle Pain: An Interview Study", *Clinical Nursing Studies*, 2(2), Pp. 30.

Eldridge, S.M., Lancaster, G.A., Campbell, M.J., Thabane, L., Hopewell, S., Coleman, C.L. and Bond, C.M. (2016), "Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework", *PloS One*, 11(3), Pp. e0150205. [Online] [Accessed June 2020] doi.org/10.1371/journal.pone.0150205

Engeset, J., Stuge, B. And Fegran, L. (2014), "Pelvic Girdle Pain Affects The Whole Life--A Qualitative Interview Study In Norway On Women's Experiences With Pelvic Girdle Pain After Delivery", *BMC Research Notes*, 7, Pp. 686.

Epton, T., Currie, S. And Armitage, C.J. (2017), "Unique Effects Of Setting Goals On Behavior Change: Systematic Review And Meta-Analysis", *Journal Of Consulting And Clinical Psychology*, 85(12), Pp. 1182–1198.

Escriche-Escuder, A. et al. (2020) 'Assessment of the Quality of Mobile Applications (Apps) for Management of Low Back Pain Using the Mobile App Rating Scale

(MARS)', International journal of environmental research and public health, 17(24). doi:10.3390/ijerph17249209.

Faller, H., Koch, U., Brähler, E., Härter, M., Keller, M., Schulz, H., Wegscheider, K., Weis, J., Boehncke, A., Hund, B., Reuter, K., Richard, M., Sehner, S., Szalai, C., Wittchen, H.-U., & Mehnert, A. (2016). Satisfaction with information and unmet information needs in men and women with cancer. *Journal of Cancer Survivorship: Research and Practice*, *10*(1), Pp. 62–70. https://doi.org/10.1007/s11764-015-0451-1

Fang, M.L., Canham, S.L., Battersby, L., Sixsmith, J., Wada, M. and Sixsmith, A. (2019), "Exploring Privilege in the Digital Divide: Implications for Theory, Policy, and Practice", *The Gerontologist*, academic.oup.com, 59(1), pp. e1–e15.

Fatmarizka, T., Ramadanty, R.S. And Khasanah, D.A. (2021), "Pregnancy-Related Low Back Pain And The Quality Of Life Among Pregnant Women : A Narrative Literature Review", *Journal Of Public Health For Tropical And Coastal Region*, Public Health Faculty, Diponegoro University, Semarang, Indonesia, 4(3), Pp. 108–116.

Fawcett, E.J. *et al.* (2019) 'The Prevalence of Anxiety Disorders During Pregnancy and the Postpartum Period: A Multivariate Bayesian Meta-Analysis', *The Journal of clinical psychiatry*, 80(4). doi:10.4088/JCP.18r12527.

Feilzer, M. (2010), "Doing Mixed Methods Research Pragmatically: Implications For The Rediscovery Of Pragmatism As A Research Paradigm", Journal Of Mixed Methods Research, Sage Publications, 4(1), Pp. 6–16.

Fishburn, S., & Cooper, T. (2015). Pelvic girdle pain: Are we missing opportunities to make this a problem of the past? *British Journal of Midwifery*, *23*(11), Pp. 774–778. https://doi.org/10.12968/bjom.2015.23.11.774

Flaherty, S.J., Mccarthy, M.B., Collins, A.M. And Mcauliffe, F.M. (2019), "A Different Perspective On Consumer Engagement: Exploring The Experience Of Using Health Apps To Support Healthier Food Purchasing", *Journal Of Marketing Management*, 35(3-4), Pp. 310–337.

Fleming, T. *et al.* (2018) 'Beyond the Trial: Systematic Review of Real-World Uptake and Engagement With Digital Self-Help Interventions for Depression, Low Mood, or Anxiety', *Journal of medical Internet research*, 20(6), p. e199. doi:10.2196/jmir.9275.

Fletcher, A., Jamal, F., Moore, G., Evans, R.E., Murphy, S. and Bonell, C. (2016), "Realist complex intervention science: Applying realist principles across all phases of the Medical Research Council framework for developing and evaluating complex interventions", *Evaluation* , 22(3), pp. 286–303.

Fredriksen, E.H., Harris, J., Moland, K.M. And Sundby, J. (2014), "'They Ask Whether This Is Real Or Fake': A Qualitative Norwegian Study Of Pregnancy Complaints And Access To Social Benefits", *Health Care For Women International*, 35(3), Pp. 266–284.

Fredriksen, E.H., Moland, K.M. And Sundby, J. (2008), "'Listen To Your Body'. A Qualitative Text Analysis Of Internet Discussions Related To Pregnancy Health And Pelvic Girdle Pain In Pregnancy", *Patient Education And Counseling*, 73(2), Pp. 294–299.

Freeman, T. (2006), "'Best Practice' In Focus Group Research: Making Sense Of Different Views", *Journal Of Advanced Nursing*, 56(5), Pp. 491–497.

Freyne, J., Yin, J., Brindal, E., Hendrie, G.A., Berkovsky, S. And Noakes, M. (2017), "Push Notifications In Diet Apps: Influencing Engagement Times And Tasks", *International Journal Of Human–Computer Interaction*, Taylor & Francis, 33(10), Pp. 833–845.

Fukano, M., Tsukahara, Y., Takei, S., Nose-Ogura, S., Fujii, T. And Torii, S. (2021), "Recovery Of Abdominal Muscle Thickness And Contractile Function In Women After Childbirth", 18(4), [Online] [Accessed January 2022] Available at: Https://Doi.Org/10.3390/Ijerph18042130.

Fulton, E.A., Kwah, K.L., Wild, S. And Brown, K.E. (2018), "Lost In Translation: Transforming Behaviour Change Techniques Into Engaging Digital Content And Design For The Stopapp", *Healthcare (Basel, Switzerland)*, 6(3), [Online] [Accessed September 2021] Available At: Https://Doi.Org/10.3390/Healthcare6030075.

Furber, C. (2010), "Framework Analysis: A Method For Analysing Qualitative Data", *African Journal Of Midwifery And Women's Health*, Mark Allen Group, 4(2), Pp. 97–100.

Gagnon, M.-P., Ngangue, P., Payne-Gagnon, J., & Desmartis, M. (2016). m-Health adoption by healthcare professionals: a systematic review. *Journal of the American Medical Informatics Association: JAMIA*, *23*(1), Pp212–220. https://doi.org/10.1093/jamia/ocv052

Gardner, T., Refshauge, K., Mcauley, J., Hübscher, M., Goodall, S. And Smith, L. (2019), "Combined Education And Patient-Led Goal Setting Intervention Reduced Chronic Low Back Pain Disability And Intensity At 12 Months: A Randomised Controlled Trial", *British Journal Of Sports Medicine*, 53(22), Pp. 1424–1431.

Garg, S., Garg, D., Turin, T.C. And Chowdhury, M.F.U. (2016), "Web-Based Interventions For Chronic Back Pain: A Systematic Review", *Journal Of Medical Internet Research*, 18(7), P. E139. [Online] [Accessed May 2019] DOI: 10.2196/jmir.4932

Gausel, A.M., Malmqvist, S., Andersen, K., Kjærmann, I., Larsen, J.P., Dalen, I. And Økland, I. (2020), "Subjective Recovery From Pregnancy-Related Pelvic Girdle Pain

The First 6 Weeks After Delivery: A Prospective Longitudinal Cohort Study", *European Spine Journal: Official Publication Of The European Spine Society, The European Spinal Deformity Society, And The European Section Of The Cervical Spine Research Society*, 29(3), Pp. 556–563.

Geerligs, L., Rankin, N. M., Shepherd, H. L., & Butow, P. (2018). Hospital-based interventions: a systematic review of staff-reported barriers and facilitators to implementation processes. *Implementation Science: IS*, *13*(1), Pp36. https://doi.org/10.1186/s13012-018-0726-9

Geraghty, A.W.A., Stanford, R., Stuart, B., Little, P., Roberts, L.C., Foster, N.E., Hill, J.C., *Et Al.* (2018), "Using An Internet Intervention To Support Self-Management Of Low Back Pain In Primary Care: Findings From A Randomised Controlled Feasibility Trial (Supportback)", *BMJ Open*, 8(3), P. E016768. [Online] [Accessed May 2021] DOI: 10.1136/bmjopen-2017-016768

Gilleard, W.L. And Brown, J.M. (1996), "Structure And Function Of The Abdominal Muscles In Primigravid Subjects During Pregnancy And The Immediate Postbirth Period", *Physical Therapy*, 76(7), Pp. 750–762.

Gleeson, D.M., Craswell, A. And Jones, C.M. (2019), "Women's Use Of Social Networking Sites Related To Childbearing: An Integrative Review", *Women And Birth: Journal Of The Australian College Of Midwives*, 32(4), Pp. 294–302.

Goyal, S., Morita, P.P., Picton, P., Seto, E., Zbib, A. And Cafazzo, J.A. (2016), "Uptake Of A Consumer-Focused Mhealth Application For The Assessment And Prevention Of Heart Disease: The <30 Days Study", *Jmir Mhealth And Uhealth*, 4(1), P. E32. [Online] [Accessed December 2021] doi: 10.2196/mhealth.4730

Grant, M.J. And Booth, A. (2009), "A Typology Of Reviews: An Analysis Of 14 Review Types And Associated Methodologies", *Health Information And Libraries Journal*, 26 (2), Pp. 91–108.

Greene, J.C., Caracelli, V.J. And Graham, W.F. (1989), "Toward A Conceptual Framework For Mixed-Method Evaluation Designs", *Educational Evaluation And Policy Analysis*, American Educational Research Association, 11(3), Pp. 255–274.

Green, J. And Thorogood, N. (2004), *Qualitative Methods For Health Research*, London. Sage.

Guba, E.G., Lincoln, Y.S. And Others. (1994), "Competing Paradigms In Qualitative Research", *Handbook Of Qualitative Research*, California. Sage Publications. Vol. 2 No. 163-194.

Gutke, A. Boissonnault, J. Brook, G., And Stuge, B. (2018) 'The Severity and Impact of Pelvic Girdle Pain and Low-Back Pain in Pregnancy: A Multinational Study', *Journal of women's health*, 27(4), pp. 510–517. doi:10.1089/jwh.2017.6342.

Gutke, A., Betten, C., Degerskär, K., Pousette, S. And Olsén, M.F. (2015), "Treatments For Pregnancy-Related Lumbopelvic Pain: A Systematic Review Of Physiotherapy Modalities", *Acta Obstetricia Et Gynecologica Scandinavica*, 94(11), Pp. 1156–1167.

Gutke, A., Ostgaard, H.C. And Oberg, B. (2006), "Pelvic Girdle Pain And Lumbar Pain In Pregnancy: A Cohort Study Of The Consequences In Terms Of Health And Functioning", *Spine*, 31(5), Pp. E149–55.

Gwaltney, C.J., Shields, A.L. And Shiffman, S. (2008), "Equivalence Of Electronic And Paper-And-Pencil Administration Of Patient-Reported Outcome Measures: A Meta-Analytic Review", *Value In Health: The Journal Of The International Society For Pharmacoeconomics And Outcomes Research*, 11(2), Pp. 322–333.

Haack, S. (2004) 'Pragmatism, Old and New', *Contemporary Pragmatism*, 1(1), pp. 3–41. doi:10.1163/18758185-90000126.

Hall, H.R. And Roussel, L.A. (2020), *Evidence-Based Practice: An Integrative Approach To Research, Administration, And Practice*, Burlington, MA. Jones & Bartlett Learning. Available from: 9781284098754_FMxx_i_xxxii.pdf (jblearning.com)

Hämeen-Anttila, K., Nordeng, H., Kokki, E., Jyrkkä, J., Lupattelli, A., Vainio, K., & Enlund, H. (2014). Multiple information sources and consequences of conflicting information about medicine use during pregnancy: a multinational Internet-based survey. *Journal of Medical Internet Research*, *16*(2), Pp e60. [Online] [Accessed February 2022] Available at: https://doi.org/10.2196/jmir.2939

Hawker, G.A. et al. (2011) 'Measures of adult pain: Visual analog scale for pain (VAS pain), numeric rating scale for pain (NRS pain), McGill pain questionnaire (MPQ), short-form McGill pain questionnaire (SF-MPQ), chronic pain grade scale (CPGS), short form-36 bodily pain scale (SF-36 BPS), and measure of intermittent and constant osteoarthritis pain (ICOAP)', Arthritis care & research, 63 Suppl 11(S11), pp. S240–52. doi:10.1002/acr.20543.

Hawkins, J., Madden, K., Fletcher, A., Midgley, L., Grant, A., Cox, G., Moore, L., *Et Al.* (2017), "Development Of A Framework For The Co-Production And Prototyping Of Public Health Interventions", *BMC Public Health*, 17(1), Pp. 689.

Haywood, K.L. (2007), "Patient-Reported Outcome Ii: Selecting Appropriate Measures For Musculoskeletal Care", *Musculoskeletal Care*, Wiley, 5(2), Pp. 72–90.

Health Education England on behalf of the Secretary of State for Health and Social Care. (2019), *The Topol Review Preparing the Healthcare Workforce to Deliver the Digital Future*, Liverpool. Health Education England. available at: https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-2019.pdf.

Health Research Authority (2021)[Online] 'What approvals and decisions do I need?' https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/ Date accessed: 30th November 2021

Health Research Authority (2022a) *Guidance for using patient data* [Online] [Accessed August 2022] Available from: https://www.hra.nhs.uk/covid-19-research/guidance-using-patient-data/#research

Health Research Authority (2022b) *Confidentiality Advisory Group* [Online] [Accessed August 2022] Available from: https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/confidentiality-advisory-group/

Heapy, A.A., Higgins, D.M., Goulet, J.L., Lachappelle, K.M., Driscoll, M.A., Czlapinski, R.A., Buta, E., *Et Al.* (2017), "Interactive Voice Response-Based Self-Management For Chronic Back Pain: The Copes Noninferiority Randomized Trial", *Jama Internal Medicine*, 177(6), Pp. 765–773.

Hensher, M., Cooper, P., Dona, S.W.A., Angeles, M.R., Nguyen, D., Heynsbergh, N., Chatterton, M.L., et al. (2021), "Scoping review: Development and assessment of evaluation frameworks of mobile health apps for recommendations to consumers", *Journal of the American Medical Informatics Association: JAMIA,* 28(6), pp. 1318–1329.

Hernandez-Reyes, A., Camara-Martos, F., Molina Recio, G., Molina-Luque, R., Romero-Saldana, M. And Moreno Rojas, R. (2020), "Push Notifications From A Mobile App To Improve The Body Composition Of Overweight Or Obese Women: Randomized Controlled Trial", *JMIR Mhealth And Uhealth*, 8(2), P. E13747-. [Online] [Accessed December 2021] DOI: 10.2196/13747

Hesse-Biber, S. (2015), "Mixed Methods Research: The 'Thing-Ness' Problem", *Qualitative Health Research*, 25(6), Pp. 775–788.

Hesse-Biber, S.N. And Burke Johnson, R. (2015), *The Oxford Handbook Of Multimethod And Mixed Methods Research Inquiry*, Oxford. Oxford University Press.

Hewitt, S., Sephton, R. And Yeowell, G. (2020), "The Effectiveness Of Digital Health Interventions In The Management Of Musculoskeletal Conditions: Systematic Literature Review", *Journal Of Medical Internet Research*, Journal Of Medical Internet Research, 22(6), P. E15617. [Online] [Accessed May 2021] DOI: 10.2196/15617

Hickman, L.A., Neubert, S. And Reich, K. (2009), *John Dewey Between Pragmatism And Constructivism*, New York. Fordham University Press

Higgins, J.P.T., Thomas, J., Chandler, J., Cumpston, M., Li, T., Page, M.J. And Welch, V.A. (2019), *Cochrane Handbook For Systematic Reviews Of Interventions*, New Jersey. John Wiley & Sons.

Hillyard, M., Sinclair, M., Murphy, M., Casson, K. And Mulligan, C. (2021), "The Impact Of Covid-19 On The Physical Activity And Sedentary Behaviour Levels Of Pregnant Women With Gestational Diabetes", *Plos One*, 16(8), Pp. E0254364. [Online] [Accessed January 2022] doi.org/10.1371/journal.pone.0254364

Hodges, P.W. And Richardson, C.A. (1999), "Altered Trunk Muscle Recruitment In People With Low Back Pain With Upper Limb Movement At Different Speeds", *Archives Of Physical Medicine And Rehabilitation*, 80(9), Pp. 1005–1012.

Hoffmann, T.C. *et al.* (2014) 'Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide', *BMJ* , 348. doi:10.1136/bmj.g1687. Available from: https://www.bmj.com/content/348/bmj.g1687

Holmes, A.G.D. (2020) 'Researcher Positionality - A Consideration of Its Influence and Place in Qualitative Research - A New Researcher Guide', Shanlax International Journal of Education, 8(4), pp. 1–10. doi:10.34293/education.v8i4.3232.

Hou, J., Yang, R., Yang, Y., Tang, Y., Deng, H., Chen, Z., Wu, Y., *Et Al.* (2019), "The Effectiveness And Safety Of Utilizing Mobile Phone-Based Programs For Rehabilitation After Lumbar Spinal Surgery: Multicenter, Prospective Randomized Controlled Trial", *JMIR Mhealth And Uhealth*, 7(2), Pp. E10201. [Online] [Accessed May 2021] doi: 10.2196/10201

Hughson, J.-A.P., Daly, J.O., Woodward-Kron, R., Hajek, J. And Story, D. (2018), "The Rise Of Pregnancy Apps And The Implications For Culturally And Linguistically Diverse Women: Narrative Review", *JMIR Mhealth And Uhealth*, 6 (11), P. E189. [Online] [Accessed June 2021] Available at: https://mhealth.jmir.org/2018/11/e189/PDF

Hungerford, B., Gilleard, W. And Hodges, P. (2003), "Evidence Of Altered Lumbopelvic Muscle Recruitment In The Presence Of Sacroiliac Joint Pain", *Spine*, 28(14), Pp. 1593–1600.

Hussain, T., Smith, P. And Yee, L.M. (2020), "Mobile Phone-Based Behavioral Interventions In Pregnancy To Promote Maternal And Fetal Health In High-Income Countries: Systematic Review", *JMIR Mhealth And Uhealth*, 8(5), P. E15111. [Online] [Accessed May 2021] doi: 10.2196/15111

Hutting, N., Johnston, V., Staal, J.B. And Heerkens, Y.F. (2019), "Promoting The Use Of Self-Management Strategies For People With Persistent Musculoskeletal Disorders: The Role Of Physical Therapists", *The Journal Of Orthopaedic And Sports Physical Therapy*, 49(4), Pp. 212–215.

INCLUDE "Improving Inclusion Of Under-Served Groups In Clinical Research: Guidance From Include Project". [Online] , Available At: Http://Www.Nihr.Ac.Uk/Documents/Improving-Inclusion-Of-Under-Served-

Groups-In-Clinical-Research-Guidance-From-Include-Project/25435 (Accessed 2 February 2022).

Information Commissioner's Office (2021) *Introduction to anonymisation: Draft anonymisation, pseudonymisation and privacy enhancing technologies guidance* [Online] [Accessed November 2021] Available from: https://ico.org.uk/media/about-the-ico/consultations/2619862/anonymisation-intro-and-first-chapter.pdf

Information Commissioner's Office (2022) *Guide to the UK General Data Protection Regulation (UK GDPR)* [Online] [Accessed August 2022] Available from: https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/

Involve. (2012), *Payment For Involvement*, No. 2011/2012, London. NIHR, Available At: Http://Www.Invo.Org.Uk/Wpcontent/Uploads/2012/11/Involvepayment-Guiderev2012.Pdf.

Irvine, A.B., Russell, H., Manocchia, M., Mino, D.E., Cox Glassen, T., Morgan, R., Gau, J.M., *Et Al.* (2015), "Mobile-Web App To Self-Manage Low Back Pain: Randomized Controlled Trial", *Journal Of Medical Internet Research*, 17(1), P. E1. [Online] [Accessed May 2021] DOI: 10.2196/jmir.3130

Jaeger, P.T., Bertot, J.C., Thompson, K.M., Katz, S.M. and DeCoster, E.J. (2012), "The Intersection of Public Policy and Public Access: Digital Divides, Digital Literacy, Digital Inclusion, and Public Libraries", *Public Library Quarterly*, Routledge, 31(1), pp. 1–20.

Jamnadass, E. Aboumarzouk, O., Kallidonis, P., Emiliani, E., Tailly, T., Hruby, S., Sanguedolce, F., Atis, G., Ozsoy, M., Greco, F., and Somani, B.K. (2018). The role of social media and internet search engines in information provision and dissemination to patients with kidney stone disease: A systematic review from European association of urologists young academic urologists. *Journal of endourology / Endourological Society*, 32 (8), pp.673–684. [Online]. Available at: doi:10.1089/end.2018.0319.

Jiang, X., Ming, W.-K. And You, J.H. (2019), "The Cost-Effectiveness Of Digital Health Interventions On The Management Of Cardiovascular Diseases: Systematic Review", *Journal Of Medical Internet Research*, 21(6), P. E13166. [Online] [Accessed December 2021] doi: 10.2196/13166

Johnson, R.B. And Onwuegbuzie, A.J. (2004), "Mixed Methods Research: A Research Paradigm Whose Time Has Come", *Educational Researcher* , American Educational Research Association, 33(7), Pp. 14–26.

Jonkman, N.H., Schuurmans, M.J., Jaarsma, T., Shortridge-Baggett, L.M., Hoes, A.W. And Trappenburg, J.C.A. (2016), "Self-Management Interventions: Proposal And

Validation Of A New Operational Definition", *Journal Of Clinical Epidemiology*, 80, Pp. 34–42.

Kahneman, D., & Frederick, S. (2005). A Model of Heuristic Judgment. In K. J. Holyoak & R. G. Morrison (Eds.), *The Cambridge handbook of thinking and reasoning* (pp. 267–293). Cambridge. Cambridge University Press.

Kanakaris, N.K., Roberts, C.S. And Giannoudis, P.V. (2011), "Pregnancy-Related Pelvic Girdle Pain: An Update", *BMC Medicine*, 9, Pp. 15.

Kayser, Lars, Christian Nøhr, Pernille Bertelsen, Lars Botin, Sidsel Villumsen, Chris Showell, and Paul Turner. 2018. "Theory and Practice in Digital Behaviour Change: A Matrix Framework for the Co-Production of Digital Services That Engage, Empower and Emancipate Marginalised People Living with Complex and Chronic Conditions" *Informatics* 5(4), Pp 41. https://doi.org/10.3390/informatics5040041

Kazemi, S.-S., Tavafian, S.-S., Hiller, C.E., Hidarnia, A. And Montazeri, A. (2021), "The Effectiveness Of Social Media And In-Person Interventions For Low Back Pain Conditions In Nursing Personnel (Smile)", *Nursing Open*, 8(3), Pp. 1220–1231.

Kenny, R., Fitzgerald, A., Segurado, R. And Dooley, B. (2020), "Is There An App For That? A Cluster Randomised Controlled Trial Of A Mobile App-Based Mental Health Intervention", *Health Informatics Journal*, 26(3), Pp. 1538–1559.

Keogh, A., Tully, M.A., Matthews, J. And Hurley, D.A. (2015), "A Review Of Behaviour Change Theories And Techniques Used In Group Based Self-Management Programmes For Chronic Low Back Pain And Arthritis", *Manual Therapy*, 20(6), Pp. 727–735.

Khorshid, M.R., Afshari, P. And Abedi, P. (2014), "The Effect Of Sms Messaging On The Compliance With Iron Supplementation Among Pregnant Women In Iran: A Randomized Controlled Trial", *Journal Of Telemedicine And Telecare*, 20(4), Pp. 201–206.

Knolle, F., Ronan, L. and Murray, G.K. (2021), "The impact of the COVID-19 pandemic on mental health in the general population: a comparison between Germany and the UK", *BMC Psychology*, 9(1), p. 60.

Kolodko, J. et al. (2021). #LetsUnlitterUK: A demonstration and evaluation of the Behavior Change Wheel methodology. *PloS one*, 16 (11), p.e0259747. [Online]. Available at: doi:10.1371/journal.pone.0259747.

Kongsted, A., Ris, I., Kjaer, P. And Hartvigsen, J. (2021), "Self-Management At The Core Of Back Pain Care: 10 Key Points For Clinicians", *Brazilian Journal Of Physical Therapy*, 25(4), Pp. 396–406.

König, L.M., Attig, C., Franke, T. And Renner, B. (2021), “Barriers To And Facilitators For Using Nutrition Apps: Systematic Review And Conceptual Framework”, *Jmir Mhealth And Uhealth*, 9(6) Pp e20037 [Online] [Accessed November 2021] Available at: Https://Doi.Org/10.2196/20037.

Korstjens, I. And Moser, A. (2017), “Series: Practical Guidance To Qualitative Research. Part 2: Context, Research Questions And Designs”, *The European Journal Of General Practice*, Taylor & Francis, 23(1), Pp. 274–279.

Kovacs, F.M., Garcia, E., Royuela, A., González, L., Abraira, V. And Spanish Back Pain Research Network. (2012), “Prevalence And Factors Associated With Low Back Pain And Pelvic Girdle Pain During Pregnancy: A Multicenter Study Conducted In The Spanish National Health Service”, *Spine*, 37(17), Pp. 1516–1533.

Kraschnewski, J.L., Chuang, C.H., Poole, E.S., Peyton, T., Blubaugh, I., Pauli, J., Feher, A., *Et Al.* (2014), “Paging ‘Dr. Google’: Does Technology Fill The Gap Created By The Prenatal Care Visit Structure? Qualitative Focus Group Study With Pregnant Women”, *Journal Of Medical Internet Research*, 16(6), Pp. E147. [Online] [Accessed June 2020] doi: 10.2196/jmir.3385

Krausova, A. And Vargas-Silva, C. (2013), “London: Census Profile”, London. Migration Observatory, Available At: Https://Migrationobservatory.Ox.Ac.Uk/Wp-Content/Uploads/2016/04/Censusprofile-London.Pdf.

Krein, S.L., Kadri, R., Hughes, M., Kerr, E.A., Piette, J.D., Holleman, R., Kim, H.M., *Et Al.* (2013), “Pedometer-Based Internet-Mediated Intervention For Adults With Chronic Low Back Pain: Randomized Controlled Trial”, *Journal Of Medical Internet Research*, 15(8), P. E181. [Online] [Accessed May 2021] doi: 10.2196/jmir.2605

Kuek, A. And Hakkennes, S. (2020), “Healthcare Staff Digital Literacy Levels And Their Attitudes Towards Information Systems”, *Health Informatics Journal*, 26(1), Pp. 592–612.

Kumar, A. and Nayar, K.R. (2021), “COVID 19 and its mental health consequences”, *Journal of Mental Health* , 30(1) pp. 1–2.

Lalmas, M., O’Brien, H. and Yom-Tov, E. (2014), *Measuring User Engagement*, California. Morgan & Claypool Publishers. pp. 1–132.

Lambert, J. (2011). Statistics in brief: how to assess bias in clinical studies? *Clinical orthopaedics and related research*, 469 (6), pp.1794–1796. [Online]. Available at: doi:10.1007/s11999-010-1538-7.

Lancaster, G.A. (2015), “Pilot and feasibility studies come of age!”, *Pilot and Feasibility Studies*, 1(1), p. 1.

Larsson, M. (2009). ‘A descriptive study of the use of the Internet by women seeking pregnancy-related information’. *Midwifery*, *25*(1), Pp 14–20.

Latham, G.P. And Locke, E.A. (1991), “Self-Regulation Through Goal Setting”, *Organizational Behavior And Human Decision Processes*, 50(2), Pp. 212–247.

Lazard, A.J., Babwah Brennen, J.S. And Belina, S.P. (2021), “App Designs And Interactive Features To Increase Mhealth Adoption: User Expectation Survey And Experiment”, *JMIR Mhealth And Uhealth*, 9(11), Pp. E29815. [Online] [Accessed December 2021] doi: 10.2196/29815

Lebel, C., Mackinnon, A., Bagshawe, M., Tomfohr-Madsen, L. And Giesbrecht, G. (2020), “Elevated Depression And Anxiety Symptoms Among Pregnant Individuals During The Covid-19 Pandemic”, *Journal Of Affective Disorders*, 277, Pp. 5–13.

Lederman, R. And D’alfonso, S. (2021), “The Digital Therapeutic Alliance: Prospects And Considerations”, *JMIR Mental Health*, 8(7), P. E31385. [Online] [Accessed November 2021] doi: 10.2196/31385

Lee, K., Kwon, H., Lee, B., Lee, G., Lee, J.H., Park, Y.R. And Shin, S.-Y. (2018), “Effect Of Self-Monitoring On Long-Term Patient Engagement With Mobile Health Applications”, *Plos One*, 13(7), PP. E0201166. [Online] [Accessed November 2021] doi: 10.1371/journal.pone.0201166

Lee, S.H., Nurmatov, U.B., Nwaru, B.I., Mukherjee, M., Grant, L. And Pagliari, C. (2016), “Effectiveness Of Mhealth Interventions For Maternal, Newborn And Child Health In Low- And Middle-Income Countries: Systematic Review And Meta-Analysis”, *Journal Of Global Health*, International Global Health Society, 6 (1), P. 010401. [Online] [Accessed March 2021] doi: 10.7189/jogh.06.010401

Lewisham Council. (2019), *Joint Strategic Needs Assessment 2019 Lewisham And Greenwich*, No. 2019, Lewisham Council, London.

Licciardone, J.C. And Pandya, V. (2020), “Feasibility Trial Of An Ehealth Intervention For Health-Related Quality Of Life: Implications For Managing Patients With Chronic Pain During The Covid-19 Pandemic”, *Healthcare (Basel, Switzerland)*, 8 (4), Pp. 381 [Online] [Accessed April 2021] Available At: Https://Doi.Org/10.3390/Healthcare8040381.

Lincoln, Y.S. And Guba, E.G. (1985), *Naturalistic Inquiry*. London. Sage

Lincoln, Y.S., Lynham, S.A., Guba, E.G. (2011), “Paradigmatic Controversies, Contradictions, And Emerging Confluences, Revisited”, In: *The Sage Handbook Of Qualitative Research*, Thousand Oaks; Sage Publishers, Pp. 97–128.

Lindgaard, G., Fernandes, G., Dudek, C. And Brown, J. (2006), “Attention Web Designers: You Have 50 Milliseconds To Make A Good First Impression!”, *Behaviour & Information Technology*, Taylor & Francis, 25(2), Pp. 115–126.

Liu, C.H., Goyal, D., Mittal, L. And Erdei, C. (2021), “Patient Satisfaction With Virtual-Based Prenatal Care: Implications After The Covid-19 Pandemic”, *Maternal And Child Health Journal*, 25(11), Pp. 1735–1743.

Living With Ltd. (Updated 2022) [Online], “Living With - Build Your Own”, *Living With Ltd*, available at: https://setup.livingwith.health/new-clinic/product/lwphfi (accessed 30 March 2022).

Living With Ltd. (2022)[Online], “Products - Living With”, *Living With Ltd*, available at: https://www.livingwith.health/products/ (accessed 30 March 2022).

Living With Ltd. (2021)[Online], “Home Page - Squeezy”, *Squeezy*, available at: https://www.squeezyapp.com/ (accessed 23 April 2022).

Locke, E.A. And Latham, G.P. (2019), “The Development Of Goal Setting Theory: A Half Century Retrospective”, *Motivation Science*, 5(2), Pp. 93–105.

López-Morales, H., Del Valle, M.V., Canet-Juric, L., Andrés, M.L., Galli, J.I., Poó, F. And Urquijo, S. (2021), “Mental Health Of Pregnant Women During The Covid-19 Pandemic: A Longitudinal Study”, *Psychiatry Research*, 295, Pp. 113567.

Lorig, K.R. And Holman, H. (2003), “Self-Management Education: History, Definition, Outcomes, And Mechanisms”, *Annals Of Behavioral Medicine: A Publication Of The Society Of Behavioral Medicine*, 26(1), Pp. 1–7.

Lorig, K.R., Laurent, D.D., Deyo, R.A., Marnell, M.E., Minor, M.A. And Ritter, P.L. (2002), “Can A Back Pain E-Mail Discussion Group Improve Health Status And Lower Health Care Costs?: A Randomized Study”, *Archives Of Internal Medicine*, 162(7), Pp. 792–796.

Lussier-Desrochers, D., Normand, C. L., Romero-Torres, A., Lachapelle, Y., Godin-Tremblay, V., Dupont, M.- Ève, Roux, J., Pépin-Beauchesne, L. and Bilodeau, P. (2017) “Bridging the digital divide for people with intellectual disability”, *Cyberpsychology: Journal of Psychosocial Research on Cyberspace*, 11(1), p. Article 1. [Online] [Accessed March 2022] doi: 10.5817/CP2017-1-1

Lupton, D. (2016). The use and value of digital media for information about pregnancy and early motherhood: a focus group study. *BMC Pregnancy and Childbirth*, *16*(1), Pp171. https://doi.org/10.1186/s12884-016-0971-3

Machado, G. C., Pinheiro, M. B., Lee, H., Ahmed, O. H., Hendrick, P., Williams, C., & Kamper, S. J. (2017). ‘’Smartphone apps for the self-management of low back pain: A systematic review’’. *Best practice & research. Clinical rheumatology*, *30*(6), 1098–1109. https://doi.org/10.1016/j.berh.2017.04.002

Mackenzie, J., Murray, E. and Lusher, J. (2018) ‘Women’s experiences of pregnancy related pelvic girdle pain: A systematic review’, *Midwifery*, 56, pp. 102–111. doi:10.1016/j.midw.2017.10.011.

Mackert, M., Mabry-Flynn, A., Champlin, S., Donovan, E.E. And Pounders, K. (2016), “Health Literacy And Health Information Technology Adoption: The Potential For A

New Digital Divide", *Journal Of Medical Internet Research*, 18(10), P. E264. [Online] [Accessed March 2022] doi: 10.2196/jmir.6349

Mackintosh, N., Agarwal, S., Adcock, K., Armstrong, N., Briley, A., Patterson, M., Sandall, J., *Et Al.* (2020), "Online Resources And Apps To Aid Self-Diagnosis And Help Seeking In The Perinatal Period: A Descriptive Survey Of Women's Experiences", *Midwifery*, Vol. 90, P. 102803. [Online] [Accessed November 2020] doi.org/10.1016/j.midw.2020.102803

Malmqvist, S., Kjaermann, I., Andersen, K., Økland, I., Larsen, J.P. And Brønnick, K. (2015), "The Association Between Pelvic Girdle Pain And Sick Leave During Pregnancy; A Retrospective Study Of A Norwegian Population", *BMC Pregnancy And Childbirth*, 15, P. 237.

Manchester Metropolitan University. (2017), *BSc (Hons) Physiotherapy Programme Handbook*, Manchester. Manchester Metropolitan University, available at: https://webcdn.mmu.ac.uk/welcome/attachments/year1819/6017/BSc-Hons-Physiotherapy-Programme-Handbook-2018-2021.pdf (accessed 20 March 2022).

Mann, E.G., Lefort, S. And Vandenkerkhof, E.G. (2013), "Self-Management Interventions For Chronic Pain", *Pain Management*, 3(3), Pp. 211–222.

Mansell, G., Hall, A. And Toomey, E. (2016), "Behaviour Change And Self-Management Interventions In Persistent Low Back Pain", *Best Practice & Research. Clinical Rheumatology*, 30(6), Pp. 994–1002.

Marks, R., Allegrante, J.P. And Lorig, K. (2005), "A Review And Synthesis Of Research Evidence For Self-Efficacy-Enhancing Interventions For Reducing Chronic Disability: Implications For Health Education Practice (Part Ii)", *Health Promotion Practice*, 6(2), Pp. 148–156.

Marshall, L. H., & Comello, M. L. (2019). Stymied by a wealth of health information: How viewing conflicting information online diminishes efficacy. *Journal of Communication in Healthcare*, *12*(1), Pp4–12. https://doi.org/10.1080/17538068.2019.1580064

Maslen, S. And Lupton, D. (2018), "'You Can Explore It More Online': A Qualitative Study On Australian Women's Use Of Online Health And Medical Information", *Bmc Health Services Research*, 18(1), Pp. 916.

May, C.R., Eton, D.T., Boehmer, K., Gallacher, K., Hunt, K., Macdonald, S., Mair, F.S., *Et Al.* (2014), "Rethinking The Patient: Using Burden Of Treatment Theory To Understand The Changing Dynamics Of Illness", *BMC Health Services Research*, 14, Pp. 281.

May, S. (2010), "Self-Management Of Chronic Low Back Pain And Osteoarthritis", *Nature Reviews. Rheumatology*, 6(4), Pp. 199–209.

McBride, E., Arden, M.A., Chater, A. And Chilcot, J. (2021), "The Impact Of Covid-19 On Health Behaviour, Well-Being, And Long-Term Physical Health", *British Journal Of Health Psychology*, 26(2), Pp. 259–270.

McCambridge, J., Witton, J. And Elbourne, D.R. (2014), "Systematic Review Of The Hawthorne Effect: New Concepts Are Needed To Study Research Participation Effects", *Journal Of Clinical Epidemiology*, 67(3), Pp. 267–277.

McDonagh, M., Peterson, K., Raina, P., Chang, S., Shekelle, P. (2013). Avoiding Bias in Selecting Studies. In: *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*. Rockville (MD): Agency for Healthcare Research and Quality (US). [Online]. Available at: https://www.ncbi.nlm.nih.gov/pubmed/23487864.

McEwan, D., Harden, S.M., Zumbo, B.D., Sylvester, B.D., Kaulius, M., Ruissen, G.R., Dowd, A.J., *Et Al.* (2016), "The Effectiveness Of Multi-Component Goal Setting Interventions For Changing Physical Activity Behaviour: A Systematic Review And Meta-Analysis", *Health Psychology Review*, 10(1), Pp. 67–88.

McLellan, E., Macqueen, K.M. And Neidig, J.L. (2003), "Beyond The Qualitative Interview: Data Preparation And Transcription", *Field Methods*, Sage Publications Inc, 15(1), Pp. 63–84.

McLeod, C. et al. (2019). Choosing primary endpoints for clinical trials of health care interventions. *Contemporary clinical trials communications*, 16, p.100486. [Online]. Available at: doi:10.1016/j.conctc.2019.100486.

Medical Research Council. (2008), *Developing And Evaluating Complex Interventions*, Version 2 (2008), London: MRC.

Medical Research Council. (2015), *Process Evaluation of Complex Interventions*. Version 1, London: MRC, available at: https://www.ukri.org/wp-content/uploads/2015/05/MRC-71221-ProcessEvaluationComplexInterventions-FullGuidance.pdf.

Meerhoff, G.A., Van Dulmen, S.A., Maas, M.J., Bakker-Jacobs, A., Nijhuis-Van Der Sanden, M.W. And Van Der Wees, P.J. (2021), "Exploring The Perspective Of Patients With Musculoskeletal Health Problems In Primary Care On The Use Of Patient-Reported Outcome Measures To Stimulate Quality Improvement In Physiotherapist Practice; A Qualitative Study", *Physiotherapy Theory And Practice*, 37(9), Pp. 993–1004.

Meijer, O.G., Barbe, M.F., Prins, M.R., Schipholt, I.J.L., Hu, H. And Daffertshofer, A. (2020), "The Pelvic Girdle Pain Deadlock: 2. Topics That, So Far, Have Remained Out Of Focus", *Musculoskeletal Science & Practice*, 48, Pp. 102166. [Online] [Accessed May 2020] DOI: 10.1016/j.msksp.2020.102166

Meijer, O.G., Hu, H., Wu, W.H. And Prins, M.R. (2020), “The Pelvic Girdle Pain Deadlock: 1. Would ‘Deconstruction’ Help?”, *Musculoskeletal Science And Practice*, 48, Pp. 102169. [Online] [Accessed May 2020] DOI: 10.1016/j.msksp.2020.102169

Mens, J.M., Snijders, C.J. And Stam, H.J. (2000), “Diagonal Trunk Muscle Exercises In Peripartum Pelvic Pain: A Randomized Clinical Trial”, *Physical Therapy*, 80(12), Pp. 1164–1173.

Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D., Walker, A., & “Psychological Theory” Group. (2005). Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality & Safety in Health Care*, *14*(1), Pp. 26–33. https://doi.org/10.1136/qshc.2004.011155

Michie, S., Atkins, L. And West, R. (2014), *The Behaviour Change Wheel: A Guide To Designing Interventions*, London: Silverback Publishing.

Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., Eccles, M.P., *Et Al.* (2013), “The Behavior Change Technique Taxonomy (V1) Of 93 Hierarchically Clustered Techniques: Building An International Consensus For The Reporting Of Behavior Change Interventions”, *Annals Of Behavioral Medicine: A Publication Of The Society Of Behavioral Medicine*, 46(1), Pp. 81–95.

Michie, S., Van Stralen, M.M. And West, R. (2011), “The Behaviour Change Wheel: A New Method For Characterising And Designing Behaviour Change Interventions”, *Implementation Science: Is*, Biomed Central, 6(1), Pp. 1–12.

Michie, S., Yardley, L., West, R., Patrick, K. And Greaves, F. (2017), “Developing And Evaluating Digital Interventions To Promote Behavior Change In Health And Health Care: Recommendations Resulting From An International Workshop”, *Journal Of Medical Internet Research*, 19(6), Pp. E232. [Online] [Accessed May 2020] doi: 10.2196/jmir.7126

Milne-Ives, M., Van Velthoven, M.H. And Meinert, E. (2020), “Mobile Apps For Real-World Evidence In Health Care”, *Journal Of The American Medical Informatics Association: Jamia*, 27(6), Pp. 976–980.

Moffatt, M. and Flynn, M. (2014). Prevention of pregnancy-related lumbopelvic pain, using a single exercise and advice-based physiotherapy intervention in early pregnancy: a pilot study. *Physiotherapy Practice and Research*. [Online]. Available at: https://content.iospress.com/articles/physiotherapy-practice-and-research/ppr028.

Moffatt, M., Hamshire, C. and Selfe, J. (2021) “Pregnancy-Related Lumbopelvic Pain: Exploring the Use of Digital Media for Condition-Related Information Provision,” *MIDIRS EBM midwifery digest*, 31(3), pp. 360–370.

Moffatt, M., Selfe, P. J. and Hamshire, P. C. (2022) “Pregnancy-Related Lumbopelvic Pain: Exploring the Use of Digital Media for Condition-Related Information

Provision," *Physiotherapy: Supplement 1*, 114, p. 15. doi: 10.1016/j.physio.2021.12.257.

Mohr, D.C., Cuijpers, P. And Lehman, K. (2011), "Supportive Accountability: A Model For Providing Human Support To Enhance Adherence To Ehealth Interventions", *Journal Of Medical Internet Research*, 13(1), Pp. E30. [Online] [Accessed November 2021] DOI: 10.2196/jmir.1602

Mohr, D.C., Schueller, S.M., Tomasino, K.N., Kaiser, S.M., Alam, N., Karr, C., Vergara, J.L., *Et Al.* (2019), "Comparison Of The Effects Of Coaching And Receipt Of App Recommendations On Depression, Anxiety, And Engagement In The Intellicare Platform: Factorial Randomized Controlled Trial", *Journal Of Medical Internet Research*, 21(8), Pp. E13609. [Online] [Accessed October 2021] doi: 10.2196/13609

Moon, R. Y., Mathews, A., Oden, R., & Carlin, R. (2019). Mothers' perceptions of the internet and social media as sources of parenting and health information: Qualitative study. *Journal of Medical Internet Research*, *21*(7), Pp. e14289. [Online] [Accessed May 2020] Available at: https://doi.org/10.2196/14289

Moore, G.F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., Moore, L., *et al.* (2015), "Process evaluation of complex interventions: Medical Research Council guidance", *BMJ* , 350, Pp. h1258. [Online] [Accessed April 2022] doi:10.1136/bmj.h1258

Morgan, D.L. (2007), "Paradigms Lost And Pragmatism Regained: Methodological Implications Of Combining Qualitative And Quantitative Methods", *Journal Of Mixed Methods Research*, Sage Publications, 1(1), Pp. 48–76.

Morgan, D.L. And Morgan, D. (1997), *Focus Groups As Qualitative Research*, London: Sage.

Morino, S., Ishihara, M., Umezaki, F., Hatanaka, H., Iijima, H., Yamashita, M., Aoyama, T., *et al.* (2017), "Low back pain and causative movements in pregnancy: a prospective cohort study", *BMC Musculoskeletal Disorders*, 18(1), Pp. 416.

Morino, S., Ishihara, M., Umezaki, F., Hatanaka, H., Yamashita, M. And Aoyama, T. (2019), "Pelvic Alignment Changes During The Perinatal Period", *Plos One*, 14(10), Pp. E0223776. [Online] [Accessed June 2020] doi: 10.1371/journal.pone.0223776

Morrison, L.G. (2015), "Theory-Based Strategies For Enhancing The Impact And Usage Of Digital Health Behaviour Change Interventions: A Review", *Digital Health*, 1, Pp. 2055207615595335. [Online] [Accessed June 2020] DOI: 10.1177/2055207615595335

Morrison, L., Muller, I., Yardley, L., & Bradbury, K. (2018). The person-based approach to planning, optimising, evaluating and implementing behavioural health interventions. *The European Health Psychologist*, *20*(3), Pp. 464–469. Available from: https://www.researchgate.net/profile/Ingrid-

Muller/publication/328231801_The_person-based_approach_to_planning_optimising_evaluating_and_implementing_behavioural_health_interventions/links/5be49bab299bf1124fc41857/The-person-based-approach-to-planning-optimising-evaluating-and-implementing-behavioural-health-interventions.pdf

Moynihan, R., Sanders, S., Michaleff, Z.A., Scott, A.M., Clark, J., To, E.J., Jones, M., *Et Al.* (2021), "Impact Of Covid-19 Pandemic On Utilisation Of Healthcare Services: A Systematic Review", *BMJ Open*, 11(3), Pp. E045343. [Online] [Accessed December 2021] DOI: 10.1136/bmjopen-2020-045343

Møller, J.-J. K., Jespersen, E., Lindahl-Jacobsen, R., & Ahrenfeldt, L. J. (2020). Associations between perceived information needs and anxiety/depressive symptoms among cancer caregivers: A cross-sectional study. *Journal of Psychosocial Oncology*, *38*(2), Pp. 171–187. https://doi.org/10.1080/07347332.2019.1664699

Muench, F. And Baumel, A. (2017), "More Than A Text Message: Dismantling Digital Triggers To Curate Behavior Change In Patient-Centered Health Interventions", *Journal Of Medical Internet Research*, 19(5), Pp. E147. [Online] [Accessed November 2021] doi: 10.2196/jmir.7463

Muller, I., Santer, M., Morrison, L., Morton, K., Roberts, A., Rice, C., Williams, M., & Yardley, L. (2019). Combining qualitative research with PPI: reflections on using the person-based approach for developing behavioural interventions. *Research Involvement and Engagement*, *5*(1), Pp. 34. https://doi.org/10.1186/s40900-019-0169-8

NHS Digital. (2019), *Digital Inclusion Guide for Health and Social Care*, Leeds. NHS Digital, Available at: https://digital.nhs.uk/about-nhs-digital/our-work/digital-inclusion (accessed 15 April 2022).

National Health Service. (2019), *The NHS Long Term Plan*, London. NHS. Available at: https://www.longtermplan.nhs.uk/publication/nhs-long-term-plan/.

National Health Service. (2021), *NHS Report - Our Plan For Improving Access For Patients And Supporting General Practice 2021*, No. Bw999, London. NHS, Available At: Https://Www.England.Nhs.Uk/Coronavirus/Wp-Content/Uploads/Sites/52/2021/10/Bw999-Our-Plan-For-Improving-Access-And-Supporting-General-Practice-Oct-21.Pdf.

National Institute for Health and Care Excellence. (2018, updated 2021), "Overview | Evidence standards framework for digital health technologies | Guidance | NICE", *National Institute for Health and Care Excellence*, London. NICE, available at: https://www.nice.org.uk/corporate/ecd7 (accessed 19 April 2022).

National Institute for Health and Care Excellence (30 November 2016, Updated 11th December 2020) *Low back pain and sciatica in over 16s: assessment and management*. NG59. England: NICE. Available at: https://www.nice.org.uk/guidance/ng59/resources/low-back-pain-and-sciatica-in-over-16s-assessment-and-management-pdf-1837521693637.

National Institute For Health And Care Excellence. (2021), *Antenatal Care*, No. NG201. London: NICE. Available at: https://www.nice.org.uk/guidance/ng201

National Institute for Health and Care Excellence. (2021), *Resource Impact Statement*, No. 2021, London. NICE. Available at: https://www.nice.org.uk/guidance/ng201/resources/resource-impact-statement-pdf-11928780592837.

National Institute For Health Research. (2021), "Briefing Notes For Researchers - Public Involvement In NHS, Health And Social Care Research", London. National Institute For Health Research, 4 May, Available At: Https://Www.Nihr.Ac.Uk/Documents/Briefing-Notes-For-Researchers-Public-Involvement-In-Nhs-Health-And-Social-Care-Research/27371?Pr= (Accessed 5 March 2021).

Netz, Y., Lidor, R. and Ziv, G. (2019). Small samples and increased variability - discussing the need for restricted types of randomization in exercise interventions in old age. European review of aging and physical activity: official journal of the European Group for Research into Elderly and Physical Activity, 16, p.17. [Online]. Available at: doi:10.1186/s11556-019-0224-3

NHSX. (2021), *Digital Technology Assessment Criteria for Health and Social Care*, London. NHSX. Available at: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.nhsx.nhs.uk%2Fmedia%2Fdocuments%2FDTAC_version_1.0_FINAL_updated_16.04.odt&wdOrigin=BROWSELINK (accessed 19 April 2022).

NHSX. (2022), "Digital technology assessment criteria (DTAC)", London. NHS Transformation Directorate. Available at: https://www.nhsx.nhs.uk/key-tools-and-info/digital-technology-assessment-criteria-dtac/ (accessed 19 April 2022).

Nicholl, B.I., Sandal, L.F., Stochkendahl, M.J., Mccallum, M., Suresh, N., Vasseljen, O., Hartvigsen, J., *Et Al.* (2017), "Digital Support Interventions For The Self-Management Of Low Back Pain: A Systematic Review", *Journal Of Medical Internet Research*, 19(5), Pp. E179. [Online] [Accessed May 2021] doi: 10.2196/jmir.7290

Norén, L., Ostgaard, S., Johansson, G. And Ostgaard, H.C. (2002), "Lumbar Back And Posterior Pelvic Pain During Pregnancy: A 3-Year Follow-Up", *European Spine Journal: Official Publication Of The European Spine Society, The European Spinal*

Deformity Society, And The European Section Of The Cervical Spine Research Society, Springer, 11(3), Pp. 267–271.

Norfolk and Norwich University Hospitals NHS Foundation Trust. (2019), *Pregnancy-Related Pelvic Girdle Pain (PGP) Information for Pregnant and Post-Natal Women*, England. Norfolk and Norwich University Hospitals NHS Foundation Trust. Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjl-Oyut5b3AhXRNcAKHRhoCVkQFnoECA8QAQ&url=https%3A%2F%2Fwww.nnuh.nhs.uk%2Fpublication%2Fdownload%2Fpelvic-girdle-pain-v6&usg=AOvVaw08fz-emSnPqreCTJJjJ-hg.

Nouri, R., R Niakan Kalhori, S., Ghazisaeedi, M., Marchand, G., & Yasini, M. (2018). Criteria for assessing the quality of mHealth apps: a systematic review. *Journal of the American Medical Informatics Association: JAMIA*, *25*(8), Pp. 1089–1098. https://doi.org/10.1093/jamia/ocy050

Novick, G. (2008), "Is There A Bias Against Telephone Interviews In Qualitative Research?", *Research In Nursing & Health*, 31(4), Pp. 391–398.

Nunes, A., Limpo, T. And Castro, S.L. (2019), "Acceptance Of Mobile Health Applications: Examining Key Determinants And Moderators", *Frontiers In Psychology*, 10, Pp. 2791. [Online] [Accessed September 2021] doi: 10.3389/fpsyg.2019.02791

O'Brien, H.L., Morton, E., Kampen, A., Barnes, S.J. And Michalak, E.E. (2020), "Beyond Clicks And Downloads: A Call For A More Comprehensive Approach To Measuring Mobile-Health App Engagement", *BJPsych Open*, 6(5), Pp. E86. [Online] [Accessed September 2021] doi: 10.1192/bjo.2020.72

O'Cathain, A. (2009), "Editorial: Mixed Methods Research In The Health Sciences: A Quiet Revolution", *Journal Of Mixed Methods Research*, Sage Publications, 3 (1), Pp. 3–6.

O'Connor, S. et al. (2016). Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. *BMC medical informatics and decision making*, 16 (1), p.120. [Online]. Available at: doi:10.1186/s12911-016-0359-3.

Ofcom. (2021), *Online Nation 2021*, June 2021. London. Ofcom.

Office for National Statistics. (2022). *Population profiles for local authorities in England*. [Online]. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/populationprofilesforlocalauthoritiesinengland/2020-12-14 [Accessed 3 September 2022].

Office for National Statistics. (2021). *Population estimates by ethnic group and religion, England and Wales: 2019*. [Online]. Available at: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/populationestimatesbyethnicgroupandreligionenglandandwales/2019 [Accessed 2 August 2022].

Office For National Statistics. (2020), *Internet Access – Households And Individuals, Great Britain: 2020*, No. August 2020, England. Office For National Statistics (Ons).

Ogollah, R., Bishop, A., Lewis, M., Grotle, M. And Foster, N.E. (2019), "Responsiveness And Minimal Important Change For Pain And Disability Outcome Measures In Pregnancy-Related Low Back And Pelvic Girdle Pain", *Physical Therapy*, 99(11), Pp. 1551–1561.

O'Higgins, A., Murphy, O.C., Egan, A., Mullaney, L., Sheehan, S. And Turner, M.J. (2014), "The Use Of Digital Media By Women Using The Maternity Services In A Developed Country", *Irish Medical Journal*, 107(10), Pp. 313–315.

Oliveira, V.C., Ferreira, P.H., Maher, C.G., Pinto, R.Z., Refshauge, K.M. And Ferreira, M.L. (2012), "Effectiveness Of Self-Management Of Low Back Pain: Systematic Review With Meta-Analysis", *Arthritis Care & Research*, 64(11), Pp. 1739–1748.

Olsson, C.B., Grooten, W.J.A., Nilsson-Wikmar, L., Harms-Ringdahl, K. And Lundberg, M. (2012), "Catastrophizing During And After Pregnancy: Associations With Lumbopelvic Pain And Postpartum Physical Ability", *Physical Therapy*, 92(1), Pp. 49–57.

Olsson, C., Buer, N., Holm, K. And Nilsson-Wikmar, L. (2009), "Lumbopelvic Pain Associated With Catastrophizing And Fear-Avoidance Beliefs In Early Pregnancy", *Acta Obstetricia Et Gynecologica Scandinavica*, 88(4), Pp. 378–385.

Onchonga, D., Alfatafta, H., Ngetich, E. And Makunda, W. (2021), "Health-Seeking Behaviour Among Pregnant Women During The Covid-19 Pandemic: A Qualitative Study", *Heliyon*, 7(9), Pp. E07972. [Online] [Accessed November 2021] DOI: 10.1016/j.heliyon.2021.e07972

ORCHA. (2020)[Online], "Unique Approach - ORCHA", *ORCHA - Digital Health. Unlocked.*, 1 October, available at: https://orchahealth.com/about-us/unique-approach/ (accessed 19 April 2022).

Ostelo, R.W.J.G. and de Vet, H.C.W. (2005) 'Clinically important outcomes in low back pain', Best practice & research. Clinical rheumatology, 19(4), pp. 593–607. doi:10.1016/j.berh.2005.03.003.

O'Sullivan, P.B., Beales, D.J., Beetham, J.A., Cripps, J., Graf, F., Lin, I.B., Tucker, B., *Et Al.* (2002), "Altered Motor Control Strategies In Subjects With Sacroiliac Joint Pain During The Active Straight-Leg-Raise Test", *Spine*, 27(1), Pp. E1–8.

Overdijkink, S.B., Velu, A.V., Rosman, A.N., Van Beukering, M.D., Kok, M. And Steegers-Theunissen, R.P. (2018), "The Usability And Effectiveness Of Mobile Health Technology-Based Lifestyle And Medical Intervention Apps Supporting Health Care During Pregnancy: Systematic Review", *JMIR Mhealth And Uhealth*, 6(4), Pp. E109. [Online] [Accessed May 2021] doi: 10.2196/mhealth.8834

Oxford University Hospitals NHS Trust. (2022)[Online], "Women's and Men's Health Physiotherapy", Oxford University Hospital NHS Trust, available at: https://www.ouh.nhs.uk/services/departments/therapies/therapy-rehabilitation/women-and-men.aspx (accessed 15 April 2022).

Paige, S.R., Alber, J.M., Stellefson, M.L. And Krieger, J.L. (2018), "Missing The Mark For Patient Engagement: Mhealth Literacy Strategies And Behavior Change Processes In Smoking Cessation Apps", *Patient Education And Counseling*, 101(5), Pp. 951–955.

Palinkas, L. A. et al. (2015). Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research. *Administration and policy in mental health*, 42 (5), pp.533–544. [Online]. Available at: doi:10.1007/s10488-013-0528-y.

Patrick, K., Hekler, E.B., Estrin, D., Mohr, D.C., Riper, H., Crane, D., Godino, J., *Et Al.* (2016), "The Pace Of Technologic Change: Implications For Digital Health Behavior Intervention Research", *American Journal Of Preventive Medicine*, 51(5), Pp. 816–824.

Pel, J.J.M., Spoor, C.W., Pool-Goudzwaard, A.L., Hoek Van Dijke, G.A. And Snijders, C.J. (2008), "Biomechanical Analysis Of Reducing Sacroiliac Joint Shear Load By Optimization Of Pelvic Muscle And Ligament Forces", *Annals Of Biomedical Engineering*, 36(3), Pp. 415–424.

Pelvic Obstetric and Gynaecological Physiotherapy. (2015), POGP Advice For Healthcare Professionals, London. POGP. Available from https://pogp.csp.org.uk/system/files/publication_files/POGP-PGP%28Pros%29.pdf

Perski, O., Blandford, A., Ubhi, H.K., West, R. And Michie, S. (2017), "Smokers' And Drinkers' Choice Of Smartphone Applications And Expectations Of Engagement: A Think Aloud And Interview Study", *Bmc Medical Informatics And Decision Making*, 17(1), Pp. 25.

Perski, O., Blandford, A., West, R. And Michie, S. (2017), "Conceptualising Engagement With Digital Behaviour Change Interventions: A Systematic Review Using Principles From Critical Interpretive Synthesis", *Translational Behavioral Medicine*, 7(2), Pp. 254–267.

Persson, M., Winkvist, A., Dahlgren, L., & Mogren, I. (2013). "Struggling with daily life and enduring pain": a qualitative study of the experiences of pregnant women

living with pelvic girdle pain. *BMC Pregnancy and Childbirth*, *13*, Pp. 111. https://doi.org/10.1186/1471-2393-13-111

Petersen, J.M., Kemps, E., Lewis, L.K. And Prichard, I. (2020), "Psychological Mechanisms Underlying The Relationship Between Commercial Physical Activity App Use And Physical Activity Engagement", *Psychology Of Sport And Exercise*, 51, Pp. 101719. [Online] [Accessed August 2021] https://doi.org/10.1016/j.psychsport.2020.101719.

Petrozzi, M.J., Leaver, A., Ferreira, P.H., Rubinstein, S.M., Jones, M.K. And Mackey, M.G. (2019), "Addition Of Moodgym To Physical Treatments For Chronic Low Back Pain: A Randomized Controlled Trial", *Chiropractic & Manual Therapies*, 27, Pp. 54.

Peyton, T., Poole, E., Reddy, M., Kraschnewski, J. And Chuang, C. (2014), "'Every Pregnancy Is Different': Designing Mhealth For The Pregnancy Ecology", *Proceedings Of The 2014 Conference On Designing Interactive Systems*, Association For Computing Machinery, New York, USA, Pp. 577–586.

Petersen, F., Jacobs, M., Pather, S. (2020). *Barriers for User Acceptance of Mobile Health Applications for Diabetic Patients: Applying the UTAUT Model. In: Hattingh, M., Matthee, M., Smuts, H., Pappas, I., Dwivedi, Y.K., Mäntymäki, M. (eds) Responsible Design, Implementation and Use of Information and Communication Technology. Lecture Notes in Computer Science Series*. New York. Springer. https://doi.org/10.1007/978-3-030-45002-1_6

Pfeifer, A.-C., Uddin, R., Schröder-Pfeifer, P., Holl, F., Swoboda, W. And Schiltenwolf, M. (2020), "Mobile Application-Based Interventions For Chronic Pain Patients: A Systematic Review And Meta-Analysis Of Effectiveness", *Journal Of Clinical Medicine Research*, 9(11), [Online] [Accessed August 2021] Available at: Https://Doi.Org/10.3390/Jcm9113557.

Pham, Q., Graham, G., Carrion, C., Morita, P.P., Seto, E., Stinson, J.N. and Cafazzo, J.A. (2019), "A Library of Analytic Indicators to Evaluate Effective Engagement with Consumer mHealth Apps for Chronic Conditions: Scoping Review", *JMIR mHealth and uHealth*, JMIR mHealth and uHealth, 7(1), Pp. e11941. [Online] [Accessed January 2020] doi: 10.2196/11941

Phillips MR, Kaiser P, Thabane L, (2021) Risk of bias: why measure it, and how? *Eye* 36(2) Pp. 346–348. DOI: 10.1038/s41433-021-01759-9.

Pierce, H. *et al.* (2012) 'Pregnancy-related lumbopelvic pain: listening to Australian women', *Nursing research and practice*, 2012, p. 387428. [Online] [Accessed June 2020] doi:10.1155/2012/387428.

Pool-Goudzwaard, A., Van Dijke, G.H., Van Gurp, M., Mulder, P., Snijders, C. And Stoeckart, R. (2004), "Contribution Of Pelvic Floor Muscles To Stiffness Of The Pelvic Ring", *Clinical Biomechanics* , 19(6), Pp. 564–571.

Pool-Goudzwaard, A.L., Vleeming, A., Stoeckart, R., Snijders, C.J. And Mens, J.M.A. (1998), “Insufficient Lumbopelvic Stability: A Clinical, Anatomical And Biomechanical Approach To ‘A-Specific’low Back Pain”, *Manual Therapy*, Elsevier, 3(1), Pp. 12–20.

Del Pozo-Cruz, B., Gusi, N., Del Pozo-Cruz, J., Adsuar, J.C., Hernandez-Mocholí, M. And Parraca, J.A. (2013), “Clinical Effects Of A Nine-Month Web-Based Intervention In Subacute Non-Specific Low Back Pain Patients: A Randomized Controlled Trial”, *Clinical Rehabilitation*, 27(1), Pp. 28–39.

Prescott, J. And Mackie, L. (2017), “‘You Sort Of Go Down A Rabbit Hole...You’re Just Going To Keep On Searching’: A Qualitative Study Of Searching Online For Pregnancy-Related Information During Pregnancy”, *Journal Of Medical Internet Research*, 19(6), Pp. E194.

Priebe, J.A., Haas, K.K., Moreno Sanchez, L.F., Schoefmann, K., Utpadel-Fischler, D.A., Stockert, P., Thoma, R., *Et Al.* (2020), “Digital Treatment Of Back Pain Versus Standard Of Care: The Cluster-Randomized Controlled Trial, Rise-Up”, *Journal Of Pain Research*, 13, Pp. 1823–1838.

Prior, K.N. And Bond, M.J. (2004), “The Roles Of Self-Efficacy And Abnormal Illness Behaviour In Osteoarthritis Self-Management”, *Psychology, Health & Medicine*, 9(2), Pp. 177–192.

Prvu Bettger, J., Thoumi, A., Marquevich, V., De Groote, W., Rizzo Battistella, L., Imamura, M., Delgado Ramos, V., *Et Al.* (2020), “Covid-19: Maintaining Essential Rehabilitation Services Across The Care Continuum”, *BMJ Global Health*, 5(5) [Online] [Accessed June 2021] Available at: Https://Doi.Org/10.1136/Bmjgh-2020-002670.

Pulvirenti, M., Mcmillan, J. And Lawn, S. (2014), “Empowerment, Patient Centred Care And Self-Management”, *Health Expectations: An International Journal Of Public Participation In Health Care And Health Policy*, 17(3), Pp. 303–310.

Putnam, H. (1995), “Pragmatism”, *Proceedings Of The Aristotelian Society*. Oxford. Oxford University Press. Vol. 95, Pp. 291–306.

Rashidi Fakari, F., Simbar, M. And Saei Ghare Naz, M. (2018), “The Relationship Between Fear-Avoidance Beliefs And Pain In Pregnant Women With Pelvic Girdle Pain: A Cross-Sectional Study”, *International Journal Of Community Based Nursing And Midwifery*, 6(4), Pp. 305–313.

Rasmussen-Barr, E., Lindqvist, C., Östhols, S. And Boström, C. (2021), “Are Patient Reported Outcome Measures (Proms) Useful In Low Back Pain? Experiences Of Physiotherapists In Primary Health Care In Sweden”, *Musculoskeletal Science & Practice*, 55, Pp. 102414. [Online] [Accessed January 2022] https://doi.org/10.1016/j.msksp.2021.102414

Rawlinson, G. and Connell, L. (2021), “Out-patient physiotherapy service delivery post COVID-19: opportunity for a re-set and a new normal?”, *Physiotherapy*, 111, Pp 1-3 doi: 10.1016/j.physio.2021.02.001

Remus, A., Smith, V., Gutke, A., Mena, J.J.S., Mørkved, S., Wikmar, L.N., Öberg, B., *Et Al.* (2021), “A Core Outcome Set For Research And Clinical Practice In Women With Pelvic Girdle Pain: Pgp-Cos”, *Plos One*, 16(2), Pp. E0247466. [Online] [Accessed May 2021] DOI: 10.1371/journal.pone.0247466

Rhodes, A., Smith, A.D., Chadwick, P., Croker, H. And Llewellyn, C.H. (2020), “Exclusively Digital Health Interventions Targeting Diet, Physical Activity, And Weight Gain In Pregnant Women: Systematic Review And Meta-Analysis”, *JMIR Mhealth And Uhealth*, 8(7), Pp. E18255.[Online] [Accessed March 2021] DOI: 10.2196/18255

Richardson, C.A., Snijders, C.J., Hides, J.A., Damen, L., Pas, M.S. And Storm, J. (2002), “The Relation Between The Transversus Abdominis Muscles, Sacroiliac Joint Mechanics, And Low Back Pain”, *Spine*, 27(4), Pp. 399–405.

Ritchie, J., Lewis, J., Of Social Policy Jane Lewis, Nicholls, C.M. And Ormston, R. (2013), *Qualitative Research Practice: A Guide For Social Science Students And Researchers*, London; Sage .

Ritchie, J. And Spencer, L. (1994), “Qualitative Data Analysis For Applied Policy Research”, In Burgess, B.A. (Ed.), *Analysing Qualitative Data*, 1st Edition, London; Routledge, Pp. 173–194.

Riva, S., Camerini, A.-L., Allam, A. And Schulz, P.J. (2014), “Interactive Sections Of An Internet-Based Intervention Increase Empowerment Of Chronic Back Pain Patients: Randomized Controlled Trial”, *Journal Of Medical Internet Research*, 16(8), Pp. E180. [Online] [Accessed May 2021] DOI: 10.2196/jmir.3474

Robinson, H.S., Mengshoel, A.M., Bjelland, E.K. And Vøllestad, N.K. (2010), “Pelvic Girdle Pain, Clinical Tests And Disability In Late Pregnancy”, *Manual Therapy*, 15 (3), Pp. 280–285.

Robinson, H.S., Mengshoel, A.M., Veierød, M.B. And Vøllestad, N. (2010), “Pelvic Girdle Pain: Potential Risk Factors In Pregnancy In Relation To Disability And Pain Intensity Three Months Postpartum”, *Manual Therapy*, 15(6), Pp. 522–528.

Robinson, P.S., Balasundaram, A.P., Vøllestad, N.K. And Robinson, H.S. (2018), “The Association Between Pregnancy, Pelvic Girdle Pain And Health-Related Quality Of Life - A Comparison Of Two Instruments”, *Journal Of Patient-Reported Outcomes*, 2, Pp. 45.

Rogers, H. L., Pablo Hernando, S., Núñez-Fernández, S., Sanchez, A., Martos, C., Moreno, M., & Grandes, G. (2021). Barriers and facilitators in the implementation of an evidence-based health promotion intervention in a primary care setting: a

qualitative study. *Journal of Health Organization and Management*, *ahead-of-print*(ahead-of-print). https://doi.org/10.1108/JHOM-12-2020-0512

Rosalina, D., Yuliari, K., Setianingsih, D. And Zati, M.R. (2021), "Factors Influencing The Digital Literacy Competency Of College Students In The Industrial Revolution Era 4.0", *International Journal Of Economics, Business And Applications*, 6(2), Pp. 81–92.

Russell, E., Lloyd-Houldey, A., Memon, A. And Yarker, J. (2018), "Factors Influencing Uptake And Use Of A New Health Information App For Young People", *Journal Of Technology In Human Services*, Routledge, 36(4), Pp. 222–240.

Ryan, P. and Sawin, K. J. (2009). The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. *Nursing outlook*, 57 (4), pp.217–225.e6. [Online]. Available at: doi:10.1016/j.outlook.2008.10.004.

Sadr, S., Pourkiani-Allah-Abad, N. And Stuber, K.J. (2012), "The Treatment Experience Of Patients With Low Back Pain During Pregnancy And Their Chiropractors: A Qualitative Study", *Chiropractic & Manual Therapies*, 20(1), Pp. 32.

Sander, L.B., Paganini, S., Terhorst, Y., Schlicker, S., Lin, J., Spanhel, K., Buntrock, C., *Et Al.* (2020), "Effectiveness Of A Guided Web-Based Self-Help Intervention To Prevent Depression In Patients With Persistent Back Pain: The Prod-Bp Randomized Clinical Trial", *Jama Psychiatry* , 77(10), Pp. 1001–1011.

Santarossa, S., Kane, D., Senn, C.Y. And Woodruff, S.J. (2018), "Exploring The Role Of In-Person Components For Online Health Behavior Change Interventions: Can A Digital Person-To-Person Component Suffice?", *Journal Of Medical Internet Research*, 20(4), Pp. E144. [Online] [Accessed November 2021] DOI: 10.2196/jmir.8480

Sarker, A., Chandrashekar, P., Magge, A., Cai, H., Klein, A. And Gonzalez, G. (2017), "Discovering Cohorts Of Pregnant Women From Social Media For Safety Surveillance And Analysis", *Journal Of Medical Internet Research*, 19(10), Pp. E361.[Online] [Accessed June 2021] doi: 10.2196/jmir.8164

Sayakhot, P. And Carolan-Olah, M. (2016), "Internet Use By Pregnant Women Seeking Pregnancy-Related Information: A Systematic Review", *BMC Pregnancy And Childbirth*, 16, Pp. 65.

Schlicker, S., Baumeister, H., Buntrock, C., Sander, L., Paganini, S., Lin, J., Berking, M., *Et Al.* (2020), "A Web- And Mobile-Based Intervention For Comorbid, Recurrent Depression In Patients With Chronic Back Pain On Sick Leave (Get.Back): Pilot Randomized Controlled Trial On Feasibility, User Satisfaction, And Effectiveness", *JMIR Mental Health*, 7(4), Pp. E16398. [Online] [Accessed May 2021] doi: 10.2196/16398

Schnitman, G., Wang, T., Kundu, S., Turkdogan, S., Gotlieb, R., How, J. And Gotlieb, W. (2021), "The Role Of Digital Patient Education In Maternal Health: A Systematic Review", *Patient Education And Counselling*, [Ahead of print] Available at: Https://Doi.Org/10.1016/J.Pec.2021.06.019.

Schoeppe, S., Alley, S., Van Lippevelde, W., Bray, N.A., Williams, S.L., Duncan, M.J. And Vandelanotte, C. (2016), "Efficacy Of Interventions That Use Apps To Improve Diet, Physical Activity And Sedentary Behaviour: A Systematic Review", *The International Journal Of Behavioral Nutrition And Physical Activity*, 13(1), Pp. 127.

Scobbie, L., Dixon, D. And Wyke, S. (2011), "Goal Setting And Action Planning In The Rehabilitation Setting: Development Of A Theoretically Informed Practice Framework", *Clinical Rehabilitation*, 25(5), Pp. 468–482.

Seale, C. and Silverman, D. (1997). Ensuring rigour in qualitative research. *European journal of public health*, 7 (4), pp.379–384. [Online]. Available at: doi:10.1093/eurpub/7.4.379 [Accessed 20 August 2022].

Seckler, E., Regauer, V., Rotter, T., Bauer, P., & Müller, M. (2020). Barriers to and facilitators of the implementation of multi-disciplinary care pathways in primary care: a systematic review. *BMC Family Practice*, *21*(1), Pp 113. https://doi.org/10.1186/s12875-020-01179-w

Sekhon, M., Cartwright, M. And Francis, J.J. (2017), "Acceptability Of Healthcare Interventions: An Overview Of Reviews And Development Of A Theoretical Framework", *BMC Health Services Research*, 17(1,) Pp. 88.

Serlachius, A. and Sutton, S. (2009) 'Self-management and behaviour change: theoretical models', In: Newman, S., Steed, E., and Mulligan, K. (eds) *Chronic Physical Illness: Self Management and Behavioural Interventions*. Maidenhead, England: Open University Press, pp. 47–63.

Shabir, H., D'Costa, M., Mohiaddin, Z., Moti, Z., Rashid, H., Sadowska, D., Alam, B., & Cox, B. (2022). The Barriers and Facilitators to the Use of Lifestyle Apps: A Systematic Review of Qualitative Studies. *European Journal of Investigation in Health, Psychology and Education*, *12*(2), Pp. 144–165. https://doi.org/10.3390/ejihpe12020012

Sharma. (2017). Pros and cons of different sampling techniques. *International journal of applied research and studies*. [Online]. Available at: https://www.academia.edu/download/58765080/Pros_and_cons_of_sampling.pdf

Shebib, R., Bailey, J.F., Smittenaar, P., Perez, D.A., Mecklenburg, G. And Hunter, S. (2019), "Randomized Controlled Trial Of A 12-Week Digital Care Program In Improving Low Back Pain", *NPJ Digital Medicine*, 2, Pp. 1.

Shepherd, J. (2005), "Symphysis Pubis Dysfunction: A Hidden Cause Of Morbidity", *British Journal Of Midwifery*, 13(5), Pp. 301–307.

Shieh, C., Mays, R., Mcdaniel, A. And Yu, J. (2009), “Health Literacy And Its Association With The Use Of Information Sources And With Barriers To Information Seeking In Clinic-Based Pregnant Women”, *Health Care For Women International*, 30(11), Pp. 971–988.

Sim, J. and Waterfield, J. (2019), “Focus group methodology: some ethical challenges”, *Quality & Quantity*, 53(6), pp. 3003–3022.

Sim, J. (2019). Should treatment effects be estimated in pilot and feasibility studies? Pilot and feasibility studies, 5, p.107. [Online]. Available at: doi:10.1186/s40814-019-0493-7.

Skivington, K., Matthews, L., Simpson, S.A., Craig, P., Baird, J., Blazeby, J.M., Boyd, K.A., *Et Al.* (2021), “A New Framework For Developing And Evaluating Complex Interventions: Update Of Medical Research Council Guidance”, *BMJ* , British Medical Journal Publishing Group, Vol. 374, [Online] Available at: Https://Doi.Org/10.1136/Bmj.N2061.

Skouteris, H., & Savaglio, M. (2021). The Use of Social Media for Preconception Information and Pregnancy Planning among Young Women. *Journal of Clinical Medicine Research*, *10*(9). [Online] [Accessed 24th May 2021]. Available at: https://doi.org/10.3390/jcm10091892

Slama-Chaudhry A, Golay A. World Health Organization. Regional Office for Europe (2019) Patient education and self-management support for chronic disease: methodology for implementing patient-tailored therapeutic programmes. *Public health panorama*; 5(2-3) Pp. 357–61. Available from: https://apps.who.int/iris/handle/10665/330106

Slepian, P.M., Peng, M., Janmohamed, T., Kotteeswaran, Y., Manoo, V., Blades, A.M., Fiorellino, J., *Et Al.* (2020), “Engagement With Manage My Pain Mobile Health Application Among Patients At The Transitional Pain Service”, *Digital Health*, 6, PP. 2055207620962297. [Online] [Accessed 18th October 2021]. doi:10.1177/2055207620962297 Available at: https://journals.sagepub.com/doi/full/10.1177/2055207620962297

Smith, P.G., Morrow, R.H. and Ross, D.A. (2015) Types of intervention and their development. Oxford. Oxford University Publications. Available at: https://www.ncbi.nlm.nih.gov/books/NBK305514/ (Accessed: 26 March 2022).

Snijders, C.J., Vleeming, A. And Stoeckart, R. (1993a), “Transfer Of Lumbosacral Load To Iliac Bones And Legs Part 1: Biomechanics Of Self-Bracing Of The Sacroiliac Joints And Its Significance For Treatment And Exercise”, *Clinical Biomechanics* , 8(6), Pp. 285–294.

Snijders, C.J., Vleeming, A. And Stoeckart, R. (1993b), “Transfer Of Lumbosacral Load To Iliac Bones And Legs Part 2: Loading Of The Sacroiliac Joints When Lifting In A Stooped Posture”, *Clinical Biomechanics* , 8(6), Pp. 295–301.

Staniszewska, S., Denegri, S., Matthews, R. And Minogue, V. (2018), “Reviewing Progress In Public Involvement In NIHR Research: Developing And Implementing A New Vision For The Future”, *BMJ Open*, 8(7), Pp. E017124. [Online] [Accessed 2nd of February 2022] Doi: 10.1136/bmjopen-2017-017124

Statista. (2020)[Online], “Retention Rate On Day 1 And Day 30 Of Mobile App Installs Worldwide As Of August 2020, By Category”, *Statista*, Statista, Available At: Https://Www.Statista.Com/Statistics/259329/Ios-And-Android-App-User-Retention-Rate/ (Accessed 9 March 2021).

Statista. (2021), *Share Of Adults Who Own A Smartphone In The United Kingdom (UK) In 2008 And 2019 To 2021 By Demographics*, Hamburg. Statista.

Sterne, J.A.C. *et al.* (2019) ‘RoB 2: a revised tool for assessing risk of bias in randomised trials’, *BMJ* , p. l4898. [Online] [Accessed 23rd March 2021] doi:10.1136/bmj.l4898.

Stevens, A., Köke, A., Van Der Weijden, T. And Beurskens, A. (2017), “Ready For Goal Setting? Process Evaluation Of A Patient-Specific Goal-Setting Method In Physiotherapy”, *BMC Health Services Research*, 17(1)p, P. 618.

Stuge, B. (2019), “Evidence Of Stabilizing Exercises For Low Back- And Pelvic Girdle Pain - A Critical Review”, *Brazilian Journal Of Physical Therapy*, 23(2), Pp. 181–186.

Stuge, B., Garratt, A., Krogstad Jenssen, H. And Grotle, M. (2011), “The Pelvic Girdle Questionnaire: A Condition-Specific Instrument For Assessing Activity Limitations And Symptoms In People With Pelvic Girdle Pain”, *Physical Therapy*, Oxford Academic, 91(7), Pp. 1096–1108.

Stuge, B., Jenssen, H.K. And Grotle, M. (2017), “The Pelvic Girdle Questionnaire: Responsiveness And Minimal Important Change In Women With Pregnancy-Related Pelvic Girdle Pain, Low Back Pain, Or Both”, *Physical Therapy*, Oxford Academic, 97 (11), Pp. 1103–1113.

Stuge, B., Sætre, K. And Brækken, I.H. (2012), “The Association Between Pelvic Floor Muscle Function And Pelvic Girdle Pain--A Matched Case Control 3d Ultrasound Study”, *Manual Therapy*, 17(2), Pp. 150–156.

Stuge, B., Sætre, K. And Ingeborg Hoff, B. (2013), “The Automatic Pelvic Floor Muscle Response To The Active Straight Leg Raise In Cases With Pelvic Girdle Pain And Matched Controls”, *Manual Therapy*, 18(4), Pp. 327–332.

Stuge, B., Jenssen, H.K. and Grotle, M. (2017), “The Pelvic Girdle Questionnaire: Responsiveness and Minimal Important Change in Women With Pregnancy-Related

Pelvic Girdle Pain, Low Back Pain, or Both", *Physical Therapy*, Oxford Academic, 97(11), pp. 1103–1113.

Sullivan, G.M. And Sargeant, J. (2011), "Qualities Of Qualitative Research: Part I", *Journal Of Graduate Medical Education*, 3(4), Pp. 449–452.

Suman, A., Schaafsma, F.G., Van Dongen, J.M., Elders, P.J.M., Buchbinder, R., Van Tulder, M.W. And Anema, J.R. (2019), "Effectiveness And Cost-Utility Of A Multifaceted Ehealth Strategy To Improve Back Pain Beliefs Of Patients With Non-Specific Low Back Pain: A Cluster Randomised Trial", *BMJ Open*, 9(12), Pp. E030879.[Online] [Accessed December 16th 2020] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6924789/

Svendsen, M.J., Wood, K.W., Kyle, J., Cooper, K., Rasmussen, C.D.N., Sandal, L.F., Stochkendahl, M.J., *Et Al.* (2020), "Barriers And Facilitators To Patient Uptake And Utilisation Of Digital Interventions For The Self-Management Of Low Back Pain: A Systematic Review Of Qualitative Studies", *BMJ Open*, 10(12), P. E038800. [Online] [Accessed 15th December 2021] Available at: https://bmjopen.bmj.com/content/10/12/e038800

Swire-Thompson, B. And Lazer, D. (2020), "Public Health And Online Misinformation: Challenges And Recommendations", *Annual Review Of Public Health*, 41, Pp. 433–451.

Szinay, D., Cameron, R., Naughton, F., Whitty, J.A., Brown, J. And Jones, A. (2021), "Understanding Uptake Of Digital Health Products: Methodology Tutorial For A Discrete Choice Experiment Using The Bayesian Efficient Design", *Journal Of Medical Internet Research*, 23(10), Pp. E32365.[Online] [Accessed 2nd December 2021] Available at: https://www.jmir.org/2021/10/e32365

Szinay, D., Jones, A., Chadborn, T., Brown, J. And Naughton, F. (2020), "Influences On The Uptake Of And Engagement With Health And Well-Being Smartphone Apps: Systematic Review", *Journal Of Medical Internet Research*, 22(5), P. E17572. , 23(10), Pp. E32365.[Online] [Accessed 2nd December 2021] Available at: https://www.jmir.org/2020/5/e17572/

Szinay, D., Perski, O., Jones, A., Chadborn, T., Brown, J. And Naughton, F. (2021), "Influences On The Uptake Of Health And Well-Being Apps And Curated App Portals: Think-Aloud And Interview Study", *Jmir Mhealth And Uhealth*, 9(4), Pp. E27173. [Online] [Accessed 2nd December 2021] Available at: https://mhealth.jmir.org/2021/4/e27173/

Tahsin, F., Tracy, S., Chau, E., Harvey, S., Loganathan, M., Mckinstry, B., Mercer, S.W., *Et Al.* (2021), "Exploring The Relationship Between The Usability Of A Goal-Oriented Mobile Health Application And Non-Usage Attrition In Patients With Multimorbidity: A Blended Data Analysis Approach", *Digital Health*, 7, P.

20552076211045579. [Online] [Accessed 2nd February 2021] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8642112/

Tarricone, R., Petracca, F., Ciani, O. and Cucciniello, M. (2021), "Distinguishing features in the assessment of mHealth apps", *Expert Review of Pharmacoeconomics & Outcomes Research*, 21(4), pp. 521–526.

Tashakkori, A., Burke Johnson, R. And Teddlie, C. (2020), *Foundations Of Mixed Methods Research: Integrating Quantitative And Qualitative Approaches In The Social And Behavioural Sciences*, London. Sage Publications .

Taylor, K. (2009), "Paternalism, Participation And Partnership—The Evolution Of Patient Centeredness In The Consultation", *Patient Education And Counseling*, 74 (2), Pp. 150–155.

Teddlie, C. And Tashakkori, A. (2009), *Foundations Of Mixed Methods Research: Integrating Quantitative And Qualitative Approaches In The Social And Behavioral Sciences*, London. Sage.

Thomas Craig, K.J., Morgan, L.C., Chen, C.-H., Michie, S., Fusco, N., Snowdon, J.L., Scheufele, E., *et al.* (2021), "Systematic review of context-aware digital behavior change interventions to improve health", *Translational Behavioral Medicine*, 11(5), pp. 1037–1048.

Thorneloe, R., Epton, T., Fynn, W., Daly, M., Stanulewicz, N., Kassianos, A., Shorter, G.W., *Et Al.* (2020), "Scoping Review Of Mobile Phone App Uptake And Engagement To Inform Digital Contact Tracing Tools For Covid-19", PsyArXiv Preprints. Preprint April [Online] [Accessed 15th December 2021] Available at: Https://Doi.Org/10.31234/Osf.Io/Qe9b6.

Timlin, D. et al. (2020) 'Are dietary interventions with a behaviour change theoretical framework effective in changing dietary patterns? A systematic review', BMC public health, 20(1), p. 1857. [Online] [Accessed 13th March 2022] doi:10.1186/s12889-020-09985-8.

Toelle, T.R., Utpadel-Fischler, D.A., Haas, K.-K. And Priebe, J.A. (2019), "App-Based Multidisciplinary Back Pain Treatment Versus Combined Physiotherapy Plus Online Education: A Randomized Controlled Trial", *NPJ Digital Medicine*, 2, Pp. 34.

Tofthagen, C. (2012), "Threats To Validity In Retrospective Studies", *Journal Of The Advanced Practitioner In Oncology*, 3(3), Pp. 181–183.

Tong, H.L. And Laranjo, L. (2018), "The Use Of Social Features In Mobile Health Interventions To Promote Physical Activity: A Systematic Review", *NPJ Digital Medicine*, 1, Pp. 43.

Torous, J., Nicholas, J., Larsen, M.E., Firth, J. And Christensen, H. (2018), "Clinical Review Of User Engagement With Mental Health Smartphone Apps: Evidence, Theory And Improvements", *Evidence-Based Mental Health*, 21(3), Pp. 116–119.

Treweek, S., Banister, K., Bower, P., Cotton, S., Devane, D., Gardner, H.R., Isaacs, T., *Et Al.* (2021), "Developing The Include Ethnicity Framework—A Tool To Help Trialists Design Trials That Better Reflect The Communities They Serve", *Trials*, 22 (1), Pp. 337.

Truong, B. T., Lupattelli, A., Kristensen, P., & Nordeng, H. (2017). Sick leave and medication use in pregnancy: a European web-based study. *BMJ Open*, *7*(8), Pp. e014934. [Online] [Accessed 20th May 2020] https://doi.org/10.1136/bmjopen-2016-014934

Tulinayo, F.P., Ssentume, P. And Najjuma, R. (2018), "Digital Technologies In Resource Constrained Higher Institutions Of Learning: A Study On Students' Acceptance And Usability", *International Journal Of Educational Technology In Higher Education*, 15(1), Pp. 1–19.

Twycross, A. and Shorten, A. (2014). Service evaluation, audit and research: what is the difference? *Evidence-based nursing*, 17 (3), pp.65–66. [Online]. Available at: doi:10.1136/eb-2014-101871

University of Manchester. (2022)[Online], "BMidwif Midwifery/ Course details", *University of Manchester BMidwif Midwifery Course Details*, available at: https://www.manchester.ac.uk/study/undergraduate/courses/2022/11660/bmidwif-midwifery/course-details/#course-profile (accessed 20 March 2022).

UK Government (Updated 15 March 2021)[Online], "Accessible Communication Formats", *Gov.Uk*, UK Government, Available At: Https://Www.Gov.Uk/Government/Publications/Inclusive-Communication/Accessible-Communication-Formats (Accessed 2 February 2022).

UK Research and Innovation (2022) *Open Research* UKRI [Online] [Accessed 20th August 2022] Available from: https://www.ukri.org/what-we-offer/supporting-healthy-research-and-innovation-culture/open-research/

Vaghefi, I. And Tulu, B. (2019), "The Continued Use Of Mobile Health Apps: Insights From A Longitudinal Study", *JMIR Mhealth And Uhealth*, 7(8), Pp. E12983. [Online] [Accessed 16th January 2022] Available at: doi:10.2196/12983.

Valentine, L., Mcenery, C., Bell, I., O'sullivan, S., Pryor, I., Gleeson, J., Bendall, S., *Et Al.* (2020), "Blended Digital And Face-To-Face Care For First-Episode Psychosis Treatment In Young People: Qualitative Study", *JMIR Mental Health*, 7(7), P. E18990. [Online] [Accessed 2nd March 2022] Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7420518/

Van Benten, E., Pool, J., Mens, J. And Pool-Goudzwaard, A. (2014), "Recommendations For Physical Therapists On The Treatment Of Lumbopelvic Pain During Pregnancy: A Systematic Review", The Journal Of Orthopaedic And Sports Physical Therapy, 44(7), Pp. 464–73, A1–15.

Van Tulder M, Furlan A, Bombardier C., (2003) Updated method guidelines for systematic reviews in the cochrane collaboration back review group. *Spine* 28(12): Pp. 1290–1299. DOI: 10.1097/01.BRS.0000065484.95996.AF.

Van Wingerden, J.P., Vleeming, A., Buyruk, H.M. And Raissadat, K. (2004), "Stabilization Of The Sacroiliac Joint In Vivo: Verification Of Muscular Contribution To Force Closure Of The Pelvis", European Spine Journal: Official Publication Of The European Spine Society, The European Spinal Deformity Society, And The European Section Of The Cervical Spine Research Society, 13(3), Pp. 199–205.

Vasiliou, V.S., Dockray, S., Dick, S., Davoren, M.P., Heavin, C., Linehan, C. And Byrne, M. (2021), "Reducing Drug-Use Harms Among Higher Education Students: Myuse Contextual-Behaviour Change Digital Intervention Development Using The Behaviour Change Wheel", *Harm Reduction Journal*, 18(1), Pp. 56.

Velu, A. V., van Beukering, M. D., Schaafsma, F. G., Frings-Dresen, M. H., Mol, B. W., van der Post, J. A., & Kok, M. (2017). 'Barriers and Facilitators for the Use of a Medical Mobile App to Prevent Work-Related Risks in Pregnancy: A Qualitative Analysis'. *Journal of Medical Internet Research research protocols*, *6*(8), Pp. e163. [Online] [Accessed 3rd September 2021] Available at: https://doi.org/10.2196/resprot.7224

Venkatesh, V. And Davis, F.D. (2000), "A Theoretical Extension Of The Technology Acceptance Model: Four Longitudinal Field Studies", *Management Science*, Informs, 46(2), Pp. 186–204.

Vermani E., Mittal, R., And Weeks, A. (2010), "Pelvic Girdle Pain And Low Back Pain In Pregnancy: A Review", *Pain Practice: The Official Journal Of World Institute Of Pain*, 10(1), [Online] [Accessed 2nd July 2020] Available at: Https://Doi.Org/10.1111/J.1533-2500.2009.00327.X.

Vleeming, A., Albert, H.B., Ostgaard, H.C., Sturesson, B. And Stuge, B. (2008), "European Guidelines For The Diagnosis And Treatment Of Pelvic Girdle Pain", *European Spine Journal: Official Publication Of The European Spine Society, The European Spinal Deformity Society, And The European Section Of The Cervical Spine Research Society*, 17(6), Pp. 794–819.

Vleeming, A., Schuenke, M.D., Masi, A.T., Carreiro, J.E., Danneels, L. And Willard, F.H. (2012), "The Sacroiliac Joint: An Overview Of Its Anatomy, Function And Potential Clinical Implications", *Journal Of Anatomy*, 221(6), Pp. 537–567.

Vøllestad, N.K., Torjesen, P.A. And Robinson, H.S. (2012), “Association Between The Serum Levels Of Relaxin And Responses To The Active Straight Leg Raise Test In Pregnancy”, *Manual Therapy*, 17(3), Pp. 225–230.

Wade, D.T. (2009), “Goal Setting In Rehabilitation: An Overview Of What, Why And How”, *Clinical Rehabilitation*, 23(4), Pp. 291–295.

Waffenschmidt, S., Knelangen, M., Sieben, W. (2019). Single screening versus conventional double screening for study selection in systematic reviews: a methodological systematic review. *BMC medical research methodology*, 19 (1), p.132. [Online]. Available at: doi:10.1186/s12874-019-0782-0.

Walters, C., West, S., & A Nippita, T. (2018). Pelvic girdle pain in pregnancy. *Australian Journal of General Practice*, *47*(7), Pp. 439–443. https://doi.org/10.31128/AJGP-01-18-4467

Warmbrod, J.R. And Robert Warmbrod, J. (2014), “Reporting And Interpreting Scores Derived From Likert-Type Scales”, *Journal Of Agricultural Education*. 55(5) Pp. 30-47

Watts G (2020) COVID-19 and the digital divide in the UK. *The Lancet. Digital health* 2(8) Pp. e395–e396. [Online] [Accessed 16th January 2022] DOI: 10.1016/S2589-7500(20)30169-2.

Wei, Y., Zheng, P., Deng, H., Wang, X., Li, X. And Fu, H. (2020), “Design Features For Improving Mobile Health Intervention User Engagement: Systematic Review And Thematic Analysis”, *Journal Of Medical Internet Research*, 22(12), Pp. E21687. [Online] [Accessed 15th November 2021] Available at: https://www.jmir.org/2020/12/e21687/

Wellock, V.K. And Crichton, M.A. (2007), “Symphysis Pubis Dysfunction: Women’s Experiences Of Care”, *British Journal Of Midwifery*, 15(8), Pp. 494–499.

West, R. and Michie, S. (2016). *A Guide to Development and Evaluation of Digital Behaviour Change Interventions in Healthcare*. Illustrated. West, R. and Michie, S. (Eds). Sutton: Silverback Publishing.

Williams, A., Fossey, E., Farhall, J., Foley, F. And Thomas, N. (2021), “Impact Of Jointly Using An E-Mental Health Resource (Self-Management And Recovery Technology) On Interactions Between Service Users Experiencing Severe Mental Illness And Community Mental Health Workers: Grounded Theory Study”, *JMIR Mental Health*, 8(6), Pp. E25998. [Online] [Accessed 3rd October 2021] Available at: https://mental.jmir.org/2021/6/e25998

Witham, M.D., Anderson, E., Carroll, C.B., Dark, P.M., Down, K., Hall, A.S., Knee, J., *Et Al.* (2020), “Ensuring That Covid-19 Research Is Inclusive: Guidance From The Nihr Include Project”, *BMJ Open*, 10(11), Pp. E043634. [Online] [Accessed November 2021] Available at: https://europepmc.org/article/pmc/7646322

Wright, E.M., Matthai, M.T. And Meyer, E. (2019), “The Influence Of Social Media On Intrapartum Decision Making: A Scoping Review”, *The Journal Of Perinatal & Neonatal Nursing*, 33(4), Pp. 291–300.

Wrosch, C., Scheier, M.F., Miller, G.E., Schulz, R. And Carver, C.S. (2003), “Adaptive Self-Regulation Of Unattainable Goals: Goal Disengagement, Goal Reengagement, And Subjective Well-Being”, *Personality & Social Psychology Bulletin*, 29(12), Pp. 1494–1508.

Wu, J.J.Y., Ahmad, N., Samuel, M., Logan, S. And Mattar, C.N.Z. (2021), “The Influence Of Web-Based Tools On Maternal And Neonatal Outcomes In Pregnant Adolescents Or Adolescent Mothers: Mixed Methods Systematic Review”, *Journal Of Medical Internet Research*, 23(8), P. E26786. [Online] [Accessed February 2022] Available at: https://pubmed.ncbi.nlm.nih.gov/34435961/

Wuytack, F., Curtis, E. And Begley, C. (2015a), “Experiences Of First-Time Mothers With Persistent Pelvic Girdle Pain After Childbirth: Descriptive Qualitative Study”, *Physical Therapy*, 95(10), Pp. 1354–1364.

Wuytack, F., Curtis, E. And Begley, C. (2015b), “The Health-Seeking Behaviours Of First-Time Mothers With Persistent Pelvic Girdle Pain After Childbirth In Ireland: A Descriptive Qualitative Study”, *Midwifery*, 31(11), Pp. 1104–1109.

Wuytack, F. *et al.* (2018) ‘Prognostic factors for pregnancy-related pelvic girdle pain, a systematic review’, *Midwifery*, 66, pp. 70–78. doi:10.1016/j.midw.2018.07.012.

Xiong, J., Lipsitz, O., Nasri, F., Lui, L.M.W., Gill, H., Phan, L., Chen-Li, D., *et al.* (2020), “Impact of COVID-19 pandemic on mental health in the general population: A systematic review”, *Journal of Affective Disorders*, 277, pp. 55–64.

Yamato, T., Maher C, Saragiotto B, Moseley A, Hoffmann T, Elkins M, Brooks D. (2016). The TIDieR Checklist Will Benefit the Physiotherapy Profession. *Physiotherapy Canada. Physiotherapie Canada*, 68 (4), pp.311–314. [Online]. Available at: doi:10.3138/ptc.68.4.GEE.

Yang, J., Wei, Q., Ge, Y., Meng, L. And Zhao, M. (2019), “Smartphone-Based Remote Self-Management Of Chronic Low Back Pain: A Preliminary Study”, *Journal Of Healthcare Engineering*, 2019, P. 4632946. [Online] [Accessed June 2020] Available at: https://pubmed.ncbi.nlm.nih.gov/30881606/

Yardley, L., Ainsworth, B., Arden-Close, E. And Muller, I. (2015), “The Person-Based Approach To Enhancing The Acceptability And Feasibility Of Interventions”, *Pilot And Feasibility Studies*, 1, Pp. 37.

Yardley, L., Morrison, L., Bradbury, K. And Muller, I. (2015), “The Person-Based Approach To Intervention Development: Application To Digital Health-Related

Behavior Change Interventions", *Journal Of Medical Internet Research*, 17(1), Pp. E30. [Online] [Accessed April 2020] DOI: 10.2196/jmir.4055

Yu, J.Y., Goldberg, T., Lao, N., Feldman, B.M. And Goh, Y.I. (2021), "Electronic Forms For Patient Reported Outcome Measures (Proms) Are An Effective, Time-Efficient, And Cost-Minimizing Alternative To Paper Forms", *Pediatric Rheumatology Online Journal*, 19(1), Pp. 67. [Online] [Accessed November 2021] Available at: DOI: 10.1186/s12969-021-00551-z

Zahari, Z., Ishak, A. And Justine, M. (2020), "The Effectiveness Of Patient Education In Improving Pain, Disability And Quality Of Life Among Older People With Low Back Pain: A Systematic Review", *Journal Of Back And Musculoskeletal Rehabilitation*, 33(2), Pp. 245–254.

Zhu, C., Zeng, R., Zhang, W., Evans, R., & He, R. (2019). 'Pregnancy-Related Information Seeking and Sharing in the Social Media Era Among Expectant Mothers: Qualitative Study'. *Journal of Medical Internet Research*, *21*(12), Pp. e13694. [Online] [Accessed January 2020] Available at: DOI: 10.2196/13694

APPENDIX 1: PRISMA CHECKLIST FOR SYSTEMATISED REVIEW

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	Report identified as a systematised review
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	No specific abstract for the review was included. The findings of the review have been included in the thesis abstract as recommended by the examination team
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	Pg 36
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	Pg 37
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	Pg 38-39
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	Pg 39
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	Pg 39
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	Pg 40
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	Pg 41
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time	Pg 41

Section and Topic	Item #	Checklist item	Location where item is reported
		points, analyses), and if not, the methods used to decide which results to collect.	
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	Pg 41
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	Pg 40
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	Pg 41
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	Pg 42
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	N/A as no statistical pooling planned
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	Pg 42
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Pg 41-42
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	N/A as no statistical pooling was planned
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	N/A as no statistical pooling/meta-analysis was planned
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	N/A as no meta-analysis was planned
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Pg 42
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	Pg 44

Section and Topic	Item #	Checklist item	Location where item is reported
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	Pg 42-43
Study characteristics	17	Cite each included study and present its characteristics.	Table 2.2
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	Figure 2.2
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Table 2.5
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	Pg 126-130
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	N/A as no statistical pooling/meta-analysis was performed
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	N/A as no statistical pooling/meta-analysis was performed
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	N/A as no statistical pooling/meta-analysis was performed
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	N/A as no statistical pooling/meta-analysis was performed
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Pg 128-129
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	Pg 130-137
	23b	Discuss any limitations of the evidence included in the review.	Pg 130-137
	23c	Discuss any limitations of the review processes used.	Pg 137
	23d	Discuss implications of the results for practice, policy, and future research.	Pg 130-137
OTHER INFORMATION			
Registration and	24a	Provide registration information for the review, including register name and registration	Pg 42

Section and Topic	Item #	Checklist item	Location where item is reported
protocol		number, or state that the review was not registered.	
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	Pg 42
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	N/A as the review is not registered and there is no publicly available version of the protocol for comparison
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	Pg 42
Competing interests	26	Declare any competing interests of review authors.	Pg 42

APPENDIX 2: TIDIER CHECKLIST USED TO INFORM THE SYSTEMATISED REVIEW DATA EXTRACTION

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____

	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	_____	_____
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	_____	_____
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

APPENDIX 3: COMPLETED COREQ (CONSOLIDATED CRITERIA FOR REPORTING QUALITATIVE RESEARCH) CHECKLIST

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	Page 166, 168
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	Page 169-170
Occupation	3	What was their occupation at the time of the study?	Page 169-170
Gender	4	Was the researcher male or female?	Page 169-170
Experience and training	5	What experience or training did the researcher have?	Page 169-170
Relationship with Participants			
Relationship established	6	Was a relationship established prior to study commencement?	Page 166, 169
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	Page 165, 166
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Page 169-170
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Lengthy entry: Section 3.3 – 3.4 (Pages 143-150)
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 164/5, 168
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, Email	Page 164-165, 168
Sample size	12	How many participants were in the study?	Page 182
Non-participation	13	How many people refused to participate or dropped out? Reasons?	Page 181
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	Page 166, 169
Presence of non-Participants	15	Was anyone else present besides the participants and researchers?	Page 166, 169

Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	Page 182
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 165, 168
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	Page 166, 169
Field notes	20	Were field notes made during and/or after the interview or focus group?	Page 166, 169
Duration	21	What was the duration of the interviews or focus group?	Page 166, 169
Data saturation	22	Was data saturation discussed?	Page 181
Transcripts returned	23	Were transcripts returned to participants for comment and/or	Page 166, 169
Number of data coders	24	How many coders coded the data?	Page 171
Description of the coding tree	25	Did the authors provide a description of the coding tree	Page 172, 174
Derivation of themes	26	Were themes identified in advance or derived from the data?	Page 173
Software	27	What software, if applicable, was used to manage the data?	Page 171
Participant checking	28	Did participants provide feedback on the findings	Page 179-180
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings?	Multiple relevant entries: Section 4.3.1 – 4.3.4.4 (Pages 184-216)
Clarity of major themes	30	Were major themes clearly presented in the findings	Page 183, then multiple relevant entries: Section 4.3.1 – 4.3.4.4 (Pages 184-216)
Clarity of minor themes	31	Is there a discussion of minor themes	Multiple relevant entries: Section 4.3.1 – 4.3.4.4 (Pages 184-216)

APPENDIX 4: TOPIC GUIDE USED FOR PHASE 1 SERVICE USER INTERVIEWS

Semi-structured interview schedule: patient group with a previous history of back pain or pelvic girdle pain

Introductory script: *Firstly I would like to introduce myself: My name is Maria Moffatt and I am a PhD student from Manchester Metropolitan University. I would like to thank you for taking the time to speak to me today.*

Before we continue, I want to recap the purpose of today's discussion. The aim of this project is to explore the idea of using digital media to provide pregnant women with information about back pain and pelvic girdle pain in pregnancy, in order to try to help reduce the occurrence and impact of these problems.

You have been invited to speak to me today as you are currently a user of the antenatal clinic services at the Xxx, and you have some experience of back pain and pelvic girdle pain in either this or a previous pregnancy.

I would like you to remember that there are no right or wrong answers to any of the questions I ask, and I am just as interested in negative comments as I am in positive comments.

I will be audio-recording the discussion today to make sure that I don't miss anything important you have to say, but please be reassured that everything you say today will be kept confidential.

Would you like to ask any questions before we start?

OK, so if you are happy then let's begin.

Interview questions:

The four main areas I would like to cover today are:

1) If/how you currently use digital media
2) How you feel about the use of the internet to access health information
3) How you feel online health information should be presented
4) What information you feel would be useful to other pregnant women regarding back pain and/or pelvic girdle pain
5) How a digital media-based health intervention might be presented to make it as useful as possible

So firstly, I'd like to clarify that when I talk about 'digital media', I'm referring to any electronic or internet-based application that allows us to share information, so this could include: Websites, Apps, Facebook, Twitter, LinkedIn, Whatsapp, Instagram, Flickr, Snapchat and many more.

1. Firstly I'd like you to tell me about any ways you currently use digital media in your personal life. For example …
    - *What mobile apps, websites, social media apps do you currently use?*

- *Which mobile apps, websites, social media apps do you use most frequently?*
- *How often do you access these sites?*

2. Who do you contact/share information with?
3. How do you access these sites: Do you use your mobile, tablet, PC?
4. Do you like to upload content yourself or do you prefer to view what other people have uploaded?

If the informant indicates that they do not use any apps or social media sites:

- *What is it that puts you off from using apps or media platforms?*
- *Have you ever used apps or social media platforms in the past?*
- *Is there anything that would encourage you to engage with these in the future?*

5. Next I would like you to tell me how you feel about using the internet to access health information? For example …
    - *What are the positive aspects of being able to access health information online?*
    - *What, if anything deters you from accessing health information online?*
    - *What factors affect the level of trust you have in online health information?*
    - *How do you feel online health information compares to information provided to you directly by a healthcare professional?*

6. Can you give me an example of a time you have accessed health or pregnancy-related information online? For example …
    - *What prompted you to access this information online rather than asking your GP or midwife?*
    - *How was the information presented – for example was the information written, were photos/diagrams used, were videos used?*
    - *Can you tell me what you liked about the way the information was presented?*
    - *Was there anything that you would've liked to be improved about the way the information was presented to help you to understand it better?*

7. When you first began to experience back pain/pelvic girdle pain, what information did you feel you needed to help you manage the problem?

8. How did you go about seeking the information or advice you wanted? For example …
    - *Did you discuss your pain with your doctor or midwife? If so, what information/advice were you given?*
        - *Were you given any written resources/leaflets?*
        - *If so, what were these? Were these useful?*
        - *If so, why did you find them useful?*

- *Was there any information you felt was lacking/ or any other information you would've found useful?*
- *Were you directed to any particular websites?*
- *If so, what were these? Were these useful?*
- *If so, why did you find them useful?*
- *Was there any information you felt was lacking?*

If the informant indicates that they searched online for information independently with no guidance from a healthcare professional

- *Why did you choose to search online rather than discussing the problem with your healthcare provider?*
- *How useful were the information resources you found online?*
- *Was there anything specific you felt was lacking from the information you found?*
- *What difficulties, if any, did you encounter when searching for this information online?*

9. As I explained at the start, the aim of this project is to assess if it is feasible to design an advice and information package, about back pain and pelvic girdle pain in pregnancy that can be made available to pregnant women via digital media. So how do you feel about the idea of making this sort of information available via digital media? For example…
    - *What do you think might be the positive aspects of presenting information in this way compared to traditional leaflets or information booklets?*
    - *Is there anything that would deter you from accessing information provided in this way?*

Well I think we have covered all of the important areas I was keen to discuss. Is there anything you would like to add before we finish?

OK then, I think we can conclude the session there. I would like to thank you once again for giving your time to share your thoughts.

APPENDIX 5: TOPIC GUIDE USED FOR THE PHASE 1 CLINICIAN FOCUS GROUPS

Focus Group Guide: Midwives staff group

Good morning/afternoon/evening and welcome to our discussion session. Thank you for taking the time to speak to us. My name is Maria Moffatt and assisting me today is _____. We are both from Manchester Metropolitan University, and as part of my PhD project we are exploring the idea of using mobile technologies such as social media or mobile phone apps to provide pregnant women with information about pregnancy-related lumbopelvic pain, in order to try to help reduce the occurrence and impact of this problem.

You have been invited because you are all midwives working within this Trust who are frequently involved with the care of pregnant women with lumbopelvic pain.

I would like you to remember that there are no right or wrong answers to any of the questions asked today, just differing points of view. Please also feel free to share your point of view even if it is different to what others have said, and keep in mind that we are just as interested in negative comments as we are in positive comments.

Everything said in this discussion will be kept confidential and I must remind you all to respect the confidentiality of any information provided by others in the group.

We are audio-recording the discussion today to ensure that we do not miss any important comments made. It is therefore helpful if only one person speaks at a time and if we all try to speak as clearly as possible.

Does anyone have any questions before we begin?

OK, so if everyone is happy, let's begin!

The four main areas I'd like to cover today are:

1. If/how you currently use websites, social media or mobile phone apps in your personal lives
2. Your views on the use of websites, social media sites or mobile phone apps for health promotion information
3. How you feel digital, social-media-based or app-based health promotion interventions could be integrated within your current clinical practice
4. What you feel the potential barriers and facilitators to the implementation of digital, app-based or social-media-based healthcare interventions might be in an NHS setting

So just to clarify, when I use the term social media, I'm referring to any internet-based application that allows us to share information, so this could include: Facebook, Twitter, LinkedIn, Whatsapp, Instagram, Flickr and many more. So, firstly I'd like you to tell me about how you currently interact with social media or use mobile phone apps in your personal lives. When I talk about apps, I mean any mobile phone applications that you can download to your smartphone.

Probes if required?

1a. Which platforms/sites/apps do you access most frequently?

1b. Who do you contact/share information with via apps/social media?

1c. How often do you access these sites/use these apps?

1d. How do you usually access websites/social media sites? Do you use your mobile phone, tablet or computer?

1e. If any individual indicates that they do not access social media sites or apps at all:

> What is it that deters you from using social media/apps?
>
> Is there anything that could be altered that would encourage you to begin using social media sites/apps in the future?

Making health information available via social media sites such as Facebook or via mobile phone apps is a novel way of delivering health promotion messages to the public and has been successfully used in other fields of healthcare such as diabetes management and sexual health promotion, but what do you think are the potential advantages and disadvantages of making health information available in this way?

Probes if required

2a. What might be the advantages of health professionals making health information accessible to their patients via social media platforms/mobile phone apps as opposed to written/printed booklets?

2b. What might be the drawbacks of replacing face-to-face information provision with an online exchange?

I'd like to talk more specifically about lumbopelvic pain now. I want you to think about how you usually approach the management of pregnant women with this condition. What sort of information or resources do you usually provide to help these women better manage their condition?

Probes if required:

3a. What information do you feel is important for them to be given in order to help them manage their condition?

3b. What materials or resources do you use to help your patients understand and retain the information you provide to them about their condition? For example do you use information leaflets, websites, models or diagrams to help with your explanation?

As you all now know, the ultimate aim of this project is to explore whether an advice and information package about lumbopelvic pain is suitable to be made available to pregnant women via websites/social media or via the use of a mobile phone app. In what ways could an intervention like this be used to support your current clinical practice?

Probes if required

4a. How could your use of printed information leaflets change if you and your patients had access to a social media-based or app-based information package like this?

4b. In what way might such an intervention impact on the frequency at which you refer your patients to physiotherapy services?

What practical problems would have to be overcome to make the use of web-based/social-media-based interventions/app-based interventions feasible in an NHS setting?

5a.What additional equipment do you think would be needed for clinicians in this setting to be able to interact with social-media-based interventions or app-based interventions?

5b. In what ways would your current IT systems restrict your use of social-media-based interventions?

5c. In what ways would your Trust's information security policies restrict your use of social-media-based interventions or app-based interventions?

5d. What training would you feel is necessary to allow you to implement social-media-based or app-based interventions into your current practice?

Well I think we have covered all the areas we planned to discuss. Is there anything anyone would like to add before we finish?

OK. I think we can conclude the session there. I would like to thank you all once again for joining the discussion and for sharing your thoughts with us.

Focus Group Guide: Physiotherapists staff group

Good morning/afternoon/evening and welcome to our discussion session. Thank you for taking the time to speak to us. My name is Maria Moffatt and assisting me today is _____. We are both from Manchester Metropolitan University, and as part of my PhD project we are exploring the idea of using mobile technologies such as social media or mobile phone apps to provide pregnant women with information about pregnancy-related lumbopelvic pain, in order to try to help reduce the occurrence and impact of this problem.

You have been invited because you are physiotherapists working within this Trust who are all in some way involved with the care of pregnant women referred for treatment of lumbopelvic pain.

I would like you to remember that there are no right or wrong answers to any of the questions asked today, just differing points of view. Please also feel free to share your point of view even if it is different to what others have said, and keep in mind that we are just as interested in negative comments as we are in positive comments.

Everything said in this discussion will be kept confidential and I must remind you all to respect the confidentiality of any information provided by others in the group.

We are audio-recording the discussion today to ensure that we do not miss any important comments made. It is therefore helpful if only one person speaks at a time and if we all try to speak as clearly as possible.

Does anyone have any questions before we begin?

OK, so if everyone is happy, let's begin!

The four main areas I'd like to cover today are:

1. If/how you currently use websites, social media or mobile phone apps in your personal lives

2. Your views on the use of websites, social media sites or mobile phone apps for health promotion information

3. How you feel web-based, social-media-based or app-based health promotion interventions could be integrated within your current clinical practice

4. What you feel the potential barriers and facilitators to the implementation of web-based, app-based or social-media-based healthcare interventions might be in an NHS setting

So, just to clarify, when I use the term social media, I'm referring to any internet-based application that allows us to share information, so this could include: Facebook, Twitter, LinkedIn, Whatsapp, Instagram, Flickr and many more. So, firstly I'd like you to tell me about how you currently interact with social media or use mobile phone apps in your personal lives.

Probes if required?

1a. Which platforms/sites/apps do you access most frequently?

1b. Who do you contact/share information with via web/social media?

1c. How often do you access these sites/use these apps?

1d. How do you usually access websites/social media sites? Do you use your mobile phone, tablet or computer?

1e. If any individual indicates that they do not access social media sites or apps at all:

What is it that deters you from using social media/apps?

Is there anything that could be altered that would encourage you to begin using social media sites/apps in the future?

Making health information available via social media sites such as Facebook or via mobile phone apps is a novel way of delivering health promotion messages to the public and has been successfully used in other fields of healthcare such as diabetes management and sexual health promotion, but what do you think are the potential advantages and disadvantages of making health information available in this way?

Probes if required

2a. What might be the advantages of health professionals making health information accessible to their patients via websites/social media platforms/mobile phone apps as opposed to written/printed booklets?

2b. What might be the drawbacks of replacing face-to-face information provision with an online exchange?

I'd like to talk more specifically about lumbopelvic pain now. I want you to think about how you usually approach the management of pregnant women with this condition. What sort of information or resources do you usually provide to help these women better manage their condition?

Probes if required:

3a. What information do you feel is important for them to be given in order to help them manage their condition?

3b. What materials or resources do you use to help your patients understand and retain the information you provide to them about their condition? For example do you use information leaflets, websites, models or diagrams to help with your explanation?

As you all now know, the ultimate aim of this project is to explore whether an advice and information package about lumbopelvic pain is suitable to be made available to pregnant women via website/social media or via the use of a mobile phone app. In what ways could an intervention like this be used to support your current clinical practice?

Probes if required

4a. How could your use of printed information leaflets change if you and your patients had access to a social media-based or app-based information package like this?

4b. In what way might such an intervention impact on your physiotherapy management of these patients?

What practical problems would have to be overcome to make the use of social-media-based interventions or app-based interventions feasible in an NHS setting?

5a.What additional equipment do you think would be needed for clinicians in this setting to be able to interact with social-media-based interventions or app-based interventions?

5b. In what ways would your current IT systems restrict your use of social-media-based interventions?

5c. In what ways would your Trust's information security policies restrict your use of social-media-based interventions or app-based interventions?

5d. What training would you feel is necessary to allow you to implement social-media-based or app-based interventions into your current practice?

Well I think we have covered all the areas we planned to discuss. Is there anything anyone would like to add before we finish?

OK. I think we can conclude the session there. I would like to thank you all once again for joining the discussion and for sharing your thoughts with us.

APPENDIX 6: THEMATIC FRAMEWORKS FOR THE PHASE 1 QUALITATIVE DATA FOR EACH OF THE THREE STAKEHOLDER GROUPS

Coding framework generated from transcripts of interviews with patients Name of Theme/Subtheme	Numerical code
The use of apps and social media	1
Reasons for using apps and social media	1.1
Reasons for not using apps and social media/factors that deter use	1.2
Frequency of engagement with apps and social media	1.3
Method of access	1.4
Attitude towards the use of apps and social media for information provision	1.5
Online health information-seeking behaviours	2
Reasons for seeking health information online	2.1
Seeking factually accurate information	2.2
Negative impact of seeking health information online	2.3
Perceived impact of face-to-face input from HCP	2.4
Deciphering trustworthiness of online health information	2.5
Preferred format and presentation of online health information	2.6
Self-management	3
Attitude towards self-management	3.1
Attitude towards pain in pregnancy	3.2
Confusion surrounding pregnancy-related lumbopelvic pain (PLPP)	3.3
Information provision in the context of PLPP	4
Timing of information provision	4.1
Value of adequate information provision	4.2
Information identified by participants as useful or required	4.3

Coding framework generated from transcript of physiotherapist focus group Theme/subtheme	Code
Information seeking and information provision in the context of PLPP	1
Information-seeking behaviours	1.1
Online Vs Face-to-face information provision	1.2
Deciphering trustworthiness of information (amongst both patients and clinicians)	1.3
Apps and SoMe as platforms for information provision	1.4
Attitudes towards the use of mobile phone apps for PLPP management in the current clinical practice	2
Proposed use of app in current clinical practice	2.1
Facilitators to effective use of app	2.2
Facilitators to uptake of app by other healthcare professionals	2.3
Acceptability of apps to patients and professionals	2.4
PLPP management in the context of the NHS	3
Lack of standardisation of care pathway for patients experiencing PLPP	3.1
Interprofessional relationships and boundaries	3.2
Conflicting information and approaches amongst different professional groups	3.3
Professional lived experience as a facilitator to improved PLPP management	3.4
Importance of the timing of intervention	3.5
Patients' expectations of physiotherapy treatment for PLPP	3.6
Impact and importance of adequate PLPP management	3.7
Attitude towards PLPP and its management	4
Myths and confusion surrounding PLPP	4.1
Delineating PLPP from 'normal aches and pains of pregnancy'	4.2
Lack of awareness of PLPP amongst patients	4.3
Physiotherapists' perception of factors affecting recovery from PLPP	4.4
Importance of adequate and accurate information provision to facilitate self-management	4.5
Positive attitude towards the use of apps to support self-management	4.6
Importance of reassurance to support self-management	4.7
Varying motivation for self-management amongst PLPP patients	4.8

Coding framework generated from transcripts of Midwifery focus group Name of theme/subtheme	Numerical code
Online Information-Seeking amongst pregnant women	1
Information-seeking behavior amongst pregnant women	1.1
Impact of independent online health information seeking	1.2
Deciphering trustworthiness of health-related information	1.3
Health information provision in the context of PLPP	2
Online Vs face-to-face information provision	2.1
Current trends in information provision in the NHS	2.2
PLPP management in the context of the NHS	3
Barriers to optimal PLPP management and the perceived impact of these barriers	3.1
Facilitator to optimal PLPP management	3.2
Current PLPP management strategies in the host setting	3.3
Variations and perceived inequities in PLPP service provision	3.4
Attitudes toward the use of mobile apps for PLPP information provision in current clinical practice	4
Barriers to use of apps in current clinical practice	4.1
Facilitators to use of apps in current clinical practice	4.2
Suggested use and function of proposed app in current clinical practice	4.3
Attitudes towards PLPP and its management	5
Midwives' perception of PLPP as a problem	5.1
Midwives' attitudes towards PLPP self-management	5.2

APPENDIX 7: LIST OF SYSTEMATIC REVIEWS AND CLINICAL GUIDELINES USED TO INFORM THE LIST OF RECOMMENDED PLPP SELF-MANAGEMENT BEHAVIOURS

Title of Paper, First author, Source, Year of publication
Pelvic girdle pain and pregnancy. Information for you Royal College of Obstetricians and Gynaecologists 2015
The effectiveness of stabilising exercises in pelvic girdle pain during pregnancy and after delivery: A systematic review Almousa et al Physiotherapy Research International 2018
Exercise for the prevention and treatment of low back, pelvic girdle and lumbopelvic pain during pregnancy: a systematic review and meta-analysis Davenport et al British Journal of Sports Medicine 2018
Pelvic Girdle Pain in the Antepartum Population Physical Therapy Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health from the Section on Women's Health and the Orthopaedic Section of the American Physical Therapy Association Clinton et al 2017
Exercise for the prevention of low back and pelvic girdle pain in pregnancy: A meta-analysis of randomized controlled trials Shiri et al European Journal of Pain 2017
The Effectiveness of Exercise in Treatment of Pregnancy-Related Lumbar and Pelvic Girdle Pain: A Meta-Analysis and Evidence-Based Review Belogolovsky et al Journal of Women's Health Physical Therapy 2015
Treatments for pregnancy-related lumbopelvic pain: a systematic review of physiotherapy modalities

Gutke et al ACTA Obstetricia et Gynaecologica 2015
Pregnancy Care Guidelines: 59 Pelvic girdle pain Australian Government Department of Health Updated May 2019
Recommendations for Physical Therapists on the Treatment of Lumbopelvic Pain During Pregnancy: A Systematic Review Van Benten et al Journal of Orthopaedic and Sports Physical Therapy 2014
The Role of Exercise in the Management of Pelvic Girdle and Low Back Pain in Pregnancy: A Systematic Review of the Literature Boissonnault et al Journal of Women's Health Physical Therapy 2012
The Effects of Core and Lower Extremity Strengthening on Pregnancy-Related Low Back and Pelvic Girdle Pain: A Systematic Review Lillios and Young Journal of Women's Health Physical Therapy 2012
MANAGEMENT OF PELVIC GIRDLE PAIN IN PREGNANCY AND POST-PARTUM Chartered Physiotherapists Women's Health and Continence and Directorate of Strategy and Clinical Programmes Health Service Executive 2012
Effectiveness of physical therapy for pregnancy related low back and/or pelvic pain after delivery: A systematic review Ferreira et al Physiotherapy Theory and Practice 2013
RCOG release: Early diagnosis and treatment of pelvic girdle pain can improve a woman's quality of life Royal college of Obstetricians and Gynaecologists 2015

European guidelines for the diagnosis and treatment of pelvic girdle pain Vleeming et al European Spine Journal 2008
Pregnancy-related pelvic girdle pain – Guidance for healthcare professionals Pelvic Obstetric and Gynaecological Physiotherapy group 2015

APPENDIX 8: COMPLETE LIST OF REFERENCES USED FOR CONSTRUCTION OF THE APP CONTENT

Akmeşe, Z. B. and Oran, N. T. (2014) 'Effects of Progressive Muscle Relaxation Exercises Accompanied by Music on Low Back Pain and Quality of Life During Pregnancy', *Journal of Midwifery and Women's Health,* 59(5), pp. 503-509.

Albert, H., Godskesen, M., Korsholm, L. and Westergaard, J. (2006) 'Risk factors in developing pregnancy-related pelvic girdle pain', *Acta Obstetricia et Gynecologica Scandinavica,* 85(5), pp. 539-544.

Albert, H., Godskesen, M. and Westergaard, J. (2001) 'Prognosis in four syndromes of pregnancy-related pelvic pain', *Acta Obstetricia et Gynecologica Scandinavica,* 80(6), pp. 505-510.

Albert, H. B., Godskesen, M. and Westergaard, J. G. (2002) 'Incidence of four syndromes of pregnancy-related pelvic joint pain', *Spine,* 27(24), pp. 2831-2834.

Aldabe, D., Milosavljevic, S. and Bussey, M. D. (2012) 'Is pregnancy related pelvic girdle pain associated with altered kinematic, kinetic and motor control of the pelvis? A systematic review', *European Spine Journal,* 21(9), pp. 1777-1787.

Backhausen, M. G., Tabor, A., Albert, H., Rosthøj, S., Damm, P. and Hegaard, H. K. (2017) 'The effects of an unsupervised water exercise program on low back pain and sick leave among healthy pregnant women – A randomised controlled trial', *PLoS ONE,* 12(9).

Bastiaanssen, J. M., De Bie, R. A., Bastiaenen, C. H. G., Essed, G. G. M. and Van Den Brandt, P. A. (2005a) 'A historical perspective on pregnancy-related low back and/or pelvic girdle pain', *European Journal of Obstetrics Gynecology and Reproductive Biology,* 120(1), pp. 3-14.

Bastiaanssen, J. M., De Bie, R. A., Bastiaenen, C. H. G., Heuts, A., Kroese, M. E. A. L., Essed, G. G. M. and Van Den Brandt, P. A. (2005b) 'Etiology and prognosis of pregnancy-related pelvic girdle pain; design of a longitudinal study', *BMC Public Health,* 5.

Bertuit, J., Van Lint, C. E., Rooze, M. and Feipel, V. (2018) 'Pregnancy and pelvic girdle pain: Analysis of pelvic belt on pain', *Journal of Clinical Nursing,* 27(1-2), pp. e129-e137.

Bewyer, K. J., Bewyer, D. C., Messenger, D. and Kennedy, C. M. (2009) 'Pilot data: association between gluteus medius weakness and low back pain during pregnancy', *The Iowa orthopaedic journal,* 29, pp. 97-99.

Bishop, A., Holden, M. A., Ogollah, R. O. and Foster, N. E. (2016) 'Current management of pregnancy-related low back pain: A national cross-sectional survey of UK physiotherapists', *Physiotherapy (United Kingdom),* 102(1), pp. 78-85.

Bjelland, E. K., Eberhard-Gran, M., Nielsen, C. S. and Eskild, A. (2011) 'Age at menarche and pelvic girdle syndrome in pregnancy: A Population study of 74 973 women', *BJOG: An International Journal of Obstetrics and Gynaecology,* 118(13), pp. 1646-1652.

Bjelland, E. K., Eskild, A., Johansen, R. and Eberhard-Gran, M. (2010) 'Pelvic girdle pain in pregnancy: The impact of parity', *American Journal of Obstetrics and Gynecology,* 203(2), pp. 146.e1-146.e6.

Bjelland, E. K., Kristiansson, P., Nordeng, H., Vangen, S. and Eberhard-Gran, M. (2013a) 'Hormonal contraception and pelvic girdle pain during pregnancy: A population study of 91 721 pregnancies in the Norwegian Mother and Child Cohort', *Human Reproduction,* 28(11), pp. 3134-3140.

Bjelland, E. K., Owe, K. M., Stuge, B., Vangen, S. and Eberhard-Gran, M. (2015) 'Breastfeeding and pelvic girdle pain: A follow-up study of 10 603 women 18 months after delivery', *BJOG: An International Journal of Obstetrics and Gynaecology,* 122(13), pp. 1765-1771.

Bjelland, E. K., Stuge, B., Engdahl, B. and Eberhard-Gran, M. (2013b) 'The effect of emotional distress on persistent pelvic girdle pain after delivery: A longitudinal population study', *BJOG: An International Journal of Obstetrics and Gynaecology,* 120(1), pp. 32-40.

Bjelland, E. K., Stuge, B., Vangen, S., Stray-Pedersen, B. and Eberhard-Gran, M. (2013c) 'Mode of delivery and persistence of pelvic girdle syndrome 6 months postpartum', *American Journal of Obstetrics and Gynecology,* 208(4), pp. 298.e1-298.e7.

Bisson, DL, Newell, SD, Laxton, C, on behalf of the Royal College of Obstetricians and Gynaecologists. (2019) 'Antenatal and Postnatal Analgesia. Scientific Impact Paper No. 59'. *British Journal of Obstetrics and Gynaecology*; 126: pp. e115– 24.

Bogaert, M. Stack, S. Partington, J. Marceca, A. Tremback-Ball. (2018) 'The effects of stabilization exercise on low back pain and pelvic girdle pain in pregnant women' *Annals of Physical and Rehabilitation Medicine,* Volume 61, Supplement, pp e157-e158,

Casagrande, D., Gugala, Z., Clark, S. M. and Lindsey, R. W. (2015) 'Low Back Pain and Pelvic Girdle Pain in Pregnancy', *Journal of the American Academy of Orthopaedic Surgeons,* 23(9), pp. 539-549.

Clinton, S.C., Newell, A., Downey, P.A. and Ferreira, K. (2017) 'Pelvic Girdle Pain in the Antepartum Population: Physical Therapy Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health From the Section on Women's Health and the Orthopaedic Section of the American Physical Therapy Association' *Journal of Women's Health Physical Therapy* 41(2), PP 102-125

Close, C., Sinclair, M., Liddle, D., Mc Cullough, J. and Hughes, C. (2016) 'Women's experience of low back and/or pelvic pain (LBPP) during pregnancy', *Midwifery,* 37, pp. 1-8.

Close, C., Sinclair, M., Liddle, S. D., Madden, E., McCullough, J. E. M. and Hughes, C. (2014) 'A systematic review investigating the effectiveness of Complementary and Alternative Medicine (CAM) for the management of low back and/or pelvic pain (LBPP) in pregnancy', *Journal of Advanced Nursing,* 70(8), pp. 1702-1716.

Eggen, M. H., Stuge, B., Mowinckel, P., Jensen, K. S. and Hagen, K. B. (2012) 'Can supervised group exercises including ergonomic advice reduce the prevalence and severity of low back pain and pelvic girdle pain in pregnancy? A randomized controlled trial', *Physical Therapy,* 92(6), pp. 781-790.

Elden, H., Fagevik-Olsen, M., Ostgaard, H. C., Stener-Victorin, E. and Hagberg, H. (2008a) 'Acupuncture as an adjunct to standard treatment for pelvic girdle pain in pregnant women: Randomised double-blinded controlled trial comparing acupuncture with non-penetrating sham acupuncture', *BJOG: An International Journal of Obstetrics and Gynaecology,* 115(13), pp. 1655-1668.

Elden, H., Gutke, A., Kjellby-Wendt, G., Fagevik-Olsen, M. and Ostgaard, H. C. (2016) 'Predictors and consequences of long-term pregnancy-related pelvic girdle pain: A longitudinal follow-up study', *BMC Musculoskeletal Disorders,* 17(1).

Elden, H., Lundgren, I. and Robertson, E. (2013) 'Life's pregnant pause of pain: Pregnant women's experiences of pelvic girdle pain related to daily life: A Swedish interview study', *Sexual and Reproductive Healthcare,* 4(1), pp. 29-34.

Elden, H., Ostgaard, H. C., Fagevik-Olsen, M., Ladfors, L. and Hagberg, H. (2008b) 'Treatments of pelvic girdle pain in pregnant women: Adverse effects of standard treatment, acupuncture and stabilising exercises on the pregnancy, mother, delivery and the fetus/neonate', *BMC Complementary and Alternative Medicine,* 8.

Engeset, J., Stuge, B. and Fegran, L. (2014) 'Pelvic girdle pain affects the whole life - A qualitative interview study in Norway on women's experiences with pelvic girdle pain after delivery', *BMC Research Notes,* 7(1).

Fredriksen, E. H., Harris, J. and Moland, K. M. (2016) 'Web-based discussion forums on pregnancy complaints and maternal health literacy in Norway: A qualitative study', *Journal of Medical Internet Research,* 18(5).

Fredriksen, E. H., Moland, K. M. and Sundby, J. (2008) '"Listen to your body". A qualitative text analysis of internet discussions related to pregnancy health and pelvic girdle pain in pregnancy', *Patient Education and Counseling,* 73(2), pp. 294-299.

French SD, Cameron M, Walker BF, Reggars JW, Esterman AJ (2006) 'Superficial heat or cold for low back pain.' *Cochrane Database of Systematic Reviews* 25 (1)

Garra G, Singer AJ, Leno R, Taira BR, Gupta N, Mathaikutty B, Thode HJ. (2010) 'Heat or cold packs for neck and back strain: a randomized controlled trial of efficacy' *Academic Emergency Medicine: Official journal for the society of academic emergency medicine* 17(5) pp. 484-489

Gjestland, K., Bø, K., Owe, K. M. and Eberhard-Gran, M. (2013) 'Do pregnant women follow exercise guidelines? Prevalence data among 3482 women, and prediction of low-back pain, pelvic girdle pain and depression', *British Journal of Sports Medicine,* 47(8), pp. 515-520.

Granath, A. B., Hellgren, M. S. E. and Gunnarsson, R. K. (2006) 'Water aerobics reduces sick leave due to low back pain during pregnancy', *JOGNN - Journal of Obstetric, Gynecologic, and Neonatal Nursing,* 35(4), pp. 465-471.

Gutke, A., Boissonnault, J., Brook, G. and Stuge, B. (2018) 'The Severity and Impact of Pelvic Girdle Pain and Low-Back Pain in Pregnancy: A Multinational Study', *Journal of Women's Health,* 27(4), pp. 510-517.

Gutke, A., Östgaard, H. C. and Öberg, B. (2008) 'Association between muscle function and low back pain in relation to pregnancy', *Journal of Rehabilitation Medicine,* 40(4), pp. 304-311.

Hall, H., Cramer, H., Sundberg, T., Ward, L., Adams, J., Moore, C., Sibbritt, D. and Lauche, R. (2016) 'The effectiveness of complementary manual therapies for pregnancy-related back and pelvic pain A systematic review with meta-analysis', *Medicine (United States),* 95(38).

Ho, S. S. M., Yu, W. W. M., Lao, T. T., Chow, D. H. K., Chung, J. W. Y. and Li, Y. (2009) 'Effectiveness of maternity support belts in reducing low back pain during pregnancy: A review', *Journal of Clinical Nursing,* 18(11), pp. 1523-1532.

Hu, H., Meijer, O. G., van Dieën, J. H., Hodges, P. W., Bruijn, S. M., Strijers, R. L., Nanayakkara, P. W., van Royen, B. J., Wu, W. and Xia, C. (2010) 'Muscle activity during the active straight leg raise (ASLR), and the effects of a pelvic belt on the ASLR and on treadmill walking', *Journal of Biomechanics,* 43(3), pp. 532-539.

Kanakaris, N. K., Roberts, C. S. and Giannoudis, P. V. (2011) 'Pregnancy-related pelvic girdle pain: An update', *BMC Medicine,* 9.

Kaplan, Ş., Alpayci, M., Karaman, E., Çetin, O., Özkan, Y., İlter, S., Şah, V. and Şahin, H. G. (2016) 'Short-term effects of kinesio taping in women with pregnancy-related low back pain: A randomized controlled clinical trial', *Medical Science Monitor,* 22, pp. 1297-1301.

Katonis, P., Kampouroglou, A., Aggelopoulos, A., Kakavelakis, K., Lykoudis, S., Makrigiannakis, A. and Alpantaki, K. (2011) 'Pregnancy-related low back pain', *Hippokratia,* 15(3), pp. 205-210.

Kordi, R., Abolhasani, M., Rostami, M., Hantoushzadeh, S., Mansournia, M. A. and Vasheghani-Farahani, F. (2013) 'Comparison between the effect of lumbopelvic belt and home based pelvic stabilizing exercise on pregnant women with pelvic girdle pain; A randomized controlled trial', *Journal of Back and Musculoskeletal Rehabilitation,* 26(2), pp. 133-139.

Kovacs CS, Ralston SH. (2015) ‘Presentation and management of osteoporosis presenting in association with pregnancy or lactation’ *Osteoporosis International* 26(9) pp. 2223-2241

Kovacs, F. M., Garcia, E., Royuela, A., González, L. and Abraira, V. (2012) 'Prevalence and factors associated with low back pain and pelvic girdle pain during pregnancy: A

multicenter study conducted in the spanish national health service', *Spine,* 37(17), pp. 1516-1533.

Mens, J. M. A., Damen, L., Snijders, C. J. and Stam, H. J. (2006) 'The mechanical effect of a pelvic belt in patients with pregnancy-related pelvic pain', *Clinical Biomechanics,* 21(2), pp. 122-127.

Mens, J. M. A., Pool-Goudzwaard, A. and Stam, H. J. (2009) 'Mobility of the pelvic joints in pregnancy-related lumbopelvic pain: A systematic review', *Obstetrical and Gynecological Survey,* 64(3), pp. 200-208.

Mogren, I. (2007) 'Perceived health six months after delivery in women who have experienced low back pain and pelvic pain during pregnancy', *Scandinavian Journal of Caring Sciences,* 21(4), pp. 447-455.

Mogren, I. M. (2005) 'Previous physical activity decreases the risk of low back pain and pelvic pain during pregnancy', *Scandinavian Journal of Public Health,* 33(4), pp. 300-306.

Mogren, I. M. (2006) 'BMI, pain and hyper-mobility are determinants of long-term outcome for women with low back pain and pelvic pain during pregnancy', *European Spine Journal,* 15(7), pp. 1093-1102.

Mogren, I. M. and Pohjanen, A. I. (2005) 'Low back pain and pelvic pain during pregnancy: Prevalence and risk factors', *Spine,* 30(8), pp. 983-991.

Nilsson-Wikmar, L., Holm, K., Öijerstedt, R. and Harms-Ringdahl, K. (2005) 'Effect of three different physical therapy treatments on pain and activity in pregnant women with pelvic girdle pain: A randomized clinical trial with 3, 6, and 12 months follow-up postpartum', *Spine,* 30(8), pp. 850-856.

Owe, K. M., Bjelland, E. K., Stuge, B., Orsini, N., Eberhard-Gran, M. and Vangen, S. (2016) 'Exercise level before pregnancy and engaging in high-impact sports reduce the risk of pelvic girdle pain: A population-based cohort study of 39 184 women', *British Journal of Sports Medicine,* 50(13), pp. 817-822.

Owe, K. M., Nystad, W. and Bø, K. (2009) 'Correlates of regular exercise during pregnancy: The Norwegian Mother and Child Cohort Study', *Scandinavian Journal of Medicine and Science in Sports,* 19(5), pp. 637-645.

Palastanga, N., Field, D., and Soames, R. (1989). *Anatomy and human movement: structure and function*. Oxford [England], Heinemann Medical Books.

Pelvic Obstetric and Gynaecological Physiotherapists (2015) ‘Pregnancy-related pelvic girdle pain. Guidance for healthcare professionals’ POGP

Pelvic Obstetric and Gynaecological Physiotherapists (2018) ‘Pregnancy-related pelvic girdle pain and other common conditions in pregnancy. Guidance for mothers-to-be and new mothers’ POGP

Persson, M., Winkvist, A., Dahlgren, L. and Mogren, I. (2013) '"Struggling with daily life and enduring pain" : A qualitative study of the experiences of pregnant women living with pelvic girdle pain', *BMC Pregnancy and Childbirth,* 13.

Robinson, H. S., Mengshoel, A. M., Bjelland, E. K. and Vøllestad, N. K. (2010a) 'Pelvic girdle pain, clinical tests and disability in late pregnancy', *Manual Therapy,* 15(3), pp. 280-285.

Robinson, H. S., Veierød, M. B., Mengshoel, A. M. and Vøllestad, N. K. (2010b) 'Pelvic girdle pain - Associations between risk factors in early pregnancy and disability or pain intensity in late pregnancy: A prospective cohort study', *BMC Musculoskeletal Disorders,* 11.

Soliday, E. and Betts, D. (2018) 'Treating Pain in Pregnancy with Acupuncture: Observational Study Results from a Free Clinic in New Zealand', *JAMS Journal of Acupuncture and Meridian Studies,* 11(1), pp. 25-30.

Stafne, S. N., Salvesen, K. Å., Romundstad, P. R., Stuge, B. and Mørkved, S. (2012) 'Does regular exercise during pregnancy influence lumbopelvic pain? A randomized controlled trial', *Acta Obstetricia et Gynecologica Scandinavica,* 91(5), pp. 552-559.

Stuge, B. (2015) 'Current knowledge on low back pain and pelvic girdle pain during pregnancy and after childbirth: A narrative review', *Current Women's Health Reviews,* 11(1), pp. 68-74.

Stuge, B., Saetre, K. and Ingeborg Hoff, B. (2013) ‘The automatic pelvic floor muscle response to the active straight leg raise test in cases with pelvic girdle pain and matched controls’ *Manual Therapy* 18 pp. 327-332

Stuge, B., Saetre, K. and Ingeborg Hoff, B. (2012) ‘The association between pelvic floor function and pelvic girdle pain- A matched case-control 3D ultrasound study’ *Manual Therapy* 17(2) pp. 150-156

Stuge, B., Garratt, A., Jenssen, H. K. and Grotle, M. (2011) 'The pelvic girdle questionnaire: A condition-specific instrument for assessing activity limitations and symptoms in people with pelvic girdle pain', *Physical Therapy,* 91(7), pp. 1096-1108.

Stuge, B., Holm, I. and Vøllestad, N. (2006) 'To treat or not to treat postpartum pelvic girdle pain with stabilizing exercises?', *Manual Therapy,* 11(4), pp. 337-343.

Stuge, B., Lærum, E., Kirkesola, G. and Vøllestad, N. (2004) 'The Efficacy of a Treatment Program Focusing on Specific Stabilizing Exercises for Pelvic Girdle Pain after Pregnancy: A Randomized Controlled Trial', *Spine,* 29(4), pp. 351-359.

Vermani, E., Mittal, R. and Weeks, A. (2010) 'Pelvic girdle pain and low back pain in pregnancy: A review', *Pain Practice,* 10(1), pp. 60-71.

Vleeming, A., Albert, H. B., Östgaard, H. C., Sturesson, B. and Stuge, B. (2008) 'European guidelines for the diagnosis and treatment of pelvic girdle pain', *European Spine Journal,* 17(6), pp. 794-819.

Vleeming, A., De Vries, H. J., Mens, J. M. A. and Van Wingerden, J. P. (2002) 'Possible role of the long dorsal sacroiliac ligament in women with peripartum pelvic pain', *Acta Obstetricia et Gynecologica Scandinavica,* 81(5), pp. 430-436.

Vøllestad, N. K., Torjesen, P. A. and Robinson, H. S. (2012) 'Association between the serum levels of relaxin and responses to the active straight leg raise test in pregnancy', *Manual Therapy,* 17(3), pp. 225-230.

Vøllestad NK, Stuge B. (2009) ‘Prognostic factors for recovery from postpartum pelvic girdle pain.’ *European Spine Journal* 18(5) pp.718-726

W. H. Wu, O. G. Meijer, K. Uegaki, J. M. A. Mens, J. H. van Dieën, P. I. J. M. Wuisman, H. C. Östgaard (2004) ‘Pregnancy-related pelvic girdle pain (PPP), I: Terminology, clinical presentation, and prevalence’ *European Spine Journal* 13(7) PP.575-589

Yao, X., Li, C., Ge, X., Wei, J., Luo, J. and Tian, F. (2017) 'Effect of acupuncture on pregnancy related low back pain and pelvic pain: A systematic review and meta-analysis', *International Journal of Clinical and Experimental Medicine,* 10(4), pp. 5903-5912.

APPENDIX 9: EARLY DRAFT OF APP CONTENT FOR DEMONSTRATION PURPOSES

Please note that the highlighting and formatting was done by staff at the app development company to reflect the different type of coding required for different sections of text.

Collection title:

Pelvic Pain

Collection summary:

This content gives you information on pregnancy-related lower back pain and pregnancy-related pelvic girdle pain

Hero image for content package:

Warning Page:

SUMMARY NEEDED a short one, one sentence, 2 lines max

Introduction (each section needs a Title, we can't have text/content that is not under a section which needs to have a title)

If you begin to experience pain in your lower back or pelvis, it is essential that you inform your midwife or GP so that other causes of the pain (not relating to bone, joint, muscle or connective tissue) can be excluded.

You should seek medical attention for your back pain immediately if any of the following points apply:

You are experiencing any vaginal bleeding

You are leaking fluid from your vagina

You are experiencing any abdominal contractions

You feel that your baby is moving less than normal

You are experiencing any bladder or bowel changes, such as:

Increased difficulty when trying to urinate

Decreased sensation when trying to urinate

Decreased feeling when using toilet paper to wipe yourself

An inability to fully empty the bladder or bowel

Increasing difficulty when you try to stop or control the flow of urine

Not knowing when the bladder is either full or empty

Loss of sensation when you pass a bowel motion

Losing control of the bladder or bowel

You are experiencing a loss of sensation in the genitals during sexual intercourse

You are experiencing progressively worsening weakness or altered sensation in your legs

You are tripping/falling, or having difficulty controlling your legs

You are experiencing altered sensation (such as pins and needles or numbness) in the area around your genitals and back passage.

Numbness in or around your back passage or buttocks

You are experiencing severe back pain that never changes or eases when you move or change position

You have a fever

You experience pain or burning when urinating

You have experienced any unexplained weight loss

You have been diagnosed with cancer in the past

You have any other illness or medical condition including HIV, or any condition that requires the use of steroid medication

You have severe pain in your upper back

You have experienced a fall, or any other trauma to the spine or abdomen

You are experiencing severe difficulty weight bearing through your legs

What is Pregnancy-related lower back pain (LBP)

Summary: This section gives you the definitions of pregnancy-related lower back pain and pregnancy-related pelvic girdle pain, and explains the difference between the two conditions. This section also provides examples of the type of symptoms that may be experienced with each of these conditions, and explains the things that can affect the chances of these conditions developing and the speed of recovery.

Introduction (each section needs a Title, we can't have text/content that is not under a section which needs to have a title)

Pregnancy-related lower back pain is the term used to describe pain that comes from the lower part of the spine (known as the lumbar region) either during your pregnancy, or in the weeks immediately after you have had your baby. The pain may originate from the muscles, joints, ligaments or discs in the lumbar spine and is similar to the type of back pain experienced by people who are not pregnant.

A recent research study performed in Spain, suggests that in the later stages of pregnancy, over 70% of women are affected by pregnancy-related lower back pain.

Possible symptoms of pregnancy-related lower back pain

Pregnancy-related lower back pain resembles the pain you may have experienced in your back before you were pregnant.

The pain is felt in the lower back, in what is known as the lumbar region.

The pain is usually dull and may be made worse by bending forwards or backwards.

Movement of the spine is usually restricted, and pressing the muscles in the lumbar region can be painful.

If the nerves in the spine are affected, you may experience pain spreading down the leg. Depending on which nerves are involved, this can travel all the way into the foot.

You may also experience pins and needles, numbness or weakness in the leg due to involvement of the spinal nerves.

What is pregnancy-related pelvic girdle pain

Pregnancy-related pelvic girdle pain is the term now used to describe pain that originates from any of the joints of the pelvis during pregnancy or in the period immediately after you have had your baby.

You may have heard healthcare professionals referring to this type of pain as 'SPD' or 'Syphysis Pubis Dysfunction', however this term is no longer used as the pain is

rarely limited to the symphysis pubis (the joint at the front of the pelvis where the 2 pubic bones meet) as this term would suggest.

The pain can occur in the symphysis pubis at the front of the pelvis, in the sacroiliac joints at the back of the pelvis, or both.

2 Images required

https://www.istockphoto.com/gb/photo/human-pelvis-anterior-view-red-highlight-on-sacroiliac-joint-pain-area-3d-medical-gm1024096662-274813385

https://www.istockphoto.com/gb/photo/anterior-view-of-human-pelvis-bone-with-red-highlight-on-pubic-symphysis-joint-pain-gm1024110968-274816846

The exact proportion of women suffering from pregnancy-related pelvic girdle pain is difficult to accurately estimate as different research studies have used different criteria to diagnose the condition. However, a recent guideline published by the American Physical Therapy Association on the management of this condition states that in the later stages of pregnancy up to 70% of pregnant women may be affected by either pregnancy-related pelvic girdle pain or pregnancy related lower back pain.

It is thought that around 20-25% of pregnant women will suffer from pregnancy-related pelvic girdle pain severely enough to seek medical help.

Possible symptoms of pregnancy-related pelvic girdle pain

Pelvic girdle pain can be felt at the back of the pelvis in the region of the sacroiliac joints as shown in the picture below. It can be on one side or both sides.

Image required- the image below will need some shading adding to highlight the painful area once the image has been downloaded.

https://www.istockphoto.com/gb/photo/pains-of-pregnancy-gm467192330-60835188

Pelvic girdle pain can also be felt at the front of the pelvis in the region called the symphysis pubis, where the two pubic bones meet.

Image required – again, we may need to add some shading to make this image clearer

https://www.istockphoto.com/gb/photo/pregnant-woman-with-hands-on-her-stomach-pregnancy-health-care-and-bladder-aches-gm668516134-122088987

If the pain is experienced at the back of the pelvis, this can spread down the back of the legs but tends not to travel into the foot.

If the pain is experienced in the front of the pelvis (symphysis pubis), this can spread into the groin or down the inner thigh.

The pain is often described as stabbing, shooting, dull or burning and some people report a ‘catching’ sensation in the leg when walking.

The pain of pregnancy-related pelvic girdle pain usually comes and goes depending on what you are doing, rather than being constant.

The pain can be aggravated by being in one position for too long, or by performing simple activities such as: walking, climbing stairs, getting up from a sitting position, standing on one leg, getting in/out of a car, twisting, turning over in bed, crossing your legs, lying flat on your back, lying on your side, or by lifting and carrying.

Participating in sexual intercourse can also be problematic due to difficulty getting comfortable in a suitable position.

Some people with pregnancy-related pelvic girdle pain are aware of a clicking sensation in the pelvic joints during certain movements, and this clicking may or may not be painful.

Pregnancy-related pelvic girdle pain is thought to have a greater impact on pain and function than pregnancy-related lower back pain.

The most common time for pregnancy related pelvic girdle pain to occur is between the 14th and 30th week of pregnancy.

Risk factors

There are several factors that have been shown to increase the likelihood of developing lower back pain or pelvic girdle pain during pregnancy. These include:

Previous pregnancies (multiparity)

A previous history of lower back pain or pelvic girdle pain prior to pregnancy

A history of lower back pain or pelvic girdle pain in a previous pregnancy

Previous trauma to the lower back or pelvis

Dissatisfaction with work, including a heavy workload, poor working postures or repetitive tasks

General joint hypermobility is thought to increase the risk of developing pelvic girdle pain in pregnancy

There is also some evidence to suggest that both smoking and a higher body mass index (BMI, which is a is a measure that uses your height and weight to work out if your weight is healthy) may increase the risk of developing pelvic girdle pain during pregnancy.

Recovery

For most women with pregnancy-related pelvic girdle pain, the symptoms will settle spontaneously in the weeks after the baby is born.

Unfortunately, it is thought that somewhere between 7 and 25% of women with pregnancy-related pelvic girdle pain will continue to have symptoms after the baby is born, and that around 8-10% of women with the condition may still have symptoms 1-2 years after giving birth.

There are several factors thought to increase the likelihood of experiencing ongoing problems after giving birth. These include:

Early onset of pelvic girdle pain symptoms within the first 12 weeks of pregnancy

Having pain in the back as well as pain in the joints of the pelvis (i.e. having both pregnancy-related lower back pain and pregnancy-related pelvic girdle pain)

Pain in more than one of the pelvic joints (e.g. pain in both sacroiliac joints or pain in the sacroiliac joint as well as the symphysis pubis)

Increased emotional or psychological distress caused by the condition

Work dissatisfaction

Lack of belief that pelvic girdle pain symptoms will improve

Causes of pregnancy-related lower back pain and pregnancy-related pelvic girdle pain

Introduction

The exact cause of pregnancy-related back pain and pelvic girdle pain is not fully understood, but is thought to be a combination of the following three factors:

Postural changes

Hormonal changes

Changes to the muscles of the abdomen and pelvis

In this section, each of these three factors will be discussed in detail with an explanation of how they are thought to contribute to pregnancy-related back pain and pelvic girdle pain.

Postural changes

As your pregnancy progresses and your baby grows, the increased weight of the baby causes a deepening of the curve of your lower back. As this happens your pelvis also tips forward into what is known as anterior pelvic tilt.

This shown in the picture below.

Image required- If possible, I would like to add arrows to this image to make the postural changes clearer

https://www.istockphoto.com/gb/photo/aches-and-pains-gm512753585-47635832

This change in posture is thought to increase the pressure on the intervertebral discs and put more demand on the muscles of your lower back, which must work against the weight of the baby pulling you forwards. This can lead to pain in the lower back.

Finally, the increased anterior tilt of the pelvis is thought to put increased strain on the ligaments that stabilise the sacroiliac joints at the back of the pelvis. This therefore contributes to the development of pelvic girdle pain.

Tenderness over one particular ligament of the sacroiliac joint has been shown to be present in the majority of women with pregnancy-related pelvic girdle pain.

Hormonal changes

During pregnancy your body produces a hormone called relaxin.

During pregnancy, as your levels of relaxin rise, this reduces the stiffness of your ligaments, not just those in your pelvis, but throughout your entire body.

Under normal circumstances, the joints of the pelvis (the sacroiliac joints at the back of the pelvis and the symphysis pubis at the front) allow very little movement to occur thanks to the strong ligaments supporting them.

As these ligaments become more lax during pregnancy due to the action of relaxin, this can allow increased or unwanted movement to occur within the pelvic joints as you move around, which can lead to joint irritation and pain.

It is however important to remember that every pregnant woman will experience an increase in relaxin levels, but not every pregnant woman will develop pelvic girdle pain. For this reason, we know that other factors, such as postural changes and muscular changes, must also be at play.

Research has shown that those women most severely affected by pregnancy-related pelvic girdle pain do not necessarily have higher relaxin levels. Once again, this evidence supports the idea that hormonal factors alone cannot be the sole cause of pregnancy-related pelvic girdle pain.

Changes to the muscles of the abdomen and pelvis

As explained above, the joints of your pelvis are extremely stable. This is partly due to the strong ligaments supporting these joints, but also due to the many muscles that help to support them and control their movement.

The deep abdominal muscles (especially the transversus abdominis muscle which is like an inbuilt corset around your spine), the pelvic floor muscles, the deep spinal

muscles and even the diaphragm, all work together to support the lower back and pelvis. These are often referred to as your 'core' muscles.

Image required- couldn't find an appropriate image on the website-

For now, will have to use this:

https://www.istockphoto.com/gb/photo/the-transversus-abdominis-gm486520902-72622179

But want one like this:

http://www.handson-austin.com/wp-content/uploads/Core-Muscle.jpg

The muscles in your buttock (also known as the gluteal muscles), are also extremely important for supporting the sacroiliac joints at the back of the pelvis.

As your baby gets bigger, your abdominal muscles stretch to accommodate your growing baby, this makes it more difficult for these muscles to do their job of supporting your spine and pelvis.

As the weight of your baby increases, you also have more pressure pushing down on your pelvic floor muscles. Once again, this makes it more difficult for these muscles to do their job of supporting the joints of your pelvis.

Women with pregnancy-related pelvic girdle pain are more likely to suffer from urinary incontinence although they may not necessarily have an obvious weakness of the pelvic floor muscles. This supports the idea of a link between pelvic girdle pain and a change in the way the pelvic floor muscles work.

There is some evidence to suggest that strengthening the muscles that stabilise the pelvis may reduce pain and improve quality of life in women suffering from pelvic girdle pain. This supports the idea that weakness of the muscles of the pelvis and spine may be linked to the development of pelvic girdle pain.

Research has also shown that women who have weakness of the gluteal muscles and abdominal muscles in early pregnancy are more likely to develop pregnancy-related pelvic girdle pain, again, this supports the idea that altered muscle function may be linked to this condition.

A small study has linked pregnancy-related pelvic girdle pain to weakness of the gluteus medius muscle. This muscle is located on the outside of the hip and helps to stabilise the pelvis when we walk. It is suggested that weakness of this muscle may affect the way forces travel through the pelvis during walking activities, resulting in irritation of the joints. Further research would be required to confirm this idea.

Finally, large research studies have shown that women who exercise more frequently before they become pregnant are less likely to develop pregnancy-

related pelvic girdle pain. Once again, this evidence supports the idea that better muscle function may reduce the chances of pelvic girdle pain developing.

Anatomy

Summary: This section provides information about the anatomy of the spine and pelvis and will help you to better understand the pregnancy-related changes discussed in other sections of this app.

Spine

The spine has 33 individual bones stacked one on top of the other.

The function of the spine is to allow us to stand upright whilst protecting our spinal cord from injury.

When viewed from the side, the adult spine has a natural 'S' shaped curve. The neck (or cervical region as it is known) and the lower back (or lumbar region) have slight inward curves, while the thoracic spine (the section of the spine that attaches to the ribs) and the sacral region (section of the spine between the lumbar region and coccyx) have outward curves.

Image required

https://www.istockphoto.com/gb/photo/human-spine-gm482519152-70094467

The lumbar spine has 5 bones or vertebrae which are numbered top to bottom from L1-L5.

The vertebrae in the lumbar region are larger than those in other areas of the spine as they have to bear more weight.

Image required

https://www.istockphoto.com/gb/photo/infographic-diagram-of-human-lumbar-vertebrae-with-sacrum-or-spine-bone-anatomy-gm1019419280-273964512

Each of the vertebrae of your spine is separated from its neighbour by what is known as an intervertebral disc.

The intervertebral discs (or 'discs' for short) aid the mobility of the spine and also perform the important role of providing increased shock absorption.

Image required

https://www.istockphoto.com/gb/photo/lumbar-spine-anatomy-segment-gm647358620-117442895

The discs are made up of an outer ring consisting of criss-crossing fibrous bands, and a jelly-like centre known as the nucleus. The nucleus contains a high proportion of fluid.

Image required

https://www.istockphoto.com/gb/vector/spine-anatomy-showing-intervertebral-disc-gm118972465-12169458

The fluid content of the disc is highest first thing in the morning as water is absorbed into the disc when you lie down at night. Some of the fluid content of the disc is pushed out during the day whilst you are upright due to the increased pressure of your body weight on the discs. This is why you may have heard that you are taller first thing in the morning!

As we age, our discs gradually lose the ability to absorb fluid and therefore become thinner or flatter. This is one of the reasons we get shorter as we get older.

The spinal column has strong ligaments running from the top to the bottom on both the front and the back, which help to prevent excessive movement of the vertebrae, to stabilise the spine, and to support the intervertebral discs.

The sacrum is the part of the spine between the lumbar region and the coccyx, and is what connects the spine to the pelvis.

There are 5 sacral vertebrae which are all fused together.

The Pelvic girdle

The sacrum and the two pelvic bones (left and right) form a bony ring which is known as the pelvic girdle.

Image required

https://www.istockphoto.com/gb/photo/3d-illustration-of-human-body-hip-bone-gm846667868-138713911

The part of the pelvic bone to join to the sacrum is the called the ilium. Where the sacrum and the ilium join, is known as the sacroiliac joint.

The sacroiliac joints have strong ligaments at the front and back which serve to stabilise the joint and allow forces to be efficiently transferred from the pelvis to the spine during weight bearing activities.

Image required

https://www.istockphoto.com/gb/vector/skeleton-hip-with-ligaments-front-gm637748232-113923555

Where the two pubic bones meet at the front of the pelvic ring is known as the symphysis pubis.

In a non-pregnant adult, only a very small amount of movement is allowed at the symphysis pubis due to the strong ligaments surrounding the joint, and the inter-pubic disc which helps to join the two bones together.

The inter-pubic disc is made of similar material to the intervertebral discs of the spine and helps to strengthen the joint.

Image required.

https://www.istockphoto.com/gb/photo/pelvis-anterior-view-gm858502536-142338633

Emotional impact of pregnancy-related pelvic girdle pain

Summary: As both pregnancy-related lower back pain and pregnancy-related pelvic girdle pain can have a significant impact on everyday life, it is not surprising that many women experiencing these conditions report that their mood and emotional wellbeing are also affected. In this section you will find some examples of the potential emotional impact of pregnancy-related pelvic girdle pain that have been uncovered in recent research studies.

Introduction

In recent years, health professionals and researchers have become more aware of the emotional impact of pelvic girdle pain during pregnancy.

Several research studies have explored how pregnant women feel about pelvic girdle pain and how it has affected their experience of pregnancy.

Some of the feelings described by the women taking part in these studies have included fear, frustration, guilt, anxiety and low mood. We will discuss these further below.

Women have reported feeling scared by the amount of pain they are experiencing and worry how the condition may affect the delivery of their baby.

Fear of not being able to complete everyday tasks or care for older children has also been reported

Fear of becoming a burden to family or partners has been reported because of the help required with everyday tasks

Frustration at the lack of information available regarding pelvic girdle pain has been reported multiple times in the research literature. Some women have also reported frustration at the lack of help they have received from their maternity healthcare providers

Difficulty sleeping due to pain has been said to result in feeling fatigued, snappy or low in mood

Some women have reported feeling guilty for not being able to enjoy their pregnancy and worry how this may affect their family or their ability to bond with their unborn baby

Frustration at having to ‘slow down’ and not being able to do what they would normally do, has caused some women to feel ‘snappy’ and ‘moody’

The pain and activity limitation experienced as a result of pelvic girdle pain, has led some women to report symptoms of anxiety and depression

If you are experiencing any of the negative emotions described above, you are certainly not alone. However, it is extremely important that you discuss these feelings with your midwife as soon as possible, so that any extra help and support you require can be provided to you.

Self-management

Summary: Although you should always seek help from your midwife or doctor if you think you have pregnancy-related back pain or pelvic girdle pain, there are a few things you can do yourself that may help you to better manage the pain. In this section we will discuss each of these in detail.

Heat application

If image required for title, one of the following may suffice
https://www.istockphoto.com/gb/photo/hot-and-cold-pack-gm474218036-64425929

https://www.istockphoto.com/gb/photo/business-woman-putting-an-ice-pack-on-her-back-pain-gm610852378-104970811

There is some research evidence to support the idea that superficial heat application can be useful in the management of lower back pain in the general population. It is therefore possible that applying some heat to the affected area may provide some temporary relief from pregnancy-related back pain or pelvic girdle pain.

Whether you prefer to use a hot water bottle, soak in a warm bath, or stand under warm running water in the shower, the application of heat may make you feel more comfortable.

During pregnancy, it is advised that you do not apply anything hot enough (or soak in a bath that is hot enough) to raise your core body temperature significantly, as this can be dangerous for you and your baby. If you are unsure what is a safe temperature, then you should ask your midwife for advice.

It is also advisable that when using hot water bottles or hot packs during pregnancy, that you check your skin more frequently than usual. Your skin can be significantly more sensitive during pregnancy and may therefore be at an increased risk of burning.

Cold application

If image required for title page, one of the following may suffice: https://www.istockphoto.com/gb/photo/plastic-bag-with-ice-cubes-on-white-background-gm1149079293-310540082

https://www.istockphoto.com/gb/photo/holding-ice-gel-pack-on-elbow-medical-concept-photo-gm486877689-38604642

As many people are familiar with the idea of using ice to manage soft tissue injuries such as ankle sprains or knee injuries, it may not be surprising to hear that cold packs or ice packs can be used to help with the management of pregnancy-related lower back pain and pelvic girdle pain.

There is very little research evidence specifically exploring the use of ice for the management of these conditions, but as with heat application, there is some evidence that those in the general population suffering with low back pain experience a beneficial effect of cold application.

You could use some ice cubes wrapped in a damp tea towel, some frozen peas wrapped in a damp tea towel, or alternatively you can purchase an ice pack from larger high-street pharmacies.

It is important that you do not apply ice directly to your skin!

Once again, it is extremely important that you are careful to check your skin frequently when attempting any kind of cold application treatment in order to avoid 'ice burns'. Your skin can be much more sensitive during your pregnancy.

There is no available evidence to suggest any adverse effects from the application of cold packs during pregnancy as long as the necessary caution is taken to protect the skin.

If you are at all concerned about the effect of using cold therapy during pregnancy, you should talk to your midwife or physiotherapist before attempting this type of home treatment.

Pelvic belts

If image required for title page: https://www.istockphoto.com/gb/photo/spine-pain-pregnant-woman-with-orthopedic-support-belt-pregnancy-bandage-gm841868514-137363215

There is some evidence to support the use of pelvic support belts in the management of pregnancy-related pelvic girdle pain.

You should always consult a Physiotherapist before making the decision to purchase a pelvic support belt as there are many different types on the market and your therapist can advise you on the best choice for you.

There are two main types of belt available: A thinner, strap-like belt that sits around the pelvis (under your bump), and a thicker belt, which is broader at the back and supports under the lower part of your bump at the front.

2 Images required

https://www.istockphoto.com/gb/photo/pregnant-woman-standing-in-the-supporting-bandage-for-pregnant-gm1077976298-288776633

https://www.istockphoto.com/gb/photo/pregnant-woman-with-orthopedic-support-belt-pregnancy-bandage-gm653097928-118604761

Some types of belt are made of a flexible or stretchy material and may be referred to a 'non-rigid' belts.

Others are made of non-stretchy material and may be referred to as 'rigid' belts.

Pelvic belts are thought to help with the pain of pelvic girdle pain in two main ways, although more evidence is needed to confirm this.

Firstly, the compressive force applied to the pelvis when wearing a pelvic belt is thought to provide support to the pelvic joints during weight bearing activities such as walking.

Secondly, wearing a pelvic belt is thought to stimulate certain nerves in the skin and soft tissues of the pelvis, improving what is known as your proprioception. This means that a pelvic belt may allow you a better sense of how your pelvic joints are moving, which in turn encourages the muscles that support the pelvic joints to work more effectively to control any excessive movement.

Although it has been shown that wearing a belt is safe, there is some debate about their effectiveness as the results of different research studies have been conflicting.

There is debate about which type of belt is more effective, as different researchers have used different belts in their studies. It has however been suggested that non-rigid belts may be more comfortable and therefore better tolerated.

There is currently no clear guidance on how long a pelvic belt should be used for to give the best results, or whether the belt should be worn throughout the day or for specific tasks.

Most physiotherapists recommend that pelvic belts should be worn when performing standing and walking activities, but often advise that the belts are not required (and can actually be quite uncomfortable) during sitting activities.

A recent study by a group of Belgian researchers compared the use of two types of belt, a narrow flexible belt and a wide rigid belt.

The study found that both types of belt were useful in improving pain levels, but suggested that the narrow flexible belt may be more useful for improving pelvic

girdle pain and global pain, whilst the wider belt may be better for reducing lower back pain.

Women in this study wore the belt on average for 2 ½ hours per day, for 4 days per week, for an average period of 9 weeks. This supports the idea that pelvic belts do not need to worn continuously throughout the day for a benefit to be seen.

In summary, it is worth considering the use of a pelvic support belt if you have pregnancy-related pelvic girdle pain, however it is always advisable to ask for guidance from a Physiotherapist in order to ensure you choose the best type of belt for your symptoms.

Relaxation techniques

If image required for title page: https://www.istockphoto.com/gb/photo/relaxed-young-pregnant-woman-listening-to-music-gm183535347-14892681

There is some evidence to suggest that a relaxation technique called progressive muscular relaxation (PMR) may be useful in the management of lower back pain in pregnant women.

The PMR technique involves deep breathing and progressive relaxation (tense–release) of major muscle groups.

The goal of PMR is to achieve physical and mental relaxation in order to reduce the response to stress and to reduce sensitivity to pain.

An example of a short PMR session can be found on YouTube via the following link https://www.youtube.com/watch?v=912eRrbes2g

Look after your posture

If image require for title page: https://www.istockphoto.com/gb/photo/back-pain-kidney-inflammation-ache-in-womans-body-gm693673844-128117829

Standing and sitting with good posture can help to avoid aggravation of pregnancy-related back pain or pelvic girdle pain.

Try to avoid standing with an exaggerated curve in your lower back by gently using your abdominal muscles to pull your bump in towards you and slightly tucking your tailbone underneath you

Try to avoid standing with your chin poking forwards and your shoulders rounded

Image required https://www.istockphoto.com/gb/photo/postural-dysfunction-check-up-check-up-of-correct-posture-gm684056282-125606973

Avoid wearing high heels or completely flat, unsupportive shoes

Avoid standing in the same position for prolonged periods, try to change position regularly

Try to stand with equal weight on both feet

Avoid slumped sitting postures

Try sitting in a supportive chair or consider using a rolled-up towel or lumbar support in the small of your back to help you maintain a good position

Avoid sitting cross-legged

Avoid sitting in the same position for prolonged periods

Modify your daily activities

If image require for title page: https://www.istockphoto.com/gb/photo/bringing-in-the-shopping-gm680680000-129842811

The pelvic obstetric and gynaecological physiotherapy group (POGP), recommend the following changes to your daily activities to help avoid aggravating your symptoms:

Remain active within the limits of your pain, but try to avoid activities that you know aggravate your symptoms

Accept any offers of help from friends or family with daily chores, and ask for additional help if needed

Rest more frequently and consider sitting down for activities that normally involve standing, such as ironing

Consider alternative sleeping positions such as lying on your side with pillows between your knees

When turning over in bed, try squeezing your knees together and squeeze your buttocks to avoid putting strain on your pelvic joints

Go up stairs one leg at a time, leading with the least painful leg

Use a handrail when climbing the stairs

Minimise the need to climb stairs by bringing everything you need downstairs in the morning

If you have already had your baby or have other young children/toddlers to look after, try setting up changing stations both upstairs and downstairs to avoid the need to climb stairs at every nappy change

Consider using a rucksack to carry things around the house, particularly if your symptoms are severe and you require the use of crutches

When getting into and out of a car, squeeze your knees together and move both legs together.

Consider alternative positions for sexual intercourse such as lying on your side or kneeling on all fours

In order to minimise the need for travel, if you have multiple hospital appointments to attend (such as midwifery and physiotherapy), consider trying to arrange them all for the same day

Avoid standing on one leg. You may therefore consider sitting down to get dressed or when putting on your shoes

Avoid activities that put uneven stresses through your pelvis or involve asymmetrical positions of the pelvis, such as sitting cross-legged, pushing and pulling to one side and carrying things (such as toddlers) on one hip

Avoid bending and twisting when lifting and carrying

Avoid sitting on the floor if at all possible. If you do need to sit on the floor, for example if you have toddlers to care for, you might consider sitting on a cushion and avoid sitting with your legs crossed

Try to avoid carrying heavy weights such as shopping bags where possible

Avoid vacuum cleaning if possible as this often requires both heavy lifting and twisting. If you cannot get help with this task from someone else, then try to keep the vacuum cleaner close to your body and walk forwards and backwards with it rather than standing on the spot and pushing and pulling it.

If you would like more information about how you can help yourself at home, the Pelvic Partnership website has some useful suggestions, and can be accessed via the following link

https://pelvicpartnership.org.uk/practical-suggestions-at-home/

Birth planning

If image required for title page: https://www.istockphoto.com/gb/photo/home-birth-gm854103360-239443735

Summary: In this section you will find some information that you may find useful when planning the birth of your baby. This information is intended to help promote a discussion between you and your midwife about the best birthing options for you and your baby. Only your midwife can provide specific information, tailored to your individual circumstances.

Introduction

According to the Royal College of Obstetricians and Gynaecologists (RCOG), the majority of women suffering from pelvic girdle pain in pregnancy will be able to have a normal, spontaneous vaginal delivery.

Occasionally, if the symptoms of pelvic girdle pain are extremely severe, and attempts at managing the symptoms conservatively have been unsuccessful, then alternative options for delivery such as an early induction of labour, or caesarean section may be discussed.

For most women with pelvic girdle pain, a normal delivery is achievable, but may require consideration of alternative positions for labour such as:

All fours

Supported kneeling

Side lying

Labour/birth in water

If you are suffering with pelvic girdle pain, it is likely that you will have difficulty opening your legs. For this reason, it is advisable to measure the distance you can comfortably open your legs (sometimes referred to as your safe distance) in the weeks leading up to your due date, and document this in your birth plan. Your midwifery team can then use this information to ensure your delivery is in a position that is as comfortable as possible.

After the birth of your baby you may require stitches to your perineum which usually requires you to be positioned in stirrups, or in what is known as the lithotomy position.

It is sometimes possible for stitching to be performed in alternative positions, however if you are told that you must be positioned in stirrups, request that both of your legs are lifted at the same time, your safe distance is not exceeded, and that you are in this position for this shortest time possible.

Image required: This image needs an arrow and a label adding once the image has been downloaded

https://www.istockphoto.com/gb/photo/the-obstetrician-is-taking-delivery-gm954315880-260548306

Medication

If image required for title page:
https://www.istockphoto.com/gb/photo/gynecologist-doctor-and-pregnant-woman-at-hospital-gm869270600-144989379

Summary: Before you make the decision to take any pain-relieving medication (analgesia), it is useful to discuss this with your midwife, pharmacist, doctor or nurse so that they can recommend the most suitable and safe options for you. In this section you will find some information that is intended to help promote this discussion between you and your healthcare provider.

Introduction

According to the Royal College of Obstetricians and Gynaecologists (RCOG), non-pharmacological treatments, such as heat, cold compresses, acupuncture, physiotherapy, relaxation and exercise should be considered as first line treatments for the relief of pain.

However, if the measures above are not working well enough for you, and you are considering the use of oral medication, then the information below may help you understand the options available to you.

Paracetamol

According to the RCOG, paracetamol is widely used as a first-choice analgesic (pain-killer) for mild to moderate pain, and remains the pain-killer of choice in pregnant and breastfeeding women.

Paracetamol is currently not known to be harmful throughout pregnancy and breastfeeding. However, the RCOG stress that it is important to understand that many over-the-counter cold remedies contain paracetamol, and that if these are taken alongside paracetamol for pain relief, this can lead to an accidental overdose. Therefore, before taking any over-the-counter medication, check the label carefully. The recommended dose of paracetamol must not be exceeded.

The use of non-steroidal anti-inflammatory drugs (NSAIDs) such as Ibuprofen, is not recommended for the management of pelvic girdle pain during pregnancy. Ibuprofen may be considered for certain other conditions, such as ankylosing spondylitis, but only before the 30th week of pregnancy.

The use of NSAIDs should be avoided altogether after 30 weeks of pregnancy due to the potential for adverse effects on the developing baby and a possible impact on the onset and duration of labour.

Codeine

Opioid medications such as Codeine may be considered for the management of moderate to severe pain during pregnancy if the use of paracetamol has not been effective.

However, codeine is not routinely recommended in the last trimester of pregnancy due to the potential for adverse effects in the unborn child after delivery. Codeine should be avoided altogether when a mother is breastfeeding.

There are a small number of combinations of paracetamol and codeine available to buy over the counter. However, the RCOG recommend that opioid medications should only be taken after you have been assessed by your midwife or doctor, and that they should be prescribed by an appropriately qualified healthcare practitioner so that the benefit and risk of their use can be carefully explained and considered.

Alternative treatment options to consider

Summary: In this section you will find information about several alternative treatment options that you may wish to consider in order to help you manage your back pain or pelvic girdle pain.

Disclaimer (summary was too long)

As not all these options will suit everybody, it is advisable to discuss the information in this section with your midwife before proceeding with any of these treatments.

Massage

If image required for title page: https://www.istockphoto.com/gb/photo/pregnant-woman-receiving-a-back-massage-from-masseur-gm840830882-137036689

There is a very small amount of research evidence to suggest that soft tissue massage may help in the management of pregnancy-related lower back pain and pelvic girdle pain.

There is no evidence that massage causes any significant adverse effects to the mother or the baby during pregnancy when it is performed in an appropriate position, by an appropriately qualified individual.

Massage may therefore be considered as a safe alternative treatment option.

If you are unsure if massage is right for you, you should discuss this with your midwife or doctor.

Other alternative treatment options – Taping consider taking out "Other alternative…" -too long

If image required for title page: https://www.istockphoto.com/gb/photo/pregnant-woman-wearing-kinesio-tape-gm494285166-77360869

'Kinesio taping' involves the use of a specially-designed elastic, adhesive tape being applied to the skin, and has been used in the management of sports injuries since the 1970's.

In 2017, a small study that explored the use of 'Kinesio taping' for the management of pregnancy-related pelvic girdle pain was published

The study reported that Kinesio taping resulted in improved pain levels in women with pregnancy-related pelvic girdle pain, both whilst the tape was being worn, and for several days after the tape had been removed.

As there are many different tapes available on the market, and a huge variety of taping techniques to choose from, you should discuss the use of Kinesio taping with your physiotherapist before attempting any treatment like this at home.

Other alternative treatment options – Manipulation consider taking out "Other alternative…" -too long

If image required for title page:
https://www.istockphoto.com/gb/photo/physiotherapist-massaging-womans-back-gm473625394-64841669

'Joint manipulation' is a term that is often used to describe small (low amplitude), quick (high velocity) movements of your spinal joints that are performed by a practitioner such as an osteopath, chiropractor or specialist physiotherapist.

There is some research evidence to suggest that joint manipulations may be helpful in reducing pregnancy-related pelvic girdle pain.

Adverse events from spinal joint manipulations in the general population are rare.

According to a recent guideline on the management of pregnancy-related pelvic girdle pain, there is little to no evidence that joint manipulations are harmful to the mother or the baby when the mother is an otherwise healthy pregnant woman. This statement was however made on the assumption that the techniques are performed correctly by an appropriately qualified individual.

Other alternative treatment options – Yoga consider taking out "Other alternative…" -too long

If image required for title page:

https://www.istockphoto.com/gb/photo/happy-pregnant-women-exercising-on-mats-in-gym-gm534001758-94666837

There have been several research studies that have explored the use of yoga for the management of pregnancy-related lower back pain and pelvic girdle pain.

The evidence suggests that modified yoga classes may be useful in reducing pregnancy-related lower back pain and pelvic girdle pain.

Before attending any yoga class, you must ensure that your instructor is appropriately qualified to teach yoga to pregnant women and that they are aware that you are suffering from pregnancy related low back pain/pelvic girdle pain.

Before you decide to attend a yoga class, it is advisable to discuss this with your midwife or physiotherapist. Your midwife can assess if they feel that yoga-based exercises are an appropriate option for you, and may even be able to signpost you to antenatal yoga classes in your local area.

Other alternative treatment options – Pilates consider taking out "Other alternative…" -too long

If image required for title page: https://www.istockphoto.com/gb/photo/pregnant-women-doing-pilates-gm530473281-54817526

Pilates as we know it today, is a form of exercise that was originally developed by a man named Joseph Pilates in the 1930's and 1940's.

The exercises were originally developed to help rehabilitate hospital patients and were aimed at improving both strength and flexibility.

Many different modifications of Pilates exercises exist today, but they all have in common the aim of improving posture and strengthening the 'core' muscles whilst focusing on the breathing cycle.

As we know, pregnancy-related lower back pain and pelvic girdle pain are thought to occur partly due to changes in the muscles that support the spine and pelvis. It would therefore make sense that an exercise regime based on strengthening these muscles may be of benefit to sufferers of these conditions.

Several research studies have explored the use of Pilates-based 'stability' exercises for the management of pregnancy-related lower back pain and pelvic girdle pain with largely positive results.

Many physiotherapists also use Pilates-based exercises when developing home exercise programs for their patients.

Before attending any Pilates class, you must ensure that your instructor is appropriately qualified to teach Pilates to pregnant women, that they are aware that you are suffering from pregnancy related low back pain/pelvic girdle pain, and that they have the relevant experience required to manage these conditions.

Many Physiotherapists are now also choosing to become certified Pilates instructors, and some will teach modified classes for pregnant women.

You may therefore consider opting for a class taught by a qualified Physiotherapist, as they may be more familiar with your condition and may be better-placed to modify the exercises for your individual needs.

Other alternative treatment options – Exercises in water consider taking out "Other alternative…" -too long

If image required for title page: https://www.istockphoto.com/gb/photo/women-taking-water-aerobics-class-gm168006443-25318171

Water aerobics classes for pregnant women, which are sometimes referred to as 'Aquarobics' or 'Aquanatal' classes, have been shown to reduce pain levels in women with pregnancy-related lower back pain and to reduce the number of sick days taken due to pain.

A recent study carried out in Denmark also showed that water-based exercises carried out by healthy pregnant women twice per week, over a period of 12 weeks,

starting at 16-17 weeks of pregnancy, reduced the likelihood of lower back pain being reported at 32 weeks of pregnancy.

Before you attend any such exercise class, you should ensure that your instructor is appropriately qualified to teach water-based exercises to pregnant women, that they are aware that you are suffering with pregnancy-related lower back pain/pelvic girdle pain and that they have the relevant experience in managing these conditions.

It is advisable to discuss the option of water-based exercises with your midwife before you choose to attend a class so that they can assess if they feel that this form of exercise is safe for you. They may even be able to signpost you to an appropriate class in your local area.

Other alternative treatment options – Acupuncture consider taking out "Other alternative…" -too long

If image required for title page: https://www.istockphoto.com/gb/photo/patient-and-acupuncture-treatment-on-back-gm477893083-26787652

Acupuncture is a treatment taken from traditional Chinese medicine.

It involves the insertion of fine needles at certain sites in the body for therapeutic purposes.

Acupuncture is often seen as a form of complementary or alternative medicine.

Western medical acupuncture is the use of acupuncture following a medical diagnosis. It involves stimulating sensory nerves in the skin and muscles, resulting in the body producing natural substances, such as the pain-relieving chemicals known as endorphins.

It is likely that the substances produced by the body during acupuncture treatment are responsible for the beneficial effects.

Several research studies have explored the use of acupuncture for the management of pregnancy-related lower back pain and pelvic girdle pain with encouraging results.

A research study published in 2008 found that women with pregnancy-related pelvic girdle pain who underwent acupuncture treatment did not experience any significant pregnancy-related adverse events. All of the women in this study were at least 12 weeks pregnant when their acupuncture treatment began.

Many acupuncture practitioners will not treat women during the first trimester of their pregnancy due to a theoretical risk of inducing unwanted uterine contractions (contractions of the uterus) or causing harm to the developing baby.

There are also certain acupuncture points that practitioners of traditional Chinese acupuncture will avoid throughout pregnancy, as traditional Chinese medicine

teaches that these points present a risk during pregnancy. There is no known evidence to support this.

Before seeking acupuncture treatment, you should first discuss this with your midwife or doctor. Many NHS Trusts have healthcare practitioners (Physiotherapists, midwives, nurses and GPs) that are qualified in the use of acupuncture. Your midwife may be able to advise you if this is the case in your local area.

Should you choose to seek acupuncture treatment independently, you should ensure that your acupuncturist is appropriately qualified, has experience of treating pregnant women, and that they use pre-sterilised, single-use needles that are properly disposed of following treatment.

Healthcare professionals who can help you

Summary: This section explains how each member of the multidisciplinary healthcare team can help you manage your pregnancy-related lower back pain or pregnancy-related pelvic girdle pain.

Introduction

You may not require input from every member of the multidisciplinary team, but this section will help you to understand what services are available and how they can be accessed.

Midwife

When you begin to experience pain in your back or pelvis, your midwife is your first port of call. Below is a list of ways that your midwife may be able to help you manage your pregnancy-related lower back pain or pelvic girdle pain:

Assess for and exclude other causes of pain not related to bone, joint, muscle or connective tissue

Provide advice regarding pain management and the use of oral medications

Refer you to a physiotherapist for assessment if your pain is affecting your day-to-day activities

If your symptoms are severe, your midwife can refer you on to an Obstetrician for further assessment

Discuss your options for labour and delivery, considering your pain and level of function

Refer you to an occupational therapist if your pain is causing severe difficulties in managing your day-to-day activities

Refer to social services who may be able to provide additional help at home if you are having severe difficulties caring for yourself or your family

Physiotherapist

Treatment by a physiotherapist can usually be accessed through the national health service (NHS) via your GP, midwife or obstetrician.

Alternatively, you may choose to seek physiotherapy treatment privately.

The provision of physiotherapy services by NHS Trusts across the UK varies greatly and therefore not every physiotherapy department will offer the same range of treatment options.

Below is a list of treatments that are commonly provided by physiotherapists in the UK:

Education about pregnancy-related lower back pain and pelvic girdle pain

Advice regarding modification of everyday activities in order to avoid aggravation of symptoms

Individualised exercise programs addressing your own individual needs, goals and functional ability

Manual therapy or 'hands on' treatment may be provided. This may include joint mobilisations and/or soft tissue techniques (similar to massage)

Provision of a pelvic support belt (or advice on the best type of pelvic support belt for your needs if they are unable to provide one to you directly)

Possible provision of walking aids such as crutches if you are in severe pain and are having difficulty walking

Possible use of Transcutaneous electrical nerve stimulation (TENS)

Acupuncture is performed by some physiotherapists for pain relief

Hydrotherapy, which involves exercises in warm water, may be offered by some physiotherapy departments

General Practitioner (GP)

Your own Doctor can be a great help if you are suffering from pregnancy-related lower back pain or pelvic girdle pain. Below is a list of the ways in which your GP can help you:

Assess for and exclude other causes of pain not related to bone, joint, muscle or connective tissue

Provide advice regarding pain management and the use of oral medications

Prescribe stronger, prescription medications if over-the-counter options have not been effective

Refer you to a physiotherapist for assessment if your pain is affecting your day-to-day activities

Refer to social services if your pain is so severe that it is affecting your ability to care for yourself or your family

GPs may be able to refer to occupational therapy services if you require aids or adaptations to help you manage day-to-day activities around your home

Consultant Obstetrician

If your pregnancy-related lower back pain or pelvic girdle pain symptoms are severe, or if other causes of lower back pain (not related to joint, muscle or connective tissue) are suspected, your midwife may refer you to a consultant obstetrician for further assessment.

Below is a list of ways in which your consultant obstetrician may be able to help you:

Assess for, exclude or manage other pregnancy-related causes of lower back pain not related to bone, joint, muscle or connective tissue

Assist with pain management by providing advice regarding medication or prescribing stronger/opioid pain medications if over-the-counter alternatives have not been effective

Discuss options for labour and delivery including whether early induction of labour or a caesarean section may be appropriate

Refer you to a physiotherapist for assessment if your pain is affecting your day-to-day activities

Refer you to an occupational therapist if your pain is causing severe difficulties in managing your day-to-day activities

Refer to social services who may be able to provide additional help at home if you are having severe difficulties caring for yourself or your family

Consultant Orthopaedic Surgeon

Women are only referred to see an Orthopaedic surgeon during pregnancy in exceptional circumstances. If their pain is extremely severe and not responding to conservative treatment, if a problem affecting the nerves of the spine is suspected, or if a rare problem affecting the bones of the thigh and/or pelvis is suspected, then a referral to an orthopaedic consultant may be required.

If a referral to orthopaedic services is made, the consultant may need to request that some tests, such as an MRI scan of the spine and/or pelvis are performed, in order exclude any problems that may require immediate intervention.

MRI scans are thought to be the safest option for imaging of the spine and pelvic joints during pregnancy. However, MRI scans will usually be delayed until the second trimester of pregnancy unless there is a clear clinical need for this to be done immediately.

X-Rays and CT scans will usually be deferred until after the birth unless absolutely necessary, in order to protect the growing baby from the effects of radiation.

Some women may be referred to an orthopaedic surgeon for assessment if their pregnancy-related lower back pain or pelvic girdle pain symptoms fail to settle after the birth of the baby despite receiving appropriate treatment.

In these cases, the consultant may discuss the option of injection therapy to help manage the pain. There are several types of injection that may be considered, but the type chosen and the location of the injection, will be dependent on the findings of the consultant's examination and the results of any scans that may have been performed.

In extremely rare cases, if all other treatment options have been exhausted, and a woman is suffering from debilitating pelvic girdle pain, then surgical fixation of the pelvis may be considered.

This is the absolute last resort and will only be discussed if the symptoms of pelvic girdle pain are disabling and all other treatment options have been unsuccessful.

Useful links

Summary: In this section you will find a list of useful links to online resources that provide information, advice and support for pregnant women experiencing pregnancy-related lower back pain and pelvic girdle pain.

Introduction

The Pelvic Obstetric and Gynaecological Physiotherapy group (POGP) website has some useful information on a range of pelvic health topics

These can be found via the following link:

https://pogp.csp.org.uk/content/information-patients

The pelvic pain partnership is a charitable organisation who provide information and support to women with pelvic girdle pain. They have a range of resources available, and their website can be found via the following link:

https://pelvicpartnership.org.uk/

The NHS website has some brief information about pregnancy-related lower back pain and pelvic girdle pain. This information can be accessed via the following links:

https://www.nhs.uk/conditions/pregnancy-and-baby/backache-pregnant/

https://www.nhs.uk/conditions/pregnancy-and-baby/pelvic-pain-pregnant-spd/

Healthtalk.org provides information about various health-related issues and comes from a unique partnership between a charity called DIPEx and The Health Experiences Research Group or 'HERG' at The University of Oxford's Nuffield Department of Primary Healthcare Sciences. Via the following link, you can listen to interviews with women experiencing back pain and/or pelvic girdle pain:

http://www.healthtalk.org/Pregnancy_children/Pregnancy/Topic/2021/

Tommy's.org provide information and advice to pregnant women and new parents on a range of topics. Their page on pregnancy-related back pain can be found via the following address:

https://www.tommys.org/pregnancy-information/im-pregnant/midwives-answer/how-can-i-reduce-irritable-back-pain

The National Childbirth Trust (NCT) provide advice, help and support to pregnant women and new parents. Their page on pregnancy-related back pain and pelvic girdle pain can be found via the following link:

https://www.nct.org.uk/pregnancy/worries-and-discomforts/common-discomforts/back-pain-pregnancy?gclid=EAIaIQobChMIiqmev5fw4gIVLbvtCh1owwHmEAAYASAAEgJhjPD_BwE

If you are considering seeking private physiotherapy treatment, you can find a physiotherapist in your local area via the Chartered Society of Physiotherapists website via the following link:

https://www.csp.org.uk/public-patient/find-physiotherapist

If you considering accessing acupuncture treatment privately, you can seek advice via the Acupuncture Association of Chartered Physiotherapists (AACP) or the British Medical Acupuncture Society via the following links:

https://www.aacp.org.uk/

http://www.medical-acupuncture.co.uk/

Acknowledgements

The information regarding activity modification was taken and modified from the POGP leaflet entitled 'Pregnancy-related pelvic girdle pain guidance for healthcare professionals'.

The information regarding medication is taken from the Royal College of Obstetricians and Gynaecologists scientific impact paper number 59 dated December 2018.

The ‘medication’ section content was reviewed by medication safety pharmacist Mrs Leah Guy (Aintree Hospital, Liverpool).

Dr Holly George MBCHB (ST3 obstetrics and gynaecology. North west deanery) helped review the content and commented on the ‘warning’ section, ‘birth planning’ section and ‘medication’ section.

APPENDIX 10: EXERCISES INCLUDED IN THE APP WITH WORDING AMENDED FOLLOWING SERVICE USER REPRESENTATIVE FEEDBACK

Deep abdominal muscle contraction

Introduction

This exercise is designed to work the deep abdominal muscle known as the transversus abdominis which helps to support your spine, trunk and pelvis..

Instructions

- Start in a comfortable position either standing or sitting in a supportive chair.
- Place your hands on the lower part of your abdomen, just under your bump.
- Take a breath in, then as you breathe out, draw your belly button upwards and inwards towards your spine, so that you feel the weight of your bump gently lift off your hands.
- Try to hold this position whilst continuing to breathe normally for 3 breath cycles.
- Slowly relax your abdominal muscles and allow the weight of your bump to lower back into your hands.
- Aim to perform 10 repetitions of this exercise, 3 times per day.
- Remember that this exercise should not cause you any pain, but you may feel your baby kicking more for a short time after you have performed this exercise. This is perfectly normal and only happens because the baby is aware of the movement of your abdomen.
- If you do experience pain when performing this exercise, you should stop and seek advice from your midwife or physiotherapist.

Buttock squeezes

Introduction

This exercise is designed to work the largest of your buttock muscles known as the gluteus maximus.

This muscle is thought to play an important role in stabilising the sacroiliac joints at the back of the pelvis.

Instructions

- Stand upright with your feet hip distance apart and your arms relaxed by your sides.
- Squeeze your buttock muscles firmly together and hold this position for 5 seconds.
- Try to focus on engaging both buttock muscles at the same time and relaxing both sides at the same time.
- Aim to perform 10 repetitions of this exercise, 3 times per day.
- Remember that this exercise should not cause you any pain in your back or pelvis.
- If you do experience pain when attempting this exercise, try squeezing the buttock muscles more gently at first, and reducing the length of time you hold the squeeze.
- If the above modification does not help and you still find this exercise painful, you should stop and seek advice from your midwife or physiotherapist.

Standing hip abduction

Introduction

This exercise is designed to gently work the muscle on the outside of both of your hips, known as the gluteus medius.

The gluteus medius muscle plays an important role in stabilising the pelvis during walking activities..

Instructions

- Stand upright with your feet hip distance apart and your hands either on your hips or relaxed by your sides.
- Imagine that your feet are on a sheet of tissue paper.
- Try to gently push your feet apart as if you were trying to tear the tissue paper under your feet. As you do this, you will feel the muscles on the outside of your hip tighten.
- Hold this position for 5 seconds.
- Aim to perform 10 repetitions of this exercise, 3 times per day.

- Remember that this exercise should not cause you any pain in your lower back or pelvis.
- If you do experience any pain whilst performing this exercise, you should stop and seek advice from your midwife or physiotherapist.

Pelvic Floor Muscle Exercises

Introduction

The pelvic floor muscles lie across the base of your pelvis and help to keep the pelvic organs such as the bladder, bowel and uterus in the correct position.

The pelvic floor muscles also work alongside your other 'core' muscles to help support the joints of your pelvis.

The National Institute for Health and Care Excellence (NICE) recommend that all healthy pregnant women should be taught pelvic floor muscle exercises early in pregnancy to help prevent problems such as stress incontinence. You may therefore already be doing these exercises regularly.

Instructions

- You can perform pelvic floor muscle exercises standing, sitting or lying.
- The exercises are slightly easier to do when sitting or lying. You may therefore wish to start in one of these positions and progress to doing them in standing at you get stronger.
- After 18 weeks of pregnancy, it is recommended that you do not lie flat on your back, therefore if you wish to do these exercises in a lying position, you should lie on your side.
- The description of the pelvic floor exercises used below is taken from the Pelvic Obstetric and Gynaecological Physiotherapists information leaflet and the Living With pelvic health app.
- You will need to practice both long holds, which we call 'slow exercises' and short squeezes which we call 'quick exercises'.
- To perform the slow exercises, first tighten the muscles around your back passage, as if you're trying to stop yourself passing wind.
  Whilst you hold this squeeze, tighten around your vagina and urethra as if you are trying to stop yourself from passing urine.
  Aim to hold this squeeze for up to 10 seconds and repeat 10 times.

Make sure you fully relax your pelvic floor between each repetition.

You may have to start with holding for just 3-5 seconds and progress up to 10 second holds as you get stronger.

- To perform the quick exercises, you should quickly tighten the pelvic floor muscles in the same way as described above and then immediately relax them.

  Aim to perform 10 quick squeezes if possible.
- You should aim to perform 10 slow exercises followed by 10 quick exercises at least 3 times per day.
- It is normal to feel your lower tummy muscles tighten as you do your pelvic floor exercises, but your thighs and buttocks should stay relaxed.
- Try not to hold your breath when doing these exercises. Breathe in and out as normally as you can.

Deep breathing exercises

Introduction

The aim of this exercise is to encourage normal movement of the trunk and ribcage during breathing.

It is thought that a normal relaxed breathing pattern may be helpful in reducing back pain and pelvic girdle pain.

Instructions

- Either stand in an upright position with your feet hip distance apart or sit in an upright supportive chair.
- Place your hands over your lower ribs.
- As you take a slow deep breath in, feel the lower part of your ribcage becoming broader and deeper. You may feel your fingertips moving away from each other.
- As you breathe out, allow both sides of your lower ribcage to sink back towards each other.
- Repeat this slow deeper breathing pattern for 3-4 breaths.
- Aim to perform this exercise 3 times per day.
- Remember that this exercise should not cause you any pain in your ribcage, lower back, or pelvis.

- If you do experience any pain whilst performing this exercise, you should stop and seek advice from your midwife or physiotherapist.

Seated Pelvic Tilt

Introduction

This exercise is designed to encourage mobility of the spine and to gently stretch the muscles that extend the lower back.

Instructions

- Sit up tall in a comfortable supportive chair.
- Gently draw in your abdominal muscles and allow your bottom and tailbone to tuck underneath you so that your lower back gently presses into the back of the chair.
- Hold this position for 3 seconds, then slowly return to the start position.
- Aim to perform 10 repetitions of this exercise, 3 times per day.
- Remember that this exercise should not cause you any pain in your lower back or pelvis, although a mild stretching sensation may be felt.
- If you do experience any pain whilst performing this exercise, you should stop and seek advice from your midwife or physiotherapist.

APPENDIX 11: AMENDMENTS TO THE WORDING OF THE POSTURE AND ACTIVITY MODIFICATION SECTIONS OF APP CONTENT FOLLOWING SERVICE USER REPRESENTATIVE FEEDBACK

Look after your posture

Some clinicians believe that standing and sitting with good posture can help to avoid aggravation of pregnancy-related back pain or pelvic girdle pain, however the traditional advice about what makes 'good posture' is now being challenged by researchers

The advice all clinicians can agree on is that rather than worrying too much about *how* you sit or stand, it is more important to make sure that you try to avoid staying in the same position for prolonged periods,and try to change your posture regularly.

Image required

Some women find it more comfortable to avoid wearing high heels or completely flat, unsupportive shoes

- If you are experiencing pelvic girdle pain, standing with all your weight on one leg can sometimes make the pain in your lower back or pubic area feel worse. If this is the case for you, then try to stand with equal weight on both feet as much as possible
- Try to avoid staying in slumped sitting postures for prolonged periods of time
- If sitting in soft chair or couch is uncomfortable for you, try sitting in a supportive chair or consider using a rolled-up towel or lumbar support in the small of your back to help you maintain a comfortable position
- Sitting with your legs crossed may be uncomfortable for you. If this is the case, try to avoid sitting cross-legged for prolonged periods of time

Modify your daily activities

Image required

The pelvic obstetric and gynaecological physiotherapy group (POGP), recommend the following changes to your daily activities to help avoid aggravating your symptoms:

- Remain active within the limits of your pain, but try to limit activities that you know aggravate your symptoms
- Accept any offers of help from friends or family with daily chores, and ask for additional help if needed
- Rest more frequently and consider sitting down for activities that normally involve standing, such as ironing, if these give you difficulty or significantly aggravate your symptoms
- Consider alternative sleeping positions such as lying on your side with pillows between your knees if your usual sleeping position is aggravating your pain

- If turning over in bed causes you pain, try squeezing your knees together and squeeze your buttocks as you turn to give some extra support to your pelvic joints

  If climbing stairs is painful, try going up stairs one leg at a time, leading with the least painful leg and use the handrail

- If climbing stairs aggravates your pain, minimise the need to climb stairs by bringing everything you need downstairs in the morning

- If you have already had your baby or have other young children/toddlers to look after, try setting up changing stations both upstairs and downstairs to avoid the need to climb stairs at every nappy change

- If lifting heavy objects aggravates your pain, consider using a rucksack to carry things around the house, particularly if your symptoms are severe and you require the use of crutches

- If opening your legs is very painful, when getting into and out of a car, squeeze your knees together and move both legs together.

- If opening your legs is painful, consider alternative positions for sexual intercourse such as lying on your side or kneeling on all fours

- In order to minimise the need for travel, if you have multiple hospital appointments to attend (such as midwifery and physiotherapy), consider trying to arrange them all for the same day

- As standing on one leg is often difficult and painful when you have pelvic girdle pain, you may wish to consider sitting down to get dressed or when putting on your shoes

- Many women find that activities that put uneven stresses through your pelvis such as sitting cross-legged, pushing and pulling to one side and carrying things (such as toddlers) on one hip can aggravate their pain. If this is the case for you, then you should try to limit these activities if you can.

- If you do need to sit on the floor, for example if you have toddlers to care for, you might consider sitting on a cushion or trying to avoid sitting with your legs crossed if you find these things difficult or painful.

- If carrying heavy weights aggravates your pain, then try to minimise heavy lifting as far as possible and ask for help if you can.

- Many women report that vacuum cleaning aggravates their pelvic girdle pain. If you cannot get help with this task from someone else, then try to keep the vacuum cleaner close to your body and walk forwards and backwards with it rather than standing on the spot and pushing and pulling it.

- If you would like more information about how you can help yourself at home, the Pelvic Partnership website has some useful suggestions, and can be accessed via the following link

https://pelvicpartnership.org.uk/practical-suggestions-at-home/

APPENDIX 12: POST-PRINT COPY OF PAPER ACCEPTED FOR PUBLICATION IN THE JOURNAL OF EVIDENCE BASED MIDWIFERY

The full PDF version of the post-print document can be found after the appended approval documents

Pregnancy-related lumbopelvic pain: exploring the use of digital media for condition-related information provision

Maria Moffatt[1], Prof Claire Hamshire and Prof James Selfe

[1]*Corresponding author*

Date submitted: 2 December 2020. **Date accepted:** 12 May 2021. **First published:** 24 May 2021

Please cite this article as **Moffat M (2021) Pregnancy-related lumbopelvic pain: exploring the use of digital media for condition-related information provision. *Evidence Based Midwifery*. Post-print online May 2021**

Corresponding Author Details
Maria Moffatt
Manchester Metropolitan University
Faculty of Health, Psychology and Social Care
Brooks Building
53 Bonsall Street
M15 6GX
M.Moffatt@mmu.ac.uk

Abstract

***Background*:** Online health information-seeking is thought to be common among pregnant women, and the use of digital media has been widely adopted.

Women with pregnancy-related lumbopelvic pain (PLPP) are often disappointed with the volume and content of condition-related information offered by their healthcare providers and alternative modes of information provision therefore need to be explored. The widespread adoption of digital media suggests that such platforms may provide a convenient alternative for information delivery.

***Aims of this study*:** To explore the PLPP-related information-seeking practices of women experiencing this condition and the attitudes of National Health Service (NHS) service users and healthcare professionals towards the use of digital media for PLPP-related information provision.

Ethical approval: Ethical and HRA approvals were gained for this study (REC reference 15/NI/0270).

APPENDIX 13 EVIDENCE OF RESEARCH ETHICS COMMITTEE AND HRA APPROVALS FOR PHASES 1 AND 3

Evidence of appropriate regulatory approvals for Phases 1 and 3 can be found on the next page.

Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel:+44 (0) 28 9260 3107
Fax: +44 (0) 28 9260 3619
www.orecni.hscni.net

HSC REC B

21 December 2015

Mrs Maria Moffatt
9 Rufford Avenue
Maghull
Liverpool
L31 9BY

Dear Mrs Moffatt

Study title:	**Exploring patient's views on the use of a social-media-based intervention for the prevention of lumbopelvic pain in pregnancy: A focus group study**
REC reference:	**15/NI/0270**
Protocol number:	**2**
IRAS project ID:	**183127**

The Proportionate Review Sub-committee of the HSC REC B reviewed the above application on 21 December 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Katrina Greer, recb@hscni.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

The PR Sub-Committee confirmed the study raised no material ethical issues *under the following headings:*

- **Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)**

- **Informed consent process and the adequacy and completeness of participant information**

- **Suitability of the applicant and supporting staff**

- **Independent review**

- **Suitability of supporting information**

- **Other general comments**

Ethical issues raised, noted and resolved in discussion:

- **Social or scientific value; scientific design and conduct of the study**

The research literature identifies LBP & PGP as significant problems for pregnant women. Research also highlights the need to tailor preventative measures and information to the circumstances of the pregnant woman, who may be in employment and are also more familiar with accessing social media for healthcare advice.

It is stated there is a paucity of controlled trials utilising social media based health promotion interventions. It is arguable that this study is a first step in the right direction.

The focus group size is based on recommendations given in previous research (Barbour and Kitzing 1999 and Kruegor et al 1994)

- **Recruitment arrangements and access to health information, and fair participant selection**

Healthy pregnant women age 18+ will be recruited. The criteria for inclusion/exclusion appears satisfactory.

Appropriate participants will be identified by their midwife at antenatal clinics at Ormskirk DGH and given relevant participant information. If they wish to participate they will be asked to contact the researchers within 2 weeks by email or phone. This is satisfactory.

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

The Committee noted that provisions have been made for withdrawal in the event of loss of capacity and contact details will be held on the student researchers password protected computer linked to the university.

Data generated from the study will be anonymised when transcribed.

The University of Central Lancashire policy on information governance on research involving human participants will apply.

Personal data will be stored for 3 months after the end of the study and all data in relation to the study will be stored for 5 years.

- **Suitability of research summary**

Confirmed as satisfactory

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter]	1	15 December 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Letter showing indemnity cover]		28 July 2015
Interview schedules or topic guides for participants [Focus group guide]	1	28 August 2015
Interview schedules or topic guides for participants [Focus group guide, group 2]	1	28 August 2015
IRAS Checklist XML [Checklist_15122015]		15 December 2015
Letter from sponsor [Letter confirming University sponsorship]	1	09 December 2015
Other [CV Dr Hazel Roddam]		
Participant consent form [Consent form for participants]	2	07 September 2015
Participant information sheet (PIS) [Participant information sheet group 1]	1	07 September 2015
Participant information sheet (PIS) [Study participant information sheet group 2]	1	07 September 2015
REC Application Form [REC_Form_15122015]		15 December 2015
Referee's report or other scientific critique report [Research programme approval document]		21 April 2015
Research protocol or project proposal	2	07 September 2015
Summary CV for Chief Investigator (CI) [Maria Moffatt short CV]	1	07 December 2015
Summary CV for supervisor (student research) [Short CV James Selfe]	1	02 November 2015

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

There were no declarations of interest declared for this study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

<u>Reporting requirements</u>

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

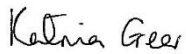
HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

15/NI/0270	**Please quote this number on all correspondence**

Yours sincerely



pp:
Professor Patrick Murphy
Chair

Email: prs@hscni.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Mrs Denise Forshaw*

HSC REC B

Attendance at PRS Sub-Committee of the REC meeting on 21 December 2015

Committee Members:

Name	*Profession*	*Present*
Mr John Edward Mone	Retired (Former Executive Director of Nursing)	Yes
Professor Patrick Murphy	Advisor on Social & Economic Policy	Yes
Dr Seamus O'Brien	Outcomes Manager, Primary Joint Unit	Yes

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Katrina Greer	PRS Manager

HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Lissue Industrial Estate West
Rathdown Walk
Moira Road
Lisburn
BT28 2RF
Tel: 028 95361400
www.orecni.hscni.net
HSC REC B

HSC REC B
27 September 2016

Mrs Maria Moffatt
9 Rufford Avenue
Maghull
Liverpool
L31 9BY

Dear Mrs Moffatt

Study title:	**Exploring patient's views on the use of a social-media-based intervention for the prevention of lumbopelvic pain in pregnancy: A focus group study**
REC reference:	**15/NI/0270**
Amendment number:	**Substantial Amendment #1**
Amendment date:	**15 September 2016**
IRAS project ID:	**183127**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave **a favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Interview schedules or topic guides for participants [Semi-structured interview schedule- group 1version 1]	v1	15 September 2016
Interview schedules or topic guides for participants [Semi-structured interview schedule- group 2 version 1]	v1	15 September 2016
Notice of Substantial Amendment (non-CTIMP) [Notice of substantial amendment #1]		15 September 2016
Participant consent form [Amended Consent form for participants version 3]	V3	15 September 2016
Participant information sheet (PIS) [Amended study participant	v2	15 September 2016

Information sheet group 1 no previous LPP Version 2]		
Participant information sheet (PIS) [Amended Study Participant Information sheet group 2 previous history of LPP version 2]	v2	15 September 2016
Research protocol or project proposal [Amended Study protocol to attach to ethics amendment application version 3]	v3	15 September 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/NI/0270: Please quote this number on all correspondence

Yours sincerely

pp Professor Patrick Murphy
HSC REC B Chair

E-mail: recb@hscni.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Paul Mansour, Southport and Ormskirk NHS Trust*
Mrs Denise Forshaw

HSC REC B

Sub-Committee of the REC

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Siobhan McCullough	Nurse / Lecturer	Yes	
Professor Patrick Murphy	Advisor on Social & Economic Policy	Yes	Chair

HSC Business Services Organisation

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Unit 4, Lissue Industrial Estate West
Rathdown Walk
Moira Road
Lisburn
BT28 2RF
Tel: 028 95361400
www.orecni.hscni.net
HSC REC B

30 November 2018

Mrs Maria Moffatt
9 Rufford Avenue
Maghull
Liverpool
L31 9BY

Dear Mrs Moffatt

Study title:	**Exploring patient's views on the use of a social-media-based intervention for the prevention of lumbopelvic pain in pregnancy: A focus group study**
REC reference:	**15/NI/0270**
Amendment number:	**Substantial Amendment 2**
Amendment date:	**27 July 2018**
IRAS project ID:	**183127**

The above amendment was reviewed at the meeting of the Sub-Committee held on 30 November 2018 in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [TWIMC 2017 EL & PL Cover (2) 1.pdf]		28 November 2017
Letter from sponsor [15NI0270_Sponsor letter for sub amend_17072018 (1) 1.pdf]		11 July 2018
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_ReadyForSubmission 2.pdf]		27 July 2018
Other [Focus Group Guide midwives 4.docx]	1	05 March 2018
Other [Focus Group Guide Physiotherapists 4.docx]	1	05 March 2018

Other [15NI0270_CI declaration form signed by CI and sponsor_17072018.pdf.4p2tlfd.pdf]		11 July 2018
Participant consent form [Amended Consent form for participants version 5 without logo 3.docx]	5	03 July 2018
Participant information sheet (PIS) [Amended study participant Information sheet group 2 previous LPP Version 3 3.docx]	3	03 July 2018
Participant information sheet (PIS) [Study Participant Information sheet group 3 physiotherapists 5.docx]	2	03 July 2018
Participant information sheet (PIS) [Study Participant Information sheet group 4 midwives 7.docx]	3	03 July 2018
Research protocol or project proposal [Amended Study protocol to attach to ethics amendment application version 4 5.docx]	4	05 March 2018

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/.

15/NI/0270: Please quote this number on all correspondence

Yours sincerely

Denise Nesbitt

P.P

Dr Anne Moorhead
Vic-Chair

E-mail: recb@hscni.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Paul Mansour, Southport and Ormskirk NHS Trust*
Mrs Maria Moffatt

HSC REC B

Attendance at Sub-Committee of the REC meeting on 30 November 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr John Edward Mone	Retired (Former Executive Director of Nursing)	Yes	
Dr Anne Moorhead (Chaired the meeting)	Senior Lecturer in Health & Communication	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Denise Nesbitt	REC B Manager

NHS
Health Research Authority

Mrs Maria Moffatt
9 Rufford Avenue
Maghull
Liverpool
L31 9BY

Email: hra.approval@nhs.net

14 May 2019

Dear Mrs Moffatt

Letter of HRA and HCRW Approval for a study processed through pre-HRA Approval systems

Study title:	**Exploring patient's views on the use of a social-media-based intervention for the prevention of lumbopelvic pain in pregnancy: A focus group study**
IRAS project ID:	**183127**
Sponsor	**Manchester Metropolitan University**

Thank you for your request to bring the above referenced study, processed under pre-HRA Approval systems, under HRA and HCRW Approval.

I am pleased to confirm that the study has been given **HRA and HCRW Approval.** This has been issued on the basis of an existing assessment of regulatory compliance, which has confirmed that the study is compliant with the UK wide standards for research in the NHS.

The extension of HRA and HCRW Approval to this study on this basis allows the sponsor and participating NHS organisations in England and Wales to set-up the study in accordance with HRA and HCRW Approval processes, with decisions on study set-up being taken on the basis of capacity and capability alone.

Participation of NHS Organisations in England and Wales

Please note that full information to enable set up of participating NHS organisations in England and Wales is not provided in this letter, on the basis that activities to set up these NHS organisations is likely to be underway already.

The sponsor should provide a copy of this letter, together with the local document package and a list of the documents provided, to participating NHS organisations in England and

Wales that are being set up in accordance with HRA Approval Processes. It is for the sponsor to ensure that any documents provided to participating organisations are the current, approved documents.

For non-commercial studies the local document package provided to NHS organisations should include an appropriate Statement of Activities and HRA Schedule of Events. The sponsor should also provide the template agreement to be used in the study, where the sponsor is using an agreement in addition to the Statement of Activities. Participating NHS organisations in England should be aware that the Statement of Activities and Schedule of Events for this study have not been validated, but it is expected that the sponsor provides these to participating NHS organisations. Any changes that are appropriate to the content of the Statement of Activities and Schedule of Events should be agreed in a pragmatic fashion as part of the process of assessing, arranging and confirming capacity and capability to deliver the study.

For commercial studies the local document package should include a validated industry costing template and the template agreement to be used with participating NHS organisations in England and Wales.

It is critical that you involve both the research management function (e.g. R&D office and, if the study is on the NIHR portfolio, the LCRN) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

If subsequent NHS organisations in England and/or Wales are added, an amendment should be submitted.

After HRA and HCRW Approval

In addition to the document, *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC Favourable Opinion, please note the following:

- HRA and HCRW Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- Amendments will be categorised (for both substantial and non-substantial) and issued confirmation of continued HRA and HCRW Approval.

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA and HCRW Approval provides an approval for research involving patients or staff in NHS organisations in England and Wales.

If your study involves NHS organisations Northern Ireland and/or Scotland, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/.

Your IRAS project ID is 183127. Please quote this on all correspondence.

Yours sincerely

HRA Assessment team

Email: hra.approval@nhs.net

Copy to: *Miss Alison Lloyd, Manchester Metropolitan University*
Dr Paul Mansour, Southport and Ormskirk NHS Trust

R & D Clinical Director Dr Christos Zipitis
R&D Managers Mrs Christine Birchall and Mrs Pamela O'Connell
R & D Co-ordinator Mrs Sandra Latham

Wrightington, Wigan and Leigh NHS
NHS Foundation Trust

Research and Development Dept

Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
WN6 9EP
01257 256465
Email: Sandra.Latham@wwl.nhs.uk

Maria Moffatt
Research Physiotherapist
Upper Limb Unit
Wrightington Hospital
Wigan
WN6 9EP

13th July 2016:

Dear Maria

RE: Exploring patient's views on the use of a social-media-based intervention for the prevention of lumbopelvic pain in pregnancy: A focus group study

This letter is confirmation that you have Research and Development approval to conduct the above titled research study within Wrightington, Wigan and Leigh NHS Foundation Trust.

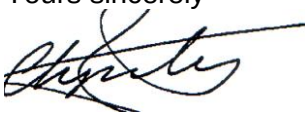
I would like to draw your attention to the following Trust policies: Health and Safety at Work Act, Data Protection Act 1998, Human Tissue Act 2004: Good Clinical Practice.

It is a requirement that the Research and Development Department are informed of:

- Any Amendments arising from the research study.
- Any Serious Adverse Events (SAE's) that might arise during the course of the study.
- Any presentations or publications arising from the study.

The Trust expects all Chief Investigators to submit a final report to the Research and Development Committee at the end of the study.

Yours sincerely



Dr Christos Zipitis
Clinical Director of Research and Development

Diane O'Grady
Senior Client Adviser
Marsh Ltd
Belvedere
12 Booth Street
Manchester
M2 4AW
0161 954 7215 Fax +44 (0) 161 954 7210
Diane.ograd y@marsh.com
www.marsh.com

28 November 2017

To Whom It May Concern

Dear Sir/Madam

EVIDENCE OF INSURANCE – Manchester Metropolitan University
As requested by the above client, we are writing to confirm that we act as Insurance Brokers to the client and that we have arranged insurance(s) on its behalf as detailed below:

COMBINED LIABILITY

INSURER	:	Allianz Insurance Company Ltd
POLICY NUMBER	:	40/SZ/25433370/08
EXPIRY DATE	:	Noon 1 December 2018
LIMIT OF LIABILITY	:	GBP10,000,000 any one occurrence in respect of Public Liability GBP10,000,000 any one occurrence and in the aggregate in respect of Products Liability GBP10,000,000 any one occurrence and in the aggregate in respect of Pollution Liability GBP 25,000,000 any one occurrence in respect of Employers' Liability As per policy
DEDUCTIBLES	:	GBP 1,000 any one occurrence in respect of Third Party Property Damage GBP 5,000 any one occurrence in respect of Pollution Clean Up Costs Nil in respect of all other claims

EXCESS LIABILITY

INSURER	AIG Europe Ltd
POLICY NUMBER	24652000
EXPIRY DATE	Midnight 30 November 2018

LIMIT OF LIABILITY In respect of Public/ Products liability GBP 40,000,000 in excess of GBP 10,000,000

In respect of Employers Liability GBP 5,000,000 in excess of GBP 25,000,000

We have placed the insurance which is the subject of this letter after consultation with the client and based upon the client's instructions only. Terms of coverage, including limits and deductibles, are based upon information furnished to us by the client, which information we have not independently verified.

This letter is issued as a matter of information only and confers no right upon you other than those provided by the policy. This letter does not amend, extend or alter the coverage afforded by the policies described herein. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this letter may be issued or pertain, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions, limitations, exclusions and cancellation provisions and may also be subject to warranties. Limits shown may have been reduced by paid claims.

We express no view and assume no liability with respect to the solvency or future ability to pay of any of the insurance companies which have issued the insurance(s).

We assume no obligation to advise yourselves of any developments regarding the insurance(s) subsequent to the date hereof. This letter is given on the condition that you forever waive any liability against us based upon the placement of the insurance(s) and/or the statements made herein with the exception only of wilful default, recklessness or fraud.
This letter may not be reproduced by you or used for any other purpose without our prior written consent.

This letter shall be governed by and shall be construed in accordance with English law.

Yours faithfully,

Diane O'Grady
Diane O'Grady
Senior Client Adviser
For and on behalf of Marsh Ltd

Health Research Authority
London - Bloomsbury Research Ethics Committee
HRA RES Centre Manchester
3rd Floor Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 02071048285

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 March 2021

Mrs Maria Moffatt
Manchester Metropolitan University
Brooks Building, Bonsall Street
Manchester
M15 6GX

Dear Mrs Moffatt

Study title:	**An app-based intervention to support the self-management of pregnancy-related lumbopelvic pain: a mixed methods feasibility study**
REC reference:	**21/PR/0084**
IRAS project ID:	**290483**

Thank you for your letter of 17 March 2021. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 05 March 2021

Documents received

The documents received were as follows:

Document	*Version*	*Date*
IRAS Application Form [IRAS_Form_24032021]		24 March 2021
Other [Response to Ethical Review]		17 March 2021

Research protocol or project proposal [Amended Protocol with IRAS ID date and version number]	4	15 March 2021

Approved documents

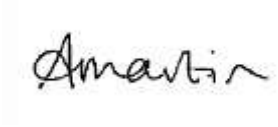
The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Contract/Study Agreement template [Organisation Information Document]	1	09 February 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of indemnity]	1	15 January 2021
Interview schedules or topic guides for participants [Interview topic guide for app users]	2	15 December 2020
Interview schedules or topic guides for participants [Interview topic guide for clinicians]	2	15 December 2020
IRAS Application Form [IRAS_Form_24032021]		24 March 2021
Letter from sponsor [Sponsorship letter from MMU]	1	15 January 2021
Letters of invitation to participant [Amended invitation email wording]	2	09 February 2021
Letters of invitation to participant [Amended invitation email wording clinicians]	2	09 February 2021
Non-validated questionnaire [Demographic questions to be asked at start of interview]	1	09 February 2021
Other [Declaration of conformity for the app and supporting online platform]	1	01 January 2021
Other [Response to Ethical Review]		17 March 2021
Participant consent form [Consent to contact]	1	08 January 2021
Participant consent form [Consent form for interviews]	2	15 January 2021
Participant information sheet (PIS) [PIS app users amended]	3	15 January 2021
Participant information sheet (PIS) [PIS for clinicians distributing the app]	3	15 January 2021
Research protocol or project proposal [Amended Protocol with IRAS ID date and version number]	4	15 March 2021
Schedule of Events or SoECAT	1	10 February 2021
Summary CV for Chief Investigator (CI) [CI for the CI]	1	02 November 2020
Summary CV for student [PhD student CV]	1	02 November 2020

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

IRAS Project ID: 290483 Please quote this number on all correspondence

Yours sincerely



Anna Martin
Approvals Officer

E-mail: bloomsbury.rec@hra.nhs.uk

Copy to: Mrs Maria Moffatt

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor James Selfe
Manchester Metropolitan University
Brooks Building, Bonsall Street
Manchester
M15 6GX

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

26 March 2021

Dear Professor Selfe

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**An app-based intervention to support the self-management of pregnancy-related lumbopelvic pain: a mixed methods feasibility study**
IRAS project ID:	**290483**
REC reference:	**21/PR/0084**
Sponsor	**Manchester Metropolitan University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **290483**. Please quote this on all correspondence.

Yours sincerely,

Damilola Odunlami

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: Ms Rachel Heron

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [Organisation Information Document]	1	09 February 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Evidence of indemnity]	1	15 January 2021
Interview schedules or topic guides for participants [Interview topic guide for app users]	2	15 December 2020
Interview schedules or topic guides for participants [Interview topic guide for clinicians]	2	15 December 2020
IRAS Application Form [IRAS_Form_19012021]		19 January 2021
IRAS Application Form XML file [IRAS_Form_19012021]		19 January 2021
IRAS Checklist XML [Checklist_10022021]		10 February 2021
Letter from sponsor [Sponsorship letter from MMU]	1	15 January 2021
Letters of invitation to participant [Amended invitation email wording]	2	09 February 2021
Letters of invitation to participant [Amended invitation email wording clinicians]	2	09 February 2021
Non-validated questionnaire [Demographic questions to be asked at start of interview]	1	09 February 2021
Other [Declaration of conformity for the app and supporting online platform]	1	01 January 2021
Participant consent form [Consent to contact]	1	08 January 2021
Participant consent form [Consent form for interviews]	2	15 January 2021
Participant information sheet (PIS) [PIS app users amended]	3	15 January 2021
Participant information sheet (PIS) [PIS for clinicians distributing the app]	3	15 January 2021
Research protocol or project proposal	3	09 February 2021
Schedule of Events or SoECAT	1	10 February 2021
Summary CV for Chief Investigator (CI) [CI for the CI]	1	02 November 2020
Summary CV for student [PhD student CV]	1	02 November 2020

IRAS project ID	290483

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Single centre study.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No application for external funding will be made. No funds will be provided to the participating organisation to support this study.	A PI is expected at the participating organisation.	All study activities will be undertaken by local staff employed by the NHS organisation. Therefore, no honorary research contracts or letters of access are expected for this study.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

11/02/2019

Project Title: Pregnancy-related Lumbopelvic pain: Exploring the use of social media for preventative healthcare advice

EthOS Reference Number: 0464

Ethical Opinion

Dear Maria Moffatt,

The above application was reviewed by the Research Ethics and Governance Team and on the 11/02/2019, was certified. The certification is in place until the end of your project and is based on the documentation submitted with your application.

Application Documents

Document Type	File Name	Date	Version
Additional Documentation	Letter from sponsor	09/12/2015	1
Ethical Approval Supporting Information	Amended study participant Information sheet group 1 no previous LPP Version 2	01/09/2016	2
Additional Documentation	annual-progress-report-form-research 16-3-18	16/03/2018	1
Additional Documentation	Study Participant Information sheet group 4 midwives	03/07/2018	3
Additional Documentation	Study Participant Information sheet group 3 physiotherapists	03/07/2018	3
Additional Documentation	Amended study participant Information sheet group 2 previous LPP Version 3	03/07/2018	3
Additional Documentation	Amended Consent form for participants version 5 without logo	03/07/2018	5
Additional Documentation	Amended Study protocol to attach to ethics amendment application version 4	03/07/2018	4
Ethical Approval Supporting Information	Study Participant Information sheet group 4 midwives	03/07/2018	3
Ethical Approval Supporting Information	Study Participant Information sheet group 3 physiotherapists	03/07/2018	3
Ethical Approval Supporting Information	Amended study participant Information sheet group 2 previous LPP Version 3	03/07/2018	3
Ethical Approval Supporting Information	Amended Consent form for participants version 5 without logo	03/07/2018	5
Ethical Approval Supporting Information	Amended Study protocol to attach to ethics amendment application version 4	03/07/2018	4
Ethical Approval Application Form	AmendmentForm_ReadyForSubmission	10/07/2018	1
Additional Documentation	AmendmentForm_ReadyForSubmission	01/08/2018	1
Additional Documentation	IRAS ID 183127 REC REF 15-NI-0270 Favourable Opinion Substantial Amendment - 30.11.2018_DN	30/11/2018	1
Ethical Approval Letter	IRAS ID 183127 REC REF 15-NI-0270 Favourable Opinion Substantial Amendment - 30.11.2018_DN (1)	30/11/2018	1
Additional Documentation	IRAS ID 183127 REC REF 15-NI-0270 Favourable Opinion Substantial Amendment - 30.11.2018_DN (1)	04/02/2019	1

Conditions of certification

The Research Ethics and Governance Team would like to highlight the following conditions

Adherence to Manchester Metropolitan University's Policies and procedures

This ethical approval is conditional on adherence to Manchester Metropolitan University's Policies, Procedures, guidance and Standard Operating procedures. These can be found on the Manchester Metropolitan University Research Ethics and Governance webpages.

Amendments

If you wish to make a change to this approved application, you will be required to submit an amendment in accordance with Health Research Authority guidelines. Please contact the Research Ethics and Governance team for advice around how to do this.

We wish you every success with your project.

Research Ethics and Governance Team

From:	SIMPSON, Victoria (LEWISHAM AND GREENWICH NHS TRUST)
To:	Maria Moffatt; ROBSON, Myra (LEWISHAM AND GREENWICH NHS TRUST)
Cc:	GRAY, Valerie (LEWISHAM AND GREENWICH NHS TRUST); RD (LEWISHAM AND GREENWICH NHS TRUST); Rachel Heron; KELLY, Hannah (LEWISHAM AND GREENWICH NHS TRUST)
Subject:	IRAS 290483. Confirmation of Capacity and Capability at Lewisham & Greenwich NHS Trust
Date:	21 May 2021 10:01:19
Attachments:	image002.png Organisation_Information_Document_NonCommercial_v1 09-2-2021.pdf

Dear All,

RE: IRAS 290483. Confirmation of Capacity and Capability at Lewisham & Greenwich NHS Trust.

Full Study Title: An app-based intervention to support the self-management of pregnancy-related lumbopelvic pain: a mixed methods feasibility study

This email confirms that **Lewisham & Greenwich NHS Trust** has the capacity and capability to deliver the above referenced study. Please find attached our agreed Organisational Information Document as confirmation.

We agree to start this on a date to be agreed when the sponsor gives the green light to begin.

Maria please ensure the study record is created in EDGE local portfolio management system.

You will be required to update your recruitment activity to the EDGE. It is expected that this data is updated as close to real time as possible, but at least by the end of each week.

Please let LH.RD@nhs.net know who will be responsible for updating this data for LGT.

If you have any queries throughout your project, please do not hesitate to contact me. Meanwhile, may I wish you success in your project.

BW
Vicke

Victoria Simpson
Research Facilitator

Lewisham & Greenwich NHS Trust
R&D Department, Queen Elizabeth Hospital
Education Centre, Room EC.1,
Stadium Road, Woolwich,
London, SE18 4QH

QE Tel: 020 8836 6790 | UHL Tel: 0203 192 6361
Email: vsimpson1@nhs.net | lh.rd@nhs.net | lg.coronatrials@nhs.net

Diane O'Grady
Senior Client Adviser
Marsh Ltd
Belvedere
12 Booth Street
Manchester
M2 4AW
0161 954 7215 Fax +44 (0) 161 954 7210
Diane.ogrady@marsh.com
www.marsh.com

7 January 2021

To Whom It May Concern

Dear Sir/Madam

EVIDENCE OF INSURANCE – Manchester Metropolitan University
As requested by the above client, we are writing to confirm that we act as Insurance Brokers to the client and that we have arranged insurance(s) on its behalf as detailed below:

COMBINED LIABILITY

INSURER	:	Allianz Insurance Company Ltd
POLICY NUMBER	:	40/SZ/25433370
EXPIRY DATE	:	Noon 01 December 2021
LIMIT OF LIABILITY	:	GBP10,000,000 any one occurrence in respect of Public Liability GBP10,000,000 any one occurrence and in the aggregate in respect of Products Liability GBP10,000,000 any one occurrence and in the aggregate in respect of Pollution Liability GBP 25,000,000 any one occurrence in respect of Employers' Liability As per policy
DEDUCTIBLES	:	GBP 1,000 any one occurrence in respect of Third Party Property Damage GBP 5,000 any one occurrence in respect of Pollution Clean Up Costs Nil in respect of all other claims

EXCESS LIABILITY

INSURER	AIG Europe Ltd
POLICY NUMBER	24652000
	Midnight 30 November 2021

EXPIRY DATE

LIMIT OF LIABILITY In respect of Public/ Products liability GBP 40,000,000 in excess of GBP 10,000,000

In respect of Employers Liability GBP 5,000,000 in excess of GBP 25,000,000

We have placed the insurance which is the subject of this letter after consultation with the client and based upon the client's instructions only. Terms of coverage, including limits and deductibles, are based upon information furnished to us by the client, which information we have not independently verified.

This letter is issued as a matter of information only and confers no right upon you other than those provided by the policy. This letter does not amend, extend or alter the coverage afforded by the policies described herein. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this letter may be issued or pertain, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions, limitations, exclusions and cancellation provisions and may also be subject to warranties. Limits shown may have been reduced by paid claims.

We express no view and assume no liability with respect to the solvency or future ability to pay of any of the insurance companies which have issued the insurance(s).

We assume no obligation to advise yourselves of any developments regarding the insurance(s) subsequent to the date hereof. This letter is given on the condition that you forever waive any liability against us based upon the placement of the insurance(s) and/or the statements made herein with the exception only of wilful default, recklessness or fraud.
This letter may not be reproduced by you or used for any other purpose without our prior written consent.

This letter shall be governed by and shall be construed in accordance with English law.

Yours faithfully,

Diane O'Grady
Diane O'Grady
Senior Client Adviser
For and on behalf of Marsh Ltd

Template Version No: 1.6

Organisation Information Document – Non-Commercially Sponsored Studies

(Template version: 1.6)

Guidance on Using This Document

Please use this document to create the outline Organisation Information Document/s that you will submit with your IRAS Form. In most instances the Organisation Information Document should be localised before sharing with participating NHS / HSC organisations.

Questions/items marked with an asterisk * (Questions 1-3, 5, 8 and 12-15 and 18, as well as items throughout the appendices as applicable) must be completed prior to submission of the IRAS Form in all cases. Only if the localised Organisation Information Document is to be used as the Agreement between the parties should the Sponsor or authorised delegate check the relevant check boxes at the top of each subsequent appendix and complete the authorisation section.

Items marked with a caret ^ are completed by the participating NHS / HSC organisation, after the Local Information Pack is shared and where relevant.

Remaining questions may be answered on the localised Organisation Information Document either by the Sponsor or authorised delegate prior to sharing the Local Information Pack, or by the participating NHS / HSC organisation (or collaboratively between the two) after the Local Information Pack is shared, as appropriate.

To provide an answer in the document, click in a box with the grey text (click here to enter text), or choose the relevant option if presented with a drop-down list.

A separate guidance document is provided and should be consulted prior to completion of this document. Please also read the question specific guidance where present.

We welcome your feedback on the use of the UK Local Information Pack using our online feedback form.

Study Information

1.* IRAS Project ID	**290483**
2.* Full Title of the Study	An app-based intervention to support the self-management of pregnancy-related lumbopelvic pain: a mixed methods feasibility study
3.* Legal Name(s) of Sponsor/Co-Sponsors/Joint-Sponsors	Manchester Metropolitan University
4. Contact details of person acting on behalf of Sponsor for questions relating to study set up. Please enter details of the person who is the Sponsor's main point of contact for all correspondence on setting up the study at this NHS / HSC organisation. This contact may be the Sponsor, a Study Manager, Clinical Research Scientist or Study Coordinator. Where a Contract Research Organisation (CRO) or Clinical Trials Unit (CTU) has been delegated to handle set up on behalf of the Sponsor, the contact at the CRO or CTU should be named here.	
Name	**Rachel Heron**
Telephone Number	N/A as working from home at present
Email Address	R.Heron@mmu.ac.uk
5.* Are all participating NHS / HSC organisations undertaking the same protocol activities?	
Yes	
If 'No' give details of the activities taking place at NHS / HSC organisations that you will use this outline Organisation Information Document with. Additional outline Organisation Information Documents may be required for NHS / HSC organisations undertaking different activities.	
N/A	

Participating NHS / HSC Organisation Information

6. Name of Participating NHS / HSC Organisation. If this Organisation Information Document is being used as an Agreement the name must be entered prior to agreement.
Lewisham and Greenwich NHS Trust
7. Location/s*:* Please provide detail below where it is planned to undertake the research only at specified locations with the participating NHS / HSC organisation (i.e. hospital(s), GP Practice(s) and/or Research Unit(s))**.** It is not intended that the level of detail provided here captures individual departments within the participating NHS / HSC organisation.

Location (enter text below)	**Activity** (enter text below)
NHS hospital physiotherapy department	Check eligibility and seek consent for the research team to contact patient to invite them to take part during normal clinical encounter either face-to-face or virtually. All other activities undertaken by the research team.

8*. What is the role of the person responsible for research activities at the participating NHS / HSC organisation?

- Principal Investigators are expected to be in place at participating NHS / HSC organisations where locally employed staff take responsibility for research procedures. In this scenario Principal Investigator should be selected even for single centre studies where the Chief Investigator will also be the Principal Investigator.
- Where this is not the case, local collaborators are expected to be in place where central study staff will be present at the participating organisation to undertake research procedures (the role of the Local Collaborator is to facilitate the presence of Sponsor / CRO research staff).
- Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at the participating NHS / HSC organisation, select Chief Investigator.

Principal Investigator

9. Contact details of person responsible for research activities at this participating NHS / HSC organisation as indicated in question 8 (if known). If known, please enter the details of the person you have spoken to about their role in this study at this participating NHS / HSC organisation. If unknown, please leave blank and that person can be identified and listed here during the setup of the study.

Name	Myra Robson
Post / Job Title	Pelvic Health Clinical Lead Physiotherapist
Name of Employing Organisation	Lewisham and Greenwich NHS Trust
Email Address	Myra.robson@nhs.net
Telephone number	N/A

Timescales

10. Predicted Start and End Dates of the Study at this Participating NHS / HSC Organisation The Sponsor or authorised delegate should propose a date on which it intends to start and complete research activity at this participating NHS / HSC organisation. Alternatively, this may be left blank when the Local Information Pack is shared, for agreement during study set up at the Participating NHS / HSC Organisation.	
Predicted Start Date (activities at this organisation)	26/02/2021
Predicted End Date (activities at this organisation)	31/12/2021
For many types of study the following dates are not applicable and this may be stated in answer. Where they are applicable, they should be provided by the Sponsor or authorised delegate before sharing the Local Information Pack, as indicative targets for agreement, or they may be negotiated between Sponsor or authorised delegate and participating NHS / HSC organisation after sharing the pack.	
Predicted Site Initiation Visit Date	26/02/2021
Predicted Start Date for participant recruitment	01/03/2021
Predicted End Date for participants recruitment (i.e. when the study moves into "follow up" activities.)	31/08/2021
Predicted End Date for all study activities (i.e. "last patient visit" completed and study is ready to be archived.)	31/12/2021

Participant Numbers

11. How many research participants are expected at this participating NHS / HSC organisation? For studies not directly involving human participants, please indicate the number of samples or data-sets to be obtained. Please state if number of participants is per month, per year, overall, etc.
Up to 18 overall for the qualitative study

Study set up and delivery arrangements at Participating NHS / HSC Organisations

12*. The following are needed at the participating NHS / HSC organisation to deliver the study: e.g. specific equipment, patient/participant groups, service support, nursing time, etc. Please detail any specific requirements for participating NHS / HSC organisations to deliver this study, including by clarifying any requirements on participating NHS / HSC organisations relating to monitoring / self-monitoring, e.g. requirements for staff signature and delegation logs to be returned to the Sponsor and/or any particular access requirements that the Sponsor may have that it wishes to bring to the attention of the participating NHS / HSC organisation, likelihood of staff not employed at the participating NHS / HSC organisation coming on site, etc.

Local physiotherapists will screen potential participants and seek their consent for the research team to contact them during their normal clinical encounter (either face-to-face or virtually). No additional time is required.

A single consent to contact form will be completed/signed either by the patient during a face-to-face appointment or by the clinician if during a virtual consultation – these forms will be provided to site staff by the research team. These will be filed alongside the study site file which will also be provided by the research team and stored locally in line with local policy.

13*. The following training will be provided by the Sponsor or authorised delegate for local research team members. Where only specific team members (e.g. the Principal Investigator) will receive this training, this should be specified.

The external research team will discuss the consent to contact form with local staff by phone or via Microsoft Teams. This training will take around 10 minutes to complete.

14*. The Sponsor expects that local research team members will have the following skills and where they do not have those skills that they will undertake the relevant training before undertaking the relevant study activities. It would not be usual for the Sponsor to expect study specific training additional to that which it will provide. This section does however allow Sponsors to state, for example, that when they expect **training in Good Clinical Practice** for appropriate team members where the study is a Clinical Trial of an Investigational Medicinal Product, they will accept UK nationally recognised GCP training, training recognised on the **Transcelerate mutual recognition scheme**, etc.

No additional training is required as participants will be approached by site staff during a normal clinical encounter and the rest of the study procedures are carried out by the external research team.

15*. The following funding/resources/equipment, etc. is to be provided to this participating NHS / HSC organisation. The Sponsor should answer this question whether this Organisation Information Document is to be used as the Agreement with the

participating NHS / HSC organisation or not. Where the document is intended as the Agreement, further detail should be provided in Appendix 2.
All study related documentation will be provided to site staff, but no funding is being received for this study.

16^ The Participating NHS / HSC Organisation confirms (by use of the drop-down box) that the Principal Investigator, where one is required, is aware of and has agreed to discharge their responsibilities in line with the UK Policy Framework for Research and Social Care..	Confirmed
17^ The Participating NHS / HSC Organisation has considered and mitigated any conflict/s of interest declared by the principal investigator.	Yes
The PI assisted the researcher in the development of the app under exploration in this study. However, the PI has no financial interest in the app and is not undertaking any research procedures other than seeking consent for the researcher to invite the patient to take part in the study.	

Sponsor Authorisation

18* Authorised on behalf of Sponsor by:	
Name	Rachel Heron
Job Title	Research Ethics and Governance Manager
Organisation Name	Manchester Metropolitan University
Date	09 February 2021

Appendices

(Contents)

The sponsor or authorised delegate should answer the question at the top of Appendix 1 and, if it intends that this Organisation Information Document will be incorporated into an exchange of correspondence to form the Agreement ("Agreement") between itself and the participating NHS / HSC organisation, the questions that appear at the top of each subsequent appendix.

Appendix 1: General Provisions

***Does the Sponsor intend that this Organisation Information Document forms the Agreement between itself and the participating NHS / HSC Organisation, or has a separate site agreement been provided?**	Organisation Information Document

It is recommended that the Organisation Information Document is used as the Agreement between Sponsor and participating NHS / HSC organisation for studies that are not clinical trials or investigations. The model Non-Commercial Agreement (mNCA) should be used for clinical trials or investigations.

Where the Organisation Information Document is to be used as the Agreement between the Sponsor and participating NHS organisation (hereafter singly "Party" or collectively the "Parties"), this document forms a formal legal contract between the Parties. In all cases where this document is the Agreement between the Parties, this Appendix 1 applies in full.

Additionally, the Sponsor or authorised delegate should use the questions at the top of each subsequent appendix to indicate whether or not that appendix also forms part of the Agreement.

Text highlighted in yellow is optional, including where alternative versions of the same clause may be used. The applicable option/s should be selected and text not to be used should be deleted prior to IRAS submission. No changes should be made to any text that does not appear in yellow highlight.

1. OBLIGATIONS OF THE PARTIES

1.1. The Parties agree to comply with all relevant laws, regulations and codes of practice applicable to this Agreement including to the performance of the study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects" (where applicable) and the UK Policy Framework for Health and Social Care Research. The Parties shall conduct the study in accordance with:

1.1.1. the Protocol, including appropriately made amendments thereto (which is/are hereby incorporated into this Agreement by reference);

1.1.2. the terms of all relevant permissions and approvals. These may include, but are not limited to the terms and conditions of the favourable opinion given by the relevant NHS Research Ethics Committee, where applicable.

1.2. The Parties shall carry out their respective responsibilities in accordance with this Agreement.

1.3. The Parties agree to comply with all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants and study personnel.

1.4. The Sponsor shall, on the giving of reasonable prior written notice to the Participating NHS / HSC Organisation, have the right to audit the Participating NHS / HSC Organisation's compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Participating NHS / HSC Organisation's premises and to all relevant documents and other information relating to the study.

1.5. The Participating NHS / HSC Organisation shall;

1.5.1. promptly notify the Sponsor should any responsible body conduct or give notice of intent to conduct any inspection at the Participating NHS / HSC Organisation in relation to the study;

1.5.2. allow the Sponsor to support the preparations for such inspection; and

1.5.3. following the inspection, provide the Sponsor with the results of the inspection relevant to the study. The Sponsor will be responsible for sharing such results with the funder if required.

1.6. In accordance with participant consent, the Participating NHS / HSC Organisation shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant data for monitoring and source data verification. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the study, reasonable access to relevant members of staff at the Participating NHS / HSC Organisation and the right to examine any procedures or records relating to the study, subject at all times to clause 6 of this appendix. The Sponsor will alert the Participating NHS / HSC Organisation promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the study.

2. LIABILITIES AND INDEMNITY

2.1. Nothing in this clause 2 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the data protection legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its agent(s), fraud or fraudulent

misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

2.2. Where a Party is a non-NHS/HSC organisation, or an NHS/HSC organisation that is not a member of an NHS indemnity scheme, then that Party shall maintain all proper insurance or equivalent indemnity arrangements to cover liabilities arising from its participation in the study, in respect of any claims brought by or on behalf of a participant. Where the Party is an NHS/HSC organisation and is a member of an NHS indemnity scheme, it shall maintain its membership therein or otherwise ensure it has appropriate cover against claims arising as a result of clinical negligence by the Party and/or its agents brought by or on behalf of the participants. Each Party shall provide to the other such evidence of their insurance or equivalent indemnity cover maintained pursuant to clause 2.2 as the other Party shall from time to time reasonably request, such evidence might comprise confirmation that an NHS/HSC organisation is a member of one of the NHS indemnity schemes.

2.4. Subject to clauses 2.5, 2.6 and 2.8, the Participating NHS / HSC Organisation shall indemnify the Sponsor agents, against any reasonable claims, proceedings and related costs, expenses, losses, damages and demands to the extent they arise or result from the negligent acts or omissions of, or the wilful misconduct of the Participating NHS / HSC Organisation, or its agents, in its performance of this Agreement or in connection with the study.

2.5. An indemnity under clauses 2.3 or 2.4 shall only apply if the indemnified Party:

2.5.1. informs the Party providing the indemnity in writing as soon as reasonably practicable following receipt of notice of the claim or proceedings;

2.5.2. upon the indemnifying Party's request and at the indemnifying Party's cost gives the indemnifying Party full control of the claim or proceedings and provides all reasonable assistance; and

2.5.3. makes no admission in respect of such claim or proceedings other than with the prior written consent of the indemnifying Party.

2.6. Any indemnity under clauses 2.3 or 2.4 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from the negligent acts or omissions or wilful misconduct or breach of statutory duty of the indemnified Party.

2.7. The indemnity under clause 2.3 shall not apply to the extent any claims, proceedings and related costs, expenses, losses, damages or demands arise or result from:

2.7.1. Participating NHS / HSC Organisation carrying out a treatment or procedure that would be routinely undertaken at or for that Participating NHS / HSC Organisation as part of National Health Service treatment; or

2.7.2. Participating NHS / HSC Organisation preparing, manufacturing or assembling any equipment which is not done in accordance

2.7.2.1. with the protocol; or

2.7.2.2. with written instructions of the manufacturer; or

2.7.2.3. (where such instructions differ from the instructions of the manufacturer) other written instructions of the Sponsor.

2.8. No Party shall be liable to another in contract, tort/delict, breach of statutory duty or otherwise for any loss of profits, revenue, reputation, business opportunity, contracts, or any indirect, consequential or economic loss arising directly or indirectly out of or in connection with this Agreement.

2.9. If a Party incurs any loss or damage (including costs and expenses) ("Loss") arising or resulting from this Agreement and:

2.9.1. All Parties are NHS bodies as defined in Section 9(4) of the National Health Service Act 2006 or Section 17 of the National Health Service (Scotland) Act 1978 or Section 7 (4) of the NHS (Wales) Act 2006 or Articles 16 and 26 of the Health and Personal Social Services (Northern Ireland) Order 1972, which established the Boards and Central Services Agency respectively and Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991: which established Trusts in Northern Ireland as appropriate; or

2.9.2. One or more Party is a NHS body and the other Party (ies) is a NHS Foundation Trust; or

2.9.3. All Parties are NHS Foundation Trusts;

Then clauses 2.10, 2.11 and 2.12 shall apply.

2.10. If all Parties are NHS bodies / NHS Foundation Trusts in England, Wales or Northern Ireland and are indemnified by the same indemnity scheme (being one of the NHS Resolution's clinical negligence schemes or the Welsh Risk Pool or the Clinical Negligence Fund in Northern Ireland) and the Party incurring any loss can recover such loss under one of the indemnity schemes, then such Party shall rely on the cover provided by the indemnity scheme and not seek to recover the Loss from the other Party (ies). Where the other Party (ies) caused or contributed to the Loss, it undertakes to notify the relevant indemnity scheme(s) to take this into account in determining the future levies of all Parties in respect of the indemnity schemes.

2.11. If:

2.11.1. The Parties are members of the same indemnity scheme in England, Wales or Northern Ireland and the Party incurring the Loss is not indemnified for that Loss by its indemnity schemes; or

2.11.2. All Parties are NHS bodies in Scotland; or

2.11.3. The Parties are NHS bodies/Foundation Trusts established in different jurisdictions within the United Kingdom;

Then the Parties shall apportion such Loss between themselves according to their respective responsibility for such Loss.

2.12. If one or more Parties are NHS Foundation Trusts and the Party incurring the Loss is not responsible for all or part of the Loss and is not indemnified in respect of the Loss by one of the indemnity schemes then the Party incurring the Loss shall be entitled to recover the Loss from the other Party (ies) pursuant to the provisions of this Agreement.

2.13. **[SINGLE SPONSOR]** Subject to clause 2.1 and 2.7 the liability of the Participating NHS / HSC Organisation to the Sponsor and the liability of the Sponsor to the Participating NHS / HSC Organisation arising out of or in connection with any breach of this Agreement or any act or omission of either Party in connection with the performance of the study should be the greater of the amount of fees payable by the Sponsor to the Participating NHS / HSC Organisation under this Agreement or one hundred thousand (£100,000 GBP) pounds. For the avoidance of doubt, this cap applies also but not exclusively to the indemnities offered under clauses 2.3 and 2.4.

2.14. Notwithstanding clause 2.13, in the case of equipment loaned by or on behalf of the Sponsor to the Participating NHS / HSC Organisation for the purposes of the study, the Participating NHS / HSC Organisation's liability for damage to or loss of that equipment arising from its negligence shall exclude fair wear and tear and shall not exceed the replacement value of the equipment.

2.15. The Sponsor/co-Sponsors/joint-Sponsors agree/s that in respect of any personal injury or death of any participant as a result of participation in the study, it/they will provide no-fault compensation and will be insured to pay out on any such claims.

3. PUBLICITY

3.1. Neither Party shall use the name, logo or registered image of the other party or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

3.2. The content and timing of any publicity, advertising or press release shall be agreed by both Parties, such agreement not to be unreasonably withheld.

4. PUBLICATION

4.1. In accordance with all relevant laws, regulations and codes of practice, it is agreed that the Sponsor has an obligation to and shall publish the results of the full study and that the Participating NHS / HSC Organisation shall not publish any study data, including through presentation or submission of an abstract, without the prior permission in writing from the Sponsor (which shall not be unreasonably withheld or delayed).

5. FREEDOM OF INFORMATION

5.1. Parties to this Agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another Party shall notify and consult that Party, as soon as reasonably practicable, and in any event, not later than seven (7) working days after receiving the request.

5.2. The Parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the Party responding to the request.

5.3. Where the Party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other Party in writing, giving at least four (4) working days' notice of its intended disclosure.

6. CONFIDENTIALITY

6.1. Subject to clause 5 above, the Participating NHS / HSC Organisation agrees to treat the results, excluding any clinical data of the study, as confidential information of the Sponsor and the Sponsor agrees to treat personal data and confidential patient information as confidential information.

6.2. The receiving Party agrees:

6.2.1. To take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this Agreement

6.2.2. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the Study are made aware of, and abide by, the requirement of this clause 6.2.

6.2.3. To use confidential information solely in connection with the operation of the Agreement and not otherwise, except in the case where the confidential information is personal data and/or confidential patient information, where it may be used solely on the basis of maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.2.4. Not to disclose confidential information in whole or in part to any person without the disclosing Party's prior written consent or, where the confidential information is personal data and/or confidential patient information, without maintaining the common law duty of confidentiality and in accordance with the requirements of the data protection legislation, including but not limited to an appropriate legal basis/special category condition, appropriate transparency information and that the purpose is not incompatible with the original purpose.

6.3. The provision of clause 6.2 shall not apply to the whole or any part of the confidential information that is:

6.3.1. lawfully obtained by the receiving Party free of any duty of confidentiality;

6.3.2. already in the possession of the receiving Party and which the receiving Party can show from written records was already in its possession (other than as a result of a breach of clause 6.2.1 or 6.2.2);

6.3.3. in the public domain (other than as a result of a breach of clause 6.2.1 or 6.2.2);

6.3.4. independently discovered by employees of the receiving Party without access to or use of confidential information;

6.3.5. necessarily disclosed by the receiving Party pursuant to a statutory obligation;

6.3.6. disclosed with prior written consent of the disclosing Party;

6.3.7. necessarily disclosed by the receiving Party by virtue of its status as a public authority in terms of the FOIA or the FOI(S)A;

6.3.8. published in accordance with the provisions of clause 4.

6.4. The restrictions contained in clause 6.2 shall remain in force without limit in time in respect of personal data and any other information which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 2: Finance Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
*Are there funds / resources / equipment, etc. being provided to this participating NHS / HSC organisation by the Sponsor? If no, this appendix should be left blank. If yes, this finance appendix forms part of the Agreement between the participating NHS / HSC organisation and the Sponsor.	No

A. Financial Arrangements

	*Area of Cost	*Payment (£ Sterling)
1*	N/A	No funding will be provided
2*	Click here to enter text	Click here to enter text
3*	Click here to enter text	Click here to enter text
4*	Click here to enter text	Click here to enter text
5*	Click here to enter text	Click here to enter text

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment of the agreed costs on presentation of a VAT invoice in which the VAT is stated as a separate item. Such invoices should quote the Participating NHS / HSC Organisation's VAT registration number. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

Schedule of payments and details of payment arrangements

*Invoices to be submitted [Insert FREQUENCY OR INTERVAL e.g. quarterly] to:

[Insert JOB TITLE, NAME OF BODY & ADDRESS]

^Payment to be made by cheque payable to:

[Insert NAME OF PARTICIPATING NHS / HSC ORGANISATION]

^and remitted to:

[Insert JOB TITLE/POSITION]

[Insert ADDRESS]

^Or arrange BACS Transfer to: [Insert BANK NAME].

^Sort code: [Insert SORT CODE]

^Account: [Insert ACCOUNT NUMBER]

^And send the relevant paper work to [Insert ADDRESSEE FOR PAPERWORK] at the above address

Invoices must be paid promptly [within xx days of receipt]. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding has been irrecoverably reclaimed by the funder as a result of such delay or inadequacy.

B. Supplies Arrangements

Any equipment, materials, consumables, software or other items being provided by the Sponsor or procured by the participating organisation for use in the study shall be specified below.

Note 1: Parties should complete the table below. If the Participating NHS / HSC Organisation is to procure any items and is to be reimbursed by the Sponsor this should be specified in this appendix. Similarly if the Participating NHS / HSC Organisation is to pay the Sponsor for any items provided to the Participating NHS / HSC Organisation by or on behalf of the Sponsor this should be specified in this appendix.

Note 2: Parties should specify in this appendix, as appropriate, arrangements for:

- Ownership of items
- Insurance
- Storage instructions

- Instructions for use, return and/or destruction
- Any training to be provided
- Maintenance of equipment

Item	Quantity	Frequency of supply	Responsibility to supply/procure (either Sponsor or Participating NHS / HSC Organisation only)
Consumables: Consent to contact forms. Any unused items to be disposed of as per local guidance	50	One-time	N/A
Study site file complete with all relevant documents. To be stored locally in line with local policy.	1	One-time	N/A
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text
Click here to enter text	Click here to enter text	Click here to enter text	Click here to enter text

Appendix 3: Material Transfer Provisions

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Does this study involve the transfer of human biological material from this participating NHS / HSC organisation to the Sponsor or its agents? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

Material, as used in this appendix, means any clinical biological sample or portion thereof, derived from participants, including any information related to such Material, supplied by the Participating NHS / HSC Organisation to the Sponsor/Joint Sponsors/either of the Co-Sponsors or [its] / [their] nominee.

1. In accordance with the protocol, the Participating NHS / HSC Organisation shall send Material to the Sponsor/joint Sponsors/a co-Sponsor or, in accordance with provision 7 below, to a third party nominated by the Sponsor/joint Sponsor s/either of the co-Sponsors.
2. The Participating NHS / HSC Organisation warrants that all Material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the protocol.
3. Subject to provision 2 above, the Materials are supplied without any warranty, expressed or implied, including as to their properties, merchantable quality, fitness for any particular purpose, or that the Materials are free of extraneous or biologically active contaminants which may be present in the Materials.
4. The Sponsor/joint Sponsors/one of the co-Sponsors shall ensure, or procure through an agreement with the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above that:
   - 4.1. the Material is used in accordance with the protocol, the consent of the participant, and the ethics approval for the study;
   - 4.2. the Material is handled and stored in accordance with applicable law;
   - 4.3. the Material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent.
5. The Parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

6. The Participating NHS / HSC Organisation and the Sponsor/joint Sponsors/a co-Sponsor shall each be responsible for keeping a record of the Material that has been transferred according to this appendix.
7. To the extent permitted by law the Participating NHS / HSC Organisation and its staff shall not be liable for any consequences of the supply to or the use by the Sponsor/joint Sponsors/co-Sponsor of the Material or of the supply to or the use by any third party to whom the Sponsor/joint Sponsors/co-Sponsor subsequently provides the Material or the Sponsor's/joint Sponsors'/co-Sponsor's nominee as stated in provision 1 above, save to the extent that any liability which arises is a result of the negligence of the Participating NHS / HSC Organisation.
8. The Sponsor/joint Sponsors/co-Sponsor undertake(s) that, in the event that Material is provided to a third party in accordance with provision 2 above, [it] / [they] shall require that such third party shall undertake to handle any Material related to the study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in this appendix.
9. Any surplus Material that is not returned to the Participating NHS / HSC Organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)).

**These provisions do not remove the need for the Sponsor to clearly lay out in their protocol (and to potential participants in the participant information) at a minimum the following information for all Material taken: 1) The nature of the Materials, 2) The reason that the Material is being taken, 3) where the Material is to be sent and, 4) what will happen to any remaining Material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction). Detailed guidance on what information should be included in a protocol may be found on the HRA website: www.hra.nhs.uk*

Appendix 4: Data Processing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS / HSC organisation, please select an option below.	
* Does this study involve any processing of personal data by this participating NHS / HSC organisation on behalf of the Sponsor. If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation. For the avoidance of doubt, when used, these provisions are intended to form a legally binding contractual obligation for the purposes of compliance with the GDPR, specifically GDPR Article 28 (3).	Yes

1. For the purposes of the data protection legislation, the Sponsor is the controller and the Participating NHS / HSC Organisation is the Sponsor's processor in relation to all processing of personal data that is processed for the purpose of this study and for any future research use under the controllership of the Sponsor, that would not have taken place but for this Agreement regardless where that processing takes place.
2. The Parties acknowledge that whereas the Sponsor is the controller in accordance with Clause 1 of this appendix, the Participating NHS / HSC Organisation is the controller of the personal data collected for the purpose of providing clinical care to the participants. This personal data may be the same personal data, collected transparently and processed for research and for care purposes under the separate controllerships of the Sponsor and Participating NHS / HSC Organisation.
3. Where the Participating NHS / HSC Organisation is the Sponsor's processor and thus where the processing is undertaken by the Participating NHS / HSC Organisation for the purposes of the study, Clauses 5.a. to 5.j below will apply. For the avoidance of doubt, such Clauses do not apply where the Participating NHS / HSC Organisation is processing the participant personal data as a controller.
4. The Participating NHS / HSC Organisation agrees only to process personal data for and on behalf of the Sponsor in accordance with the instructions of the Sponsor and for the purpose of the study and to ensure the Sponsor’s compliance with the data protection legislation;
5. The Participating NHS / HSC Organisation agrees to comply with the obligations applicable to processors described by Article 28 GDPR including, but not limited to, the following:
    a. to implement and maintain appropriate technical and organisational security measures sufficient to comply at least with the obligations imposed on the controller by Article 28(1);

b. to not engage another processor without the prior written authorisation of the Sponsor (Article 28(2))

c. to process the personal data only on documented instructions from the Sponsor unless required to do otherwise by legislation, in which case the Participating NHS / HSC Organisation shall notify the Sponsor before processing, or as soon as possible after processing if legislation requires that the processing occurs immediately, unless legislation prohibits such notification on important grounds of public interest (Article 28(3a)).;

d. to ensure that personnel authorised to process personal data are under confidentiality obligations (Article 28(3b));

e. to take all measures required by Article 32 GDPR in relation to the security of processing (Article 28(3c));

f. to respect the conditions described in Article 28(2) and (4) for engaging another processor (Article 28(3d));

g. to, taking into account the nature of the processing, assist the Sponsor, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising data subjects' rights (Article 28(3e));

h. to assist the controller, to ensure compliance with the obligations pursuant to Articles 32 to 36 GDPR taking into account the nature of the processing and the information available to the Participating NHS / HSC Organisation (Article 28(3f));

i. to, at the choice of the Sponsor, destroy or return all personal data to the Sponsor at the expiry or early termination of the Agreement, unless storage is legally required (Article 28(3g)) or where that personal data is held by the Participating NHS / HSC Organisation as controller for the purpose of clinical care or other legal purposes; and

j. to maintain a record of processing activities as required by Article 30(2) GDPR.

6. The Participating NHS / HSC Organisation shall ensure that:

a. its agents do not process personal data except in accordance with this Agreement (and in particular the protocol);

b. it takes all reasonable steps to ensure the reliability and integrity of any of its agents who have access to the personal data and ensure they:

i. are aware and comply with the Participating NHS / HSC Organisation 's duties under this clause;

ii. are subject to mandatory training in their information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data; and

iii. are informed of the confidential nature of the personal data and understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.

7. The Participating NHS / HSC Organisation agrees to:

   a. allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Participating NHS / HSC Organisation's compliance with the obligations described by this Appendix, data protection legislation in general and Article 28 GDPR in particular, on reasonable notice subject to the Sponsor complying with all relevant health and safety and security policies of the participating site and/or to provide the Sponsor with evidence of its compliance with the obligations set out in this Agreement; and

   b. obtain prior agreement of the Sponsor to store or process personal data outside the European Economic Area.

8. Where the Participating NHS / HSC Organisation stores or otherwise processes personal data outside of the European Economic Area as the Sponsor's processor, it warrants that it does so in compliance with the Data Protection Legislation.

Appendix 5: Data Sharing Agreement

Where this Organisation Information Document is to be used as the Agreement between Sponsor and Participating NHS/HSC organisation, please select an option below.	
* Does this study involve the transfer of personal data from this participating NHS / HSC organisation to the Sponsor or its agents, or transfer of confidential information between the Parties? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	Yes

1. Personal data shall not be disclosed to the Sponsor by the participating NHS / HSC organisation, save where this is required directly or indirectly to satisfy the requirements of the protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
2. The Sponsor agrees to use personal data solely in connection with the operation of the Agreement, or otherwise for purposes not incompatible with this original purpose (Article 5, 1 (b) GDPR), and not otherwise. In particular,
   2.1. Not to disclose personal data to any person except in accordance with applicable legal requirements and codes of practice.
3. The Sponsor agrees to comply with the obligations placed on a controller by the data protection legislation. This is not limited to, but includes, being responsible for and able to demonstrate compliance with the principles relating to processing of personal data (Article 5 GDPR)
4. The Sponsor agrees to ensure persons processing personal data under this Agreement are equipped to do so respectfully and safely. In particular:
   4.1. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the participating NHS / HSC organisation) processing personal data understand the responsibilities for information governance, including their obligation to process personal data securely and to only disseminate or disclose for lawful and appropriate purposes.
   4.2. To ensure any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating NHS / HSC Organisation) have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable data breaches.
5. The Sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses. In particular,
   5.1. To ensure that personal data are only accessible to persons who need it for the purposes of the study and to remove access as soon as reasonably possible once it is no longer needed.
   5.2. To ensure all access to personal data on IT systems processed for study purposes can be attributed to individuals.

5.3. To identify, review and improve processes which have caused breaches or near misses, or which force persons processing personal data to use workarounds which compromise data security.
5.4. To adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice.
5.5. To take action immediately following a data breach or near miss.

6. The Sponsor agrees to ensure personal data are processed using secure and up to date technology. In particular,
6.1. To ensure no unsupported operating systems, software or internet browsers are used to support the processing of personal data for the purposes of the study.
6.2. To put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework such as Cyber Essentials.
6.3. To ensure IT suppliers are held accountable via contracts for protecting personal data they Process and for meetings all relevant information governance requirements.

Appendix 6: Intellectual Property Rights

Where this Organisation Information Document is to be used as the Agreement between Participating NHS / HSC organisation, please select an option below.	
* Does this study require the protection of background intellectual property rights, or is there potential for the generation of new intellectual property? If no, this appendix does not form part of this Agreement. If yes, these provisions form part of the Agreement between the Sponsor and this participating NHS / HSC organisation.	No

1. All background intellectual property rights (including licences) and know how and their improvements used in connection with the Study shall remain the property of the Party introducing the same and the exercise of such rights for purposes of the Study shall not knowingly infringe any third party's rights.
2. All intellectual property rights and know how in the Protocol, and in the study data, excluding clinical procedures developed or used by the Participating NHS / HSC Organisation independently of the Study, shall belong to the Sponsor. The Participating NHS / HSC Organisation hereby assigns all such intellectual property rights, and undertakes to disclose all such know how, to the Sponsor.
3. Subject to clauses 1 and 2, all intellectual property rights deriving or arising from the Material or any derivations of the Material provided to the Sponsor by the Participating NHS / HSC Organisation shall belong to the Sponsor.
4. At any time within the duration of the Study, the Participating NHS / HSC Organisation shall at the request and expense of the Sponsor execute all such documents and do all acts necessary to fully vest the intellectual property rights in the Sponsor. To give effect to this clause 4, the Participating NHS / HSC Organisation shall ensure that its agents involved in the Study assign such intellectual property rights falling within clauses 2 and 3 and disclose such know how to the Participating NHS / HSC Organisation.
5. Subject to this Clause 5 and Clause 6, nothing in this Appendix shall be construed so as to prevent or hinder the Participating NHS / HSC Organisation from using its own know how or clinical data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of providing clinical care to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor, or their funder. This clause 5 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results. Any study data not so published remains the confidential information of the Sponsor, or their funder.
6. The Participating NHS / HSC Organisation may, with the prior written permission of the Sponsor (such permission not to be unreasonably withheld), use study data gained during the performance of the Study, at its own risk, in the furtherance of its normal activities of commissioning clinical services, teaching and research to the extent that such use does not result in the disclosure or misuse of confidential information or the infringement of an intellectual property right of the Sponsor or their funder. This clause

6 does not permit the disclosure of any of the study data, all of which remain confidential until publication of the results of the Study.

Authorisation When Using This Organisation Information Document as An Agreement

(when used as an Agreement, the Participating NHS Organisation is a "Party" to the Agreement and the Sponsor is a "Party" to the Agreement – collectively the "Parties").

Authorisation on behalf of Participating NHS / HSC Organisation It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the Sponsor and participating NHS / HSC organisation. Instead, Sponsors are expected to accept confirmation by email from an individual empowered by the Participating NHS / HSC Organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).	
^ Authorised on behalf of Participating NHS / HSC Organisation by:	
Name	Enter name
Job Title	Enter job title
Organisation Name	Lewisham and Greenwich NHS Trust
Date	Select date of authorisation

DATA PROCESSING AGREEMENT

BETWEEN

Lewisham and Greenwich NHS Trust

(Where Living With Ltd are the clinical system supplier holding/processing the data on behalf of the data controller)

AND

Mrs Maria Moffatt, Research Associate at Manchester Metropolitan University

1. Introduction

1.1 This agreement (the "**Agreement**") is intended to be an accountable operating framework to enable lawful disclosure of Data Controller's information to the Data Processor in order to fulfil the purposes and to ensure that there are appropriate provisions and arrangements in place to properly safeguard the information entrusted to the Data Processor, including any Sensitive Personal Data.

1.2 This Agreement governs the treatment of Personal Data shared by the Data Controller to the Data Processor by virtue of the Service Level Agreement and any other subsequent agreements for the provisions of services by the Data Processor to the Data Controller ("**Services Agreements**").

2. Definitions

2.1 Certain words and expressions used in and principles of interpretation applicable to this Agreement are defined or set out in Schedule 1 (Interpretation).

2.2 The Schedules form part of this Agreement and any reference to this Agreement includes the Schedules.

2.3 If there is a conflict or inconsistency between any provision contained in the body of this Agreement and any provision contained in a Schedule, except where provided to the contrary in the former, the former prevails to the extent of the conflict or inconsistency.

3. Data Processor Obligations

3.1 All Data, remains the property of the Data Controller and shall be either returned or destroyed by the Data Processor after a period ten years after completion of the relevant Service Agreements, in a manner previously agreed with the Data Controller and to a standard recommended in the most current NHS Guidelines and Standards.

3.2 The Data Processor shall only process Data as is necessary to perform its obligations under this Agreement and the Services Agreements, and only in accordance with any instruction given by the Data Controller under this Agreement and, in particular shall not use or process Data for any purpose other than as directed by the Data Controller for the delivery of the contracted services under the Services Agreements.

3.3 The Data Processor shall not subcontract any of its processing operations performed on behalf of the Data Controller under this Agreement without the prior written consent of the Data Controller. Where the Data Processor subcontracts its obligations, with the consent of the Data Controller, it shall do so only by way of a written agreement with the sub-processor which imposes the same obligations on the sub-processor as are imposed on the Data Processor under this Agreement. Where the sub-processor fails to fulfil its obligations under such written agreement the Data Processor shall remain fully liable to the Data Controller for the performance of the sub-processor's obligations under such agreement.

3.4 The Data Processor shall continue to maintain the expertise, experience and technological resource to deliver its obligations under this Agreement.

4. Data Controller's Obligations

4.1 The Data Controller shall provide the Data Processor with the minimum amount of Data necessary to deliver the Services, and / or Process the Data Controller's Data for the Purposes, under this Agreement. In particular, Personal Data and Sensitive Data will be supplied in an anonymised format where possible.

4.2 The Data Controller shall ensure that prior to supplying any Data to the Data Processor it has satisfied all Information Governance obligations as regards the disclosure of Data to the Service Provider for processing under the terms of this Agreement.

4.3 Where the Data Controller requires the Data Processor to make available other data sets that may have lawfully been transferred to the Data Processor under section 251 of the NHS Act 2006 or under section 261 of the 2012 Health and Social Care Act, the Data Controller shall evidence to the Data Processor that it has already received this data or that it has secured a legal basis to receive this data.

4.4 The Data Controller shall make due notification to the Information Commissioner's Office including its use and Processing of Data Controller information and comply at all times with the Data Protection Legislation.

4.5 Where the Data Controller Data are held and / or processed by a clinical system supplier on behalf of the Data Controller, the Data Controller shall be responsible for instructing and authorising the clinical system supplier to transfer the Data Controller's Data to the Data Processor and ensure that these are transferred safely and securely.

5. Limitations on Data Processing

5.1 The Data to be processed under cover of this Agreement is detailed in Schedule 2 and where relevant is indicated as Personal Data or Sensitive Data as defined in Schedule 1.

5.2 The Data Processor shall not disclose Data to any third party without the prior written agreement of the Data Controller.

6. Data Protection

4.6 The Data Processor shall comply with the Data Protection Legislation, Human Rights Act 1998 and common law duty of confidentiality in relation to the processing of Personal Data and Sensitive Data under this Agreement.

6.2 The Data Processor shall only process Data in accordance with the instruction of the Data Controller in writing, as specified under this Agreement.

6.3 The Data Processor shall put in place appropriate technical and organisational measures to ensure the protection of the Data Subject to this Agreement against the accidental loss or destruction of or damage to Data, having regard to the specific requirements set out in this Agreement, the state of technical development and the level of harm that may be suffered the Data Controller and/or by a Data Subject whose data is affected, by such unauthorised or unlawful processing or by its loss, damage or destruction.

6.4 The Data Processor shall hold the Data Controller's Data in such a manner that is capable of being distinguished from other data or information processed by the Data Processor and ensures that the Data Controller's Data is not linked to any other data that is not related to the purposes without the prior authorization of the Data Controller.

6.5 The Data Controller permits the transfer to the Data processors' offices in the UK via secure email of aggregated data consisting of counts and aggregate costs only in line with the data specification in schedule 4.

6.6 The Data Processor shall put in place measures to ensure that privacy is designed into the processes and controls of new and changing information systems and processes and conduct appropriate privacy impact assessments where relevant.

7. Policies and Procedures

7.1 The Data Processor shall have confidentiality, information security, data protection and records management policies. These will describe individual responsibilities for handling Data and will be rigorously applied. Compliance with these policies will be independently audited annually and any recommendations arising adopted within a reasonable amount of time.

8. Data Processor Employees

8.1 The Data Processor shall undertake all reasonable background checks to ensure the reliability of all employees who are likely to use or have access to Data Controller's Data prior to allowing access to the Data.

8.2 The Data Processor shall include appropriate confidentiality clauses in employment contracts, including details of sanctions against any employee acting in a deliberate or reckless manner that may breach the confidentiality or the non-disclosure provisions of the Data Protection Legislation or causes damage to or loss of Data.

8.3 The Data Processor shall ensure that all employees are aware of and act in accordance with the policies referred to in 8.2 above.

8.4 The Data Processor shall ensure that all employees are adequately trained to comply with their responsibilities under Data Protection Legislation, the common law duty of confidence, this Agreement and evolving NHS codes of practice and standards that relate to Information Governance.

8.5 The Data Processor shall ensure that only those employees involved in delivery of the contracted service under the Services Agreements use or have access to the Data Controller's Data on a strict 'need to know' basis and shall implement appropriate access controls to ensure this requirement is satisfied and audited.

8.6 The Data Processor shall ensure that any employees involved in delivery of the contracted service who do not specifically need to use the Data as part of their role have restricted access to this Data.

8.7 The Data Controller shall maintain a list of all Data Processor Employees who require access to the Data Controller's Data or systems owned by the Data Controller or supplied by a third

party to the Data Controller. The Data Processor shall, as soon as practically possible and in any event not later than two (2) working days, inform the Data Controller or the third party system supplier when access rights are no longer required, for a specific Data Processor employee.

9. Data Security – Procedural

9.1 The Data Processor shall implement an information security approach that follows an asset-ownership concept for security, certifying owners, and for periodically reviewing authorised access for users. The Data Processor shall manage and administer access to the Data Processor systems, network, applications, databases and system files and data related to the services supplied under the Services Agreements.

9.2 The Data Processor shall install, update and maintain security software; research system security problems and perform security audits.

9.3 The Data Processor shall not disclose or otherwise reveal Data (in whole or in part) to any individual, business or other organisation (3rd party) not directly involved in delivery of the contracted service without the explicit written consent of the Data Controller or as required by law.

9.4 The Data Processor shall notify the Data Controller immediately (in any event within 24 hours) of any untoward incidents or activities that suggest non-compliance with any of the terms of this Agreement. This includes 'near miss' events even if no actual damage to or loss -or inappropriate disclosure of Data results.

10. Data Security – Physical

10.1 The Data Processor shall ensure that all Data is physically protected from accidental or deliberate loss or destruction arising from environmental hazards such as fire or flood.

10.2 The Data Processor shall ensure that all Data is held on premises are adequately protected from unauthorised entry and/or theft of Data or any IT equipment on which it is held by, for example, the use of burglar alarms, security doors, ram-proof pillars, controlled access systems, etc.

10.3 The Data Processor shall only make printed paper copies of Data with prior approval and only if this is essential for delivery of the contracted service under the Services Agreements.

10.4 The Data Processor shall store printed paper copies of Data in locked cabinets when not in use and shall not remove from premises unless this is essential for delivery of the contracted service under the Services Agreements, in which case paper must be transported in locked and tamper-evident containers.

11. Data Security – IT Systems

11.1 The Data Processor shall hold electronically-based Data on secure servers and ensure that measures are implemented to ensure the confidentiality, integrity and availability of the Data Controller's Data.

11.1.1 Data will, under no circumstances, be stored on portable media or devices such as USB memory sticks or CD-ROM unless agreed in writing and subject, at a minimum, to those constraints.

11.2 The Data Processor shall ensure that:

11.2.1 All portable media used for storage or transit of Data are fully encrypted to the minimum standard of accordance with NHS Guidelines on encryption to protect Trust data (January 2008).

11.2.2 Portable media are not left unattended at any time (e.g. in parked cars, in unlocked and unoccupied rooms, etc.).

11.2.3 When not in use, all portable media are stored in a locked area and issued only when required to authorised employees, with a record kept of issue and return.

11.3 The Data Processor shall not allow employees to hold Data on their own personal computers.

11.4 The Data Processor shall ensure adequate back-up facilities to minimise the risk of loss of or damage to Data and that a robust and tested business continuity plan is in place in the event of restriction of service for any reason.

11.5 The Data Processor shall transmit the Data as a password protected attachment to a secure email between the Data Controller and the Data Processor (sending the password separately to the attachment).

12. Secure Destruction

12.1 The Data Processor shall ensure that Data held in paper form regardless of whether as originally provided by the Data Controller or printed by the Data Processor is destroyed using a cross cut shredder or subcontracted to a confidential waste company that complies with European Standard EN15713.

12.2 The Data Processor shall ensure that electronic storage media used to hold or process Data is destroyed or overwritten to current CESG standards.

12.3 In the event of any bad or unusable sectors that cannot be overwritten, the Data Processor shall ensure complete and irretrievable destruction of the media itself in accordance with CESG standards.

12.4 The Data Processor shall provide, upon request, the Data Controller with copies of all relevant overwriting verification reports and/or Certificates of Destruction of Data at the conclusion of the contract.

13. Data Subject Access Rights

13.1 The Data Processor acknowledges that individuals have a right to see what Personal Data is held about them, and to know why and how it is processed.

13.2 The Data Controller has an obligation to respond to these requests.

13.3 The Data Processor agrees to notify the Data Controller in the event that it receives a subject access request or notice from a Data Subject exercising his rights under the Data Protection Legislation in relation to the Data Controller's Data or any correspondence from the Information Commissioner in relation to the processing of the Data Controller's Data and provide the Data Controller with all reasonable assistance and co-operation to enable the Data Controller to respond to such request.

14. Monitoring and Audit

14.1 The Data Processor shall permit the Data Controller to monitor compliance with the terms of this Agreement, by:

14.2 Allowing employees of the Data Controller or nominated representatives to enter any premises where Data is held, at all reasonable times and with or without prior notice, for the purpose of inspection.

14.3 Obtaining a copy of the annual independent audit of the Data Processor's Information Governance Toolkit return.

14.4 Reviewing audits trails of administrative actions taken by the Data Processor with regards to confidentiality and security – related aspects of the services such as confidentiality audits carried out by the Data Processor.

15. Freedom of Information

15.1 The parties shall cooperate with each other in respect of any Freedom of Information Act 2000 (FOIA) and the Environmental Information Regulations 2004 (EIR) requests.

16. Intellectual Property Rights

16.1 The Data Processor acknowledges and agrees that the Data Controller owns all intellectual rights in and to the Data Controller's Data and that the Data Controller's Data remains the property of the Data Controller and that the Data Processor acquires no rights or interests in or to the Data Controller's Data.

16.2 The Data Processor undertakes that it shall not sell, offer for sale or dispose or attempt to dispose of, or create or allow the creation of, any change or encumbrance over the Data Controller's Data.

17. Extent of Liability

17.1 Neither Party shall be liable to the other Party for any loss or damage, costs or expenses incurred or suffered by the other Party as a result of any breach of the terms of the Contract, unless the same were in the reasonable contemplation of the Parties at the time when they entered into the Contract.

17.2 Except in the case of death or personal injury caused by negligence, and fraudulent misrepresentation or in other circumstances where liability may not be so limited under any applicable law, the liability of either Party under or in connection with the Contract, whether arising in contract, tort, negligence, breach of statutory duty or otherwise shall not exceed the sum of £500,000, save that the Data Processor shall indemnify the Data Controller in

respect of any regulatory fines (including in excess of the £500,000 cap above) imposed by a relevant authority under the Data Protection Legislation where such fines are as a result of or in connection with the Data Processor's breach of this Agreement.

18. Indemnity

Subject to clause 17, the Data Processor shall indemnify the Data Controllers in full for any costs, losses, charges, expenses it suffers arising out of the Data Processor's loss of the Data or unauthorised or unlawful use of it whether arising in negligence or otherwise and including any fine imposed on the Data Controller by the UK Information Commissioner under the Data Protection Legislation, or otherwise by way of a civil monetary penalty under Article 83 of the General Data Protection Regulations.

19. Change Management and Governance

19.1 Any minor changes to this Agreement that may be deemed necessary from time to time by the Data Controller, or requested by the Data Processor and approved by the Data Controller, shall only be valid once issued in writing and signed by both parties.

19.2 In proposing or assessing any relocation, upgrade or change, the Data Processor will evaluate the impact on data privacy and security and advise the Data Controller of any new or increased threats or vulnerabilities that could result from such relocation, upgrade or change and the Data Processor will propose policies to protect the Data Controller from such threats or vulnerabilities.

20. Termination

20.1 The Data Controller may terminate this Agreement by giving to the Data Processor not less than one months' written notice expiring at the end of the relevant period of three months.

20.2 The Data Controller may terminate this Agreement with immediate effect by written notice to the Data Processor on or at any time after the occurrence of an event specified in clause 20.3.

20.3 The events are:-

20.3.1 the Data Processor is in material breach of this Agreement or the Services Agreement and that breach cannot be remedied;

20.3.2 the Data Processor is in material breach of this Agreement or the Services Agreement which can be remedied but the Data Processor fails to do so within 30 days starting on the day after receipt of the written notice from the Data Controller referred to in clause 20.1;

20.3.3 the Data Processor stops payment of its debts or is unable to pay its debts as they fall due;

20.3.4 the Data Processor is dissolved;

20.3.5 the Data Processor becomes or is declared insolvent or a resolution is passed for the winding up of the Data Processor or the Data Processor convenes a meeting of its creditors or makes or proposes to make any arrangement or composition with its creditors or a liquidator, an

administrative receiver, a receiver, manager, trustee or administrator or analogous officer is appointed in respect of all or any part of its property, undertaking or assets or the Data Processor becomes subject to any bankruptcy procedure or analogous insolvency procedure in any jurisdiction or any person files a notice of intention to appoint an administrator or a notice of appointment of an administrator or applies to court for an administration order in respect of the Data Processor;

20.3.6 it becomes unlawful for the Data Processor to perform all or any of its obligations under this Agreement; or

20.3.7 the Data Processor (being a natural person) shall die or become mentally incapacitated.

21. Assignment

21.1 The Data Processor shall not, without the prior written consent of the Data Controller, assign, novate, transfer, charge, dispose of or deal in any other manner with this Agreement or any of its rights or beneficial interests under it, or purport to do any of the same, nor sub-contract any or all of its obligations under this Agreement. The Data Controller may assign, transfer, charge, dispose of or deal in any manner with its rights and obligations under this Agreement. Where it does so, it shall notify the Data Processor of such change.

22. Notices

22.1 Any communication given under this Agreement shall be in writing and delivered personally, by e-mail or by pre-paid recorded, special delivery or first class post (or air mail post if to an address outside the United Kingdom) to the address of the party who is to receive such communication as set out on page 1 or to such other address in the United Kingdom as may from time to time be specified in writing by the relevant party as its address for the purpose of this clause 22.

22.2 Any notice shall be deemed to have been received:

22.2.1 if delivered by hand, on signature of a delivery receipt or at the time the notice is left at the proper address;

22.2.2 if sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second working day after posting or at the time recorded by the delivery service; and

22.2.3 if delivered by email, at the time of transmission when sent between 9am and 5pm on a working day, or otherwise at 9am on the next working day, provided the sender does not receive a delivery failure message.

22.3 Each party undertakes to notify the other party in accordance with this clause 22 if the address specified in this clause 22 is no longer an appropriate address for the service of communications.

23. Miscellaneous

23.1 Nothing in this Agreement or any arrangement contemplated by it shall constitute either party a partner, agent, fiduciary or employee of the other party.

23.2 No amendment or variation of the terms of this Agreement shall be effective unless made or confirmed in writing and signed by the parties to this Agreement.

23.3 If any provision of this Agreement shall be found by any court or body or authority of competent jurisdiction to be invalid or unenforceable, such provision shall be severed from the remainder of this Agreement which shall remain in full force and effect to the extent permitted by law.

23.4 The rights and remedies provided by this Agreement are cumulative and (unless otherwise provided in this Agreement) are not exclusive of any rights or remedies provided by law.

23.5 This Agreement does not create, confer or purport to create or confer any benefit or right enforceable by any person not a party to it (except that a person who is a permitted successor to or assignee of the rights of a party to this Agreement shall be deemed to be a party to this Agreement).

24. Legal Jurisdiction

24.1 This Agreement is governed by and shall be interpreted in accordance with the law of England and Wales.

24.2 In the event of a dispute, the parties to this Agreement agree to attempt to resolve such issues according to NHS dispute resolution procedures. In the event that agreement cannot be reached, the parties agree that the courts of England and Wales shall have exclusive jurisdiction to hear the case.

25. Entire Agreement

25.1 This Agreement constitutes the entire agreement and understanding of the parties and, except for the Services Level Agreement, supersedes any previous agreement between the parties relating to the subject matter of this Agreement but without prejudice to the rights and liabilities of the parties accrued before the date of this Agreement.

25.2 Nothing in this clause 25 shall operate to limit or exclude any liability for fraud.

Signed on behalf of the Data Controller

Signed		**Date**	
Name & Position			

(Print name & position of authorised signatory)

Signed on behalf of the Data Processor:

Signed		**Date**	
Name & Position	 Mrs Maria Moffatt Research Associate and PhD student Manchester Metropolitan University (Lead researcher)	09/04/2021	

(Print name & position of authorised signatory)

SCHEDULE 1

Interpretation

1. In this Agreement the following expressions have the following meanings:-

Term	Definition
"Agreed Purpose"	**the purpose(s) which the Data Processor may use the Data for;**
"De-personalised data"	information that relates to individuals where it is not possible to identify individuals from that information, whether in isolation or in conjunction with any other information;
"Certificate of Destruction"	a certificate which certifies that the Data and all hard and soft copies thereof have been securely destroyed by the Data Processor;
"Data"	all data shared by the Data Controller under the terms of this Agreement or the Services Agreements including as applicable, anonymised data, Record Level Pseudonymised data, High Risk Data, Sensitive Data and Personal Data;
"Data Controller"	as defined in the Data Protection Legislation, and for the purposes of this Agreement shall be the party named as the Data Controller at the beginning of this Agreement;
"Data Processor"	as defined in the Data Protection Legislation, and for the purposes of this Agreement shall be the party named as the Data Processor at the beginning of this Agreement;
"Data Protection Legislation"	(i) the Data Protection Act 2018; (ii) (unless and until no longer directly applicable in the UK) the General Data Protection Regulation ((EU) 2016/679) ("**GDPR**") and any national implementing laws, regulations and secondary legislation, as amended or updated from time to time, in the UK; (iii) any successor legislation to the GDPR or the Data Protection Act 2018 applicable in the territory; and (iv) all other data protection legislation, guidance and codes of practice issued by the Information Commissioner or by the Department of Health;
"Data Subject"	as defined in the Data Protection Legislation;
"Freedom of Information Act "	means the Freedom of Information Act 2000;
"High Risk Data"	record level Data which is Non-Personal Data and which contains sensitive items and is designated as High Risk

	Data in writing by the Data Controller and notified to the Data Processor;
"High Risk Data Terms and Conditions"	the terms and conditions of use for High Risk Data as set out in Schedule 3;
"Information Governance"	means the framework bringing together all the legal rules, guidance and best practice that apply to the handling of NHS information;
"Indirect Loss"	any indirect loss, damage, costs or expenses arising out of or in connection with this Agreement or its contemplated or lack of performance;
"Non-Personal Data"	information that does not relate to people including information about organisations, companies, resources, projects or information about people that has been aggregated to a level that is not about individuals but that could become Personal Data when merged with other data sets held by the Data Recipient;
"Personal Data"	as defined in Data Protection Legislation including Sensitive Data;
"Publish"	to make available to third parties in any form, including the production of hard copy materials, soft and/or electronic copies, e-mails and posting online;
"Purpose"	as defined in Schedule 2;
"Record Level Pseudonymised"	the processing of Personal Data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information;
"Section 251 Approval"	an approval under section 251 of the NHS Act 2006 which re-enacted Section 60 of the Health & Social Care Act 2001 whereby an organisation can process confidential medical information without the consent of the patient subject to the terms of the particular section 251 approval which is granted by the relevant authority;
"Section 251 Data"	record level identifiable Data which includes Personal Data and/or Sensitive Data which requires either patient consent or Section 251 Approval in order for the Data Processor to process it;
"Section 251 Terms and Conditions"	the terms and conditions of use for the Section 251 Data as set out in the relevant approval;
"Sensitive Data"	means sensitive personal Data or special categorises of personal data as defined in the Data Protection

	Legislation and other sensitive Data as designated by the Data Controller;

1.1 In this Agreement:-

1.1.1 any gender includes any other gender and the singular includes the plural and vice versa;

1.1.2 references to persons include bodies corporate, unincorporated associations, governments, states, partnerships and trusts (in each case, whether or not having separate legal personality);

1.1.3 the Schedules form part of this Agreement and the expression "this Agreement" includes the Schedules; and

1.1.4 any reference to a statutory provision includes a reference to any modification, consolidation or re-enactment of the provision from time to time in force and all subordinate instruments, orders or regulations made under it.

SCHEDULE 2

Purpose and Data Specification

Specification	Example
Data Subjects The data subjects are patients of Lewisham and Greenwich NHS Trust who have attended the Pelvic Health Physiotherapy Service	
Categories of Data The data to be provided to the data processor by the clinical systems supplier on behalf of the data controller includes pseudonymised data relating to the usage of the Living With Pregnancy Pain app. No personally identifiable data is to be provided to the data processor.	
Special Categories of Data The data to be processed includes app usage data and patient reported outcome measure data only. As information relating to the data subjects' health status is implicit due to their inclusion in the dataset, this dataset could be said to include special category data relating to health. This data is being accessed for the purposes of scientific research and the has been approved by the Health Research Authority. This research is in the public interest and meets the requirements of schedule 1 of the data protection act 2018.	
Processing operations The Pseudonymised Dataset will be subject to the following basic processing activities: Descriptive statistical analysis of app usage data and patient reported outcome measure data as outlined in the research protocol attached (Protocol version 4, dated 15-3-2021)	
Purposes of processing The Pseudonymised Dataset will be processed for the following purposes: **Scientific research approved by the UK Health Research Authority (REC reference 21/PR/0084).**	

SCHEDULE 3

High Risk Data and Record Level Pseudonymised Data Terms and Conditions

The Data Processor agrees to the following terms and conditions:

- To store and process the Data securely, and destroy it when it is no longer necessary;
- Use of the Data provided under this Agreement is for the sole purpose outlined within this Agreement and only where the Data Controller of the Data has authorised such use.
- The Data must not be shared with any other organisation or named individual not explicitly referred to within this Agreement.
- Users of the Data supplied are obliged to fully comply with The Data Protection Legislation.
- Together with all other related and relevant legislation and Department of Health directives covering issues of Data sharing.
- If the information received from the Data Controller is subject to a request under the Freedom of Information Act, then the Data Controller must be consulted before a response is provided.
- The Data must not be shared with any third party in the format in which it is provided by the Data Controller.
- Any publications derived from this Data by any party must be subject to the following guidance:
  ONS Guidance for Health Statistics: http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-of-health-statistics/index.html

  ONS policy on protecting confidentiality within birth and death statistics and the Code of Practice for Official Statistics: http://www.ons.gov.uk/ons/guide-method/best-practice/disclosure-control-policy-for-birth-and-death-statistics/index.html

  Anonymisation Standard for Publishing Health and Social Care Data:
  http://www.isb.nhs.uk/library/standard/128

  Hospital Episode Statistics (HES) Analysis Guide, January 2014:
  http://www.hscic.gov.uk/media/1592/HES-analysis-guide/pdf/hes-analy-guide-apr13.pdf

- Before undertaking any publication activity using this Data or any derived information, the Data Processor will undertake an organisational Risk Assessment Exercise to ensure compliance with the above guidelines.
- For results based on small numbers (1-5 individuals) appearing in an individual cell, this cell and the corresponding “total” cells will be suppressed before that information is published.
- If an individual is recognised during an analysis the confidentiality of that individual will be fully respected.
- No contact will be made with any individual(s) that could be identified from the information supplied, except where such contact is made by clinicians involved in the legitimate provision of direct health and/or social care to the individual and as agreed between the Data Controller and the Data Processor.
- Under the terms of this Agreement, access to the Data must be managed, auditable and restricted to those individuals who need to access the Data for the specific purpose/s outlined within this agreement.

11/02/2019

Project Title: Pregnancy-related Lumbopelvic pain: Exploring the use of social media for preventative healthcare advice

EthOS Reference Number: 0464

Ethical Opinion

Dear Maria Moffatt,

The above application was reviewed by the Research Ethics and Governance Team and on the 11/02/2019, was certified. The certification is in place until the end of your project and is based on the documentation submitted with your application.

Application Documents

Document Type	File Name	Date	Version
Additional Documentation	Letter from sponsor	09/12/2015	1
Ethical Approval Supporting Information	Amended study participant Information sheet group 1 no previous LPP Version 2	01/09/2016	2
Additional Documentation	annual-progress-report-form-research 16-3-18	16/03/2018	1
Additional Documentation	Study Participant Information sheet group 4 midwives	03/07/2018	3
Additional Documentation	Study Participant Information sheet group 3 physiotherapists	03/07/2018	3
Additional Documentation	Amended study participant Information sheet group 2 previous LPP Version 3	03/07/2018	3
Additional Documentation	Amended Consent form for participants version 5 without logo	03/07/2018	5
Additional Documentation	Amended Study protocol to attach to ethics amendment application version 4	03/07/2018	4
Ethical Approval Supporting Information	Study Participant Information sheet group 4 midwives	03/07/2018	3
Ethical Approval Supporting Information	Study Participant Information sheet group 3 physiotherapists	03/07/2018	3
Ethical Approval Supporting Information	Amended study participant Information sheet group 2 previous LPP Version 3	03/07/2018	3
Ethical Approval Supporting Information	Amended Consent form for participants version 5 without logo	03/07/2018	5
Ethical Approval Supporting Information	Amended Study protocol to attach to ethics amendment application version 4	03/07/2018	4
Ethical Approval Application Form	AmendmentForm_ReadyForSubmission	10/07/2018	1
Additional Documentation	AmendmentForm_ReadyForSubmission	01/08/2018	1
Additional Documentation	IRAS ID 183127 REC REF 15-NI-0270 Favourable Opinion Substantial Amendment - 30.11.2018_DN	30/11/2018	1
Ethical Approval Letter	IRAS ID 183127 REC REF 15-NI-0270 Favourable Opinion Substantial Amendment - 30.11.2018_DN (1)	30/11/2018	1
Additional Documentation	IRAS ID 183127 REC REF 15-NI-0270 Favourable Opinion Substantial Amendment - 30.11.2018_DN (1)	04/02/2019	1

Conditions of certification

The Research Ethics and Governance Team would like to highlight the following conditions

Adherence to Manchester Metropolitan University's Policies and procedures

This ethical approval is conditional on adherence to Manchester Metropolitan University's Policies, Procedures, guidance and Standard Operating procedures. These can be found on the Manchester Metropolitan University Research Ethics and Governance webpages.

Amendments

If you wish to make a change to this approved application, you will be required to submit an amendment in accordance with Health Research Authority guidelines. Please contact the Research Ethics and Governance team for advice around how to do this.

We wish you every success with your project.

Research Ethics and Governance Team

Manchester Metropolitan
University

Research and Knowledge Exchange
Ormond Building
Lower Ormond Street
Manchester M15 6BX
Email: ethics@mmu.ac.uk

11 July 2018

To whom it may concern

Role of the Research Sponsor under the Research Governance Framework for Health & Social Care

I hereby confirm that Manchester Metropolitan University would be prepared to accept the role of research sponsor as currently defined in the *Research Governance Framework for Health & Social Care Version 2 (DoH 2005),* in relation to the study:

Exploring participants' views on the use of a mobile technology-based intervention for the prevention and management of lumbopelvic pain in pregnancy

I have been informed that this study will be conducted by Maria Moffatt of Manchester Metropolitan University.

Sponsorship is conditional upon review and approval of the research by appropriate ethics, NHS and regulatory bodies.

To enable the sponsor to meet their responsibilities as listed in section 3.8 of the Research Governance Framework, Chief Investigators are asked to adhere to the responsibilities as outlined in section 3.6 of the Framework www.dh.gov.uk/research. In line with this requirement Maria Moffatt must ensure that all involved in the research project understand and discharge their responsibilities in accordance with the agreed protocol and any relevant management, ethical and regulatory approvals.

Chief Investigators are also reminded that they must register NHS Research Ethics Committee or Health Research Authority approval with the Manchester Metropolitan University Research and Knowledge Exchange Office.

If you have any queries about sponsorship of this project then please address them to Alison Lloyd, Research Ethics and Governance Manager, ethics@mmu.ac.uk, 0161 247 2836.

Yours faithfully,

Justine Daniels

Dr Justine Daniels
Director of Research and Knowledge Exchange

Pregnancy-related lumbopelvic pain: exploring the use of digital media for condition-related information provision

Maria Moffatt[1], Prof Claire Hamshire and Prof James Selfe

[1]*Corresponding author*

Date submitted: 2 December 2020. **Date accepted:** 12 May 2021. **First published:** 24 May 2021

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, pagination, typesetting, reference checking and proofreading process that may lead to differences between this version and the Version of Record.

Please cite this article as **Moffat M (2021) Pregnancy-related lumbopelvic pain: exploring the use of digital media for condition-related information provision. *Evidence Based Midwifery*. Post-print online May 2021**

Corresponding Author Details
Maria Moffatt
Manchester Metropolitan University
Faculty of Health, Psychology and Social Care
Brooks Building
53 Bonsall Street
M15 6GX
M.Moffatt@mmu.ac.uk

Abstract

***Background*:** Online health information-seeking is thought to be common among pregnant women, and the use of digital media has been widely adopted.

Women with pregnancy-related lumbopelvic pain (PLPP) are often disappointed with the volume and content of condition-related information offered by their healthcare providers and alternative modes of information provision therefore need to be explored. The widespread adoption of digital media suggests that such platforms may provide a convenient alternative for information delivery.

***Aims of this study*:** To explore the PLPP-related information-seeking practices of women experiencing this condition and the attitudes of National Health Service (NHS) service users and healthcare professionals towards the use of digital media for PLPP-related information provision.

Ethical approval: Ethical and HRA approvals were gained for this study (REC reference 15/NI/0270).

***Methods*:** Multi-method qualitative study: individual semi-structured interviews with seven NHS service users and two single-profession focus groups, one with six NHS-based midwives and one with four NHS-based physiotherapists. A framework method of thematic analysis was used. No member checking was undertaken.

***Results*:** All service users were aged 21-36 years, with gestational age <32 weeks.

All midwives were >10 years post-qualification and had experience of an antenatal clinic setting.

Two physiotherapists were 5-10 years post qualification, two were >10 years post-qualification. All had relevant experience of treating women with PPLP.

Searching online for condition-related information was reported by all service users and complex drivers for this behaviour were described. All stakeholder groups shared concerns about the quality and trustworthiness of PLPP-related information available online. The use of apps for condition-related information provision was viewed positively by all groups, but the majority of service users stated a lack of trust in health information obtained via social media.

***Conclusion*:** The development of an app-based intervention to facilitate the management of PLPP is supported by this study and is therefore worthy of further exploration.

***Keywords*:** pregnancy, low back pain, pelvic girdle pain, lumbopelvic pain, qualitative, digital media, mobile phone applications, apps, social media, online information-seeking, Evidence Based Midwifery

Background

Pregnant women are acknowledged as mass consumers of online health-related information (Gleeson et al 2019, Mackintosh et al 2020) and are thought to use the internet for multiple purposes, including searching for information relating to pregnancy symptoms (Kraschnewski et al 2014), and to aid decision-making relating to pregnancy, childbirth and future parenting (Prescott & Mackie 2017, Wright et al 2019). Around 95% of digitally active women are thought to search the internet for health-related information during the perinatal period (Makintosh et al 2020) and evidence suggests that parity (Camacho-Morell & Esparcia 2020), educational

attainment (Sayakhot & Carolan-Olah 2016), and level of health literacy (Shieh et al 2009) may all influence such behaviours.

The volume of literature relating to the use of pregnancy-related websites, social media platforms (SoMe) and smartphone apps (herein collectively referred to as digital media) is growing rapidly; in keeping with the widespread uptake of these media amongst the pregnant population (Sayakhot & Carolan-Olah 2016). Pregnant women are known to use digital media in a healthcare context for multiple purposes including self-screening (Peyton et al 2014) and preparing for healthcare appointments (Maslen & Lupton 2018). Both healthcare providers and commercial companies have therefore capitalised on this knowledge, developing multiple interventions for pregnancy-related conditions (such as gestational diabetes) using various forms of digital media as platforms for delivery (Chan & Chen 2019).

One of the most common causes of work absence amongst pregnant women in European countries is pregnancy-related lumbopelvic pain (PLPP, Backhausen et al 2018). PLPP is an overarching term that encompasses both pregnancy-related lower back pain (PLBP) and pregnancy-related pelvic girdle pain (PPGP, Vleeming et al 2008). Up to 80% of pregnant women are thought to experience PPLP at some point during their pregnancy (Kovacs et al 2012) and around 25% of these women will experience severe pain (Wu et al 2004). It is common practice in the United Kingdom (UK) for those experiencing PLPP to be referred for treatment by a physiotherapist (Bishop et al 2016). Waiting lists for physiotherapy services often vary due to local availability, meaning that women may be required to self-manage their symptoms whilst awaiting input from a physiotherapist. Online PLPP-related information resources may therefore play an important role during this period.

Currently, there is no gold standard treatment for PLPP, with exercise, manual therapy, pelvic support belts, and advice all listed as viable treatment options in recent published guidance (Clinton et al 2017). Explicit recommendations have however been made in the literature that condition-related information provision should form part of routine practice (Elden et al 2014, Close et al 2016). Despite this, patients are often disappointed by the volume and quality of information provided by their HCPs (Mackenzie et al 2018, Close et al 2016) and therefore seek advice from non-medical sources such as peers, family members or the internet (Wuytack et al

2015). As the quality and trustworthiness of online health-related information has been shown to be variable (Daraz et al 2019), a clear potential for confusion and misinformation exists (Hämeen-Anttila et al 2014. Carpenter et al 2016). The availability of high-quality information relating to PLPP would therefore be of benefit, and digital media could provide a convenient platform for delivery.

To understand the potential utility of digital media in the management of PLPP, it is essential to explore how women experiencing the condition choose to seek health-related information, and to explore their preferred modes of condition-related information provision. The successful implementation of a digital media-based intervention to support the management of PLPP would also require full endorsement by the HCPs caring for these patients. It is therefore important to investigate the perspective of such clinicians; to understand their perceptions of the information-seeking practices of their patients, and their attitudes towards the use of digital media for condition-related information provision.

The objectives of the current study were therefore as follows:

To explore the PLPP-related information-seeking practices of women currently experiencing this condition

To explore the attitudes of both NHS service users and NHS-based antenatal HCPs regarding the use of digital media for the provision of PLPP-related information

To explore the acceptability and perceived utility of the notion of a digital media-based intervention to support the self-management of PLPP

Methods

This study was a multi-method qualitative study that utilised individual semi-structured interviews with NHS antenatal service users experiencing PLPP, in addition to two focus groups; one with NHS-based midwives and another with NHS-based physiotherapists.

Otherwise healthy pregnant women, currently experiencing PLPP, aged 18 years or over, with a gestational age of 12-32 weeks, were invited by their treating clinician to participate in the study when they attended a routine antenatal visit within the host NHS Trust. Those with known pregnancy-related complications, multiple

pregnancies, and those without an adequate understanding of written and spoken English were ineligible. NHS-based midwives and physiotherapists involved in the management of women experiencing PLPP were recruited via email invitation disseminated via their line managers. All potential participants received a written information leaflet about the study to aid their decision regarding participation. Written informed consent was recorded by the researcher from each individual participant prior to data collection.

Semi-structured interviews

For the NHS service users, a semi-structured interview schedule was devised in order to ensure the specific research questions for this study were addressed sufficiently, but also to allow additional insights offered by the participants to be explored (Green & Thorogood 2009). The interview schedule aimed to address the following key areas of interest:

- If/how participants currently use digital media in relation to their pregnancy
- How participants perceive the use of the internet to access health information and how this differs from information obtained directly from a HCP
- How participants consider online health information should be presented in order to be most useful
- Participants' perceptions and beliefs about using a digital media-based intervention for the management of PLPP

All interviews were undertaken by the lead author (MM) who is a qualified physiotherapist with a special interest in PLPP and who has experience of qualitative research. Interviews were undertaken either in-person in a quiet, private room at the host NHS Trust's antenatal clinic, or via telephone. All interviews lasted between 20 and 60 minutes.

Focus groups

Small focus groups of four to six participants were utilised with the NHS-based HCPs. These focus groups provided an opportunity to access insights that may not be available from individuals and allowed group members to shape and reflect on their own perspectives after hearing those of others (Barbour & Kitzinger 1999). Both

focus groups were single profession: this decision was made to capitalise on the shared culture existent within each professional group and to ensure that differing professional perspectives could not become a cause of conflict (Barbour & Kitzinger 1999). Each focus group was moderated by the lead author and lasted around 90 minutes. The midwifery and physiotherapy focus groups were held in quiet, private rooms within the respective clinical departments of the host NHS Trusts.

The focus group guide was developed to address the following key issues and was the same for both groups of clinicians:

- If/how clinicians currently use digital media in their professional lives
- Participants' views on the use of digital media for the provision of PLPP-related information
- How participants considered digital media-based interventions for PLPP might be integrated within their current clinical practice
- The potential barriers and facilitators perceived to the implementation of a digital media-based PLPP-related intervention in an NHS setting

Due to the exploratory nature of this study, the notion of data saturation was not considered the sole determinant of the sample size (Braun & Clarke 2021). The sample size was largely influenced by the richness of the data generated across all interviews and focus groups, and pragmatic considerations including the availability of participants, and the resources available to complete the study.

All interviews and focus groups were audio-recorded and reflexive notes were taken throughout the data collection process to help inform the analysis. The audio-recordings were transcribed in an intelligent verbatim format. Data were analysed inductively, and as the study aims were clear at the outset, the framework method of analysis was chosen (Gale et al 2013). Framework analysis involves five key steps: 1) familiarization; 2) constructing a thematic framework; 3) indexing; 4) charting; 5) abstraction and interpretation (Ritchie et al 2014).

Insights provided by the service user group were given priority, as understanding their needs and preferences was deemed essential in fulfilling the aims of this study. Data collected from this group were therefore coded first and an initial thematic framework was constructed. The transcripts from both clinician focus groups were

then coded, and individual thematic frameworks were then drawn up for each. These three frameworks were then synthesised into one thematic framework that could be used to organise the entire dataset. The resulting consolidated thematic framework was reviewed and agreed by the entire research team following in-depth reflexive discussions, then re-applied across the entire dataset. A thematic chart was then constructed using Microsoft Excel (Microsoft 2016) to allow participants' responses to be compared. Key dimensions in those responses were then presented as themes and subthemes. Both the thematic charts and lists of key dimensions were reviewed and agreed by all members of the research team. Ethical approval had not been sought to contact participants again after data collection was completed, therefore no member checking was undertaken.

Results

Seven service users, six midwives and four physiotherapists consented to take part in the study. An overview of participant characteristics can be found in Table 1.

Table 1. Participant characteristics.

Characteristics of service users n=7	
Age range	21 - 36
Number of service users who were primiparous	3
Number of service users who were multiparous	4
Number of service users who hold a University degree	4
Number of service users who had experienced PLPP in a previous pregnancy	3
Characteristics of midwives n=6	
Number of midwives working in antenatal setting	6
Number of midwives with 5-10 years clinical experience	0
Number of midwives with >10 years clinical experience	6
Characteristics of physiotherapists n=4	
Number of physiotherapists working in a musculoskeletal setting	2
Number of physiotherapists working in a	2

women's health setting	
Number of physiotherapists with 5-10 years clinical experience	2
Number of physiotherapists with >10 years clinical experience	2

Two overarching themes were identified across the dataset:

- Theme 1: Information seeking and information provision in the context of PLPP
- Theme 2: Attitudes towards digital media as platforms for information provision.

Within each of these themes, four subthemes emerged, see Figures 1 and 2.

Theme 1: Information seeking and information provision in the context of PLPP

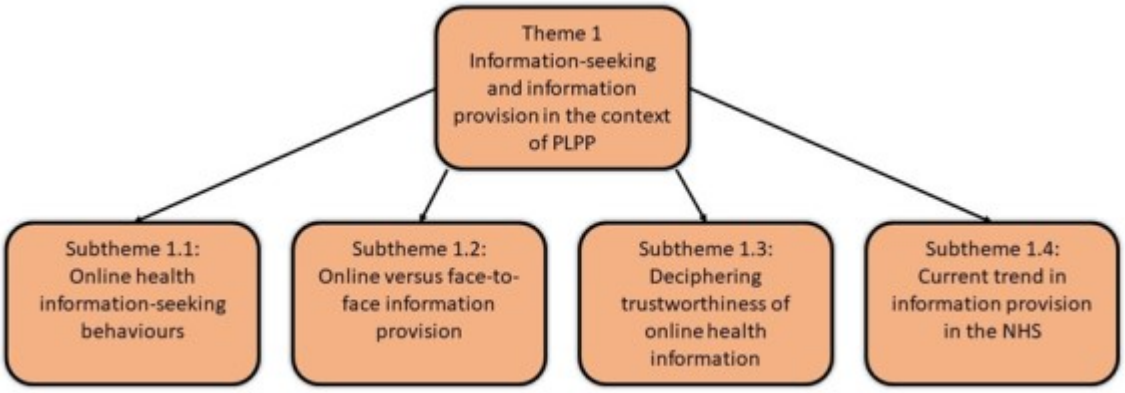


Figure 1. Relationship of theme 1 to subthemes.

Subtheme 1.1 Online health information-seeking behaviours

HCPs perceived the reasons patients choose to seek information online as rather simplistic; either to clarify information gathered during a clinical consultation or as a substitute for face-to-face information provision when access to a HCP was not possible.

'I think it's difficult with the NHS, the way it is…resources are so stretched and so that healthcare professionals aren't that easily accessible, so people are much more media savvy, tech savvy' (Midwife 6)

However, the actual reasons for seeking information online as described by the service users were far more complex. The search for reassurance featured prominently in the narratives of 5 of the 7 service users; either to establish whether the pain being experienced was normal, or to decide whether medical intervention was required. Additionally, online information-seeking was described by one service user as a way to modify the power dynamic between herself and her HCP: by acquiring information prior to her healthcare appointments, she felt able to interact with the HCP on a more equal basis and better able to critically assess any information provided to her.

'I like to have that knowledge before I go in to talk to someone. I don't like going in blind. I like to go in armed with a little bit of something otherwise you can't ask questions and you're totally reliant on what they say' (Service user 1)

All seven service users specifically identified Google as their primary search tool for online PLPP-related information.

Subtheme 1.2 Online versus face-to-face information provision

The risk of misinterpretation of online information was a concern shared by all stakeholder groups, as was the perceived potential for online information to cause unnecessary panic or distress.

'…because you do google it and you hear horror stories about like 'my pelvis was shifted' or 'I had to go on crutches' or 'I was in a wheelchair' so then you think oh God!' (Service user 3)

Three of the seven service users described an overwhelming volume of online material and the difficulty faced when attempting to filter out the factually accurate information desired.

> *'I googled everything which is a massive mistake isn't it because the information you get is just ridiculous, there's so much and you don't know what to believe'* (Service user 3)

This concern was echoed within the physiotherapy focus group.

Information provided by an HCP was believed by three service users to be more factually accurate and more reassuring than that found online. Conversely, two service users felt that the inability of some HCPs to answer questions about PLPP may create a barrier to information exchange between the patient and the professional.

> *'It's quite a quick appointment that you're in for when you're with your midwife. You have your blood pressure checked, you know, the water sample check and then you're kind of out then. So like you don't feel you've got a long enough appointment you know [to ask questions]*' (Service user 2)

Both the Midwives and Physiotherapists detailed the perceived negative consequences of their patients independently seeking information online. The risk of a missed differential diagnosis was of significant concern; particularly that symptoms indicative of serious pathology may inadvertently be overlooked.

Subtheme 1.3 Deciphering trustworthiness of online health information

The ability to decipher the trustworthiness of online health information was a concern highlighted across all stakeholder groups. HCPs described a perception that their patients may struggle to differentiate high quality, trustworthy information from misinformation or hearsay. Directing patients to trusted online resources was therefore seen as essential.

'I think if you google stuff, then it causes more panic that it actually resolves…So, what you do is you just make sure that, especially for pregnant women, that it's only the NHS website [that they use to search information], and make sure it's trusted information basically' (Midwife 6)

Two service users echoed this concern and described the difficulty they experienced in deciphering the trustworthiness of health information obtained online.

'I'm always searching something [online]. I think it's great in terms of the volume of information, but in regard to what is trusted information, that could be more helpful' (Service user 6)

In all but one case, service users described seeking information from a pre-defined list of trusted resources, including the NHS website, as a way of ensuring access to trustworthy information. The implicit trust in the NHS website was predominantly owing to the belief that information would be vetted prior to publication.

'Well if it's on the NHS one [NHS website] then that should be right shouldn't it? I don't think they'd be allowed to put anything on there that's not true' (Service user 3)

The accuracy of information obtained online was also an issue raised by HCPs, with the midwives predominantly concerned at the lack of professional control over online content.

'I think it's important that the information is out there but being able to police it being the right information is key. Because we know we haven't got any control over that have we, as healthcare professionals … the problem is if they're just googling' (Midwife 1)

The physiotherapists were concerned that independent online information-seeking may lead their patients to engage with unregulated online forums rather than trusted online information resources.

Subtheme 1.4 Current trends in information provision in the NHS

Service users described a range of experiences relating to the volume, quality, and format of PLPP-related information provided to them by their antenatal healthcare providers, with paper-based leaflets the most frequently cited mode of information provision. However, for some, the failure of HCPs to provide sufficient condition-related information had led to frustration and disappointment.

> *'And like with my midwife, I wasn't offered any information on pelvic girdle pain or sciatica and I was made to feel like, just get on with it really.'* (Service user 2)

One physiotherapist stated that she will occasionally direct patients towards trusted online resources, however the group as a whole described a current reliance on paper-based resources.

> *'…but if I'm going to recommend something, then I tend to only recommend the websites that are in the booklets we give out.'* (Physiotherapist 4)

Conversely, the midwives (based within another NHS Trust) described an institution-wide shift towards the use of online information resources in an attempt to reduce costs and save time.

> *'I mean now…we signpost and send electronic leaflets now don't we? They [patients] don't get the paper version. I think it was more of a cost related thing for the Trust.'* (Midwife 1)

Theme 2: Attitudes towards digital media as platforms for information provision.

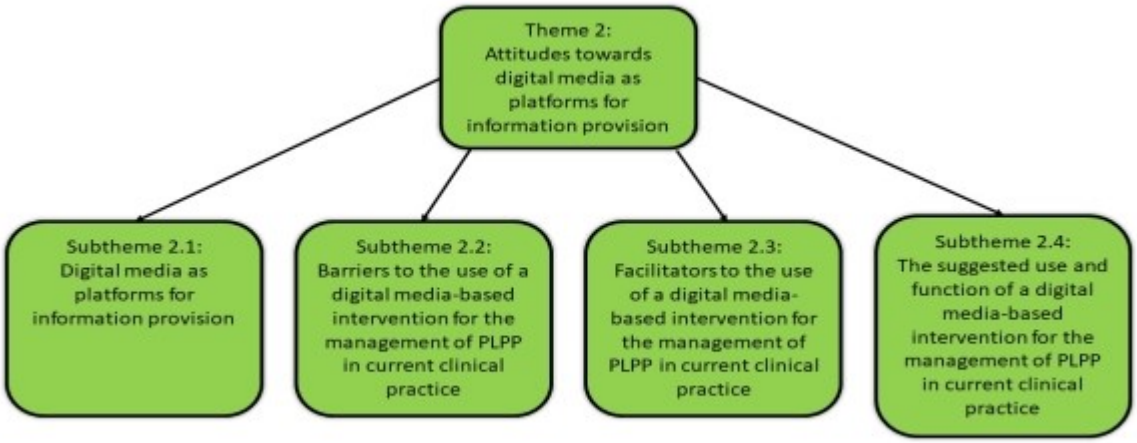


Figure 2. Relationship of theme 2 to subthemes.

Subtheme 2.1 Digital media as platforms for information provision

Each of the stakeholder groups acknowledged the potential utility of smartphone applications (apps) for information provision. Four of the seven service users reported the use of pregnancy-related apps during their current pregnancy. Two members of the physiotherapist group and three of the midwives also reported some experience of using apps to support clinical practice.

> *'NHS Squeezy [app]. That's a good one…for pelvic floor exercises, it like reminds you to do them. It's really good.'* (Physiotherapist 2)

Four of the seven service users stated a definite preference for apps over SoMe for PLPP-related information provision and cited a lack of trust in information acquired via SoMe as the principal reason for this.

> *'I think an app would be far more useful. I download apps all the time but like I said, I don't use Facebook any more or anything like that and I wouldn't use social media to look for information. I wouldn't trust information on there if I didn't know where it was from.'* (Service user 6)

Subtheme 2.2 Barriers to the use of a digital media-based intervention for the management of PLPP in current clinical practice

For the service users, significant barriers to the use of an app-based intervention included: content or layout that was not engaging; an excessive or overwhelming volume of information; and excessive use of medical jargon. The cost of apps was also identified as a factor determining use by three service users; for one participant, the need to pay for access was an insurmountable barrier to uptake.

> *'It's an expensive time as it is, so you're not going to pay for an app'* (Service user 2)

Perceived barriers to the implementation of a SoMe-based intervention into clinical practice highlighted by the physiotherapists included the lack of access to technology within different NHS Trusts and limitations imposed by NHS IT servers. The possibility for SoMe platforms to become vehicles for misinformation was also a significant concern.

> *'But I think that's the thing about Facebook isn't it, that it's become a bit of a free-for-all, a bit of a [forum] doesn't it turn into? And I know everyone will put their own opinion on'* (Physiotherapist 3)

The need to supply large amounts of personal data in order to access a digital media-based intervention was a barrier highlighted by one service user. The protection of personal data was also a concern for the midwives.

> *'As long as there was none of that spyware attached or all the other ways that they collect your data that you don't even know about'* (Midwife 2)

Subtheme 2.3 Facilitators to the use of a digital media-based intervention for the management of PLPP in current clinical practice

Several of the midwives specified that any intervention designed to support the management of PLPP would need to contain clear warnings about red flag signs and relevant safety-netting information for them to endorse it. Additionally, the

physiotherapists wanted reassurance that all information included in the content would be consistent with current practice.

> '*If it's the same information you'd give out anyway…As long as the information is consistent and doesn't contradict anything that we'd tell them [patients], then it'd help*' (Physiotherapist 1)

Provision of a broad range of condition-related information and clear advice to aid self-management were identified by each service user as key facilitators to uptake.

> *'Well it would have been nice to be given all the information under that umbrella if you will, all of the information to help me… just as much information as possible about the whole thing and what I could've done to help myself'* (Service user 2)

Subtheme 2.4 The suggested use and function of a digital media-based intervention for the management of PLPP in current clinical practice

Staff in both of the HCP focus groups believed that any digital media-based intervention for the management of PLPP should be distributed by a healthcare professional to allow the opportunity to screen for potential differential diagnoses.

> *'…Because if it's pelvic girdle pain, it could be masking a UTI or…You do need to have a discussion about it to make sure that you get a proper diagnosis'* (Midwife 2)

The physiotherapists suggested that midwives were best placed to distribute such an intervention as they would likely be the first professionals to whom the symptoms of PLPP are reported.

> *'…the women could be given an app at the first appointment that they mention it [PLPP] to the midwife'* (Physiotherapist 2)

There was agreement amongst the three stakeholder groups that early access to such an intervention would be preferable to prevent the deterioration of symptoms

and to avoid unnecessary condition-related anxiety. One midwife suggested that the intervention could be distributed to every pregnant woman in the early stages of pregnancy as a preventative measure.

> *'I'd like to give it [app-based intervention] to every woman at the first point of contact, and just say, look, this is something that might affect you in your pregnancy [PLPP], it might not, but you download the app and if you feel you need it, have a read through it and if you do feel like you need it for further support, then you've got it'* (Midwife 1)

However, three of the four physiotherapists and one service user questioned the wisdom of this approach due to the concern that PLPP-related information may seem irrelevant to those not experiencing symptoms.

> *'I think it would have been useful [to have received information about PLPP earlier in the pregnancy], but until you start having the pain, it's not really something you kind of take on board or look into.'* (Service user 4)

Discussion

The findings of this study underscore the complex drivers for online PLPP-related information-seeking amongst pregnant women and highlight the concerns shared by service users and clinicians regarding the accuracy and trustworthiness of online information. The use of digital media for PLPP-related information provision was viewed positively by all three stakeholder groups, however there was a preference for the use of apps over SoMe among the majority of service users. A range of barriers and facilitators to the implementation of a digital media-based intervention to support the management of PLPP in an NHS setting have been highlighted and need to be carefully considered.

Theme 1: Information-seeking and information provision in the context of PLPP

A recent survey by Snyder et al (2020) found that 96% of the pregnant women sampled used the internet to search for nutritional information in the perinatal period.

It is therefore unsurprising that when discussing their information-seeking behaviours, each of the service users in our sample described the use of Google to search for PLPP-related information. The stated reasons for searching for information online included: to provide reassurance; to facilitate self-screening; to alter the clinician-patient relationship dynamic; and to aid decision-making regarding the need for HCP input. Similar reasons for online health information-seeking have previously been reported in the wider health information literature, highlighting the complexity involved in women's interactions with online information (Peyton et al 2014, Maslen & Lupton 2018). These interactions were however poorly understood by the HCPs in this study, with both groups of clinicians taking an overly simplistic view of their patients' information-seeking practices; this observation may not be unique to our study sample (European Centre for Disease Prevention and Control Technical Report 2011)

Printed materials may not be the preferred format for information provision for pregnant women, as they are easily lost, misplaced or discarded (Peyton et al 2014). The midwives in this study therefore predictably described a recent shift towards the use of online resources in place of former paper-based alternatives. This was however perceived to be a cost-saving exercise rather than an attempt to address the changing needs of the patient population. This trend has not yet been adopted by all healthcare institutions, as the physiotherapists in this study demonstrated.

The majority of service users in our sample believed information obtained via a HCP to be more factually accurate and more reassuring than that obtained online. These insights are in accord with previous research which demonstrated that women who use the internet to search for information relating to childbearing, tend to view online information as a supplement to that provided by their HCP, rather than as a substitute (Willis et al 2015, Gleeson et al 2019).

Both groups of clinicians in this study shared concerns about the accuracy of online PLPP-related information in addition to the potential for online information to be misinterpreted. Similar concerns have been previously highlighted in the midwifery literature, with one 2011 survey reporting that general pregnancy-related online information was perceived to be 'not very' or 'not at all' accurate by 19% of the midwives who responded (Lagan et al 2011). Additionally, recent studies in other

areas of healthcare have demonstrated huge variability in the quality (Daraz et al 2019), accuracy (Ferreira et al 2019) and readability (Rothrock et al 2019) of online health-related information, suggesting that the concerns of the clinicians in our study are not unfounded.

Several service users in our sample described difficulty deciphering the trustworthiness of online PLPP-related information. Others however reported preferentially seeking information from trusted resources - such as the NHS website - in order to avoid this issue. The trust placed in the NHS website was owing to the perception that there would be strict regulation of its content. This reflects existing evidence which suggests that women place greater trust in resources produced by government health department websites and those produced by high profile non-government organisations (Maslen & Lupton 2018). According to the NHS website's content policy (NHS 2018, Section 4.1.3), all clinical content published via this platform is reviewed by an 'appropriately qualified and experienced clinician', supporting service users' expectation of accuracy and trustworthiness.

Our findings highlighted a shared concern amongst all three stakeholder groups regarding the potential for online information-seeking to cause unnecessary panic or distress. This is not unreasonable given that previous research has identified a positive association between health anxiety and health information seeking (McMullan et al 2019), and exposure to conflicting health information has been shown to cause confusion, frustration, and anxiety (Bianchi et al 2016). The physiotherapists were concerned that unregulated content accessed via online forums may present a risk of misinformation and unnecessary condition-related anxiety if accepted without appropriate critique. This concern is understandable given the variable quality of advice contained in online discussion threads (Cole et al 2016).

Theme 2: Attitudes towards mobile phone apps and social media as platforms for information provision

The use of a digital media-based intervention to support the management of PLPP was viewed positively by all stakeholder groups in this study, however there was a preference for the use of apps over SoMe for PLPP-related information provision among the majority of service users. A lack of trust in information obtained via SoMe

was the most common reason given for this opinion. This finding was unexpected given that pregnant women have previously been shown to be highly engaged with SoMe (Zhu et al 2019) and to view the information obtained via these channels to be useful and trusted (Larsson 2009). The conflict between our findings and those of previous work could be due to demographic differences in the study populations sampled, the different research contexts in which the studies were undertaken, or the fact that service users in our study were describing the search for specific condition-related information rather than generic pregnancy-related information.

Each of the stakeholder groups identified several general barriers to the use of a digital media-based intervention for the management of PLPP within an NHS setting: cost, data security, commercial advertising, excessive information, and limited resources were all proposed by participants. These are largely in-keeping with barriers to implementation of app-based interventions identified in other areas of healthcare (Velu et al 2017). However, evidence also suggests that levels of clinician engagement with mobile health interventions may vary across settings (Leigh et al 2020, Kerst et al 2020) and that the usability of an app may impact on patients' willingness to engage (Bayambasuren et al 2020). These additional barriers would therefore also need to be considered and mitigated throughout the intervention development process.

Many of the pitfalls of online information-seeking could be minimised if clinicians openly discussed the information obtained online with their patients; providing an opportunity for the correction of misinformation and appropriate provision of reassurance (Sayakhot & Carolan-Olah 2016, Tan & Goonawardene 2017). However, evidence suggests that patients are often reluctant to discuss their information-seeking behaviours with their clinician unless the clinician initiates the conversation, due to concerns over potential negative judgement (Tan and Goonawardene 2017). It is also acknowledged that clinical time pressures often present significant barriers to these discussions (Vennedey et al 2020). An intervention that provides high-quality PLPP-related information may therefore reduce the need for service users to tackle huge volumes of online material by ensuring their information needs are appropriately met with access to an accurate, trustworthy resource. The positive perception of the use of apps for information

provision identified in this study suggests that an app-based intervention to support the management of PLPP is worthy of further exploration.

The strengths of this study are that priority was given to the voice of the service users in order to ensure their information needs were understood, but views from all relevant stakeholder groups were collected. The focus of the study was kept purposely broad, exploring the use of multiple digital media as opposed to any single medium in isolation. The main limitation of this study is that the coding framework was initially constructed by a single team member (MM) prior to review by the research team, and no member-checking was employed.

Conclusion

Whilst this is a small-scale study and the findings may not be generalisable across settings, this work has demonstrated that the online information-seeking behaviours of women with PLPP are complex and the use of the internet to search for condition-related information is common. Difficulties deciphering the trustworthiness of online PLPP-related information were highlighted, as were concerns regarding the accuracy of online information. NHS-based service users and HCPs viewed the notion of a digital media-based intervention to support the management of PLPP in a positive light. A preference for apps over SoMe for information provision was stated by the majority of service users, owing to a lack of trust in information obtained via SoMe. The notion of an app-based intervention to support the management of PLPP is therefore worthy of further exploration.

Author Contributions

MM undertook all data collection procedures, led the data analysis and prepared the first draft of the manuscript.

MM and JS designed the original study protocol but all authors contributed to the data collection strategy

MM, JS and CH participated in data analysis and contributed to completion of the manuscript for submission.

Author Affiliation

All authors are employees of Manchester Metropolitan University

Funding

No external funding was sought or received for the completion of this study.

Conflicts of interest

Following completion of this study, the lead author has consulted with the commercial company 'Living With Ltd' to develop an app-based intervention to support the management of PLPP. This arrangement provides no financial benefit to the authors.

References

Backhausen M, Damm P, Bendix J, Tabor A, Hegaard H. (2018). 'The prevalence of sick leave: Reasons and associated predictors – A survey among employed pregnant women.' *Sexual & Reproductive Healthcare: Official Journal of the Swedish Association of Midwives* 15 54-61.

Barbour RS, Kitzinger J. (1999). *Developing Focus Group Research: Politics Theory and Practice* First Edition. SAGE Publications. London

Bishop A, Holden MA, Ogollah RO, Foster N.E (2016). 'Current management of pregnancy-related low back pain: a national cross-sectional survey of UK physiotherapists' Physiotherapy 102 (1): 78-85,

Braun V. and Clarke V. (2021). 'To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales'. Qualitative Research in Sport Exercise and Health 13 (2). 201-216 https://www.tandfonline.com/doi/full/10.1080/2159676X.2019.1704846

Byambasuren O Beller E Hoffmann T & Glasziou P. (2020). 'Barriers to and Facilitators of the Prescription of mHealth Apps in Australian General Practice: Qualitative Study'. *JMIR mHealth and uHealth 8*(7):e17447.

Camacho-Morell F & Esparcia J. (2020). ‘Influence and use of information sources about childbearing among Spanish pregnant women.’ *Women and Birth: Journal of the Australian College of Midwives 33*(4). 367–376.

Carpenter D. M Geryk L. L Chen A. T Nagler R. H Dieckmann N. F & Han P. K. J. (2016). ‘Conflicting health information: a critical research need. *Health Expectations: An International Journal of Public Participation in Health Care and Health Policy’ 19*(6). 1173–1182.

Chan K. L Chen M. (2019). ‘Effects of Social Media and Mobile Health Apps on Pregnancy Care: Meta-Analysis’. *JMIR mHealth and uHealth 7*(1). e11836.

Clinton S. C Newell A Downey P. A & Ferreira K. (2017). ‘Pelvic Girdle Pain in the Antepartum Population: Physical Therapy Clinical Practice Guidelines Linked to the International Classification of Functioning Disability and Health From the Section on Women’s Health and the Orthopaedic Section of the American Physical Therapy Association’. *Journal of Women’s Health Physical Therapy 41*(2). 102.

Close C Sinclair M Liddle D Mc Cullough J & Hughes C. (2016). ‘Women’s experience of low back and/or pelvic pain (LBPP). during pregnancy’. *Midwifery 37* 1–8.

Cole J Watkins C & Kleine D. (2016). ‘Health Advice from Internet Discussion Forums: How Bad Is Dangerous?’ *Journal of Medical Internet Research 18*(1). e4.

Daraz L Morrow A. S Ponce O. J Beuschel B Farah M. H Katabi A Alsawas M Majzoub A. M Benkhadra R Seisa M. O Ding J. F Prokop L & Murad M. H. (2019). ‘Can Patients Trust Online Health Information? A Meta-narrative Systematic Review Addressing the Quality of Health Information on the Internet’. *Journal of General Internal Medicine 34*(9). 1884–1891

Elden H Lundgren I & Robertson E. (2014). ‘The pelvic ring of pain: Pregnant women’s experiences of severe pelvic girdle pain: An interview study’. *Clinical Nursing Studies 2*(2). 30.

European Centre for Disease Prevention and Control ECDC (2011). *A literature review on health information seeking behaviour on the web: a health consumer and health professional perspective.* Stockholm. ECDC; 2011 doi 10.2900/5788

Ferreira G Traeger A. C Machado G O’Keeffe M & Maher C. G. (2019). ‘Credibility Accuracy and Comprehensiveness of Internet-Based Information About Low Back Pain: A Systematic Review’. *Journal of Medical Internet Research 21*(5). e13357.

Gale N. K Heath G Cameron E Rashid S & Redwood S. (2013). ‘Using the framework method for the analysis of qualitative data in multi-disciplinary health research’. *BMC Medical Research Methodology 13* 117.

Gleeson D. M Craswell A & Jones C. M. (2019). ‘Women’s use of social networking sites related to childbearing: An integrative review’. *Women and Birth: Journal of the Australian College of Midwives 32*(4). 294–302.

Green J, Thorogood N. (2009). *Qualitative Methods for Health Research* Second Edition. SAGE Publications. London.

Hämeen-Anttila K Nordeng H Kokki E Jyrkkä J Lupattelli A Vainio K & Enlund H. (2014). ‘Multiple information sources and consequences of conflicting information about medicine use during pregnancy: a multinational Internet-based survey’. *Journal of Medical Internet Research 16*(2). e60.

Johnson J.D. and Case D.O. (2012). *Health Information Seeking* First Edition. Peter Lang Publishing Inc. New York

Kerst A Zielasek J & Gaebel W. (2020). ‘Smartphone applications for depression: a systematic literature review and a survey of health care professionals’ attitudes towards their use in clinical practice’. *European Archives of Psychiatry and Clinical Neuroscience 270*(2). 139–152.

Kovacs F. M Garcia E Royuela A González L Abraira V & Spanish Back Pain Research Network. (2012). ‘Prevalence and factors associated with low back pain and pelvic girdle pain during pregnancy: a multicenter study conducted in the Spanish National Health Service’. *Spine 37*(17). 1516–1533.

Kraschnewski J. L Chuang C. H Poole E. S Peyton T Blubaugh I Pauli J Feher A & Reddy M. (2014). ‘Paging “Dr. Google”: does technology fill the gap created by the prenatal care visit structure?’ Qualitative focus group study with pregnant women. *Journal of Medical Internet Research 16*(6). e147.

Lagan B. M Sinclair M & Kernohan W. G. (2011). ‘A Web-based survey of midwives’ perceptions of women using the Internet in pregnancy: a global phenomenon’. *Midwifery 27*(2). 273–281.

Larsson M. (2009). ‘A descriptive study of the use of the Internet by women seeking pregnancy-related information’. *Midwifery 25*(1). 14–20.

Lee H. S. (2016). ‘Research trends in mothers’ health information seeking behaviours: A review of the literature’. *Proceedings of the Association for Information Science and Technology 53*(1). 1–6.

Leigh S Ashall-Payne L & Andrews T. (2020). ‘Barriers and Facilitators to the Adoption of Mobile Health Among Health Care Professionals From the United Kingdom: Discrete Choice Experiment’. *JMIR mHealth and uHealth 8*(7). e17704

Lupton D. (2016). 'The use and value of digital media for information about pregnancy and early motherhood: a focus group study'. *BMC Pregnancy and Childbirth 16*(1). 171.

Lupton D. (2017). '"It Just Gives Me a Bit of Peace of Mind": Australian Women's Use of Digital Media for Pregnancy and Early Motherhood'. *Societies 7*(3). 25.

Mackenzie J Murray E & Lusher J. (2018). 'Women's experiences of pregnancy related pelvic girdle pain: A systematic review'. *Midwifery 56* 102–111.

Mackintosh N Agarwal S Adcock K Armstrong N Briley A Patterson M Sandall J & Sarah Gong Q. (2020). 'Online resources and apps to aid self-diagnosis and help seeking in the perinatal period: A descriptive survey of women's experiences'. *Midwifery 90* 102803.

Maslen S & Lupton D. (2018). '"You can explore it more online": a qualitative study on Australian women's use of online health and medical information'. *BMC Health Services Research 18*(1). 916.

McMullan R. D Berle D Arnáez S & Starcevic V. (2019). 'The relationships between health anxiety online health information seeking and cyberchondria: Systematic review and meta-analysis'. *Journal of Affective Disorders 245* 270–278.

Miller L. M. S & Bell R. A. (2012). 'Online health information seeking: the influence of age information trustworthiness and search challenges'. *Journal of Aging and Health 24*(3). 525–541.

National Health Service (NHS) (2018). *'The NHS Website Content Policy V7'* NHS Available from: https://assets.nhs.uk/prod/documents/nhs-website-content-policy-2018.pdf

Peyton T Poole E Reddy M Kraschnewski J & Chuang C. (2014). '"Every pregnancy is different": designing mHealth for the pregnancy ecology'. *Proceedings of the 2014 Conference on Designing Interactive Systems* 577–586.

Prescott J & Mackie L. (2017). '"You Sort of Go Down a Rabbit Hole...You're Just Going to Keep on Searching": A Qualitative Study of Searching Online for Pregnancy-Related Information During Pregnancy'. *Journal of Medical Internet Research 19*(6). e194.

Ritchie J Lewis J McNaughton Nicholls C. and Ormston R. (2014). *Qualitative Research Practice: A Guide for Social Science Students and Researchers* Second Edition. SAGE Publications. London.

Rothrock S. G Rothrock A. N Swetland S. B Pagane M Isaak S. A Romney J Chavez V & Chavez S. H. (2019). 'Quality Trustworthiness Readability and Accuracy of Medical Information Regarding Common Pediatric Emergency Medicine-Related Complaints on the Web'. *The Journal of Emergency Medicine 57*(4). 469–477.

Sayakhot P, Carolan-Olah M (2016). 'Internet use by pregnant women seeking pregnancy-related information: a systematic review'. *BMC Pregnancy and Childbirth 16* 65.

Shieh C Mays R McDaniel A & Yu J. (2009). 'Health literacy and its association with the use of information sources and with barriers to information seeking in clinic-based pregnant women'. *Health Care for Women International 30*(11). 971–988.

Singh K Fox J. R. E & Brown R. J. (2016). 'Health anxiety and Internet use: A thematic analysis'. *Cyberpsychology: Journal of Psychosocial Research on Cyberspace 10*(2). https://doi.org/10.5817/CP2016-2-4

Snyder A Neufeld H.T. and Forbes L. (2020). 'A mixed-methods investigation of women's experiences seeking pregnancy-related online nutrition information'. BMC Pregnancy Childbirth 20 (1). 377. https://doi.org/10.1186/s12884-020-03065-w

Tan SS-L, Goonawardene N. (2017). 'Internet Health Information Seeking and the Patient-Physician Relationship: A Systematic Review'. *Journal of Medical Internet Research 19*(1). e9.

Velu A. V van Beukering M. D Schaafsma F. G Frings-Dresen M. H Mol B. W van der Post J. A & Kok M. (2017). 'Barriers and Facilitators for the Use of a Medical Mobile App to Prevent Work-Related Risks in Pregnancy: A Qualitative Analysis'. *Journal of Medical Internet Research research protocols 6*(8). e163. https://doi.org/10.2196/resprot.7224

Vennedey V Hower K. I Hillen H Ansmann L Kuntz L Stock S & Cologne Research and Development Network (CoRe-Net). (2020). 'Patients' perspectives of facilitators and barriers to patient-centred care: insights from qualitative patient interviews'. *BMJ Open 10*(5). e033449.

Vleeming A Albert H. B Ostgaard H. C Sturesson B & Stuge B. (2008). 'European guidelines for the diagnosis and treatment of pelvic girdle pain'. *European Spine Journal: Official Publication of the European Spine Society the European Spinal Deformity Society and the European Section of the Cervical Spine Research Society 17*(6). 794–819.

Willis A. M Smith S. K Meiser B Muller C Lewis S & Halliday J. (2015). 'How do prospective parents prefer to receive information about prenatal screening and diagnostic testing?' *Prenatal Diagnosis 35*(1). 100–102.

Wu W. H Meijer O. G Uegaki K Mens J. M. A van Dieën J. H Wuisman P. I. J. M & Ostgaard H. C. (2004). 'Pregnancy-related pelvic girdle pain (PPP). I: Terminology clinical presentation and prevalence'. *European Spine Journal: Official Publication of*

the European Spine Society the European Spinal Deformity Society and the European Section of the Cervical Spine Research Society 13(7). 575–589.

Wuytack F Curtis E & Begley C. (2015a). 'Experiences of First-Time Mothers With Persistent Pelvic Girdle Pain After Childbirth: Descriptive Qualitative Study'. *Physical Therapy 95*(10). 1354–1364

Wuytack F Curtis E & Begley C. (2015b). 'The health-seeking behaviours of first-time mothers with persistent pelvic girdle pain after childbirth in Ireland: A descriptive qualitative study'. *Midwifery 31*(11). 1104–1109.

Zhu C Zeng R Zhang W Evans R & He R. (2019). 'Pregnancy-Related Information Seeking and Sharing in the Social Media Era Among Expectant Mothers: Qualitative Study'. *Journal of Medical Internet Research 21*(12). e13694.

Table 1. Participant characteristics.

Characteristics of service users **n=7**	
Age range	21 - 36
Number of service users who were primiparous	3
Number of service users who were multiparous	4
Number of service users who hold a University degree	4
Number of service users who had experienced PLPP in a previous pregnancy	3
Characteristics of midwives **n=6**	
Number of midwives working in antenatal setting	6
Number of midwives with 5-10 years clinical experience	0
Number of midwives with >10 years clinical experience	6
Characteristics of physiotherapists **n=4**	
Number of physiotherapists working in a musculoskeletal setting	2
Number of physiotherapists working in a women's health setting	2
Number of physiotherapists with 5-10 years clinical experience	2
Number of physiotherapists with >10 years clinical experience	2