University of Southampton

Faculty of Environmental and Life Sciences

Psychology

Reconceptualising Patient-Reported Outcome Measures as Active Components of Specialist Musculoskeletal Care for Back Pain

by

Michelle Marie Holmes

ORCID ID: 0000-0002-6018-2235

Thesis for the degree of Doctor of Philosophy

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Dedication

There are people in your life who have a massive impact on the path you take. This thesis is dedicated to those people who, all in their own way, helped me onto the road to start a PhD, but are not able to see me complete my journey: John Snook, Wendy Lawrence, George Lewith, and Grrrr..Grandma.

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Abstract

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Patient-reported outcome measures (PROMs) are increasingly utilised in routine specialist musculoskeletal care. Using the Medical Research Council's guidance on developing and evaluating complex interventions, this thesis examined how the use of PROMs in specialist musculoskeletal care affects patients with low back pain and the mechanisms that underlie this relationship.

The early development phase consisted of a systematic review examining prior research and a theoretical review exploring the underlying concepts of PROMs. The literature indicates PROMs may have an influence throughout the treatment encounter, affecting patients through multiple processes: increasing clinicians' knowledge of patients, facilitating interactions, enabling patient-centred care, monitoring, enhancing therapeutic relationships, improving patient satisfaction, and encouraging self-management.

In the feasibility phase, a mixed-methods study explored future study procedures and estimated recruitment. Despite PROMs being routinely used in musculoskeletal care, no participants completed all PROMs. From qualitative interviews, recommendations were made to improve patient and clinician engagement with PROMs and trial processes in the future evaluation phase.

The final evaluation phase involved a randomised-controlled trial and a mixed-method process evaluation. The trial found no significant impact of PROMs on back pain-related disability. However, the process evaluation highlighted a series of processes by which PROMs may influence patient outcomes. PROMs were found to have a role within patient-clinician interactions, with patient-centred communication viewed as a key component of care.

This thesis has contributed to knowledge on implementing PROMs in specialist musculoskeletal care, including the selection and timing of PROMs, administrative processes, and training for clinicians. It provides a valuable theoretical foundation to guide future research on the use of PROMs. PROMs were found to be a useful tool for chiropractors to communicate with patients. Further research should explore how PROMs can be used to support patient-centred communication and how this might influence patients' outcomes, self-management behaviours, and satisfaction with care.

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Research Thesis: Declaration of Authorship

Print name: Michelle Holmes

Title of thesis: Reconceptualising Patient-Reported Outcome Measures as Active Components of Specialist Musculoskeletal Care for Back Pain

I declare that this thesis and the work presented in it are my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;
2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
5. I have acknowledged all main sources of help;
6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;
7. Parts of this work have been published as:-
   Holmes, M., Bishop, F., & Field, J. (2016). Reconceptualising patient-reported outcome measures: what could they mean for your clinical practice? *Pain News, 14*(2).
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Definitions and Abbreviations

CERQual.....Confidence in the Evidence from Reviews of Qualitative research

CIS .....Critical Interpretative Synthesis

CAM.....Complementary and Alternative Medicine

CSQ-CAT .....Catastrophising Subscale of the Coping Strategies Questionnaire

EMBASE.....Excerpta Medical Database and Allied and Alternative Medicine

EQ-5D .....EuroQoL Thermometer

FABPA .....Fear-Avoidance Beliefs Questionnaire Physical Activity Subscale

HRQoL.....Health-Related Quality of Life

LBP-TBQ.....Lower Back Pain – Treatment Beliefs Questionnaire

MCID .....Minimally Clinically Important Difference

MMAT .....Mixed-Method Appraisal Tool

MRC .....Medical Research Council

MSK-HQ .....Musculoskeletal Health Questionnaire

MYMOP.....Measure Yourself Medical Outcome Profile

NHS.....National Health Service

PASS-20 .....Pain Anxiety Symptoms Scale

PGIC.....Patient Global Impression of Change Scale

PPPCQ .....Patient Perception of Patient Centeredness Questionnaire

PRISMA .....Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROMs.....Patient-Reported Outcome Measures

PROMPT .....Patient-Reported Outcome Measures Pathway Theory

PSE.....Self-Efficacy for Pain Management (Questionnaire)

PSOCQ .....Pain Stages of Change Questionnaire

QoL ..... Quality of Life

RCT ..... Randomised-Controlled Trial

RTA ..... Reciprocal Translational Analysis

U.K. ..... United Kingdom

U.S ..... United States

WAI_SR ..... Working Alliance Inventory – Short-Revised

Chapter 1 Patient-reported outcome measures: an introduction

1.1 What are patient-reported outcome measures?

1.1.1 Definition

'Patient-reported outcome measures' is an umbrella term for standardised instruments collecting patients' perceptions about their health (Dawson, Doll, Fitzpatrick, Jenkinson, & Carr, 2010; Fitzpatrick, Davey, Buxton, & Jones, 1998; McKenna, 2011; Valderas, Kotzeva, et al., 2008). These subjective evaluations of health are self-completed, through paper questionnaires, electronic devices, or interviews, and typically result in a numerical score (Appleby & Devlin, 2005; Department of Health, 2008; Devlin & Appleby, 2010). These measures capture patients' views, perceptions, feelings, and experiences, unlike traditional measures of biological and physical indicators (Gilbody, House, & Sheldon, 2003). Data are provided exclusively by patients, and not reported by healthcare professionals, researchers, or caregivers (Acquadro et al., 2003; Food and Drug Administration, 2009).

These measures can address constructs of health, health status, quality-of-life and quality-of-care (Bausewein, Daveson, Benalia, Simon, & Higginson, 2011; Boyce, Browne, & Greenhalgh, 2014a; Dawson et al., 2010). Patient-reported outcome measures can refer to a single point in time or evaluate changes in health over time (Bausewein et al., 2011; Department of Health, 2008; Gilbody et al., 2003).

There are several synonyms for patient-reported outcome measures, these include: patient-based outcome measures, patient-reported outcomes (PROs), patient outcome measures (POMs), and are often used interchangeably with terms such as quality-of-life (QoL), health-related quality-of-life (HRQoL), disability, functional status, health status, performance status, subjective health status, and wellbeing (Fitzpatrick et al., 1998; Gilbody et al., 2003). This thesis will use the term patient-reported outcome measures (abbreviated to PROMs).

1.1.2 Historical development of PROMs

Donabedian (1988) identified three components to evaluate healthcare: process, structure, and outcome. Process measurements assessed healthcare quality using clinical history, assessment of biological measures, justification of treatment, and competence of treatment procedures. Structure of healthcare structure was evaluated through examining the equipment and facilities of the healthcare setting, the setting organisation, and staff qualifications. Lastly, outcomes referred to indicators of health such as mortality, survival rates, functional status, recovery rates, and disability (Donabedian, 1988). Health was traditionally measured using negative end-points, such as mortality, or through assessing biological factors, as an objective approach to quantify health (Sackett et al., 1977). Although the quantification of biological features is associated with patient experience, non-biological factors play a fundamental role in influencing patient outcomes (Fries, 1983b). Traditional measures did not provide a comprehensive assessment of patient experience of illness and treatment, highlighting a need for complementary outcome measures (Fries, 1983a, 1983b).

The idea that traditional measurement methods may not be the most accurate way to measure complex outcomes was also influenced by a shift in the provision of patient care. A report by the U.S Department of Health and Human Services in 1990 challenged the heavy focus on medical care and treatment of disease, arguing for a broader focus on health promotion and prevention of disease, emphasising a shift towards the concept of “healthcare” (Greenfield & Nelson, 1992; Mason & McGinnis, 1990). Both these factors led to the development of general health measures within research, that assessed and quantified many facets of health and illness (Sackett et al., 1977).

Alongside their use in health research, PROMs were incorporated into clinical practice with patients’ subjective views deemed valuable information to evaluate healthcare and assess the clinical efficacy of medical treatment (Fitzpatrick, Bury, Frank, & Donnelly, 1987; Greenfield & Nelson, 1992). In the early 1990s, PROMs had three main uses within clinical practice: to increase knowledge of disease trajectories, evaluate the effectiveness of treatment on individual patients, and assess the quality of the care provided (Greenfield & Nelson, 1992). Their use was suggested to be intrinsically linked to processes of providing quality healthcare; using PROMs could inform clinicians over health management and treatment plans (Greenfield & Nelson, 1992; Nelson & Berwick, 1989; Wilson & Kaplan, 1995).

1.1.3 Categorisation of PROMs

PROMs are often classified by the scope of the issue being measured; instruments may measure a broad concept such as overall health or wellbeing to focusing on a specific symptom (McDowell, 2006). A comprehensive review broadly classified PROMs into six categories: disease-specific, site or region-specific, dimension-specific, generic, summary, or individualised (see Table 1.1) (Fitzpatrick et al., 1998).

Table 1.1 - Classification of PROMs

Adapted from: Fitzpatrick et al. (1998).

Classification	Definition	Example
Disease-specific	Measuring content relevant to a disease, diagnosis or condition	The Bath Ankylosing Spondylitis Disease Activity Index, is a six item instrument in which patients self-report the severity of their: fatigue, joint pain, tenderness and morning stiffness (Garrett et al., 1994)
Site or region-specific	Assessing problems in a particular part of the body	The Bournemouth Questionnaire, which uses seven items to assess lower back pain (Bolton & Breen, 1999)
Dimension-specific	Measuring a distinct component of health, such as pain	The visual analogue scale is a one-item measure of the intensity of pain (Carlsson, 1983)
Generic	Measuring a range of concepts related to health (applied across diseases and diagnoses)	Short Form 36 measures patients' health status across eight domains associated to HRQoL (Jenkinson, Coulter, & Wright, 1993)
Summary	Short questions used to capture many aspects of health	The Census Household Questionnaire asks the question "How is your health in general?" to demonstrate overall health (UK Data Service Census Support, 2011)
Individualised	Assessing individuals' concerns about their health, with patients selecting issues that are of concern to them	Measure Yourself Medical Outcome Profile (MYMOP) asks patients to choose one or two symptoms that they are seeking help with and rate the severity of the symptom on a seven-point scale (Paterson, 1996)

Valderas and Alonso (2008) proposed a further classification of PROMs, categorising PROMs according to three elements: construct, population, and measurement (see Figure 1.1). The construct is the element of health assessed, the population of the measures classifies the PROM according to who the instrument is suited for, by age, gender, disease, and culture of individuals. The measurement of PROMs is organised by metrics, dimensionality, and adaptability. Metrics are classified as psychometric, econometric, or clinimetric. Psychometric PROMs build on theoretical models; econometric PROMs are based on decision theory, assessing health states and obtaining values based on the preferences of patients, clinicians, and experts; clinimetrics are focused on

clinical relevance. Dimensionality refers to the number of scores; index PROMs give a single score per patient, profile PROMs have more than one score. The PROM adaptability is the extent to which PROMs can be tailored to the individual patients.

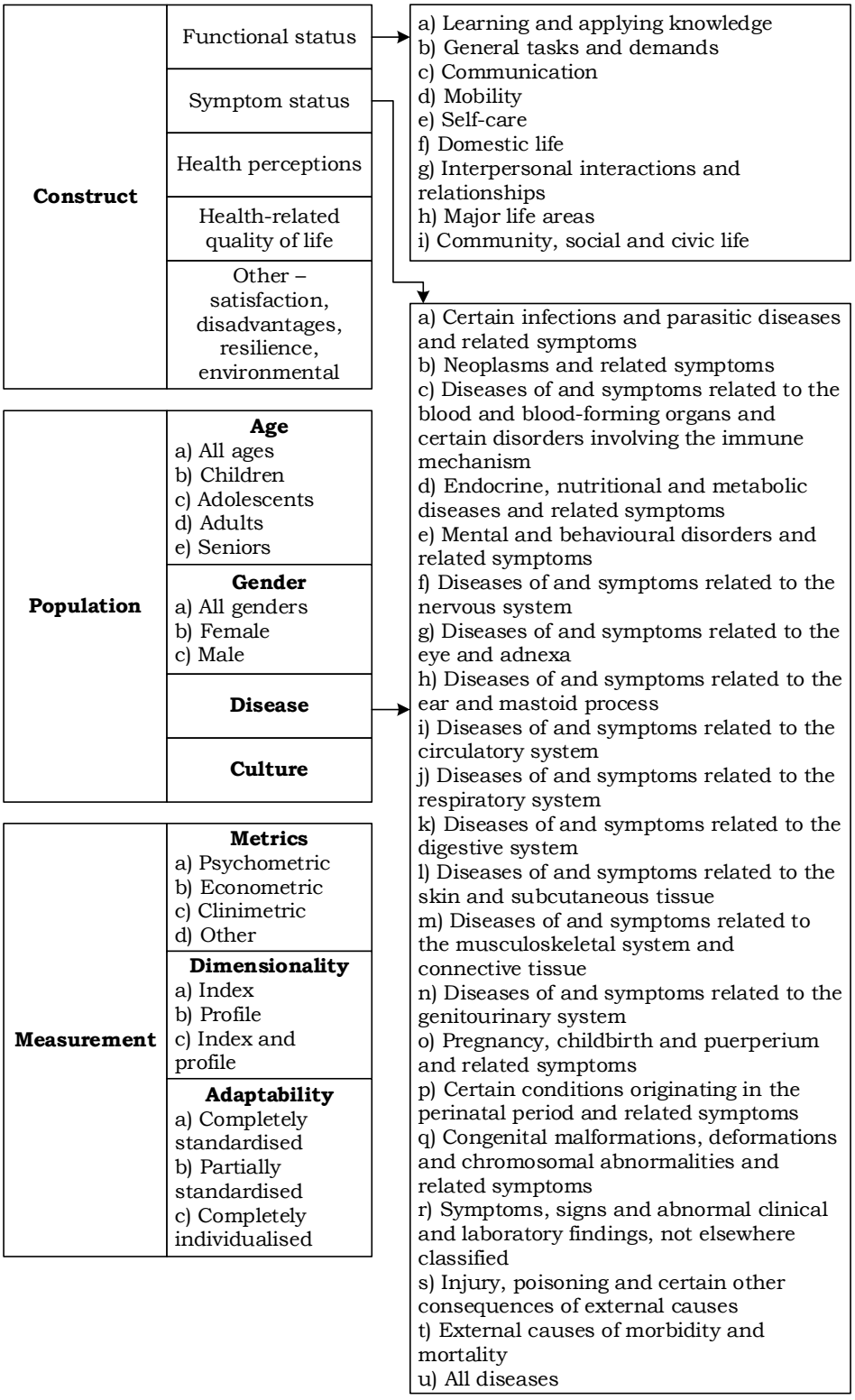


Figure 1.1 - Classification of PROMs by construct, population and measurement

Adapted from: Valderas and Alonso (2008)

1.1.4 Evaluation of PROMs

Standardised criteria known as psychometric properties (reliability, validity, and responsiveness) are used to evaluate PROMs.

Reliability

Instruments must be reliable, by having consistency in scores over time. A reliable PROM minimises random error by ensuring that any changes in scores are not due to measurement errors (i.e. differences between an observed score and the true score) (Fitzpatrick et al., 1998). The evaluation of reliability looks at both internal consistency and reproducibility. Internal consistency examines the correlation between items on outcome measures. Typically, more than one question is used when measuring a dimension of health, as several measurements will produce a more reliable estimate. Therefore, items should be highly correlated. Reproducibility assesses whether PROMs have the same results when repeated. Test-retest reliability evaluates whether results remain the same within the same person, over time.

Validity

Validity assesses whether the PROM measures what it claims to measure (Fitzpatrick et al., 1998). There are several types of validity: criterion, content, and construct (McDowell & Jenkinson, 1996). Criterion validity examines whether the PROM correlates with an established standard of comparison. Content validity describes if the measure assesses the relevant domains; whether the domains are important, appropriate, and sufficient to address the subject matter. Construct validity assesses if the measurement corresponds to the theoretical concepts it was designed to observe.

Responsiveness

Instruments must be responsive, meaning they must be able to detect small changes over time. If PROMs are unresponsive they may fail to detect changes despite patient improvement (Guyatt et al., 2007). Responsiveness is assessed through correlation of change measured by another PROM, and if the change is identified as important by patients and clinicians. The change must be determined to make a minimally clinically important difference (MCID); the smallest change that is perceived as beneficial.

1.2 Use of PROMs in clinical practice

1.2.1 Potential uses

Stakeholders may have different goals regarding use of PROMs, defining who uses PROMs, how PROMs are captured, which PROMs are appropriate, and how they inform practice. Franklin et al. (2017) classified PROMs uses for: population and health research, payer mandates, quality improvement, and individual care decisions. Hjollund, Valderas, Kyte, and Calvert (2019) simplified PROM use into examination of groups or individuals, or whether PROMs are being used on an ad hoc or systematic basis. Comparing the frameworks, there are two main suggestions for PROMs use: healthcare evaluation and individualised patient care.

Healthcare evaluation

The UK National Health Service (NHS) primarily uses aggregated PROM data for audit, with data utilised to examine the effectiveness, appropriateness, quality, and performance of healthcare (Appleby & Devlin, 2005; Department of Health, 2008; National Institute for Clinical Excellence, 2004). This can be collected internally within institutions or externally as part of mandated publicly reported data. The collection of data places pressure on healthcare providers to respond and improve patient care (Greenhalgh et al., 2017). As per their original development, PROMs also continue to be used within research to evaluate treatments or interventions (Fitzpatrick et al., 1998). PROMs can further be used within economic evaluations. For example, by combining the data from PROMs with information on the costs of treatment, it is possible to estimate overall effectiveness of treatments, quantifying any health gain and associated costs (Coronini-Cronberg, Appleby, & Thompson, 2013; Devlin, Parkin, & Browne, 2010).

Individualised patient care

PROMs can also be used at individual patient level in routine clinical practice. PROMs can aid clinicians' provision of care for patients, by presenting patients' views of their health. This can complement the traditional methods of medical history testing and physical examination. PROMs used in individualised clinical practice can be used to: 1) screen for health problems, 2) monitor health or disease progression, 3) select appropriate treatments, and 4) monitor

treatment outcomes (Gilbody, House, & Sheldon, 2002; Greenhalgh & Meadows, 1999; Nelson & Berwick, 1989).

1.2.2 Policy development on PROMs in clinical practice

In a report on health technology appraisals, the National Institute for Clinical Excellence (2004) stated that the collection of patient views may enable realistic interpretations of the evidence during the appraisal of medical, surgical and therapeutic technologies, diagnostic techniques, pharmaceuticals and health promotion activities. These data were suggested to provide an insight into the effectiveness, appropriateness, and acceptability of the technology, alongside the impact of a health technology on patients' physical or psychological symptoms, disability, functioning, and overall quality of life.

Appleby and Devlin (2005) reviewed the use of PROMs (measuring HRQoL), and considered the benefits, costs, practicalities, potential uses, and implications. Their King's Fund report acknowledged a shift from measuring healthcare to examining quality and performance from the patient's perspective, recognising that patients' views are vital to their care. Within the NHS, routine measurement has two main uses: to provide information on health of patients and any health gains from treatment, and in allocating resources, priority setting, and future planning of the NHS. The report concluded that further research is needed to decide which HRQoL measures are appropriate, how and when data should be collected and presented, and to understand cost implications.

An NHS report in 2008 highlighted the importance of using PROMs to measure patients' perspectives of effectiveness of care (Department of Health, 2008). In 2009, a new Standard NHS Contract for Acute Services was introduced, with all licensed providers of unilateral hip replacements, unilateral knee replacements, groin hernia surgery, or varicose vein surgery funded by the NHS expected to invite patients to complete pre-operative and post-operative generic and disease-specific PROMs (Greenhalgh et al., 2017). Thus, from origins in clinical research, by 2009, PROMs were used in routine clinical practice in parts of the NHS. Reflections on this programme suggested further improvements are needed to utilise PROMs within the NHS, including choosing appropriate PROMs, improving efficiency of data collection, and clarity on data interpretation and utilisation (Kyte et al., 2016).

1.2.3 Evidence on using PROMs in clinical practice

Since their development, PROMs have been theorised to have an impact on patient outcomes. Research has been conducted to identify the impact of PROMs when used in clinical practice, and assess their effectiveness within this context, with mixed results.

An early review, conducted by Greenhalgh and Meadows (1999), acknowledged that, despite the increasing use of PROMs with individual patients in clinical practice, there had been little attempt to review studies assessing the effectiveness of using PROMs. Their review examined randomised-controlled trials (RCTs) exploring the use of PROMs in routine clinical practice. The authors found a limited amount of evidence suggesting that using PROMs may influence the detection of psychological problems and facilitate communication between clinicians and patients (Greenhalgh & Meadows, 1999).

Several reviews have since been conducted assessing the impact of using PROMs in clinical practice. Espallargues, Valderas, and Alonso (2000) conducted a systematic review assessing the effectiveness of providing feedback on PROMs to clinicians. The study examined 21 RCTs which provided patients' health status to clinicians. The review concluded that the impact of providing feedback on PROMs to clinicians was unclear, but their use may modify elements of healthcare provision through increased diagnosis of conditions and use of health services (Espallargues et al., 2000).

Reviews have also focused on specific healthcare settings or conditions. Many empirical studies have focused on oncology and the impact of adopting PROMs for patients, clinicians, and healthcare organisations. One review examined if PROMs in active anti-cancer treatment was associated with patient outcomes, health service outcomes, and processes of care (Kotronoulas et al., 2014). Use of PROMs in oncology settings was found to be associated with increased supportive care, improved symptom control, and patient satisfaction (Kotronoulas et al., 2014). However, there was limited significant findings, with small effect sizes, and authors concluded that additional research was needed.

Another area of interest has been the use of PROMs within psychiatric settings. Gilbody et al. (2002) conducted a review assessing how measuring HRQoL could improve the quality of care in psychiatric and non-psychiatric settings for those with common mental disorders. RCTs and quasi-randomised trials were included in the review and results pooled using a random effects

model. The study concluded there was limited evidence to support the use of PROMs in clinical practice in these settings, with no overall difference in treatment outcome and limited evidence suggesting improvement in patient satisfaction (Gilbody et al., 2002).

Further reviews examined the usefulness of providing group-level feedback of PROMs to clinicians (Boyce & Browne, 2013). Studies were included if patients, clinicians, or groups of clinicians received PROM feedback. The authors stated that the 17 included studies were generally of poor quality; some studies did not provide a sample size calculation or effectively deal with contamination between groups. Despite the methodological limitations of the included research, the synthesis found a weak amount of evidence suggesting that PROMs had a positive impact on patient outcomes (Boyce & Browne, 2013). A realist review also examined if aggregate PROM data leads to improvements in patient care (Greenhalgh et al., 2017). Results from 75 papers suggested that reporting PROM data publicly places pressure on providers to act and improve patient care. However, providers needed clinically relevant and specific PROMs, and support and guidance from their organisation to make quality improvement to their services.

A qualitative review used thematic analysis to explore 16 studies on clinicians' experiences of using PROMs (Boyce et al., 2014a). The analysis raised issues on the practicalities of collecting data, clinicians' values of PROM data, and how clinicians made sense of the information provided. One finding stated that some clinicians viewed PROMs to have the potential to impact the processes of care, such as influencing communication, shared decision-making, and planning care (Boyce et al., 2014a). A realist review examined the use of PROMs with individual patients to identify if PROMs supported patients raising concerns and clinicians' awareness of concerns (Greenhalgh et al., 2017). The review of 39 papers identified that PROMs influenced the exchange of information, treatment decisions, and the patient-clinician relationship. This was dependent on the setting and the PROMs used, with PROMs both constraining and supporting patients' discussions with clinicians.

1.3 Research aims

Literature suggests that PROMs may impact clinically and psychologically on patients when used in clinical practice. However, important questions remain about the consequences of PROMs, for patients, clinicians, and their interactions. Despite several commentaries on employing PROMs in practice (Calvert, Kyte, Price, Valderas, & Hjollund, 2019; Porter et al., 2016), the evidence base evaluating PROMs in routine clinical practice is relatively limited with an underdeveloped theoretical basis for their use.

Greenhalgh et al. (2017) identified that not all patients benefit from PROMs completion, with further research required to understand which healthcare services PROMs should be incorporated into and how this may impact patients. For example, PROMs are increasingly being used within the treatment of musculoskeletal pain (Fawkes, 2017; McAuley et al., 2014; Newell, Diment, & Bolton, 2016) with specific guidance published on using PROMs within musculoskeletal healthcare (Gagnier, 2017; Lizzio, Dekhne, & Makhni, 2019; Wahl & Yazdany, 2016). However, there has been very little published research on using PROMs in the context of low back pain. By examining the theoretical and clinical aspects of PROMs within the context of low back pain, this thesis contributes to the current agenda to explore and improve the effectiveness and delivery of existing therapies. The following research question was proposed: does PROM use in specialist musculoskeletal care affect patients with low back pain and ,if so, through what mechanisms?

To answer this question, a series of studies were proposed. The objectives of this research were to:

1. Identify and critically appraise empirical evidence on the effects of PROMs for non-malignant pain to improve current understanding of the effects of using PROMs within routine clinical practice.
2. Identify theories and underlying mechanisms supporting the use of PROMs within clinical practice to develop a conceptual theoretical framework underpinning the use of PROMs within musculoskeletal healthcare settings.
3. Evaluate the role PROMs play in clinical practice through identifying the clinical and psychosocial effects of utilising different frequencies of PROMs in routine treatment of low back pain.

4. Evaluate the proposed model of PROMs mechanisms of action by identifying the processes by which change occurs and identifying the moderators of how PROMs may work in clinical practice.
5. Analyse patients' subjective accounts of their experiences of completing PROMs, to develop an understanding of clinical and psychosocial impact it may have on patients with low back pain and the processes involved in producing these effects.
6. Explore practitioners' experiences and views of using PROMs within their clinical practice to improve the current understanding of the role PROM collection plays in the treatment of low back pain.

1.3.1 Thesis outline

Chapter 2 defines low back pain, highlighting the prevalence and the physical and psychosocial impact of pain. This chapter also explores current guidelines on treatment, including why this research is taking place within the context of low back pain, and how this research will contribute to the current agenda to improve the effectiveness of treatment delivery.

Chapter 3 presents the methodology of the overall research, describing the phases of developing and evaluating a complex intervention. This includes discussion and debates over the methods of evaluating a complex intervention and how they have been utilised in the empirical components of this thesis.

Chapter 4 explores the clinical context for using PROMs within routine clinical practice of non-malignant pain. A systematic literature review examines the existing empirical evidence surrounding the effects of PROMs within this context (Objective 1). This literature provides insight into the clinical and psychosocial impact PROMs may have when being used within routine clinical practice.

Chapter 5 presents key psychological theories and a realist review synthesising the existing non-empirical evidence surrounding using PROMs in routine clinical practice. This literature provides insight into the potential processes through which PROMs might influence health outcomes. Through this review, a theoretical framework is presented which depicts the various components of using PROMs, the potential outcomes, mechanisms, and parameters (Objective 2).

In **Chapter 6**, a feasibility study is reported which examines the achievability of studying the effects of PROMs for low back pain patients within a specialist musculoskeletal settings. This feasibility study explores patients' and practitioners' experiences of taking part in a trial, assesses recruitment and retention rates and patients' acceptance of randomisation to treatment, and evaluates the acceptability of completing outcome measures and the appropriateness and usability of measurement tools.

Chapter 7 presents a cluster RCT, which evaluates the effects of utilising different frequencies of PROMs in routine chiropractic treatment of back pain (Objective 3). Within this trial, patients are randomised to complete PROMs at various stages during their treatment. Statistical analysis is used to show any clinical and psychosocial effects.

Chapter 8 is concerned with the mechanisms of action of using PROMs. Using the theoretical framework discussed in Chapter 5, psychological mediators were measured in the RCT to capture effects of varied PROM collection in specialist care for low back pain. Correlations, regressions, and moderation and mediation analyses are used to explore any clinical and psychosocial effects of PROMs in clinical practice (Objective 4).

Chapter 9 reports a qualitative study exploring a subset of patients' and chiropractors' experiences of completing PROMs. Semi-structured telephone interviews were conducted with participants of the RCT reported in Chapter 7. Thematic analysis was used to explore how PROMs may have an effect when used in the treatment of low back pain (Objectives 5 and 6).

In **Chapter 10** a process evaluation embedded within the RCT is reported. The qualitative data from Chapter 9 is examined in combination with the results of the RCT and statistical analysis presented in Chapter 7 and 8, providing two different perspectives and enhancing the interpretation of the data collected.

Chapter 11 considers the results of the empirical research, summarising and integrating findings and considering the results with reference to other literature in the field. This final chapter evaluates the methodological quality of the research, identifying strengths and limitations. The implications of these results are considered and recommendations for further research made. The chapter concludes with the contribution this research can make in understanding the role PROMs play within routine treatment of low back pain.

Chapter 2 PROMs in context: low back pain and specialist musculoskeletal care

2.1 Introduction

Low back pain is a major problem worldwide (Clark & Horton, 2018). Buchbinder et al. (2018) published a call for action to address the growing global burden of low back pain and promote effective strategies for the management of low back pain. PROMs are widely available and routinely used in the care of low back pain, with little understanding of the clinical impact of their use. To develop appropriate and applicable research in this area it is necessary to understand the theoretical and practical context of low back pain. This chapter provides a contextual framework for study design and by which the findings and implications may be considered. Firstly, a definition, prevalence and aetiology of low back pain are specified. The subsequent sections discuss the impact of low back pain and current recommendations for treatment. The final section outlines PROMs use within clinical practice for low back pain.

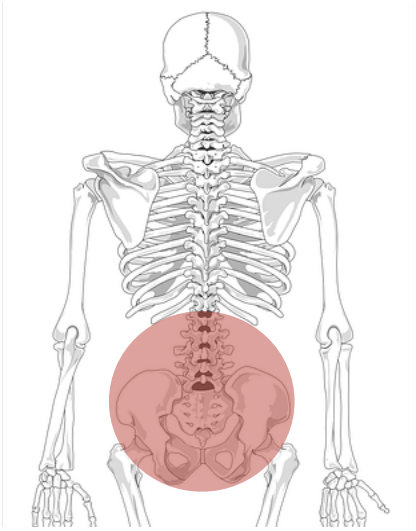


Figure 2.1 – Defined area of low back pain

2.2 Back Pain

2.2.1 Definition of back pain

Low back pain is pain, stiffness, or muscle tension between the margins of the lower ribs and the inferior gluteal folds (see Figure 2.1) (Chou, 2010; Hartvigsen et al., 2018). Low back pain is often described as either 'acute' or 'chronic', based on duration of symptoms, which vary from short lasting with little or no consequence to recurrent and long lasting. The varied nature of low back pain presentations makes it difficult to define. One commonly used definition specifies low back pain must be experienced for a minimum duration of one day, and may present with referred pain to one or both lower limbs (Hoy et al., 2014; Hoy et al., 2010). However, in a systematic review on the prevalence of low back pain, a small number of studies specified that pain must limit activity (Hoy et al., 2012).

2.2.2 Prevalence of back pain

Most adults will experience low back pain at some point during their lifetime. Globally, low back pain is the number one cause of disability (Buchbinder, Underwood, Hartvigsen, & Maher, 2020; Hartvigsen et al., 2018; Vos et al., 2015). In 2015, the prevalence was 7.3% within the global population, resulting in 540 million people worldwide being affected by low back pain at any given time (Hartvigsen et al., 2018). Within the U.K, low back pain is the leading cause of years living with disability (Vos et al., 2015), affecting a third of the population each year; over 80% of the U.K population are affected by low back pain at some point during their lifetime (Chou, 2010; da Silva et al., 2017; Hartvigsen et al., 2018; National Collaborating Centre for Primary Care, 2009; Palmer, Walsh, Bendall, Cooper, & Coggon, 2000; Vos et al., 2015).

2.2.3 Aetiology of back pain

Low back pain can result from several pathological causes, such as: vertebral fracture, axial spondyloarthritis, metastatic cancer, and spinal infections (Hartvigsen et al., 2018). However, many individuals who present to healthcare professionals with low back pain are classified as having non-specific low back pain (Maher, Underwood, & Buchbinder, 2017). Non-specific low back pain is pain where the specific nociceptive source cannot be identified and

therefore cannot be attributed to a recognisable pathology (Chou, 2010; Hartvigsen et al., 2018).

Non-specific low back pain is thought to be an episodic condition, with those experiencing low back pain likely to experience symptoms in the future (Kongsted, Kent, Axen, Downie, & Dunn, 2016). In a systematic review examining recurrence of low back pain, the best evidence suggests that 33% of individuals will experience a recurrence of low back pain within one year of a previous episode (da Silva et al., 2017). Research on low back pain trajectories suggests that few patients will develop severe chronic pain or experience a rapid recovery (Kongsted et al., 2016); most patients will have fluctuating or persistent pain of low or medium intensity. Several factors contribute to disability, although the mechanisms are not fully understood (see Figure 2.2). Additionally, patients with low back pain frequently have pain in multiple body sites, for example neck, hip, or knee (Hartvigsen, Natvig, & Ferreira, 2013). Pain in multiple locations is associated with reduced mental and physical functioning, with patients having a lessened treatment response, with increased risk of disability (Hartvigsen et al., 2013).

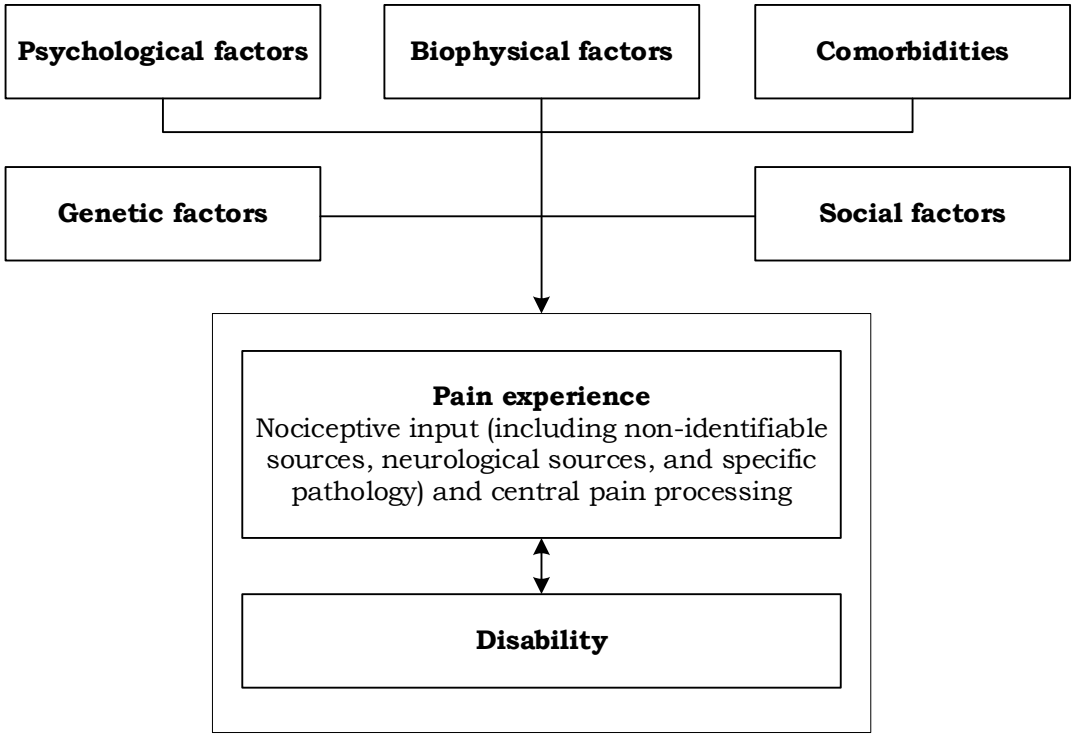


Figure 2.2 – Factors contributing to low back pain and disability

Adapted from Hartvigsen et al. (2018)

The biopsychosocial model provides a contextual framework to understand the multidimensional nature of low back pain (Lall & Restrepo, 2017; Weiner, 2008). The model is founded on the concept that biological, psychological, and social factors are an inherent part of patients' experience of pain (see Figure 2.3) (Waddell, 1987). According to the model, the development, experience, and management of low back pain encompasses a variety of factors, such as neurophysiology and pain processing, illness beliefs and coping strategies, and sociocultural factors. The biopsychosocial model is a useful framework to help understand the multiple factors that play a role in the aetiology, prognosis, and treatment for low back pain. Although the model emphasises the potential relationship between factors, it does not explain their interactions, and how they may predict and moderate outcomes (Pincus et al., 2013).

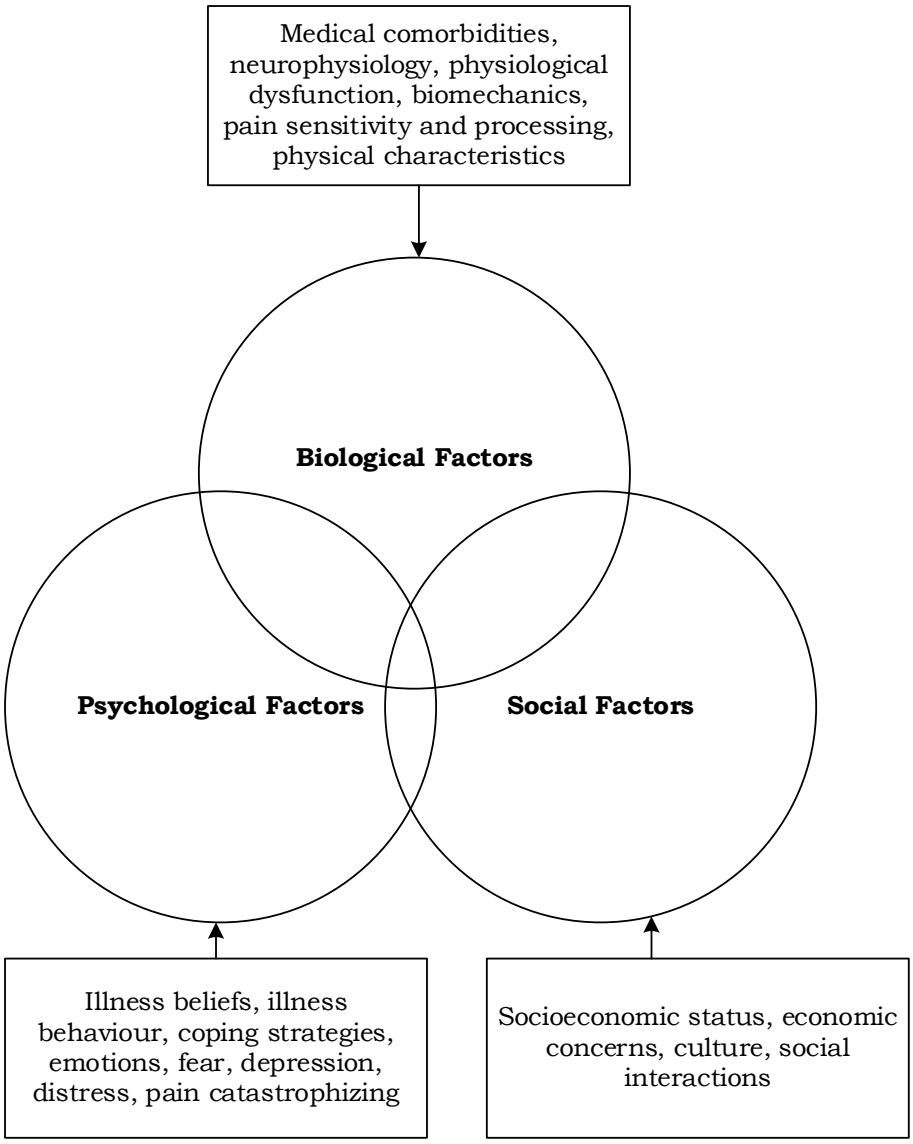


Figure 2.3 – Biopsychosocial model of low back pain

Adapted from Farrokhi et al. (2017); Lall and Restrepo (2017); Rolli Salathé and Elfering (2013)

2.3 Impact of back pain

2.3.1 Biopsychosocial impact of back pain

Several qualitative systematic reviews have explored the experience of living with low back pain. Patients with low back pain describe the sensation as ever-present or as an impending threat, that is persistent and disruptive to daily functioning (MacNeela, Doyle, O'Gorman, Ruane, & McGuire, 2015; Snelgrove & Liossi, 2013). The pain is seen as debilitating, undermining individuals' ability to undertake daily activities, including domestic chores, recreational and leisure activities, parenting, and driving (Froud et al., 2014; MacNeela et al., 2015).

In a meta-synthesis of qualitative research Snelgrove and Liossi (2013) identified that patients can find their pain distressing; patients have concerns about the future, with worries about further damage or the pain increasing. Patients can experience feelings of hopelessness, anger, and depression. The undermining of their ability to conduct daily activities can also be frustrating and distressing for patients (MacNeela et al., 2015). Furthermore, psychological factors such as anxiety, depression, fear of pain, and distress are associated with increased risk of disability (Hartvigsen et al., 2018).

Additionally, if patients with low back pain avoid social activities, this can negatively impact their relationships (Froud et al., 2014). Although patients acknowledge a need for emotional support, a withdrawal from activities can lead to social isolation from peers and their own families (Froud et al., 2014; MacNeela et al., 2015; Snelgrove & Liossi, 2013). Some patients feel that their spousal relationships suffer due to dependence on their partner, and absence of sexual activity (Froud et al., 2014; MacNeela et al., 2015). Due to the activity limitation and disabling nature of low back pain, patients describe feeling like a burden on others, especially their partners or close relatives (Snelgrove & Liossi, 2013).

2.3.2 Economic impact of back pain

There is a significant financial burden associated with low back pain. There are direct costs of healthcare for the individual patient, with additional surrounding costs, such as transportation to appointments, physical therapy, medication, and the additional costs of self-management (Bevan, 2015; Hartvigsen et al., 2018). People with low back pain also experience a need to modify tasks at work, and because of their ability to conduct work-related activities are concerned about the loss of employment (Froud et al., 2014). In Europe, low back pain is the most common cause of sick leave and early retirement (Bevan et al., 2009). The loss of work or inability to work has significant financial impact on patients (MacNeela et al., 2015). People with low back pain are less wealthy than those without the condition (Schofield et al., 2015), although the relationship between low back pain and wealth is bidirectional. Individuals with low back pain may have reduced ability to work or take early retirement (Schofield, Shrestha, Passey, Earnest, & Fletcher, 2008), impacting on income and wealth (Schofield et al., 2011). However, those with lower paid jobs, may be at more risk of developing low back pain, for example, manual labour workers have increased risk of low back pain compared to those in managerial positions (Schneider, Lipinski, & Schiltenwolf, 2006).

Low back pain also affects the U.K economy due to treatment costs, work absenteeism, and productivity loss (Hartvigsen et al., 2018). The estimated costs for the care of patients with low back pain is approximately £1 billion per year within the NHS, with private sector costs being another £500 million (National Institute for Health and Clinical Excellence, 2009). Additionally, with a significant number of individuals unable to work due to their back pain, this leads to increased employee absenteeism and substantially impacts on U.K production, estimated to cost over £10 billion per year (Maniadakis & Gray, 2000). With no recent studies on the economic impact of back pain, these estimates are now outdated; accounting for inflation and rising prevalence of back pain, the impact of back pain on the U.K economy is likely to be even higher.

2.4 Measurement of low back pain

2.4.1 Measuring low back pain

As non-specific low back pain has no known pathological cause, it is difficult to measure with biological measurements. Some objective measurements of pain used in clinical practice include pain diagrams, joint tenderness, and quantitative sensory testing. In clinical practice, patients may be asked to complete a pain location diagram, noting the area of their pain on a drawing. However, there is little high-quality evidence to support their use to assess pain (Salaffi, Sarzi-Puttini, & Atzeni, 2015). Clinicians may also assess the tenderness of joints as an objective measure in comparison to self-report. However, clinicians face difficulties in standardising this assessment (MacKichan, Wylde, & Dieppe, 2008). Quantitative sensory testing can be used to evaluate patients' response to pain, diagnosing differences in pain perceptions and pain thresholds between patients with pain and healthy controls. Those with pain can demonstrate reduced pain thresholds, however, experimental pain through sensory testing may result in different reactions to clinical pain (MacKichan et al., 2008). There is often a demand from patients to be referred for imaging of their back (for example, x-rays and magnetic resonance imaging) to receive a formal diagnosis (Buchbinder et al., 2020). However, imaging does not reflect pain and is not always appropriate, as it can be harmful, ineffective, and inefficient, by inappropriately attributing findings to a cause of pain, with high cost for little benefit (Buchbinder et al., 2020; Buchbinder et al., 2018). It is not recommended to routinely offer imaging for non-specific low back pain, with little clinical benefit in primary care settings (National Institute for Health Care Excellence, 2016).

As pain is inherently subjective, PROMs are a meaningful and valid tool to measure a patient's pain in the context of low back pain (MacKichan et al., 2008; Stamm et al., 2019). PROMs need to be relevant and meaningful to patients and clinicians when measuring low back pain and should be based on the concepts within the biopsychosocial model (Weiner, 2008). Deyo et al. (1998) proposed a core set of outcomes relevant for patients with low back pain including: symptoms, functioning, wellbeing, disability, social impact, and satisfaction with care. Despite these recommendations being frequently cited, the authors did not take patients' views into account. Even when updating their recommendations, only 15 patients participated in reaching a consensus for core outcomes for back

pain patients, compared to 280 participating experts made up of researchers and clinicians (Chiarotto et al., 2015). Whilst the updated recommendations included physical functioning, pain intensity, and HRQoL, other core domains relevant to patients, which included self-rated health and psychological functioning were not included in the recommendations (Chiarotto et al., 2015). Additionally, these core outcomes are recommended for research purposes within clinical trials and have not been explored for their use within clinical practice. Clinicians using PROMs into their practice for patients with back pain should ensure they capture dimensions that are important for patients.

2.4.2 PROMs for low back pain

Many PROMs have been developed for use with low back pain patients, assessing different components of pain, including pain severity and quality, or disability and distress (MacKichan et al., 2008). For example, Longo, Loppini, Denaro, Maffulli, and Denaro (2010) identified 28 measures for rating functional status in patients with low back pain. However, a review to identify disease-specific questionnaires for low back pain identified 15 questionnaires (Wang et al., 2012). The content of these PROMs were assessed in comparison to the International Classification of Functioning, Disability and Health. The questionnaires used a combination of classification components including body function (e.g. sensation of pain), body structure (e.g. structure of lower extremity), activity and participation (e.g. carrying out a daily routine), and environmental factors (e.g. support and relationships) (Wang et al., 2012).

Other reviews have evaluated the measurement properties of PROMs (Cleland, Gillani, Bienen, & Sadosky, 2011; Grotle, Brox, & Vøllestad, 2005). A systematic review by Grotle et al. (2005) evaluated 28 unique functional and disability questionnaires for back pain. Although some PROMs had been evaluated considering their internal consistency, test-test reliability, validity and responsiveness, some PROMs still had properties yet to be examined. An update of this review explicitly explored the responsiveness of outcome measures for patients with low back pain (Cleland et al., 2011). The study identified 40 PROMs, with two clinician assessment measures and one evaluating performance. Of the 43 total outcome measures, 31 were evaluated for responsiveness, and only 25 had been evaluated appropriately. Out of these, 13 measures demonstrated good responsiveness and good factor structure (Cleland et al., 2011).

These findings are also reflective of PROMs for chronic back pain. In a review examining 354 RCTs, 46 common outcome measures were identified to measure treatment effectiveness of chronic back pain, these included measures of functioning, psychosocial factors, QoL, and pain severity (Chapman et al., 2011). Although some measures were found to be reliable and valid (e.g. Oswestry Disability Index) others had no testing of reliability and validity (e.g. Numeric Pain Rating Scale). Some measures were also found to be responsive to change (e.g. Roland-Morris Disability Questionnaire) whereas others had limited data on responsiveness (e.g. Pain Disability Index).

The reviews found a range of 15-46 measures with varying content and responsiveness. Some common PROMs identified and evaluated across the reviews, which were found to be valid, reliable, and responsive were the Oswestry Disability Index (Fairbank & Pynsent, 2000), the Roland Morris Disability Questionnaire (Roland & Morris, 1983), Waddell Disability Index (Waddell & Main, 1984), Quebec Back Pain Disability Scale (Kopec et al., 1995), and the Bournemouth Questionnaire (Bolton & Breen, 1999). These are summarised in Table 2.1.

Table 2.1 – Summary of common PROMS for low back pain

Adapted from: Chapman et al. (2011); Cleland et al. (2011); Grotle et al. (2005); Longo et al. (2010); Wang et al. (2012).

PROM	Domains	Items	Scale	Scoring
Oswestry Disability Index	Body functions, activity and participation, environmental factors	10	6-ordinal	Percentage (0-100)
Quebec Back Pain Disability Index	Body functions, activity and participation	20	0-10 numerical	Mean (0-10)
Roland-Morris Disability Questionnaire	Body functions, activity and participation, environmental factors	24	2 options (yes/no)	Sum (0-24)
Bournemouth Questionnaire	Body functions, activity and participation	7	0-10 numerical	Mean 0-10
Waddell Disability Index	Body functions, activity and participation, environmental factors	9	2 options (yes/no)	Sum (0-9)

2.5 Treatment of back pain

2.5.1 Treatment recommendations

Due to the complex impact of back pain, and the unknown pathological cause of non-specific back pain, there are a multitude of pain management treatments (Maher et al., 2017). Before beginning treatment, patients with low back pain should be assessed for specific causes, including vertebral fractures, axial spondylitis, suspected cancer, and spinal infections (Hartvigsen et al., 2013; National Institute for Health Care Excellence, 2016).

As non-specific low back pain is thought to be episodic, treatment focuses on reducing pain, lessening the impact and associated disability, rather than on a cure (Maher et al., 2017). A review of clinical guidelines identified that recommendations for acute pain included: reassurance, advice, and prescription of pain-management medication if necessary (Koes et al., 2010). Recommendations for chronic pain included short-term use of medication or manipulation, supervised exercise, and cognitive behavioural therapy. More recently, a comparison of recommendations from U.K, U.S, and Danish guidelines, found that guidelines encourage moving away from a pharmacological approach to a more biopsychosocial model for the assessment, treatment, and ongoing management of low back pain (Maher et al., 2017). This reflects evidence suggesting that a pharmacological approach is not clinically effective for back pain (National Institute for Health Care Excellence, 2016). For example, opioids and gabapentinoids show no clinically important benefits for pain relief, with significant increased risk of adverse effects, and there is no clinical benefit of paracetamol (National Institute for Health Care Excellence, 2016). However, the recommendation to prioritise non-pharmacological approaches is not reflected in clinical practice, with patients still being prescribed opioids and gabapentinoids in the U.K, U.S, Canada, and Australia (Buchbinder et al., 2020).

Consistent across guidelines, the first-line of treatment is education about low back pain and advice to stay active (Maher et al., 2017), with recommendations for second-line treatment or complementary treatment of non-pharmacological approaches (such as spinal manipulation and massage). In accordance with guidelines, a review exploring the use of Complementary and Alternative Medicines (CAM) for back pain found that acupuncture, chiropractic, osteopathy, and massage therapy were the most common treatments used by patients with low back pain (Murthy, Sibbritt, & Adams, 2015). Additionally, for

individuals with persistent low back pain, exercise therapy and psychological therapies (such as cognitive behavioural therapy) are advised. Pharmacological treatment should only be used if there is an inadequate change in pain following non-pharmacological treatments (Maher et al., 2017).

Risk stratification using the STarT Back Tool is also recommended by the National Institute for Health Care Excellence (2016) guideline to aid clinical decision-making about the management of low back pain. The STarT Back Tool was developed from screening back pain indicators, including impact on walking and dressing, distress, bothersomeness of pain, and co-occuring pain in legs, shoulders, and neck (Hill et al., 2008). The STarT Back Tool has nine questions, with five questions making up a psychosocial subscale (examining fear, anxiety, catastrophising, depression, and bothersomeness of pain). The STarT Back Tool categorises patients at risk for developing persisting back pain with disability. Those with an overall score of three or less are categorised as low risk of chronicity. For patients with an overall score of four or above, the psychosocial subscale is then used to categorise patients into medium risk of chronicity (score ≤3 on the subscale) or high risk of chronicity (score ≥4 on the subscale). For patients categorised as low risk, simple support including reassurance, education, and advice to keep active is recommended (National Institute for Health Care Excellence, 2016). For those at higher risk of disability, exercise, manual therapy, and psychological support are suggested.

2.5.2 Specialist musculoskeletal care for back pain

One recommendation by the National Institute for Health Care Excellence (2016) is the use of manual therapy for low back pain, this is defined as 'spinal manipulation, mobilisation or soft tissue techniques such as massage' offered as a part of a treatment package which includes exercise. Manual therapy can include techniques such as massage of muscles, ligaments, and fascia, the articulation of joints, and high-velocity, low-amplitude thrusting techniques aiming to create cavitation of a synovial joint (Harvey, Burton, Moffett, Breen, & UK BEAM Trial Team, 2003). Manual therapy can be delivered by chiropractors, osteopaths, and physiotherapists. General practitioners will commonly refer to physiotherapists, however patients can self-refer to other practitioners (Harvey et al., 2003). The clinical provision of manual therapy within the NHS is also reflective of local commissioning, which may include referrals to chiropractors (National Health Service, 2020).

Chiropractic care

Chiropractic is a statutorily-regulated profession which is defined as: "*A health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health. There is an emphasis on manual treatments including spinal adjustment and other joint and soft-tissue manipulation.*" (World Federation of Chiropractic, 2001). As of March 2020, there were 3356 registered chiropractors in the U.K (Professional Standards Authority for Health and Social Care, 2020).

Chiropractors identify as spinal health experts, focusing on improving function in the neuromuscular system and overall health and wellbeing of patients (Carey, Clum, & Dixon, 2005). Chiropractors are trained to assess and manage a range of musculoskeletal conditions, including low back pain, with specialist training on biopsychosocial clinical assessment and diagnostic testing (Carey et al., 2005; Royal College of Chiropractors, 2015). Chiropractors are qualified to deliver a package of care, including pain education, self-management advice, manipulation and manual therapy treatments, and tailored exercise recommendations (Royal College of Chiropractors, 2015).

There is no systematic reporting on utilisation of chiropractic care in the U.K. Two systematic reviews have found similar utilisation rates for chiropractic care internationally, reporting 6% to 12% (Lawrence & Meeker, 2007) and 9.1% (Beliveau et al., 2017) of the population seeking chiropractic care. A review focused on CAM utilisation in Europe, found that the prevalence of chiropractic utilisation varied widely across countries (0.4% to 28.8%) (Eardley et al., 2012). This variation across countries is further highlighted by other reviews, which found prevalence of chiropractic utilisation to be higher in the U.S (3.3% to 10.9%), Canada (1.4% – 11.0%) and Australia (15.0% to 16.7%) than the U.K (1.6% to 2.2%) (Cooper, Harris, Relton, & Thomas, 2013). A more recent survey on population figures for CAM use in England, found that 766 respondents (16%) had used CAM in the past year, with 11% of those receiving chiropractic care (Sharp et al., 2018). The most common reason for seeking CAM treatment was for the treatment of musculoskeletal conditions (68%), with 38% citing back pain as a reason for seeking care. This is reflected in a review of international chiropractic utilisation, with low back pain or back conditions being the most common reason for attending chiropractic care (49.7% of patients) (Beliveau et al., 2017).

Effectiveness of chiropractic care

Chiropractic care can be difficult to evaluate, with chiropractors providing a package of care with multiple treatment modalities. There is limited research exploring the effectiveness of chiropractic care as a package of care. One review examined the effects of combined chiropractic treatments on pain, disability, and functioning for patients with low back pain (Walker, French, Grant, & Green, 2010). The review included 12 RCTs with combined chiropractic interventions (as opposed to spinal manipulation alone) and concluded that chiropractic care provided short-term and medium-term pain relief and reduced disability for patients with acute back pain. Another review included pragmatic trials which compared chiropractic care (with combinations of treatment) to standard care (Blanchette et al., 2016). Five studies were included in the review comparing chiropractic care to physical therapy (three studies), exercise therapy (one study), and medical care (one study). Chiropractic care was suggested to be as effective as physical therapy for pain relief, functional status, global improvement, and HRQoL. However, no definitive conclusions could be drawn for comparisons to exercise therapy and medical care (Blanchette et al., 2016). Both reviews made recommendations for further research into the effectiveness of chiropractic care (Blanchette et al., 2016; Walker et al., 2010).

The most common component of chiropractic care is spinal manipulation. Several studies have shown spinal manipulation as effective for patients with low back pain. The UK BEAM trial examined the effectiveness of manipulation (provided by chiropractors, osteopaths, and physiotherapists), compared to general care, exercise, or manipulation with exercise for patients with back pain (UK BEAM Trial Team, 2004). Patients receiving manipulation had a significant improvement in back pain-related disability scores at three months and at one year and those receiving manipulation with exercise also had significant improvements at these time points. Further, spinal manipulation was found to be a cost-effective addition to general practice (UK BEAM Trial Team, 2004).

The findings of multiple RCTs exploring spinal manipulation have been included in several systematic reviews (Assendelft, Morton, Emily, Suttorp, & Shekelle, 2004; Bronfort, Haas, Evans, & Bouter, 2004; Cherkin, Sherman, Deyo, & Shekelle, 2003). A large systematic review by Bronfort, Haas, Evans, Leininger, and Triano (2010) examined the effectiveness of manual therapies for a range of musculoskeletal and non-musculoskeletal conditions. Summarising over 70 RCTs, spinal manipulation and mobilisation, and massage, was found to be

effective for acute and chronic low back pain (Bronfort et al., 2010). An updated review of this work conducted in 2013, found two additional RCTs to support chiropractic manipulation for the treatment and management of low back pain (Clar, Tsertsvadze, Hundt, Clarke, & Sutcliffe, 2014). However, in comparison to other treatments, there is low quality evidence that spinal manipulation is clinically more effective than other treatments in treating both chronic back pain (Rubinstein et al., 2019; Rubinstein, van Middelkoop, Assendelft, de Boer, & van Tulder, 2011) and acute back pain (Rubinstein, Terwee, Assendelft, de Boer, & van Tulder, 2013).

Within the U.K low back pain guidelines, it is noted that manual therapy may have possible serious adverse events, although these are rare, with only minor and temporary side-effects reported in reviewed studies (National Institute for Health Care Excellence, 2016). These findings on adverse events are similarly reflected in two systematic reviews exploring manipulation for chronic low back pain. In a review on mobilisation and manipulation, eight out of 51 studies reported minor adverse events (Coulter et al., 2018). One included study reported serious adverse events in 2% of participants, however, this was deemed not to be resulting from treatment. In another review, 14 out of 47 RCTs exploring spinal manipulative therapy for chronic low back pain reported adverse events (Rubinstein et al., 2019). The majority of adverse events were seen as minor and transient (e.g. muscle stiffness, increased pain, and tiredness). In two included studies, serious adverse events were reported, but were noted as not related to the study intervention (Rubinstein et al., 2019). However, studies may not have reported or systematically registered adverse events, making the incidence of adverse events unreliable (Coulter et al., 2018; Rubinstein et al., 2019). Additionally, these reviews specifically explored manipulation, rather than chiropractic as a package of care.

Despite a lack of conclusive research on the effectiveness and safety of chiropractic care for low back pain, individually, components of chiropractic care (pain education and self-management advice, tailored exercise, and manual therapy) are found to be effective and recommended within the U.K clinical guidelines for the treatment of low back pain (National Institute for Health Care Excellence, 2016).

2.6 PROM use in specialist musculoskeletal settings

PROMs are used within the treatment of pain within specialist musculoskeletal settings, by physiotherapists, chiropractors, and osteopaths (Fawkes, 2017; McAuley et al., 2014; Newell et al., 2016). The use of PROMs has increasingly been incorporated into routine chiropractic practice (Clohesy & Schneiders, 2018; Hinton, McLeod, Broker, & MacLellan, 2010; Newell et al., 2016). It is important for chiropractors to be able to measure low back pain, as it is a common problem amongst patients visiting chiropractic clinics.

The PROMs commonly used in chiropractic practice include functional measures, such as: the Bournemouth Questionnaire (Bolton & Breen, 1999), Oswestry Disability Index (Fairbank & Pynsent, 2000), Quebec Back Pain Disability Scale (Kopec et al., 1995), Roland-Morris Questionnaire (Roland & Morris, 1983), and Waddell Disability Index (Waddell & Main, 1984). Chiropractors also use pain-specific measures, such as numerical rating scales (Jensen, Turner, & Romano, 1994) and visual analogue scales (Price, McGrath, Rafii, & Buckingham, 1983). Generic PROMs, such as the Patient Global Impression of Change Scale (Dworkin et al., 2005) and the Short-Form 36 survey (Jenkinson et al., 1993), are also used with patients.

Although previous research has been conducted to review PROMs for low back pain, there is little consensus on which PROMs should be used in practice. There are currently are no guidelines or standards for which PROMs are appropriate for use in routine clinical practice by chiropractors.

2.7 Chapter summary

This chapter highlighted the global problem of low back pain. In the UK alone, low back pain affects a third of the population each year; with over 80% of the population being affected at some point during their lifetime. Although low back pain can result from several different causes, individuals are often classified as having non-specific low back pain. Low back pain can have a significant impact on individuals and there are a multitude of treatments available, including chiropractic care. PROMs are widely available and routinely used in the care of low back pain and within chiropractic clinical practice, with limited understanding of their clinical impact. The research within this thesis aims to establish if PROMs in clinical practice affect patients with low back pain. This overview of low back pain provides an understanding of the context of the research aims, informing the methodology of the programme of research (Chapter 3) and discussion of the research implications (Chapter 11).

Chapter 3 Methodological approach to exploring PROMs as a complex intervention

3.1 Introduction

This chapter presents an outline of complex interventions and introduces the methodological paradigm chosen to address the research question and aims proposed in Chapter 1. The chapter highlights the philosophical considerations that underpin this research. Lastly, this chapter considers methods of data collection and discusses how multiple methods will be utilised in this programme of research.

3.2 Complex interventions

3.2.1 Development and evaluation of PROMs as an intervention

This thesis sets out to explore how the use of PROMs in specialist musculoskeletal care affects patients with low back pain and the mechanisms behind any effects. The Medical Research Council's (MRC) guidance on developing and evaluating complex interventions was used to aid the development of this programme of research (Craig et al., 2008). The purpose of this framework is to guide research, developing and evaluating interventions in a systematic way to create knowledge that can inform practice (Hallberg, 2015).

Craig et al. (2008) suggested that clinical trials or the analysis of previous interventions is often insufficient to inform intervention development and implementation. It is important to accumulate evidence to understand the effectiveness, core components, and underlying mechanisms of an intervention. The guidance provides a systematic process for taking an intervention from development to implementation (see Figure 3.1).

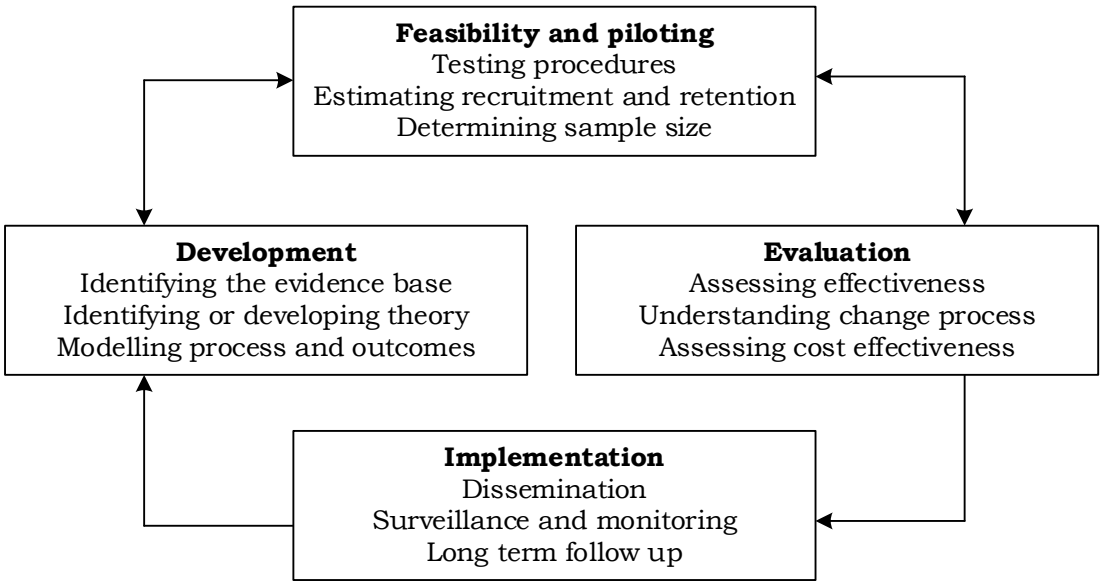


Figure 3.1 – Complex interventions framework

Adapted from: Craig et al., 2008

3.2.2 What makes PROMs complex?

The MRC framework was created to inform development, evaluation, and implementation of complex interventions. An intervention can be defined as "*any action taken by health care workers with the aim of improving the well-being of people with health and/or social care needs*" (Richards, 2015, p. 2). Complex interventions are commonly defined as those with several interacting components.

There are several dimensions to the complexity of evaluating PROMs in clinical practice: the PROMs used, the format and timing of delivery and feedback, the recipients of the PROM data, and the interpretation and utilisation of PROM data (Greenhalgh et al., 2017). Additionally, previous literature has highlighted uncertainty as to the potential multiple outcomes of PROMs (Boyce & Browne, 2013; Espallargues et al., 2000; Greenhalgh & Meadows, 1999).

The MRC's guidance on complex interventions is currently the only comprehensive resource available to help researchers develop, evaluate, and implement complex interventions. As PROMs in clinical practice constitute a complex intervention, the guidance was used to develop this programme of research.

3.3 Philosophical considerations

3.3.1 Methodology

Methodology is the approach to inquiry to answer proposed research questions (Teddlie & Tashakkori, 2009). The MRC guidance suggests both quantitative and qualitative research are appropriate when developing and evaluating complex interventions (Craig et al., 2008). Table 3.1 summarises the general differences between qualitative and quantitative approaches. Quantitative research is framed to pursue causal links and to generalise findings to larger populations (Burke Johnson & Onwuegbuzie, 2004). Quantitative research has high internal validity and researchers can draw strong conclusions about what has been demonstrated. However, findings may not be replicable in everyday situations. Qualitative methods interpret data in context, exploring meanings and processes (Burke Johnson & Onwuegbuzie, 2004). Although critics argue qualitative research is not objective or reliable, this methodology gives participants a voice and can examine subjective phenomena that may be difficult to measure objectively. Furthermore, qualitative methodologies typically do not value traditional, quantitatively orientated criteria such as objectivity (see section 3.3.2).

Table 3.1 – Simplified summary of differences between quantitative and qualitative methodologies

Adapted from: Burke Johnson and Onwuegbuzie (2004); Creswell (2014)

	Quantitative methodologies	**Qualitative methodologies**
Aims	Aims to identify relationships, explain or predict variables, and generate universal laws	Aims to create contextualised understandings and interpret meanings
Data	Numerical data focused on consensus, explanation, prediction, causal patterns, and norms	Narrative data focused on exploration, meaning and understanding
Theoretical relationship	Deductive, theory-testing	Inductive, theory is generated from data

3.3.2 Research paradigms

All research methodology is underpinned by philosophy. Research paradigms guide organised inquiry (Guba, 1990). A paradigm is a belief system, that incorporates assumptions and views about the world, and guides our thought patterns and behaviour. These beliefs underpin researchers' practice, influencing the development of research questions and methodologies (Teddlie & Tashakkori, 2009). These beliefs are shared within communities of researchers and direct disciplines and their research (Morgan, 2007).

Research paradigms are historically characterised by four philosophies of knowledge: ontology, epistemology, axiology, and methodology. Ontology concerns the nature of reality, epistemology focuses on the nature of knowledge and our perceived relationship with knowledge, axiology concerns the role of values in inquiry, and methodology refers to the generation of knowledge (Guba, 1990).

Traditional scientific research was based on positivism. A positivist epistemology takes a realist ontological view, with research being undertaken in a single reality in which objective knowledge can be produced (Yardley & Bishop, 2008). Post-positivism grew from positivism, acknowledging that whilst there is one single external reality, objectivity is not attainable, with human influence on knowledge impossible to remove (Ritchie, Lewis, McNaughton Nicholls, & Ormston, 2013). Post-positivism is associated with quantitative methodologies using rigorous methods to test hypotheses, working to create certainty; researchers are driven by theory to create single explanations, laws or facts (Teddlie & Tashakkori, 2009).

In contrast, the research paradigm constructivism rejects the idea of a single objective reality, taking a relativist approach, arguing that knowledge and understanding of reality is constructed by individuals and shaped by our social, cultural, and linguistic frameworks (Bishop, 2015). Constructivists believe that researchers construct the meaning of the research topic and inevitably influence its interpretation. Within this paradigm, research aims to gain an understanding of participants' views and experiences, and is more aligned with qualitative methodologies (Creswell, 2014). A comparison of post-positivism and constructivism can be seen in Table 3.2.

From a constructivist perspective, post-positivists may be seen to impose their preconceptions on the research topic and not take into account participants' views, individuals' values and the research context (Yardley & Bishop, 2008), limiting the understanding of the research. Critics argue post-positivist experimentation is undertaken in unnatural situations, so the findings do not have relevance to the real world and are lacking ecological validity. However, post-positivists argue that constructivist research is subjective and not rigorous, limiting the credibility and validity of the findings (Yardley & Bishop, 2008)

Table 3.2 – Overview of philosophical underpinnings of research paradigms
Adapted from: Bishop (2015); Creswell (2014); Feilzer (2010); Ritchie et al. (2013); Teddlie and Tashakkori (2009); Yardley and Bishop (2008).

	Post-positivism	**Constructivism**
Ontology	Realist assumption of a single reality with universal laws that is understandable	Relativist assumption of multiple constructed realities that are specific to individuals and cultures
Epistemology	Knowledge is objective, understanding reality is independent of the observer	Knowledge is subjective, understanding reality cannot be separated from the observer as knowledge is embedded in values and cultures
Axiology	Research is value free and unbiased, eliminating bias	Research is value bound, researchers are biased by experiences and are an inherent part of the research process
Methodology	Quantitative methodology such as experimentation, with precise measurement	Qualitative methodology to examine norms, assumptions, practices to understand people

Pragmatism

The philosophical differences have been the subject of much debate, with the incompatibility thesis suggesting that due to fundamental differences in paradigms, methodologies are impossible to integrate (Creswell & Clark, 2011; Howe, 1988; Teddlie & Tashakkori, 2009). Despite the differences, Feilzer (2010) and Morgan (2014) argued that quantitative and qualitative methodologies can be compatible with pragmatism, a philosophical system providing an overarching framework and alternative way of conceptualising research, valuing both experiences and experimentation to answer research questions. Rather than constraining choice of method, pragmatism permits a combination of qualitative

and quantitative approaches whilst respecting the different assumptions that traditionally underpin these methodologies (Burke Johnson & Onwuegbuzie, 2004).

The research outlined in this thesis adopted a pragmatist approach. Pragmatism assumes that there is an external singular reality independent of individuals, based on the natural world we live in, which constrains our experiences. However, understanding this reality is not abstract from individuals, as the social world and our human experience creates multiple social realities (Burke Johnson & Onwuegbuzie, 2004; Teddlie & Tashakkori, 2009). According to pragmatism, knowledge is produced, not absolute and is flexible to uncertainty (Feilzer, 2010). Pragmatist approaches assume knowledge is not neutral but is inevitably influenced by human interest, which they see as essential for scientific inquiry (Burke Johnson & Onwuegbuzie, 2004).

Pragmatism is outcome-orientated; the effects and desired consequences influence research questions and methods (Bishop, 2015). From a methodological perspective, it is necessary to use methods to both experiment, but also understand the context of the experiment and interpretation of experiences (Teddlie & Tashakkori, 2009). Pragmatism further acknowledges researchers' values are important in interpreting research and identifying if it is trustworthy (Creswell & Clark, 2011; Yardley & Bishop, 2008).

The aim of work conducted from a pragmatist standpoint is to produce positive real-world change (Bishop, 2015). Conventional post-positivist paradigms seek to find a single truth, but in pragmatism, truth is provisional and changes over time (Burke Johnson & Onwuegbuzie, 2004; Feilzer, 2010; Teddlie & Tashakkori, 2009). Pragmatism rejects the objective and subjective dualism that is inherent in both post-positivism and social constructivism, and argues that truth cannot be determined; researchers can only use approaches such as experience and experimentation to generate provisional knowledge (Feilzer, 2010).

One criticism of pragmatism is a lack of pragmatists discussing their ontological and epistemological approach to research. Morgan (2014) argued that pragmatism goes beyond historical philosophies of knowledge and provides a new philosophy and paradigm for research. Pragmatism does not argue about the nature of reality and knowledge but identifies the values that can guide meaningful inquiry.

3.3.3 Pragmatism and mixed-methods

The pragmatist paradigm encourages choosing the appropriate methods to answer research questions, rather than being aligned with quantitative or qualitative methodology (Teddlie & Tashakkori, 2009). Often the most appropriate methodology to answer research questions is one of mixed-methods, incorporating both quantitative and qualitative methods. Mixed-methods can be defined as: "*research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g. use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration*" (Johnson, Onwuegbuzie, & Turner, 2007, p. 123).

Use of mixed-methods allows researchers to address a range of questions, both exploratory and confirmatory, for a more complete picture of the research problem (Yardley & Bishop, 2008). This methodology may also: provide stronger inferences than single methods, expand the understanding of the phenomenon of interest, and provide the opportunity to explore conflicting views (Burke Johnson & Onwuegbuzie, 2004). Using mixed-methods may capitalise on each method's strengths and compensate for weaknesses (Creswell & Clark, 2011).

There are challenges in conducting mixed-methods research. Researchers need appropriate skills and experience with both methods, and mixed-methods can be time and resource intensive (Creswell & Clark, 2011). Despite these challenges, Greenhalgh et al. (2017) state that mixed-methods are necessary to effectively develop and evaluate PROMs, and to understand their successful implementation to improve health outcomes.

3.4 Design and conduct of complex interventions research

The MRC's guidance suggests a series of research phases, which complement each other, maximising the contributions of each element to help answer the research question (Craig et al., 2008). This thesis utilised the first three phases to develop a programme of research to answer the research question proposed in Chapter 1. The relationship between the research phases is depicted in Figure 3.2.

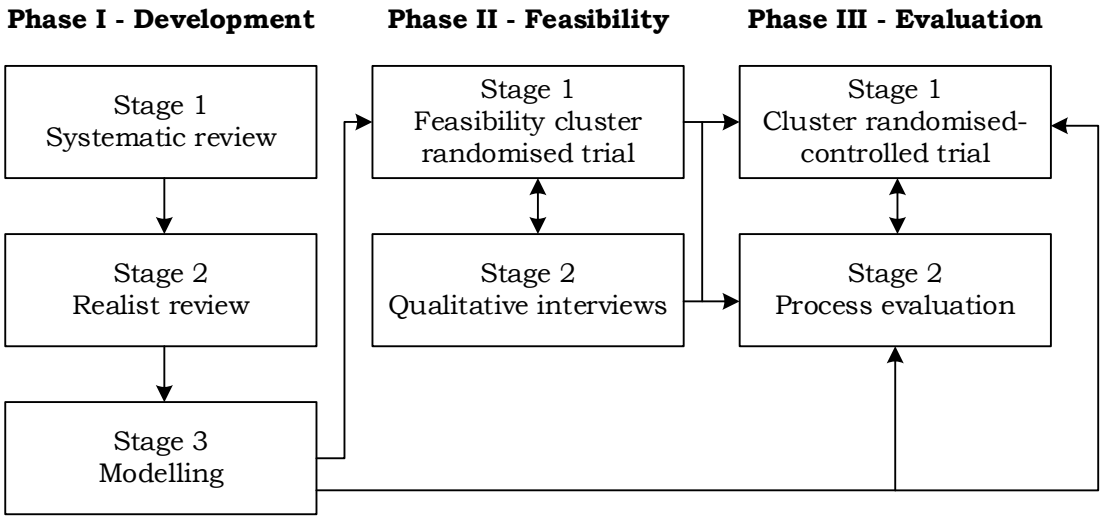


Figure 3.2 – Study phases

Phase I of the thesis was pre-clinical development work, reviewing literature on the use of PROMs. Phase II and Phase III of this research followed a sequential explanatory study design with trials conducted first, followed by qualitative interviews (Creswell & Clark, 2011). The qualitative phases explored separate study objectives from the trials and help explain their results. A two-phased approach to data collection is beneficial as these provide data from two different perspectives and enhance the interpretation of the data collected (Brannen, 2008; Creswell & Clark, 2011).

The study objectives and design for each phase are depicted in Figure 3.3. The following sections present an outline of each phase and brief discussion of the chosen study design, taking account of potential advantages and limitations.

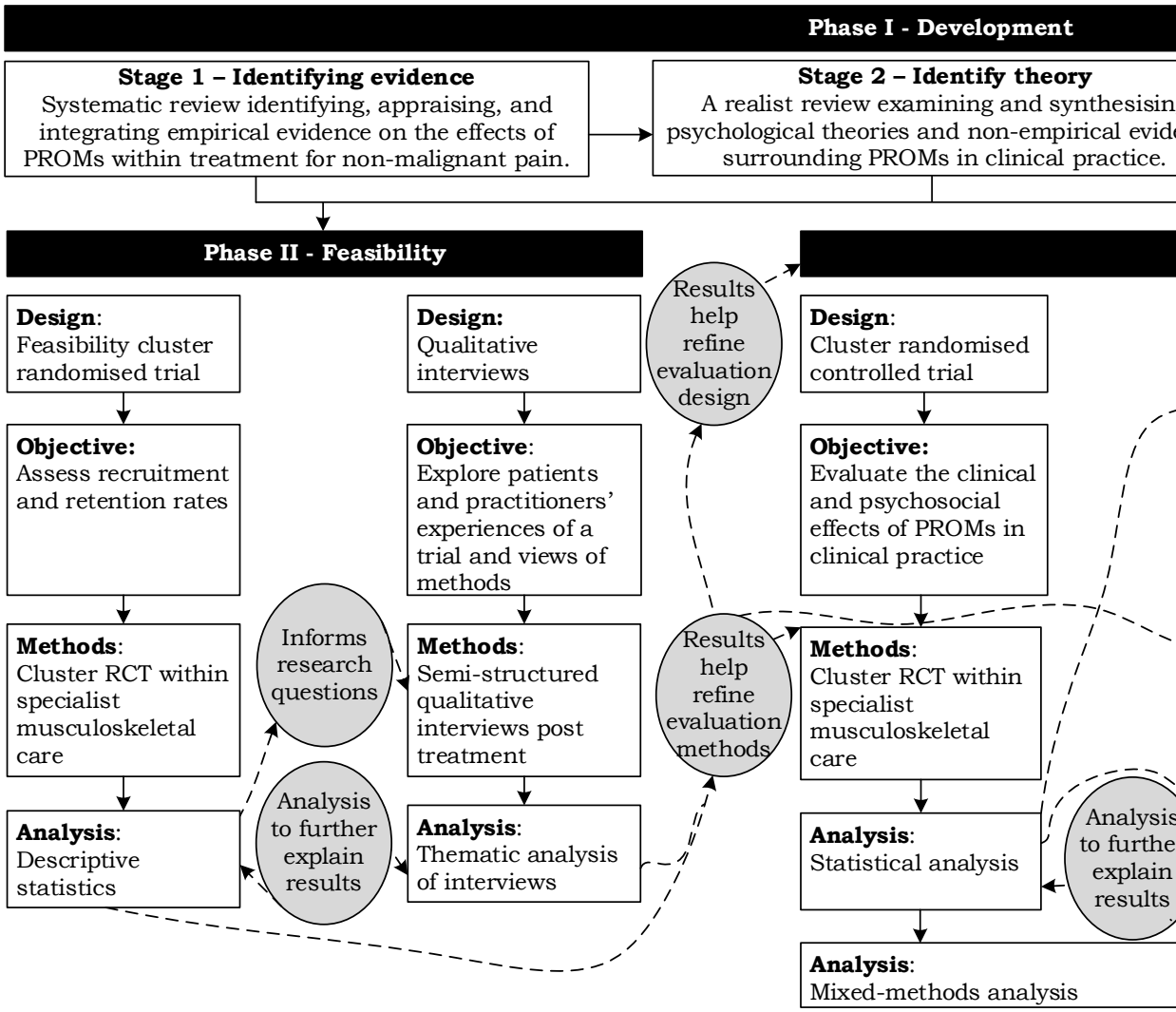


Figure 3.3 – Overview of study design and objectives

3.4.1 Phase I – Development

According to the MRC's guidance, preliminary development work is essential to identify components of the intervention and the mechanisms by which they may influence patient outcomes (Craig et al., 2008).

Stage 1 – Identify an evidence base

The first recommended stage in developing an intervention is to systematically identify and evaluate all relevant existing research. This is commonly done by conducting a systematic review "*to provide a clear answer to the question of likely intervention effect*" (Richards, 2015, p. 7). However, completing a systematic review in a traditional sense, such as meta-analysis of RCTs, may be inappropriate or unsuitable to understand complex interventions due to the interacting components and potential for multiple outcomes (Köpke, Noyes, Chandler, & Meyer, 2015).

Instead of focusing solely on RCTs, researchers should be informed by all the available and applicable evidence to make informed decisions about complex interventions (Cullum & Dumville, 2015). Integrating evidence from studies of various study designs allows for comprehensive understanding of the outcomes of an intervention, with the results validated, triangulated, and examined from differing perspectives (Hannes, 2015). Different studies can show the range of potential effects, and examine implementation in different contexts (Petticrew, 2015).

As highlighted in Chapter 1 there is little research on the use of PROMs in clinical practice for low back pain and no comprehensive review of this literature. Therefore, the first stage of this research was to identify and critically appraise published empirical evidence on the effects of PROMs in the treatment of pain through a systematic literature review (Chapter 4).

Stage 2 – Identifying theory

The second stage is to identify and assess relevant theory (Craig et al., 2008). This adds to intervention development by identifying intervention components, establishing potential mechanisms of change, identifying potential outcomes, and understanding implementation (Rycroft-Malone & Burton, 2015).

However, like many complex interventions, the use of PROMs in clinical practice has multiple stages and each stage may have relevant theory. This posed a challenge in identifying theories and underlying mechanisms of using PROMs within clinical practice. A realist review is a systematic method to approaching literature that can cope with this complexity. Realist reviews aim to provide an explanation of the mechanisms of an intervention and can be used to develop a theoretical framework about how an intervention can influence patients and the conditions under which an intervention may work (Pawson, Greenhalgh, Harvey, & Walshe, 2004; Rycroft-Malone & Burton, 2015). Realist reviews identify and synthesize key theories, ideas, and evidence about how interventions create change, to create a preliminary understanding of the intervention process (Pawson, Greenhalgh, Harvey, & Walshe, 2005).

In this thesis, a realist review was conducted (Chapter 5) to identify processes and psychological theories relevant to the question of how PROMs may influence health outcomes. The theories were explored in terms of their explanations of human behaviour, their supporting evidence, and their relevance in understanding the processes that might underpin the effects of PROMs.

Stage 3 – Process and outcome modelling

The final stage of development is to "*have modelled the way the intervention will be operationalised in practice*" (Richards, 2015, p. 9). This is known as a theory of change, but is also referred to as logic model, causal model, or path model. These models are visual depictions showing the hypothesised causal mechanisms between intervention and outcomes in a particular context (Kirby, 2004).

Modelling should be achieved using empirical evidence and relevant theory to identify the components and rationale underlying an intervention (Hardeman et al., 2005; Sermeus, 2015). Modelling the intervention and the potential processes by which the intervention works may identify potential outcomes (Buhse & Mulhauser, 2015). This can facilitate future evaluation by identifying measurement elements, and inform hypothesis testing and statistical modelling of the relationship between intervention and outcomes (Connell & Kubisch).

The insights derived from Stage 1 and 2 were integrated in Stage 3, creating a conceptual theoretical framework mapping the intervention and

psychosocial processes through which PROMs might influence patient outcomes for non-malignant pain (Chapter 5).

3.4.2 Phase II – Feasibility

Phase II involves the planning of the research evaluation using a feasibility study (Craig et al., 2008). Feasibility studies are conducted to aid the design process and assess practicalities of future research (Arain, Campbell, Cooper, & Lancaster, 2010). Despite some literature indicating that the terms 'feasibility' and 'pilot' can be used interchangeably (Thabane et al., 2010; van Teijlingen & Hundley, 2002), they are two different study designs (Arain et al., 2010). Pilot studies, although assessing feasibility, are smaller versions of studies, testing out the procedures and methods to be used, ensuring they will run accordingly (Arain et al., 2010; Leon, Davis, & Kraemer, 2011). Pilot studies also provide opportunities to estimate sample size calculations (Lancaster, Dodd, & Williamson, 2004; Thabane et al., 2010).

In comparison, feasibility studies are focused on clarifying the design of a larger study. Feasibility studies can assess many study design components including: recruitment methods, response rates, acceptability of randomisation, and outcome measure preferences (Arain et al., 2010). Another difference between pilot and feasibility studies is the analysis of data. Whilst pilot study data may be analysed and provide the first phase of results, feasibility studies will not produce significant results for the planned study but instead provide information to shape future study design (Arain et al., 2010).

RCTs commonly fail to reach the required sample size, affecting the ability to detect clinical differences. Campbell et al. (2007) conducted a review of 122 trials and found that only 31% of trials recruited 100% of their original target, with 45% of trials failing to reach 80% of their target numbers. The feasibility phase of evaluation allows for identification of the methodological, procedural, and clinical barriers, including recruitment issues, and helps to develop solutions to address them (Richards, 2015). To assess the feasibility of evaluating PROMs, Phase II tested elements from the protocol of Phase III to explore applicability and acceptability of the study design. The feasibility study (Chapter 6) assessed recruitment and retention rates, participants' acceptance of randomisation and evaluated measurement tools for their appropriateness and usability.

3.4.3 Phase III – Evaluation

The aim of the evaluation phase is to establish causality between the intervention and outcome (Craig et al., 2008). Greenhalgh et al. (2017) acknowledged that further research needs to be conducted to understand how PROMs can be used within individual patient care and to support patient self-management. Phase III was split into two parts: an RCT and a process evaluation. The RCT aimed to establish whether PROMs as an intervention are effective. The process evaluation aided interpretation of the findings of the trial, and explored the processes by which PROMs function, by examining their implementation, mechanisms and context (Craig et al., 2008). This combination of methods provides a more complete picture estimating and understanding the effects of PROMs in clinical practice, providing stronger inferences than single methods.

Stage 1 – Randomised-controlled trial

An RCT can be defined as *"a planned experiment that is designed to compare two or more forms of intervention, where allocation of participants to an intervention is 'by chance'"* (Lamb & Altman, 2015, p. 191). RCTs are considered as the most scientifically rigorous study design for evaluating healthcare interventions, comparing a theory-based intervention to an appropriate alternative (Campbell et al., 2007; Greenhalgh, 2006). Craig et al. (2008) argues that randomisation should always be considered during evaluation, as it is the most robust method of reducing bias associated with treatment allocation, predictor variables and confounding variables.

A non-randomised trial design could be used to evaluate the effectiveness of PROMs. RCT designs often have strict inclusion criteria leading to a high number of potential participants being excluded; whilst this can provide precision over treatment effects it reduces the ability to generalise to other similar populations and may produce a smaller treatment effect (Prescott et al., 1999; Weisberg, Hayden, & Pontes, 2009). Non-randomised trials often have fewer restrictions on participants, which may identify a larger treatment effect, although reviews suggest this may be due to bias (Deeks et al., 2003; Reeves et al., 1998). There are limitations to non-randomised study designs, such as selection bias due to allocation of participants to treatment groups (Reeves et al., 1998; Schulz & Grimes, 2002).

Although research designs such as preference trials, cohort studies and case-control studies are available and could be used to evaluate complex interventions (Craig et al., 2008; Pluye et al., 2011), these should only be used if RCTs are inappropriate or impractical. Literature has consistently identified that RCTs provide the best evidence with robust methods, minimising the risk of bias (Barton, 2000; Greenhalgh, 2006; Melnyk & Fineout-Overholt, 2011). Therefore, an RCT was conducted to evaluate the effect of PROMs in clinical practice (Chapter 7). To address concerns regarding applicability of the research findings, the RCT had few inclusion criteria to include a broad study population, aiming to recruit patients that reflect those in everyday clinical practice (Tunis, Stryer, & Clancy, 2003).

Stage 2 – Process evaluation

A process evaluation "*is designed to understand the mechanisms by which the intervention exerts its effects*" (Richards, 2015, p. 12). Process evaluations examine interventions and implementation. According to Moore et al. (2015) comprehensive process evaluations use a mixed-method approach, using quantitative data to test causal pathways and qualitative data to explore how an intervention works. Atkins, Odendaal, Leon, Lutge, and Lewin (2015) state that theory can help to inform process evaluations, to focus research questions and facilitate data analysis, and so the process evaluation was developed using the model produced in Phase I.

Process evaluations aim to explain variability in intervention outcomes, through statistical analysis they can clarify causal mechanisms underpinning the intervention and identify the reasons for influencing outcomes (Atkins et al., 2015; Moore et al., 2015). Process evaluations also aim to capture intervention fidelity, to identify if the intervention was delivered as intended and understand how implementation is achieved (Hasson, 2015).

A mixed-methods process evaluation was conducted, using a mediation analysis to understand the psychosocial effects of implementing PROMs (Chapter 8) and qualitative analysis of patients' and chiropractors' views and experiences of using PROMs (Chapter 9). Integration of the qualitative and quantitative data aimed to understand implementation, causal mechanisms, and any other consequences of using PROMs in specialist musculoskeletal care (Chapter 10).

3.4.4 Phase IV – Implementation

Implementation is the integration of interventions into routine practice, going beyond traditional dissemination of research to create active strategies to encourage application of research findings (Skolarus & Sales, 2015). This phase makes results accessible to decision-makers and policy-makers, to ensure the uptake of recommendations from the development and evaluation phases (Craig et al., 2008).

Skolarus and Sales (2015) acknowledge there is often a gap between best evidence on interventions and current practice. Addressing practice gaps often requires stakeholders to change behaviour, and further research may be necessary for the intervention to be successfully implemented (Skolarus & Sales, 2015). This includes assessing the evidence base on delivering the intervention, assessing barriers and facilitators to implementation, and linking any barriers to evidence-based change techniques (Van Achterberg, 2015). Researchers should also plan long-term monitoring of the intervention after implementation, monitoring adverse events and long-term outcomes (Craig et al., 2008).

As the implementation phase requires long-term follow up of an intervention in routine practice, this falls outside of the scope of this current project due to the resources available. However, following Craig et al. (2008) guidance on complex interventions, the development, feasibility, and evaluation phases of this project identified lines of inquiry for future research and recommended strategies for implementation.

3.5 Chapter summary

Although studies have been conducted to identify the impact of using PROMs in clinical practice, there has been very little published research in the context of low back pain. Due to the complex nature of evaluating PROMs, the MRC's guidance on complex interventions provided a framework on the development of this programme of research, organising the research into three phases. Phase I is a pre-clinical phase, consisting of two reviews: a systematic review examining findings from primary research (Chapter 4) and a theoretical review exploring the concepts underlying use of PROMs (Chapter 5). Phase II reports a feasibility study assessing the study procedures and estimated recruitment for future evaluation (Chapter 6). In Phase III a mixed-method study evaluates the clinical and psychosocial effects of using PROMs in clinical practice (Chapter 7), clarifies the causal mechanisms of PROMs as the proposed processes by which change occurs (Chapter 8), and analyses patients' and chiropractors' subjective accounts of their experience of using PROMs (Chapter 9). The data from Chapters 7, 8, and 9 are then integrated using a mixed-methods approach examining the context, mechanisms, and outcomes to further understand the processes of utilising PROMs (Chapter 10).

Chapter 4 The potential impact of PROMs in clinical practice for pain: a systematic review

4.1 Introduction

The use of PROMs in routine clinical practice has led to increasing evaluation of the impact of using PROMs. Previous reviews suggest PROMs may influence the detection of psychological problems, diagnosis of conditions, use of health services and facilitate communication between clinicians and patients (Espallargues et al., 2000; Greenhalgh & Meadows, 1999). Other reviews have focused on specific areas of healthcare or conditions; use of PROMs in oncology settings was associated with improvements in supportive care, symptom control, and patient satisfaction (Kotronoulas et al., 2014). In contrast, a review of the use of PROMs in psychiatric and non-psychiatric settings, concluded no overall difference in treatment outcome and limited improvement in patient satisfaction (Gilbody et al., 2002). A further review examining the usefulness of providing group-level feedback of PROMs to clinicians, stated there was a weak amount of evidence suggesting that PROMs had a positive impact on patient outcomes (Boyce & Browne, 2013).

In a review of qualitative research examining clinicians' experiences of using PROMs, some clinicians viewed PROMs as potentially impacting on the processes of care, such as influencing communication, shared decision-making, and planning care (Boyce et al., 2014a). This is reflected in a realist review of PROMs with individual patients, which suggested PROMs could influence the clinician-patient relationship, consultation discussions, and decision-making around treatment (Greenhalgh et al., 2017). However, this was dependent on settings, the PROMs used, and clinicians' perspectives on PROMs.

While these reviews provide interesting insights into the outcomes PROMs may have when used in clinical practice, Greenhalgh and Meadows (1999) and Espallargues et al. (2000) only included RCTs and non-randomised controlled trials in their reviews, with RCTs being acknowledged to be the gold standard research methodology for assessing the effectiveness of interventions. However, Cullum and Dumville (2015) argue that to understand complex interventions, all relevant studies from a broad range of study designs must be identified and

synthesised. Additionally, Gilbody et al. (2002) and Kotronoulas et al. (2014) examined PROMs in specific patient populations, and patients within these contexts may not have the same experiences of health and healthcare, with the findings not generalisable to other contexts or patient populations (Greenhalgh et al., 2017).

4.1.1 Review questions and objectives

The research to date suggests that PROMs could be viewed as active components of clinical interventions, potentially affecting the process and outcomes of care. As no previously published reviews examine PROMs in the context of non-malignant pain, a review is justified to synthesise relevant evidence to understand the potential impact of using PROMs in this context. This review aims to answer the following research question: what is the potential impact on the process and outcome of healthcare of using PROMs in routine clinical practice for non-malignant pain?

The objectives of this review were to:

1. Identify published empirical evidence on the potential impact of PROMs in clinical practice for non-malignant pain through a systematic search of the literature.
2. Integrate the findings of the included studies using Critical Interpretive Synthesis (CIS) to develop an overall argument synthesising all relevant evidence.
3. Discuss emerging concepts from published findings and improve the current understanding on the potential impact of using PROMs within routine clinical practice for non-malignant pain.

4.2 Method

4.2.1 Review methodology

This review used Critical Interpretative Synthesis (CIS). CIS was developed from meta-ethnography, as an alternative to traditional meta-analyses or qualitative syntheses, to examine diverse bodies of evidence to resolve complex problems within healthcare. CIS was designed to use both qualitative and quantitative literature to assemble arguments from all available evidence, generating a richer understanding of the phenomenon of interest (Dixon-Woods et al., 2006; Flemming, 2010). Synthesising research of various study designs improves the understanding of a complex phenomenon by viewing it from multiple perspectives; trials can identify the effectiveness of an intervention, with qualitative studies and surveys exploring the potential impact of an intervention through participant views and experiences (Hannes, 2015). CIS also allows for the inclusion of papers of low methodological quality, with methodological quality accounted for in the synthesis process (Dixon-Woods et al., 2006).

CIS is a relatively new method and, to date, has primarily been used in health services research. Entwistle, Firnigl, Ryan, Francis, and Kinghorn (2012) used CIS to explore patients' experiences of healthcare delivery and develop a concept map depicting why patients' experiences are important. In another review, CIS was used to explore various stakeholders' views on research participation in end of life care (Gysels, Evans, & Higginson, 2012). In these reviews, CIS was used where there is diverse literature and the phenomenon of interest is proposed to have many different and complex elements.

Previous reviews examining PROMs in clinical practice have found studies to be heterogeneous and meta-analysis to be unjustified (Espallargues et al., 2000; Marshall, Haywood, & Fitzpatrick, 2006; Valderas, Kotzeva, et al., 2008). Therefore meta-analysis was deemed inappropriate for this review as this may lead to incorrect conclusions and recommendations (Köpke et al., 2015). CIS was chosen as a logical approach to synthesis, as PROMs are a complex phenomenon which have been explored with various study designs. Alongside CIS, this review followed guidance set out regarding search strategies, developing inclusion and exclusion criteria and data extraction (Centre for Reviews and Dissemination, 2009; Higgins & Green, 2008). The systematic review was written up according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Liberati et al., 2009).

4.2.2 Search strategy

Through consultation with an academic librarian, a scoping search was conducted using two key terms 'patient-reported outcome measures' and 'clinical practice' to identify key databases for the research question. Following successful and relevant results, six databases were deemed appropriate and used to build a search strategy. A literature search was conducted in January 2015 using several relevant databases: PubMed; Excerpta Medical Database and Allied and Alternative Medicine (EMBASE); PsycINFO; Cochrane Library; Web of Science; and PsycARTICLES. The search used Boolean logic to combine terms from the databases' thesaurus and free-text keywords. Terms included derivatives of 'patient-reported outcome' and 'clinical practice' (see Appendix A). The study search was restricted to items published after 1985; after the emergence of PROMs in the literature (Antunes, Harding, & Higginson, 2014).

Additionally, bibliography searches of obtained studies, key authors searches, and a keyword search on Google Scholar was conducted to check for relevant studies; the UK Clinical Research Network Study Portfolio website was searched for studies being conducted at the time of the review. One search was conducted for this review and the realist review presented in Chapter 5. The search was updated in October 2019 to acquire relevant articles published since the original search date.

4.2.3 Study selection

All citations were input into the reference software Endnote version X7 (Thomas Reuters, 2014). After removing duplicate references, study titles and abstracts were screened to assess their eligibility for inclusion, followed by the screening of full-texts. At the screening stage, reviews were screened for inclusion into either this review or the realist review presented in Chapter 5. The inclusion of studies for this systematic review was pre-determined by the inclusion and exclusion criteria in Table 4.1.

Table 4.1 – Inclusion and exclusion criteria

Inclusion	Exclusion	Justification of criteria
Focused on the impact of using PROMs into routine clinical practice.	Studies which evaluated the use of PROMs as part of a larger intervention, such as counselling, were also not included as the results may not be specific to the PROMs intervention.	Studies were restricted to those exploring PROMs use in clinical practice, excluding studies investigating their use in research.
Adult patients (aged ≥18) with non-malignant pain or within healthcare settings which specifically see patients with non-malignant pain.	Adult patients without pain, patients with malignant pain, general healthcare settings (such as outpatients, emergency clinics, general practice patients and specialist services) without a focus on pain PROMs. Children or adolescents (<18).	These restrictions were placed as the experiences and treatment of malignant pain may be different to those with non-malignant pain. Children were also excluded due to the biological and psychological differences between children and adults.
Primary studies (quantitative studies, qualitative studies, mixed-method studies).	Letters, conference abstracts, editorials, commentaries, reviews, dissertations, books.	Studies were restricted to empirical literature, to examine the potential impact of PROMs rather than theoretical concepts of their use.

As part of the screening process an article was translated from Portuguese to determine its eligibility in the review. Full-texts were examined and a list of potential studies were discussed with two academic supervisors before final decision on study inclusion. The process is documented using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow chart (Figure 4.1) (Moher, Liberati, Tetzlaff, & Altman, 2009).

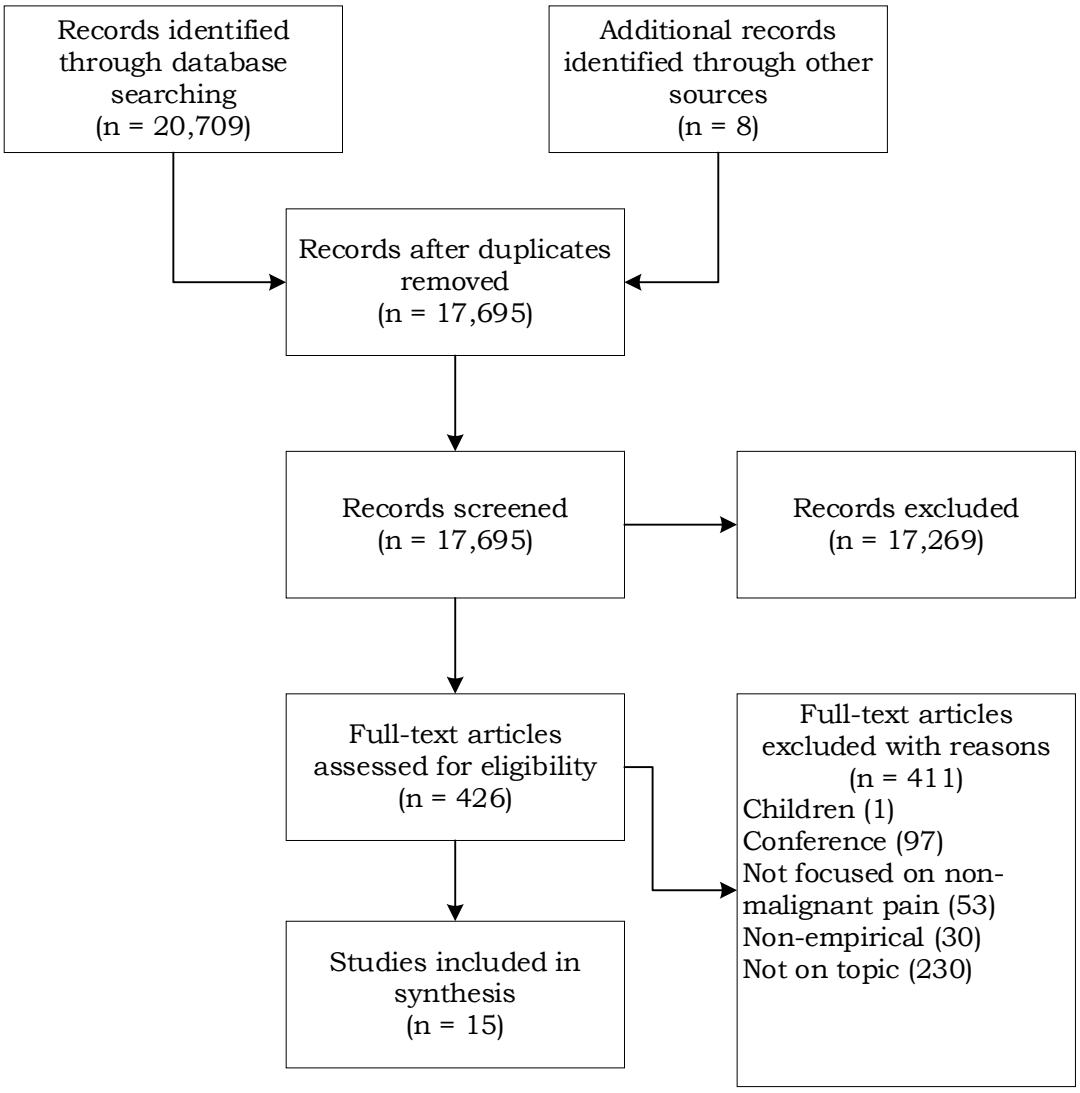


Figure 4.1 – PRISMA flowchart

4.2.4 Data extraction and synthesis

This review used CIS to discuss the emerging concepts on the potential impact of using PROMs in clinical practice (see Figure 4.2).

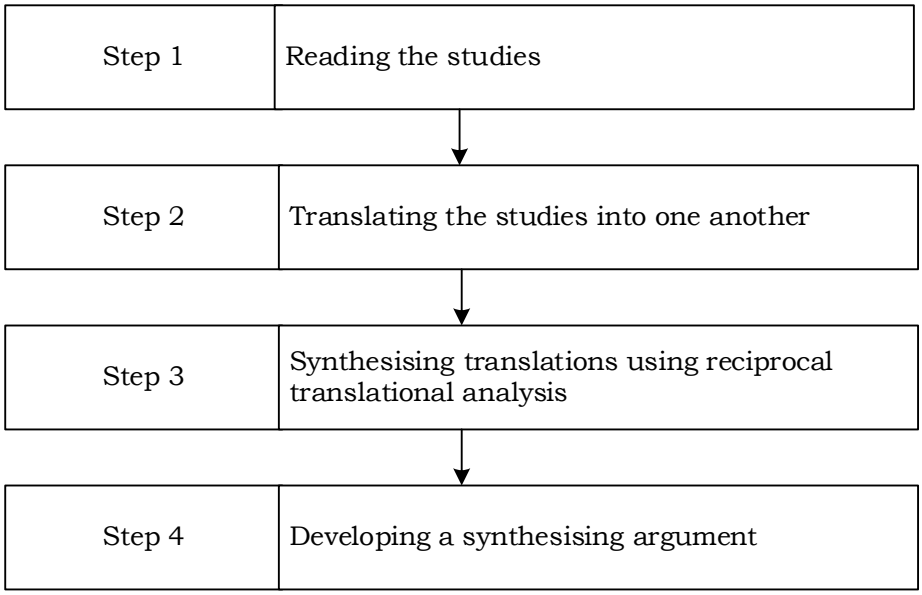


Figure 4.2 – Data synthesis process

The first step of CIS was a detailed inspection of papers; for each paper, study year, country, study design, aims, research setting, participants, intervention, PROMs used, data collection, analysis and authors' conclusions were tabulated (see Section 4.3.1). In Step 2, findings from the included studies were refined through translation; translation occurs through detailed extraction, grouping and clustering of study results. The grouping and clustering of study results was conducted through printing each study result, and then identifying the key concepts and metaphors and physically grouping these together. Findings of qualitative research were grouped using textual descriptions and example quotes from papers (Flemming, 2010). Quantitative studies were grouped looking for patterns amongst the study outcomes.

In Step 3, all the qualitative and quantitative findings from the translation step were then synthesised using Reciprocal Translational Analysis (RTA). RTA uses frameworks to compare the results of each study and interpret all the evidence (Dixon-Woods et al., 2006; Flemming, 2010). The groups developed in Step 2 were then mapped against each other in a framework (see example in Figure 4.3). Mapping the qualitative findings against quantitative results produces CIS synthetic constructs, an interpretation of the evidence, stemming from examining all the findings. Initially eleven constructs were developed and

after discussion of the data interpretation with two academic supervisors, these were refined into five constructs.

Construct:	**Positive effect**	**Adverse or no effect**
Quantitative		
Qualitative		

Figure 4.3 – Example RTA framework

Finally, in Step 4 concept mapping was used to integrate the evidence into a single framework called a synthesised argument (Flemming, 2010). Concept mapping is a method of visually depicting the phenomenon of interest; the map represents an overview of the findings and the relationships between key concepts (Popay et al., 2006). The concept map aims to explain the synthetic constructs produced in Step 3 and the relationship between studies to answer the overarching research questions (Dixon-Woods et al., 2006).

4.2.5 Assessment of synthesis

The Confidence in the Evidence from Reviews of Qualitative research (CERQual) tool was used to assess the confidence in the evidence for each of the constructs generated during the synthesis (Lewin et al., 2015). CERQual helps reviewers judge the extent to which the constructs are representative of the phenomenon being studied. The CERQual tool has four components which contribute to the assessing the confidence for each review finding: methodological limitations, relevance, coherence and adequacy of data (see Table 4.2). This assessment of confidence fits with the principles of CIS, which assembles arguments from all the available evidence, despite varying study designs and methodological quality. By using the CERQual assessment, there is a formal assessment of confidence in the assembled constructs and overall synthesised arguments (Lewin et al., 2015).

Table 4.2 – CERQual components

Adapted from: Lewin et al. (2015)

CERQual component	Definition
Methodological limitations	The extent of problems in the design, conduct or analysis of primary studies contributing to the construct
Relevance	The extent to which the primary studies contributing to the construct are applicable to the context of the review
Coherence	The extent to which the construct is supported within the primary studies in the review
Adequacy of data	Determination over the richness and quantity of data contributing to the construct

The individual studies were assessed for methodological strengths and limitations. Studies were not assessed using a weighted critical appraisal scale or given a numerical score for quality, as scales may give unjustified weighting to items and may be unreliable to assess the validity of studies (Higgins & Green, 2008). Questions were extracted from the Mixed-Method Appraisal Tool (MMAT; see Appendix B) (Pluye et al., 2011) to examine study quality and assess risk of bias (Gray & Ison, 2009). This tool was used as it was assumed that the study search would provide heterogeneous studies, from a variety of study designs. The MMAT provided a single method of analysing methodological quality for all studies, rather than applying various checklists to different studies. Although this tool is not primarily designed for this purpose, this assessment provided an overview of study quality and methodological implications of the study, which was used when synthesising the study results.

The MMAT allows for studies to be assessed according to study design and each is then evaluated on four criteria (Pluye et al., 2011). For example, RCTs are assessed on their randomisation, blinding, outcome data, and drop-out, with qualitative research being assessed on sources of data, analysis, context, and researchers' influence. The two MMAT screening questions were modified to include the five appraisal prompts used for judging study quality in CIS (Dixon-Woods et al., 2006). The Cochrane risk of bias tool (Higgins et al., 2011) and Downs and Black checklist (Downs & Black, 1998) were deemed inappropriate for the review, not allowing for assessment of the quality of the research in respect to the heterogeneous study designs.

4.3 Results

4.3.1 Study characteristics

Fifteen studies were included in the review. Thirteen studies were identified in the original search, with two studies identified as eligible in the updated search. The fifteen eligible studies included: four qualitative studies, one mixed-method study, two RCTs, two non-randomised trials, two case series, one case–control study, one audit, one case report, and one cross-sectional analytic survey. The studies included both patients and clinicians as participants, and included a variety of PROMs (see Table 4.3). PROMs were commonly completed on paper, with three studies using computer software (Ahluwalia, Giannitrapani, Dobscha, Cromer, & Lorenz, 2018; Hvitfeldt et al., 2009; Meerhoff et al., 2019).

4.3.2 Synthesis of results

Five synthetic constructs were developed using RTA, a framework for each construct can be seen in Appendix C. The five constructs are: assessment of patient, decision-making, therapeutic relationship, tracking progress and evaluating and changing treatment, and influencing outcomes. A concept map, Figure 4.4, depicts the five constructs and how these fit with the conventional stages of treatment (initial consultation, during treatment, and post-treatment.

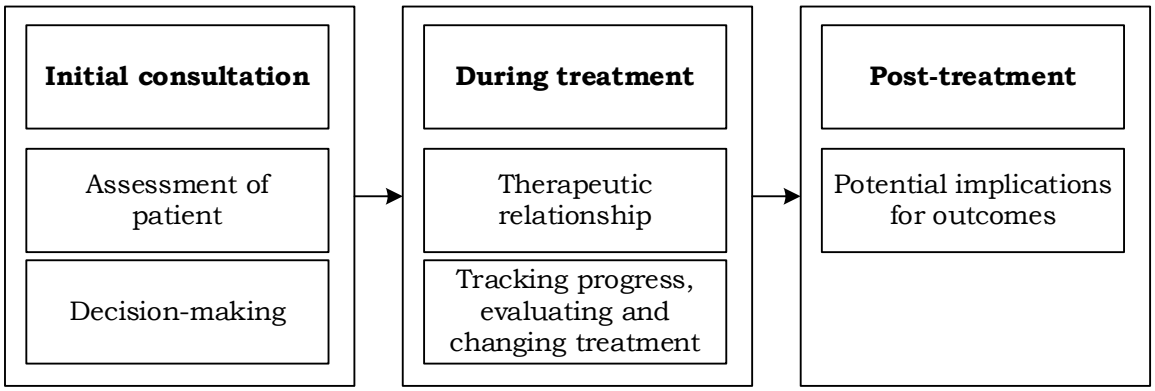


Figure 4.4 – Concept map of PROM impact

Table 4.3 – Study characteristics
* = validated measure

Authors	Country	Study design and method	Study aim	PROMS used and concepts measured	Setting and participants	Analysis
Ahluwalia et al. (2018)	U.S	Qualitative; focus groups	To explore primary care practitioners' perspectives on the impact of routine pain screening on clinical practice	Numerical Rating Scale – pain intensity	Primary care n = 60 primary care practitioners (family medicine practitioners, nurse practitioners, nurses, psychologists, social workers)	Thematic analysis
Bottega and Fontana (2010)	Brazil	Qualitative description; open-ended questionnaire	To explore nurses' views on using a PROM to assess pain	Visual Analogue Scale – pain levels	Hospital. n = 14 nurses	Thematic analysis
Boyce, Browne, and Greenhalgh (2014b)	Ireland	Qualitative description; interviews	To explore surgeons' experiences of using PROMs, to identify practical and methodological challenges, and identify attitudes on the value of the feedback and the potential impact the information had on clinical practice	Oxford Hip Score (OHS)* - hip pain and function, ED-5Q* - health status, Hip Osteoarthritis and Outcome Score (HOOS)* pain, symptoms, activity of daily living, sport and recreation function and hip related quality of life	Primary hip replacement surgery. n = 11 Surgeons	Framework analysis

Authors	Country	Study design and method	Study aim	PROMS used and concepts measured	Setting and participants	Analysis
Buchi and Sensky (1999)	Not Known	Case series; patient reported outcome measures	To demonstrate the application of PRISM in clinical practice and how it can be used facilitate patient-clinician communication	PRISM* - burden of suffering due to illness	General hospital – psychiatry. 2 patients - 1 female (33) - multiple sclerosis; 1 male (58) severe multiple trauma	Quantitative descriptive
dos Santos Silva, de Mattos Pimenta, and Lopes Monteiro da Cruz (2013)	Brazil	Non-randomised controlled trial; patients' medical reports	To test the effect of training for nurses of applying a systematized pain assessment of pain control effects decision-making regarding administration of morphine and affects pain relief for patients	Numeric Pain Rating Scale – pain level	Cardiac surgery. n = 182 cardiac surgery patients; mean age - 55.7.	Correlation of variables - Chi-square, Likelihood Ratio Test; Descriptive statistics; Comparison among groups - Kruskal-Wallis and Dunn test.
Hadjistavropoulos, MacNab, Lints-Martindale, Martin, and Hadjistavropoulos (2009)	Canada	Non-randomised controlled trial; patient reported outcome measures	To assess whether systematic pain assessment changes the clinical practice of medical practitioners	21-point box scale* - pain levels, Geriatric Pain Measure (GPM)* - pain intensity, Geriatric Depression Scale (GDS-SF)* - depression	General practice. n = 114 seniors with complex medical problems; mean age - 80.74	T-tests

Authors	Country	Study design and method	Study aim	PROMS used and concepts measured	Setting and participants	Analysis
Hvitfeldt et al. (2009)	U.S/ Sweden	Mixed-method - qualitative description and cross-sectional analytic study (triangulation design); questionnaires; Semi-structured interviews	To identify the properties of a patient-reported measurement system in two different contexts	Low back pain disability, SF-36* - health-related quality of life, Musculoskeletal Outcomes and Data Evaluation and Management System (MODEMS) - unknown	1 Spine centre (USA); 2 rheumatology clinics (Sweden). n = 88 clinical patients; n = 18 healthcare providers (15 medical doctors, 2 physiotherapists, 2 nurse practitioners)	Quantitative data - Fisher's exact 2-tailed test; qualitative data - Content analysis
Kazis, Callahan, Meenan, and Pincus (1990)	USA	Randomised-controlled trial; questionnaires, patients' medical records	To investigate the value of health status information on clinical practice for patients with rheumatoid arthritis	Arthritis Impact Measurement Scales (AIMS)* - physical, social and emotional wellbeing, Modified Health Assessment Questionnaire (MHAQ)* - health status	Arthritis Centres. n = 1920 patients with rheumatoid arthritis. n = 24 physicians.	Analysis of variance F-tests, if significant, pair-wise comparison using t-tests

Authors	Country	Study design and method	Study aim	PROMS used and concepts measured	Setting and participants	Analysis
Meerhoff et al. (2019)	The Netherlands	Qualitative; semi-structured telephone interviews	To explore patients' perspectives on using PROMs in primary care physiotherapy	Numeric Pain Rating Scale, Visual Analogue Scale, Hip Osteoarthritis Scale (HOOS)* - hip disability, the Knee Osteoarthritis Scale (KOOS)* - knee disability, Neck Disability Index (NDI)* - neck disability, Quebec Back Pain Disability Scale (QBPDS)* back pain disability, Patient-Specific Complaints	Primary care physiotherapy n = 21 patients with musculoskeletal health complaints	Thematic analysis
Mularski et al. (2006)	U.S	Case-control; patients' medical records	To measure the impact of using a PROM on the quality of pain management	Numeric Rating Scale – pain intensity	Veteran affairs medical centre. n = 600 patients	Multivariate logistic regression
Purser, Warfield, and Richardson (2014)	U.K	Audit; patients' medical records	To assess whether use of pain assessment affects the pain management behaviour of nurses	Numeric Rating Scale – pain levels	General hospital. Stage one, n = 202, Stage two, n = 60, stage three, n = 253 (medical and surgical patients).	Descriptive statistics

Authors	Country	Study design and method	Study aim	PROMS used and concepts measured	Setting and participants	Analysis
Ravaud et al. (2004)	France	Cluster-RCT; outcome measures, patients' medical record.	To evaluate the impact of an educational programme for nurses to improve pain assessment	Visual Analogue Scale – pain intensity	Surgical wards. n = 2278 surgical patients	Mixed-model ANOVA.
Schorn, Doorenbos, Gordon, and Read-Williams (2014)	U.S	Cross-sectional; survey	To assess how well a tool for pain measurement is received by healthcare providers	PEG (3-item version of the Brief Pain Inventory)* - pain intensity and interferences, Patient Health Questionnaire (PHQ-4)* - depression and anxiety, Generalised Anxiety Disorder (GAD-7)* - anxiety	Primary care. n = 30 primary care providers	Quantitative data - descriptive statistics, qualitative data - content analysis
Stratford and Binkley (1999)	Canada	Case series; patient reported outcome measures	To demonstrate the application of the Roland-Morris questionnaire in clinical scenarios can aid decision making in clinical practice	Roland-Morris Questionnaire* - disability	Physical therapy. n = 3, patients with low back pain	Quantitative descriptive

Authors	Country	Study design and method	Study aim	PROMS used and concepts measured	Setting and participants	Analysis
Thigpen and Shanley (2011)	U.S	Case report; patient reported outcome measures	To demonstrate how PROMs can aid clinical practice in rehabilitation settings	Disabilities of Arm, Shoulder and Hand (DASH)* - upper extremity disability, DASH Sports Module (DASH-SM) – symptom and function, Pennsylvania Shoulder Score (PENN)* - pain, satisfaction and function, SF-12* - general health status	Physical therapy. n = 1, patient with shoulder pain	Quantitative descriptive

Assessment of patient

Clinicians from various backgrounds, including physicians, nurse practitioners, and physical therapists, suggested the purpose of PROMs was to assess the patients' pain and quantify the impact of pain (Ahluwalia et al., 2018; Schorn et al., 2014; Thigpen & Shanley, 2011). PROMs were perceived as a useful way to view pain within the context of a patients' life (Bottega & Fontana, 2010; Buchi & Sensky, 1999). This is illustrated by a nurse in a hospital setting: *"It is important to assess and take into account the thresholds of physical pain for each different individual on different occasions and how it is impacted by cultural and physiological factors*" (Bottega & Fontana, 2010). Physiotherapy patients saw the value in PROMs assisting new patients with clarifying problems, diagnosis, and communicating with clinicians: *"I think that the questionnaires have helped me clarify my health problems, as completing the questionnaire provides me with a clearer picture of my health problems"* (Meerhoff et al., 2019, p. 5). Collectively, the qualitative literature suggested that PROMs provided a positive method to gather essential information on patients. There is, however, little information on participant characteristics or recruitment for these studies, so it is not understood if this finding is reflective of patients with non-malignant pain.

In one qualitative study, surgeons raised concerns over PROMs, seeing the data as highly subjective and questioning the patients' ability to provide "objective" data on their pain (Boyce et al., 2014b). A quote from a surgeon provides a powerful illustration of this: *"Getting patients to fill out forms is grossly inaccurate in my book… the patient 9 time(s) out of 10 wouldn't understand what hip pain is"* (Boyce et al., 2014b, p. 6). Primary care providers also felt measuring pain was not important for all patients "*We don't have to have every single patient that comes in give us a pain rating on zero to ten. It's not a vital sign"* (Ahluwalia et al., 2018, p. 564).

Kazis et al. (1990) explored clinicians' views, through a survey, on the contribution of health status reports generated from PROMs. The majority of clinicians felt that PROMs impacted overall patient assessment in some or all of their consultations and contributed to medical history taking. Thirty-eight percent of clinicians also felt that the reports contributed to physical examination during some or most of their consultations. Other clinicians felt that no contribution was made to overall patient examination, medical history taking, or physical examination. However, not all the clinicians surveyed had used the health status reports in practice, although some of their patients had completed

PROMs as part of the RCT. Their lack of experience using PROMs may have significantly influenced their views on how PROMs contribute to patient assessment.

The outcomes related to this construct are inconclusive. Clinicians had mixed views when surveyed on whether PROMs may contribute to the assessment of patients. Similarly, in the qualitative studies clinicians suggested PROMs had benefits but also voiced concerns about the validity of PROMs.

Decision-making

Clinicians felt that PROMs made valuable contributions to decision-making. Across three qualitative studies, clinicians including medical doctors, surgeons and nurses expressed that PROMs facilitated decision-making (Bottega & Fontana, 2010; Boyce et al., 2014b; Hvitfeldt et al., 2009). This is highlighted by a Swedish healthcare provider, after using PROMs in their clinic for two years: *"Work is smoother, it is much easier to form an opinion and decisions are easier to make"* (Hvitfeldt et al., 2009, p. 253). Patients also felt PROMs provided useful information to develop a treatment plan and choose appropriate treatments (Meerhoff et al., 2019).

PROM scores also enabled clinicians to provide individualised treatments based on patients' needs and direct them to appropriate care (Bottega & Fontana, 2010; Thigpen & Shanley, 2011). Within a study on nurses' use of PROMs, a nurse stated: *"This method is of great value in the performance/assistant of planning so we can assign a more expressive care in relation to the pathology and the patient as a whole. Thus, seeking to minimise the patient's suffering and pain"* (Bottega & Fontana, 2010). Using PROMs in decision-making enabled clinicians to feel they had enough information to develop an individualised treatment plan.

PROMs were also used in the decision-making process to enable clinicians to set functional goals with patients. Two case series and a case report examined how PROMs were used for goal-setting (Buchi & Sensky, 1999; Stratford & Binkley, 1999; Thigpen & Shanley, 2011). PROMs provided baseline data on patients' current situation which were used to anticipate change and set goals.

No studies quantitatively tested the hypothesis that using PROMs improves shared decision-making. However, the qualitative literature suggests that shared decision-making improves and decisions are increasingly individualised with PROM use.

Therapeutic relationship

The synthesis suggested PROMs had an impact on the therapeutic relationship between patients and clinicians through improving communication and patient engagement. A case report demonstrated how PROMs were used to improve communication between patients and physical therapists and start a dialogue regarding their care (Thigpen & Shanley, 2011). Although the authors of this study did not provide adequate details on data collection and analysis processes, other studies demonstrated similar findings. For example, in one study both patients and clinicians believed that using PROMs changed the clinician-patient interaction, as this patient explained: *"The system made it possible for the provider and I to talk about the important issues"* (Hvitfeldt et al., 2009, p. 252). In a survey of primary care providers, who all used PROMs in their clinical practice, 76% felt satisfied that PROMs measuring pain helped patients participate in their pain management (Schorn et al., 2014).

In other qualitative studies clinicians believed PROMs enabled patients to get involved in their care, including identifying patient concerns and engaging patients in self-management (Buchi & Sensky, 1999; Hvitfeldt et al., 2009; Schorn et al., 2014). One nurse stated: *"I see the implementation of the pain scale as a way to humanize care, where we can stop relying on machines and turn to the patient; to what he is saying and feeling. Giving them an active voice and a right to express themselves"* (Bottega & Fontana, 2010). This humanization of care, aided by communication and patient engagement, was thought to improve the relationship between patients and clinicians. Similarly, in a survey of doctors (some who had experienced PROMs and some who had not), the majority felt that PROMs contributed to the doctor-patient relationship (Kazis et al., 1990), although the survey did not examine whether this contribution was positive or negative. Patients also had mixed views, feeling PROMs had value in stimulating communication for new patients, but with no benefit for patients who already had a relationship with their clinician (Meerhoff et al., 2019). Overall, qualitative literature suggests that PROMs may facilitate interactions, aid communication, and promote individualised care. It is through these processes, that PROMs may improve the therapeutic relationship.

Tracking progress, evaluating and changing treatment

Several studies demonstrated using PROMs for tracking patient progress, using the scores from PROMs to evaluate treatment and change treatment plans accordingly. A survey found that 53.3% of primary care providers were satisfied that PROMs helped them to understand patient progress (Schorn et al., 2014). A case series also suggested that PROMs were used to track progress (Stratford & Binkley, 1999). This finding was also demonstrated through nurses' experiences: *"This scale is important in the sense of monitoring the evolution of the intensification of pain and even to what point the treatment is being beneficial to the patient"* (Bottega & Fontana, 2010). Patients similarly felt their physiotherapists could use PROMs to evaluate their treatment (Meerhoff et al., 2019).

Despite these findings, 30% of primary care providers were dissatisfied regarding PROMs to help them modify treatment plans (Schorn et al., 2014). Several clinicians, from two studies, did not feel that PROMs helped them modify treatment plans (Boyce et al., 2014b; Schorn et al., 2014). Several surgeons raised concerns over the information provided from PROMs, one surgeon stated: *"I just think there is a lot of effort being put in there for not a lot of surgical gain from my perspective"* (Boyce et al., 2014b, p. 6).

However, clinicians from several studies reported that PROM scores did influence treatment plans, both on an individual patient level and clinician level. In a qualitative study, PROMs encouraged two surgeons to reflect and change their clinical practice (Boyce et al., 2014b). Individual patients' treatments were also affected, one nurse stated: *"It is* [sic] *tool that allows us to quantify the pain our patient is feeling with more accuracy, and rethink whether or not the therapy being given is really effective in treating that individual"* (Bottega & Fontana, 2010).

As part of the construct on modifying a treatment plan, two sub-constructs were generated; using PROMs to change patient medication use and using PROMs to make referrals to other clinicians and health services. One case report suggested PROM scores were used to refer the patient to another service (Thigpen & Shanley, 2011). Doctors surveyed on PROM use had conflicting opinions; 50% of doctors felt that health status reports (generated from PROM data) did not contribute to patient referrals and 54% of doctors felt that reports did not impact on medication decisions (Kazis et al., 1990). However not all doctors had used PROMs in practice.

Five studies tested the impact of PROMs on medication decisions. Purser et al. (2014) found that 17% of patients had analgesia altered and 6% of patients had an additional dose of analgesia after PROMs had been employed across a hospital. Another study, which issued nurses with training on PROMs and used PROMs across a cardiac surgery ward found that after training and implementation, patients had a higher morphine consumption (dos Santos Silva et al., 2013). In comparison, three studies showed no significant differences in medication between intervention and control groups (Hadjistavropoulos et al., 2009; Kazis et al., 1990; Mularski et al., 2006). No significant differences were found in additional treatment (Mularski et al., 2006), arthritis referrals (Kazis et al., 1990), or reducing doctor visits (Kazis et al., 1990).

The effect PROMs have on tracking patient progress, evaluating and changing treatment is unclear. Surveys and interviews with clinicians identified mixed views, with additional conflicting results from trials testing the impact of PROMs on referrals and medication use.

Potential implications for outcomes

Studies suggested that PROMs might influence patients' health status, pain levels, and satisfaction. Two studies examined the impact of PROMs on patient outcomes, but no significant differences were found between the intervention and control groups on patient satisfaction (Kazis et al., 1990; Ravaud et al., 2004), or health status (Kazis et al., 1990).

PROMs were also hypothesised to impact on pain levels. Ravaud et al. (2004) conducted a cluster-RCT; three wards were assigned to the intervention group (with education and implementation of a visual analogue scale to assess pain) and three wards assigned to control. Pain significantly decreased in the intervention group compared to control (d = 0.1796 [0.0643-0.2949] p = 0.038). An additional study evaluated pain assessment through PROMs; case-coordinators in the intervention group received training on PROMs and PROMs were put into a summary sheet for patients and clinicians, with no significant differences in pain levels between intervention and control groups (Hadjistavropoulos et al., 2009). However, the intervention group did show some benefit in pain levels, reporting less pain related to strenuous activity at follow-up (d=0.4253 [0.054-0.7966] p=<0.05) (Hadjistavropoulos et al., 2009).

There is no definitive evidence as to whether PROMs have an impact on health status; with only some studies showing significant differences. Studies

showed no effect on patient satisfaction. Additionally, no studies examined adverse effects on patient outcomes, although primary care providers voiced concerns that PROMs may increase patients' awareness of their pain which could have a negative impact *"Because a lot of them sit around and just, you know…focus on the pain"* (Ahluwalia et al., 2018, p. 565)

4.3.3 Assessment of confidence

Quality assessment was conducted using an adapted version of the MMAT (Appendix B). No papers were excluded during this process, as papers of low methodological quality may have potential relevance to the review; but their reliability and validity should be considered during the synthesis of results (Dixon-Woods et al., 2006; Kazimierczak et al., 2013). The quality assessment indicated several issues regarding the credibility of the study results. Many studies did not include adequate information on participant recruitment methods or the participants' characteristics (Ahluwalia et al., 2018; Bottega & Fontana, 2010; Buchi & Sensky, 1999; Hadjistavropoulos et al., 2009; Hvitfeldt et al., 2009; Kazis et al., 1990; Mularski et al., 2006; Purser et al., 2014; Ravaud et al., 2004; Schorn et al., 2014; Stratford & Binkley, 1999; Thigpen & Shanley, 2011). Reporting both the participant demographics and recruitment methods is essential to understand the generalisability of the results, ensuring the sample adequately represents the underlying population of interest (Patel, Doku, & Tennakoon, 2003; Toerien et al., 2009).

There were also issues for specific study designs. The two case series did not adequately describe the process by which findings were produced (Buchi & Sensky, 1999; Stratford & Binkley, 1999); limiting the ability to replicate the study to validate the results. Three studies with a qualitative component showed no consideration of researchers' influence or study context (Ahluwalia et al., 2018; Bottega & Fontana, 2010; Hvitfeldt et al., 2009); researchers must acknowledge how their assumptions and previous knowledge may have informed their interpretation of the data and the implications for results. Both RCTs had insufficient information regarding randomisation, allocation, blinding, and missing data (Kazis et al., 1990; Ravaud et al., 2004). Without sufficient information, it is unclear whether randomisation to reduce bias and confounding had been successful and confidence in the results is reduced (Higgins & Green, 2008).

The overall lack of information surrounding participant characteristics and recruitment, coupled with the risk of bias from the RCTs and case studies, poses questions around the reliability and generalisability of the results. Due to these limitations, the results cannot be applied to a larger population of patients with pain. However, no findings were deemed irrelevant to the review, aiming to look at potential impact of PROMs rather than measuring the effectiveness of PROMs in clinical practice. All findings from the studies were therefore included in the synthesis and the results propose an interesting concept to be tested with further research.

Table 4.4 summarises and assesses the evidence supporting each construct. For each construct, a judgement was made against the CERQual components: methodological limitations, relevance, coherence, and adequacy. An overall assessment of confidence was made, rating whether each construct is a reasonable representation of the phenomenon of interest. Constructs could be rated: very low confidence (unclear whether it is a reasonable representation), low confidence (possibly a reasonable representation), moderate confidence (likely a reasonable representation), high confidence (highly likely a reasonable representation).

Table 4.4 – CERQual summary assessment

Review finding	Studies contributing to the review finding	Studies contradicting the review finding	Assessment of methodological limitations	Assessment of relevance	Coherence	Adequacy	Confidence
Assessment of patient	7 studies (Ahluwalia et al., 2018; Bottega & Fontana, 2010; Buchi & Sensky, 1999; Kazis et al., 1990; Meerhoff et al., 2019; Schorn et al., 2014; Thigpen & Shanley, 2011)	4 studies (Ahluwalia et al., 2018; Boyce et al., 2014b; Kazis et al., 1990; Meerhoff et al., 2019)	Moderate methodological limitations	Indirect relevance	Minor concerns about coherence (data is reasonably consistent within and across all studies)	Minor concerns about adequacy (7 studies offering moderately rich data)	Moderate confidence
Decision-making	7 studies (Bottega & Fontana, 2010; Boyce et al., 2014b; Buchi & Sensky, 1999; Hvitfeldt et al., 2009; Meerhoff et al., 2019; Stratford & Binkley, 1999; Thigpen & Shanley, 2011)		Moderate methodological limitations	Indirect relevance	No concerns about coherence (data consistent within and across all studies)	No concerns about adequacy (7 studies offering moderately rich data)	High confidence
Therapeutic relationship	6 studies (Bottega & Fontana, 2010; Buchi & Sensky, 1999;	3 studies (Kazis et al., 1990; Meerhoff et al., 2019; Schorn et al., 2014)	Moderate methodological limitations	Indirect relevance	Minor concerns about coherence (data is reasonably	Minor concerns about adequacy (6 studies offering moderat	Moderate confidence

	Hvitfeldt et al., 2009; Meerhoff et al., 2019; Schorn et al., Thi Sh 2				consistent within and across all studies)	ely rich data)	

Review finding	**Studies contributing to the review finding**	**Studies contradicting the review finding**	**Assessment of methodological limitations**	**Assessment of relevance**	**Coherence**	**Adequacy**	**Confidence**
Tracking progress, evaluating and changing treatment	10 studies (Bottega & Fontana, 2010; Boyce et al., 2014b; dos Santos Silva et al., 2013; Hvitfeldt et al., 2009; Kazis et al., 1990; Meerhoff et al., 2019; Purser et al., 2014; Schorn et al., 2014; Stratford & Binkley, 1999; Thigpen & Shanley, 2011)	5 studies (Boyce et al., 2014b; Hadjistavropoulos et al., 2009; Kazis et al., 1990; Mularski et al., 2006; Schorn et al., 2014)	Moderate methodological limitations	Indirect relevance	Major concerns about coherence (data is not consistent within and across all studies)	Minor concerns about adequacy (8 studies offering moderately rich data, 2 studies offering thin data)	Low confidence
Influencing outcomes	3 studies (dos Santos Silva et al., 2013; Hadjistavropoulos et al., 2009; Ravaud et al., 2004)	5 studies (Ahluwalia et al., 2018; dos Santos Silva et al., 2013; Hadjistavropoulos et al., 2009; Kazis et al., 1990; Ravaud et al., 2004)	Moderate methodological limitations	Indirect relevance	Major concerns about coherence (data is not consistent within and across all studies)	Substantial concerns about adequacy (3 studies offering thin data)	Very low confidence

4.4 Discussion

In this systematic review, 15 studies were identified and synthesised to explore the potential impact of the process and outcome of healthcare after using PROMs in routine clinical practice for non-malignant pain. Five areas of potential impact were identified and organised into three stages of treatment (initial consultation, during treatment, and post-treatment).

The synthesis indicated that PROMs may have some impact during the initial consultation process. Clinicians mostly believe the use of PROMs contributes in some way to the assessment of the patient with a purpose to understanding patients' pain (Ahluwalia et al., 2018; Bottega & Fontana, 2010; Buchi & Sensky, 1999; Hvitfeldt et al., 2009; Kazis et al., 1990; Meerhoff et al., 2019; Schorn et al., 2014; Thigpen & Shanley, 2011). This finding corroborates a previous systematic review on the impact of PROMs (Espallargues et al., 2000), studies included participants with chronic health conditions (including arthritis, asthma, epilepsy), psychiatric patients, and those with general medical problems. The review found that PROMs impacted the assessment of patients through acting as a screening tool and improving diagnosis (Espallargues et al., 2000).

PROMs were thought to affect the initial consultation through goal setting with the patient and decision-making for the course of treatment (Bottega & Fontana, 2010; Boyce et al., 2014b; Buchi & Sensky, 1999; Hvitfeldt et al., 2009; Meerhoff et al., 2019; Stratford & Binkley, 1999; Thigpen & Shanley, 2011). This construct was assessed as high confidence because of moderate methodological limitations, with no concerns about coherence and adequacy of data. Another previous systematic review, examining qualitative literature on clinicians' experiences of using PROMs, also identified that clinicians believed PROMs had the potential to impact planning care and joint decision-making (Boyce et al., 2014a). Whilst this review was not focused on pain and examined more broadly the use of PROMs in clinical practice, these findings suggest that PROMs may have an impact on shared decision-making and treatment planning, not only in the treatment of non-malignant pain but also in other patient populations.

Results from qualitative literature identified that during the treatment process, clinicians and patients felt the use of PROMs had some influence on the therapeutic relationship, through patient-engagement and communication (Bottega & Fontana, 2010; Buchi & Sensky, 1999; Hvitfeldt et al., 2009; Kazis et

al., 1990; Meerhoff et al., 2019; Schorn et al., 2014; Thigpen & Shanley, 2011). This finding corroborates and extends the previous qualitative systematic review by Boyce et al. (2014a), finding that clinicians felt PROMs enhanced communication. A few quantitative studies contradicted these views, with surveys indicating that clinicians do not feel PROMs contribute to the therapeutic relationship or patient engagement (Kazis et al., 1990; Schorn et al., 2014). These results may be mutually compatible; although the results suggest that many clinicians feel PROMs influence the patient-clinician interaction and relationship, others may not have experienced this or feel this is the case. Further research is needed to explore why clinicians may differ in their perceptions of PROMs; such work may help explain why PROMs do not always influence outcomes in trials.

There were also mixed findings on clinician views' about using PROMs to evaluate treatment and change treatment plans. Similarly, Greenhalgh and Meadows (1999) discussed how clinicians used the information from PROMs to change the treatment and care of their patients. Within the current study, many clinicians described using PROMs in this way (Bottega & Fontana, 2010; Boyce et al., 2014b; Schorn et al., 2014; Stratford & Binkley, 1999); however due to the lack of coherence and methodological limitations, there is low confidence in this construct.

Using the qualitative literature from the current synthesis to add to current knowledge in this area, it is important to note that some clinicians were concerned about the objectivity of the data being provided (Boyce et al., 2014b). Additionally, when un-validated PROMs are used their sensitivity to change and reliability are questionable. Validated PROMs are essential if they are to track patient progress accurately, especially if results are being used to evaluate and change treatment plans.

Specific examples of modifying treatment discussed in the literature were changing medication and referrals to other clinicians. Despite a few clinicians believing that PROMs data may aid medication decisions, there were conflicting results on medication use. Two studies reported small changes to medication use (dos Santos Silva et al., 2013; Purser et al., 2014), although other results were non-significant (Hadjistavropoulos et al., 2009; Kazis et al., 1990; Mularski et al., 2006). Although some clinicians felt the use of PROMs contributed to referrals (Kazis et al., 1990; Thigpen & Shanley, 2011), it did not have any actual impact on referrals (Kazis et al., 1990; Mularski et al., 2006). A previous review also

identified seven studies which indicated that PROM feedback to clinicians did not statistically increase referrals to other clinicians and healthcare services, however a further six studies did show a statistical increase (Espallargues et al., 2000). These conflicting results indicate that there is currently a lack of understanding surrounding the full processes by which PROMs may influence referrals, and there may be additional variables which influence the referral process; further analysis should be undertaken to explore this area.

There is also conflicting evidence showing PROMs impact on pain levels and patient satisfaction. The results from this current review showed limited to no improvement in pain levels and no significant improvement on patient satisfaction (dos Santos Silva et al., 2013; Hadjistavropoulos et al., 2009; Kazis et al., 1990; Ravaud et al., 2004). Boyce and Browne (2013) reviewed the usefulness of providing group-level feedback of PROMs to clinicians; patient populations that saw improvements were those with liver disease, and patients in mental health and oncology settings. These results may not be generalisable across study populations to include patients with non-malignant pain. Due to major concerns about the coherence of the data, substantial concerns over the richness of the data provided, and methodological limitations, there is very low confidence in this review construct. Although PROMs were hypothesised to impact pain levels and clinicians stating concerns over PROMs increasing patients awareness of pain (Ahluwalia et al., 2018), no studies investigated the impact on pain hypervigilance. This is an area for future research.

4.4.1 Strengths and limitations

This review synthesised a diverse body of evidence in accordance with CIS methodology, generating an understanding of the complexity of PROMs. As there is no current literature on the most effective method to use PROMs in clinical practice for non-malignant pain, all measures, populations, settings, and perspectives were eligible for review. For example, not all studies detailed whether patients had acute or chronic pain, two studies included both medical and surgical patients, and some studies employed a mix of validated and non-validated PROMs. Within clinical practice, clinicians may use the tool they deem the most appropriate for specific patients (Thigpen & Shanley, 2011). Therefore, studies using non-validated PROMs were included in this review to reflect the use of PROMs in clinical practice. There was substantial heterogeneity across the

included studies, limiting the generalisability of the results, and hindering the possibility of running sub-group analyses.

There were key methodological limitations surrounding lack of information, reducing the reliability of results and increasing risk of bias. Considering the methodological quality of the studies, it is suggested that whilst the five constructs may be areas of potential impact, the results cannot be taken at face-value and more research is necessary. Finally, barriers to successful use, such as clinician knowledge and education, organisation support, selection of outcome measure, and application of PROMs (Antunes et al., 2014), were deemed beyond the scope of the review. However, these are important issues which need to be addressed in future research to evaluate the impact of PROM use.

4.5 Chapter summary

This chapter aimed to provide a comprehensive overview of the potential impact of using PROMs in clinical practice within the context of pain, and the supportive evidence behind the claims. The synthesis provided preliminary evidence to suggest that PROMs may have some positive impact and that some clinicians and patients believe that PROMs could be useful in the treatment of pain. PROMs may be included in the initial consultation to assess patients and for decision-making regarding the patient's care. During the course of a patient's treatment, PROMs may be used to track the progress of a patient, evaluate current treatment and change the course of care if required. The use of PROMs may also influence the therapeutic relationship between patient and clinician. Lastly, post-treatment, PROMs may have a direct influence on other outcomes, such as pain and patient satisfaction.

As there is currently a lack of clear evidence from the literature, it is premature to make definitive recommendations for how PROMs could be used in non-malignant pain settings. All of the constructs emerging from the synthesis would benefit from further research. The synthesis of evidence from this chapter is further explored with theoretical concepts to describe and predict how PROMs may work within the treatment of non-malignant pain (Chapter 5). This understanding of potential effects and mechanisms aided the generation of hypotheses to effectively evaluate the clinical and psychosocial consequences of using PROMs in specialist musculoskeletal care for low back pain (Chapter 7 and 8).

Chapter 5 PROMs in clinical practice: a realist review and theoretical framework

5.1 Introduction

Theory can describe and predict how an intervention works. However, the theoretical basis underpinning PROMs in clinical practice is underdeveloped. A theory identifying the core components of PROMs as an intervention, the potential mechanisms, and anticipated outcomes, could improve and develop the use of PROMs within clinical practice (Moore et al., 2015). Theory can provide a foundation for future empirical research (Moore et al., 2015; Pawson et al., 2004) to examine how PROMs may influence outcomes. A theoretical framework and further research will enable clinicians to use PROMs effectively to improve clinical practice.

No theory has specifically focused on the potential effects and processes of the routine use of PROMs for patients with non-malignant pain. Within this chapter previous models of PROMs are considered and psychological theories that may relate to PROMs are outlined. This chapter contextualises the rest of the research within this thesis, with a review of theoretical and empirical literature to explain the inter- and intra-personal mechanistic processes through which PROMs might influence health outcomes in routine clinical practice for non-malignant pain.

5.1.1 Previous models of PROMs in clinical practice

Three previous theories have modelled mechanisms through which PROMs might influence patient outcomes (Greenhalgh et al., 2017; Greenhalgh, Long, & Flynn, 2005; Santana & Feeny, 2014). Greenhalgh et al. (2005) used a theory-driven approach to model the process by which PROMs may influence outcomes (see Figure 5.1). They suggested that when clinicians receive PROM data, it encourages discussion with patients, leading to concordance of treatment goals. PROMs also facilitate diagnosis of undiagnosed conditions and enable clinicians to monitor treatment and respond accordingly. When patients' monitor their treatment by completing PROMs, this may lead them to change their health behaviours and may improve their HRQoL and satisfaction with healthcare.

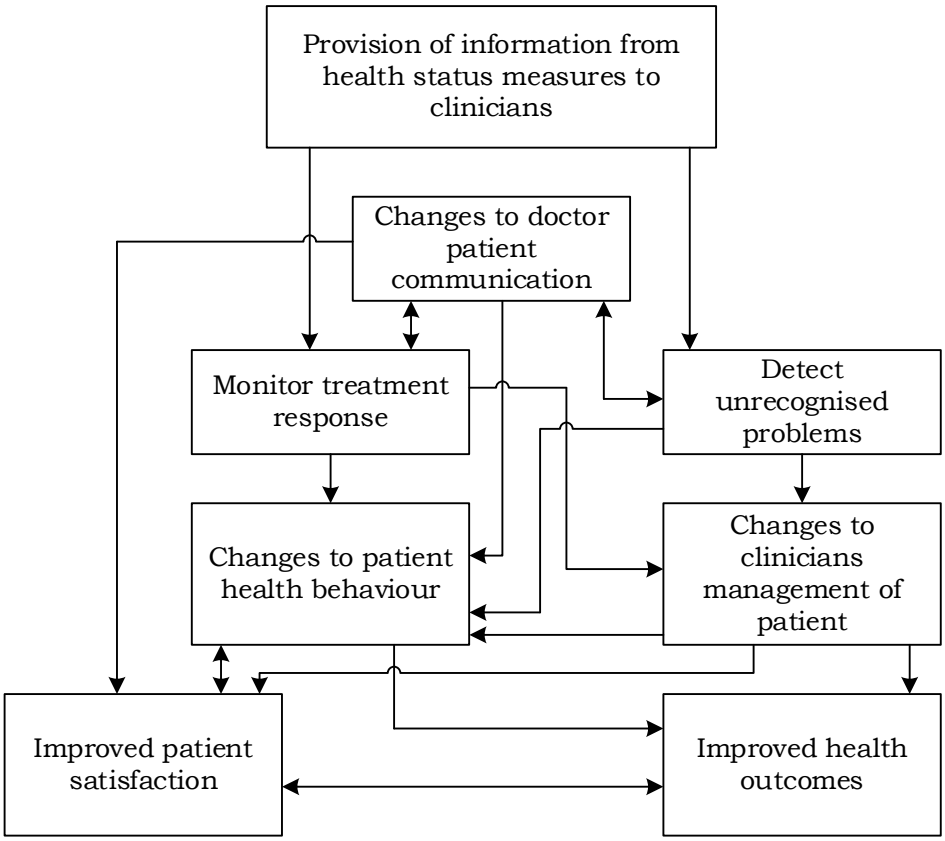


Figure 5.1 – Impact of PROMs on clinical decision-making

Adapted from: Greenhalgh et al. (2005)

Further, Greenhalgh et al. (2005) suggest three necessary conditions for PROMs to impact patient satisfaction and health outcomes: 1) patients must want to talk about the PROM data they provided, 2) clinicians must feel PROM data is appropriate to discuss with patients, 3) clinicians must feel that issues

raised are relevant, clinically meaningful, and important enough to enable strategies to change care and self-care.

A model from Santana and Feeny (2014) suggests that PROMs may influence communication, not only between patients and clinicians, but also between patients and their relatives, and amongst clinicians (see Figure 5.2). Consequently, PROM data is thought to enhance patient engagement, enabling them to take on a more active role in their care. PROMs may also influence patient management; clinicians may detect previously undiagnosed issues and employ strategies to improve patient care. PROM data is also thought to influence shared decision-making, providing information to enable mutually acceptable treatment plans. PROMs in the context of chronic care management, may have the potential to reduce adverse outcomes, decrease length of hospital admission, reduce readmission, and improve survival and HRQoL (Santana & Feeny, 2014).

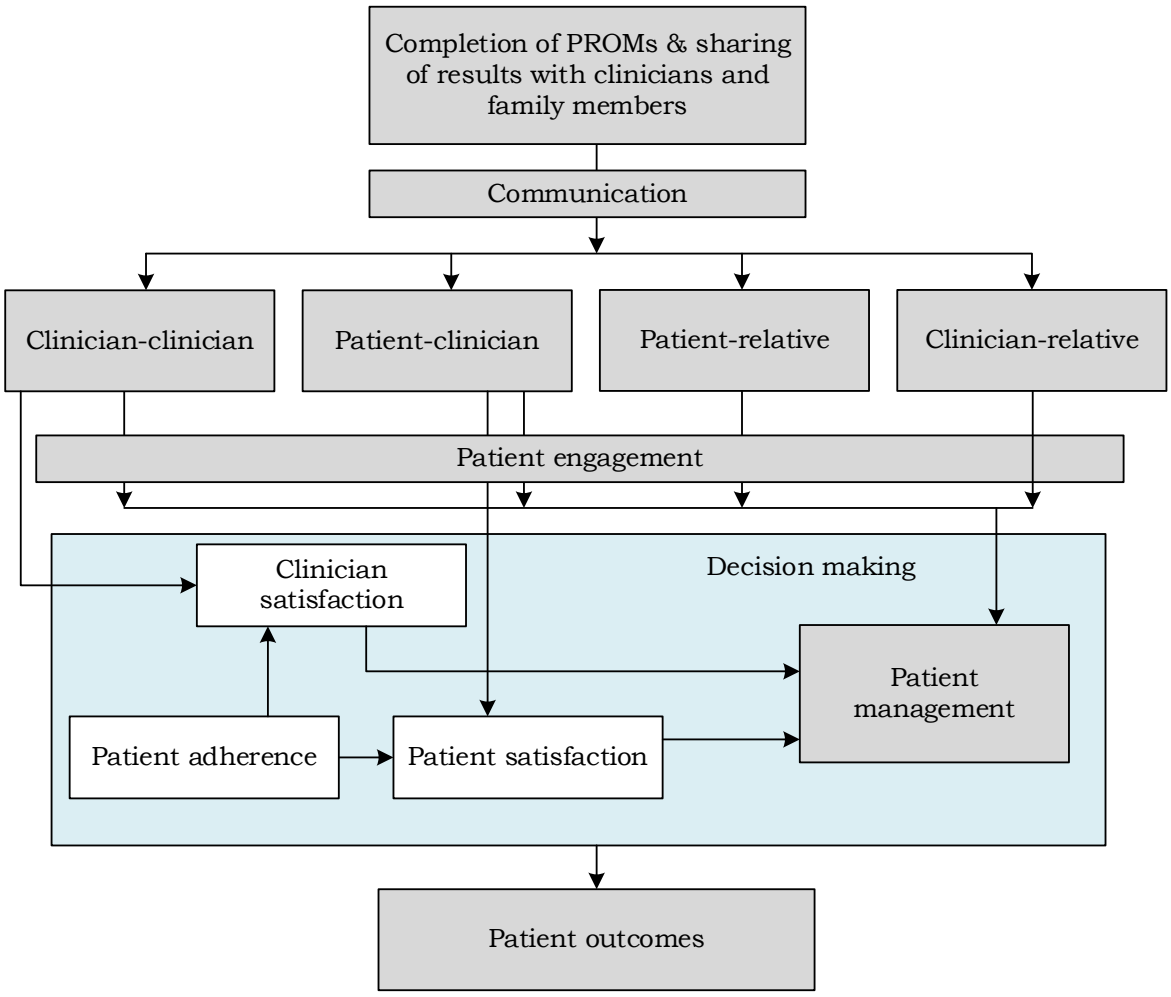


Figure 5.2 – Framework assessing the effects of PROMs

Adapted from: Santana and Feeny (2014)

Lastly, Greenhalgh et al. (2017) developed a logic model depicting PROMs for individual patients in routine clinical practice (Figure 5.3). The model illustrates that utilising PROMs may raise issues and initiate a discussion between patients and clinicians. PROMs may also act as a catalyst for action independent of the clinical consultation; patients may use PROMs to monitor their health, or clinicians may decide on a course of action without discussion with the patient. The model depicts that that through these processes, patient outcomes will improve (Greenhalgh et al., 2017).

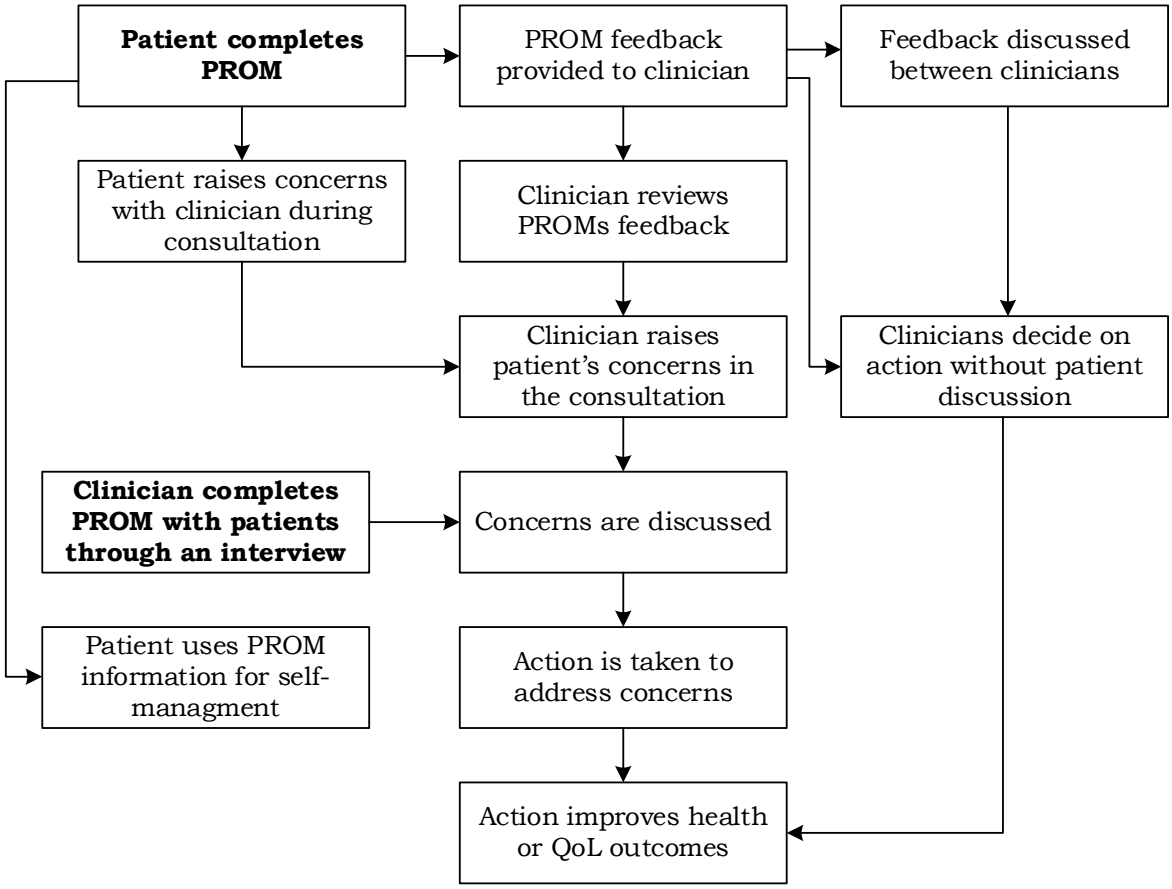


Figure 5.3 – PROMs feedback in the care of individual patients

Adapted from: Greenhalgh et al. (2017)

5.1.2 Psychological theories relating to PROMs

The three existing PROMs models provide insight into some ways in which PROMs might impact patient outcomes (Greenhalgh et al., 2017; Greenhalgh et al., 2005; Santana & Feeny, 2014), but none are comprehensive. In particular, although the models emphasise the patient-clinician interaction and treatment process, they lack explanation of mediating intrapersonal processes (Greenhalgh et al., 2017). It is therefore necessary to consider relevant psychological theories that may provide a theoretical grounding on the processes by which PROMs have an impact in clinical practice (Moore et al., 2015). This section briefly describes a series of psychological theories that may be relevant to understand how PROMs influence health outcomes. These are covered in more depth with the results of the synthesis. Psychological theories considered are: the common-sense model of self-regulation (Diefenbach & Leventhal, 1996), the extended common-sense model of self-regulation (Horne, 2003), the fear-avoidance model (Vlaeyen & Linton, 2000), self-efficacy (Bandura, 1988), protection-motivation theory (Prentice-Dunn & Rogers, 1986), self-regulation control theory (Carver & Scheier, 1982), and the integrated model of behaviour (Fishbein, 2000). These theories were chosen based on their relevance to concepts of PROM use that were identified during the review process (see Section 5.2.5).

Common-sense model of self-regulation

The common-sense model of self-regulation is based on the concept of problem-solving: selecting goals, acting on strategies to achieve goals, and removing obstacles to achieving goals (Diefenbach & Leventhal, 1996; Leventhal, Brissette, & Leventhal, 2003). The model proposes that external and internal stimuli (such as a diagnosis or the sensation of pain) constitute health threats or illnesses (Diefenbach & Leventhal, 1996). These stimuli trigger emotional and cognitive representations of illness. Together these representations define the illness for the patient and influence the course of action that follows (see Figure 5.4).

Figure 5.4 - Common-sense model of self-regulation

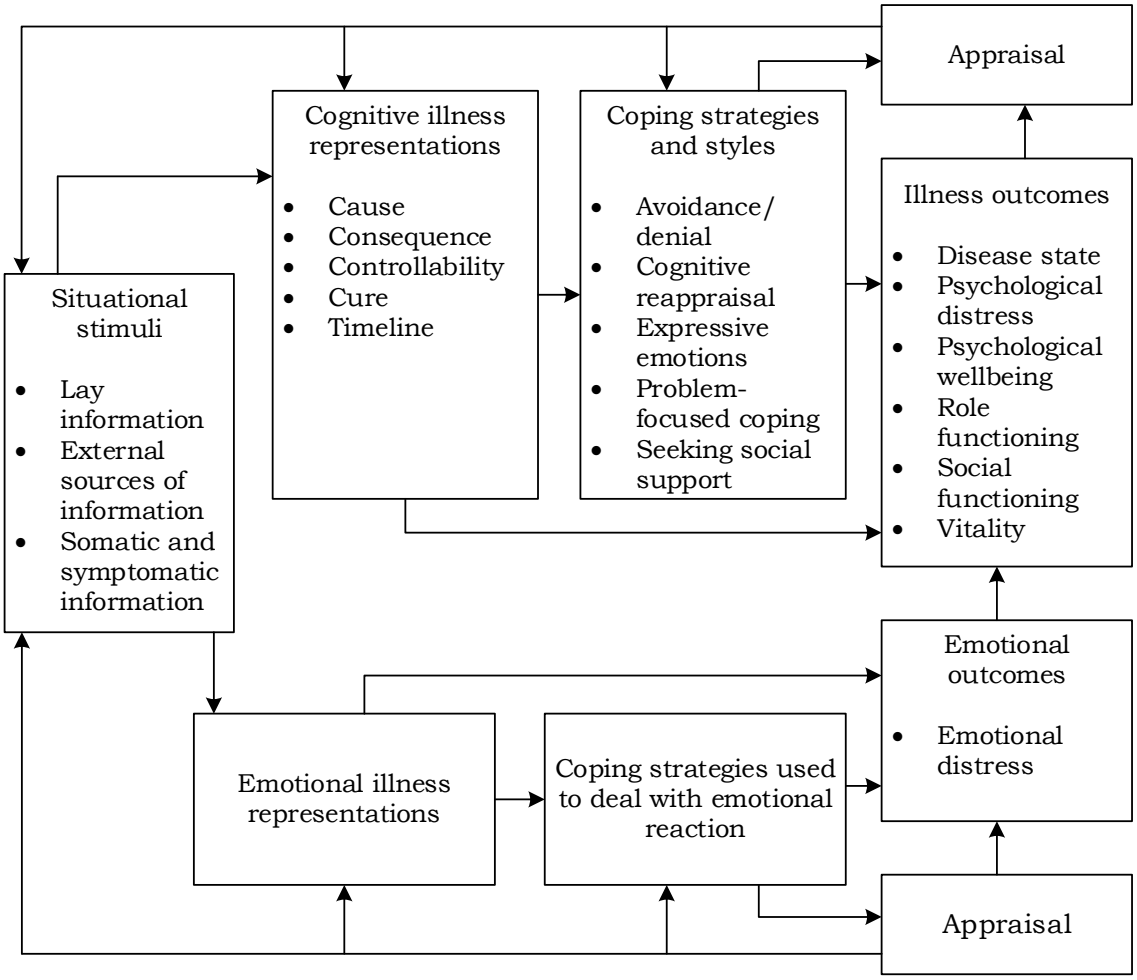


Figure 5.4 – Common-sense model of self-regulation

Adapted from: Hagger and Orbell (2003)

Hagger and Orbell (2003) conducted a meta-analysis of 45 studies examining the components of the common-sense model. The results provided support for the discriminant validity of the dimensions on the model and the relationships between illness cognitions, coping strategies, and outcomes (Hagger & Orbell, 2003).

Extended model of self-regulation

Horne (1997) developed an extended model of self-regulation to explain how the common-sense model of self-regulation could be applied to adherence (see Figure 5.5). Adherence is defined as: "*The extent to which the patient's behaviour matches agreed recommendations from the prescriber*" (Horne et al., 2005, p. 12). The extended model proposes that individuals have representations of coping strategies. These perceptions of and emotional responses to treatment, in addition to illness perceptions, are determinants of action and adherence to coping strategies. Patients' beliefs about the necessity of treatment and concerns over treatment are important determinants in patients' treatment decisions and adherence to treatment (Horne et al., 2013).

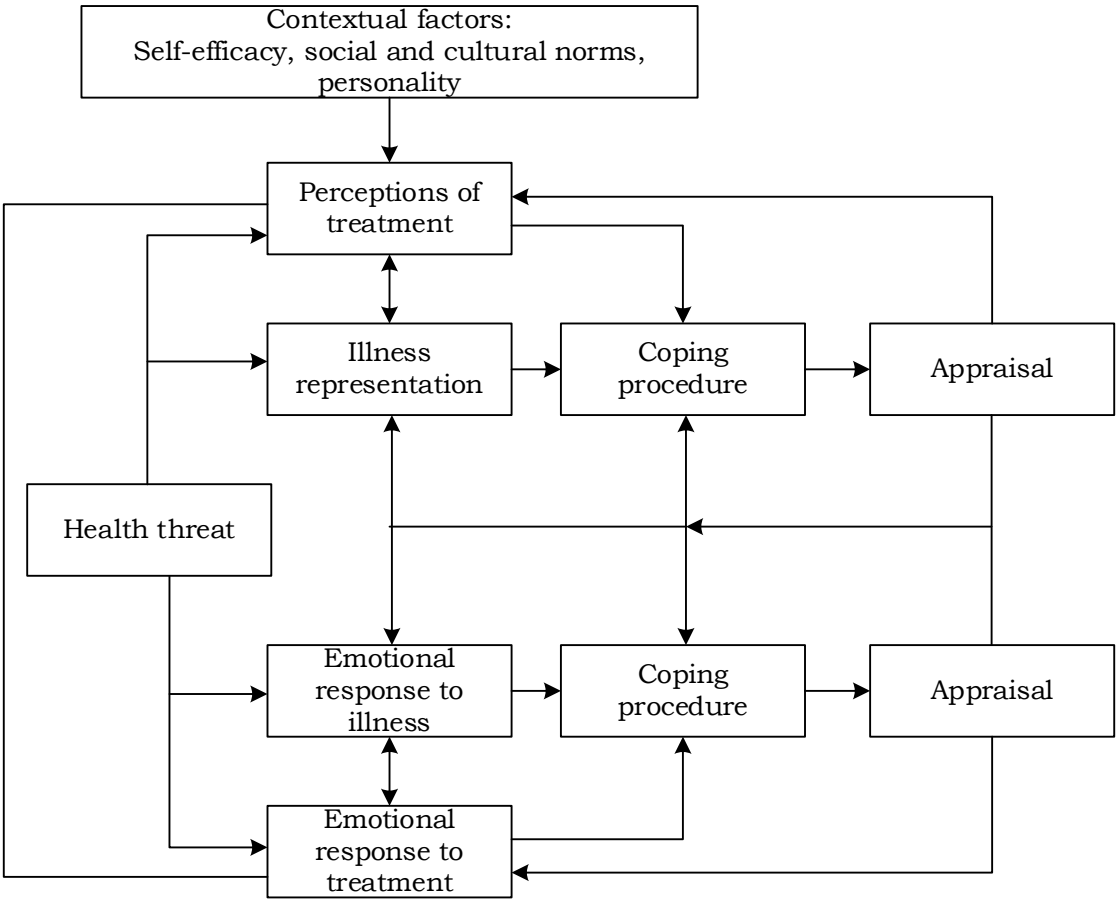


Figure 5.5 – Extended model of self-regulation

Adapted from: Horne (2003)

Fear-avoidance model

The fear-avoidance model is based on the concept that through the experience of pain and associated behaviour, individuals may become dissociated from the sensation of pain and begin to fear pain (Lethem, Slade, Troup, & Bentley, 1983; Vlaeyen & Linton, 2000). It further suggests that patients may avoid activities based on their fear of pain (see Figure 5.6).

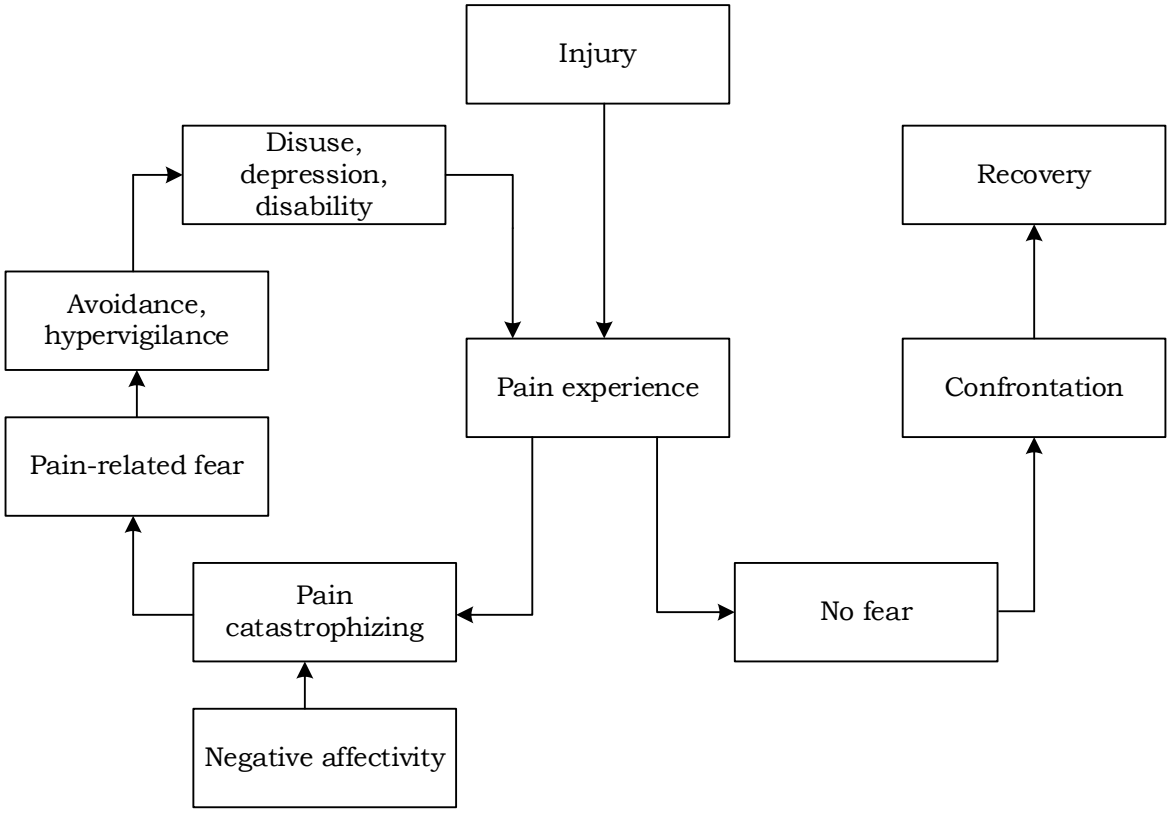


Figure 5.6 – Fear-avoidance model

Adapted from: Vlaeyen and Linton (2000)

Protection motivation theory

Protection motivation theory is a theory of fear-arousal. Fear-arousing stimulus arouses an individual to eliminate any behaviour that may produce adverse effects (Rogers, 1975). Prentice-Dunn and Rogers (1986) suggest that a threat appraisal and coping appraisal must occur to initiate a coping response (see Figure 5.7). An individual must appraise fear-arousing stimuli as noxious and think a threat likely to occur to initiate a coping response. The threat appraisal also includes perceived vulnerability to the threat and its severity. The fear resulting from a threat appraisal process can be motivating for patients to change their behaviour or undertake action to reduce the threat. The coping appraisal assesses the efficacy of a coping strategy for preventing the threat. Additionally, the individual must believe they have the capability to complete the coping strategy. Both threat appraisal and coping appraisal must occur for an individual to have the motivation to change their behaviour.

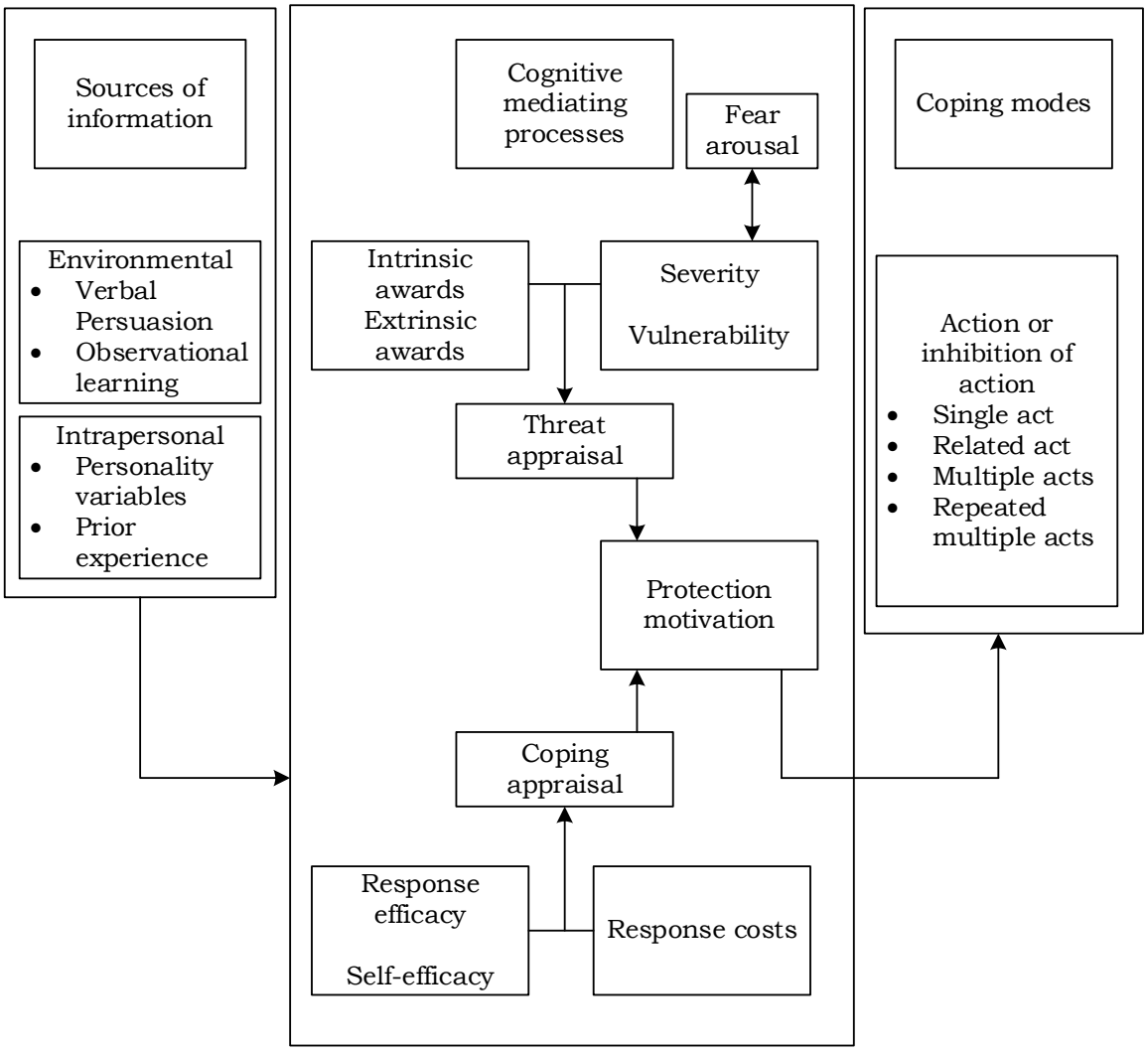


Figure 5.7 – Protection motivation theory

Adapted from Prentice-Dunn and Rogers (1986)

Self-efficacy

Self-efficacy refers to an individual's beliefs surrounding their capabilities to complete actions to create change and accomplish goals (Bandura, 1988). Self-efficacy beliefs can influence individuals' choices surrounding action, their effort to complete tasks, perseverance and resilience in the face of setbacks, and stress. Self-efficacy has an essential role in motivation to perform actions. Bandura (1988) suggests that individuals will only undertake tasks if they believe they have the capabilities to perform the task.

Self-efficacy also has a significant role in health promoting behaviours and changing risky health behaviours (Schwarzer & Fuchs, 1996). A change in health behaviour is dependent on an individual's belief that they have the capability to change and maintain that change. Within the context of pain, patients may require high self-efficacy for exercising despite pain in order to undertake physical activity when experiencing pain (Altmaier, Russell, Kao, Lehmann, & Weinstein, 1993).

Self-regulation – control theory

Self-regulation control theory is based on the idea that people's behaviour is regulated by identifying and attaining goals (Scheier & Carver, 2003). Goals are thought to be part of an action loop which motivates individuals and plays a role in directing activity (see Figure 5.8).

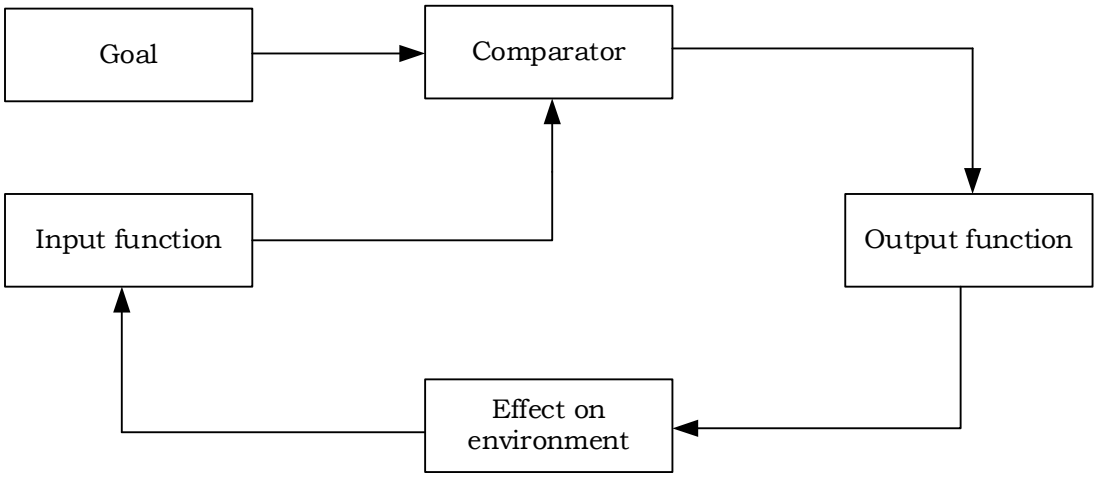


Figure 5.8 – Self-regulation control theory

Adapted from: Scheier and Carver (2003)

Integrated model of behaviour

The integrated model of behaviour (see Figure 5.9) was developed from the theory of reasoned action and the theory of planned behaviour. The model is based on the concept that behaviour is more likely to occur if an individual has a strong intention to perform it (Fishbein, 2000; Yzer, 2012). An individual must also have the necessary skills to perform the behaviour and there must be no environmental constraints preventing the behaviour being carried out (Fishbein, 2000).

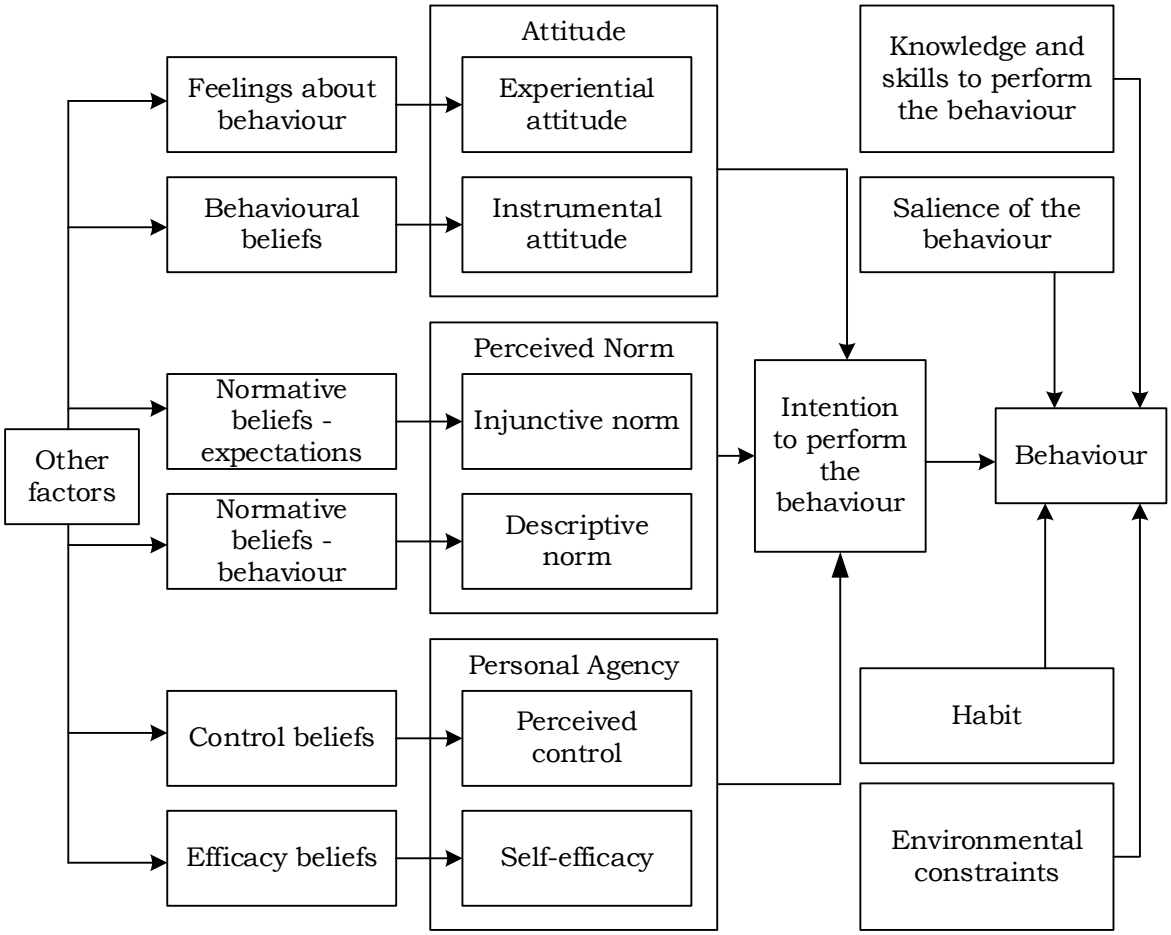


Figure 5.9 – Integrated model of behaviour

Adapted from: Montano and Kasprzyk (2008)

There is some evidence supporting the integrated model of behaviour. The initial work using this theory was conducted on HIV prevention and condom use (Fishbein, 2000; Kasprzyk, Montaño, & Fishbein, 1998). Using structural equation modelling one study found the components of the integrated model of behaviour predicted condom use (Rhodes, Stein, Fishbein, Goldstein, & Rotheram-Borus, 2007). Whilst the previous research using this model has focused on interventions for behaviour change in patients, there is no reason why this model could not be applied to clinicians.

5.1.3 Research question and objectives

It is important to further develop the theoretical basis underpinning PROMs in clinical practice for particular patient populations, as monitoring health may have different implications according to patients' conditions and practice settings (Greenhalgh et al., 2017; Pawson et al., 2004). The systematic review in Chapter 4 suggests that PROMs may have an impact on clinical practice for non-malignant pain, with some clinicians and patients believing they could be useful in the treatment of pain. However, no theory has specifically focused on the potential effects and processes involved in the routine use of PROMs for patients with non-malignant pain. Within this context, it is also necessary to consider the psychology of pain and patients' treatment beliefs and illness perceptions. The aim of this realist review was to develop a refined theory explaining the inter- and intra-personal mechanistic processes through which PROMs might influence health outcomes in routine clinical practice for non-malignant pain. The objectives of this review were to:

1. Identify processes by which PROMs might influence health outcomes, within the context of treating non-malignant pain.
2. Integrate the findings of relevant papers using realist synthesis and discuss emerging concepts.
3. Combine concepts from psychological theories and the realist theories to form a single theoretical framework to model the inter- and intra-personal processes of PROMs to guide subsequent empirical work.

5.2 Methods

5.2.1 Review methodology

A realist review was conducted. Realist reviews use a theory-driven approach to synthesise research to explain how an intervention works (Pawson et al., 2005; Wong, Westhorp, Pawson, & Greenhalgh, 2013), while acknowledging that interventions may have several inter-connected stages, each with associated theory (Pawson & Bellamy, 2006; Pawson et al., 2005). This methodology can be used to develop theory about how an intervention could influence patients and the conditions under which an intervention may work and can thus aid the development of testable complex intervention (Pawson & Bellamy, 2006; Pawson et al., 2004; Rycroft-Malone & Burton, 2015).

5.2.2 Step 1 – Literature search

This search was conducted in combination with the search conducted for the systematic review in Chapter 4 (see Section 4.2.2). A literature search was conducted on PubMed; Excerpta Medical Database and Allied and Alternative Medicine (EMBASE); PsycINFO; Cochrane Library; Web of Science; PsycARTICLES. Boolean logic was used to combine terms, which included derivatives of patient-reported outcome and clinical practice (see Appendix A).

5.2.3 Step 2 – Selection of literature

Step 2 aimed to start collating ideas about how an intervention works. This was achieved by identifying programme theories and critical pieces of non-empirical literature exploring how PROMs may work (Pawson et al., 2005). Included papers theorised about the potential mechanisms of action of PROMs in routine clinical practice for non-malignant pain (Rycroft-Malone & Burton, 2015). Papers were included if they focused on PROMs used with patients with non-malignant pain, within healthcare settings which routinely see patients with non-malignant pain, or the general use of PROMs in clinical practice. Study titles and abstracts were screened to assess eligibility, followed by screening of full texts. Studies were screened for inclusion into either this realist review or the systematic review presented in Chapter 4. The process is documented using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart (Figure 5.10) (Moher et al., 2009).

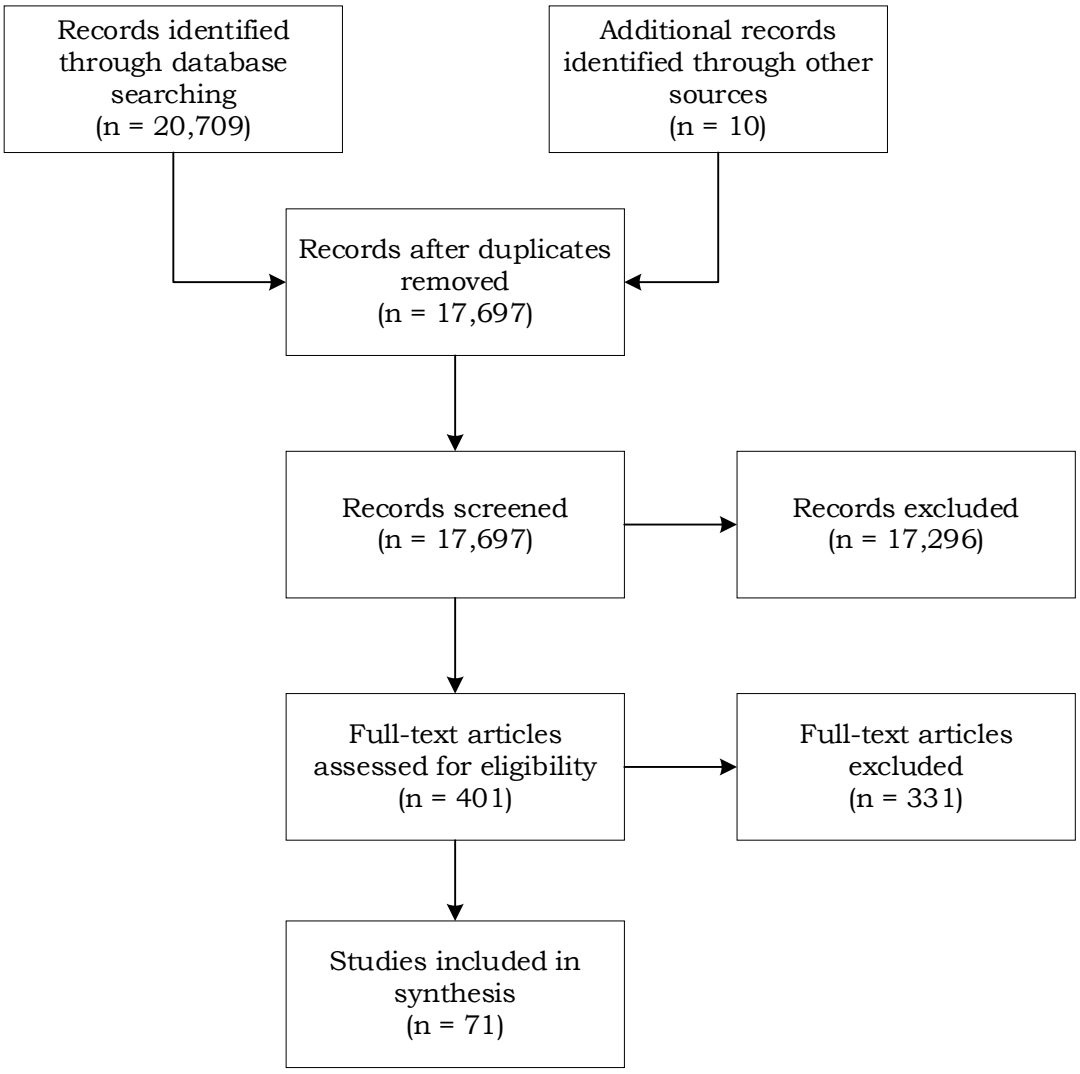


Figure 5.10 – PRISMA flowchart

5.2.4 Step 3 – Identifying common mechanisms

Step 3 aimed to formalise a model on PROMs, speculating on the context, mechanisms, and outcomes of PROMs as an intervention (Pawson & Bellamy, 2006). To achieve this, textual data was inputted into qualitative software, NVivo (version 10) which was used for analysis (QSR International, 2010). Data extraction was undertaken through note-taking, with papers examined for key ideas on the mechanism of PROMs. The synthesis was carried out looking for common patterns within the text, such as mechanisms and outcomes and coded inductively (Rycroft-Malone & Burton, 2015). The codes were examined for patterns and aggregated to create themes. In discussion with an academic supervisor, these themes formed a preliminary conceptual explanation regarding PROMs (Pawson et al., 2004; Rycroft-Malone & Burton, 2015).

5.2.5 Step 4 – Searching for relevant evidence

Step 4 integrated empirical evidence from the systematic review in Chapter 4 to support the theorised model (Pawson & Bellamy, 2006; Pawson et al., 2005). An additional search was carried out to identify formal theories that might further refine the theorised model (Pawson et al., 2004; Wong, Westhorp, et al., 2013). Two reviewers (MH and FLB) identified relevant psychological theories to the preliminary conceptual model developed in Step 3, to generate additional insights into the intrapersonal processes by which PROMs might influence health outcomes. Theories included were: the common-sense model of self-regulation (Diefenbach & Leventhal, 1996), the extended common-sense model of self-regulation (Horne, 2003), the fear-avoidance model (Vlaeyen & Linton, 2000), self-efficacy (Bandura, 1988), protection-motivation theory (Prentice-Dunn & Rogers, 1986), the integrated model of behaviour (Fishbein, 2000), and self-regulation control theory (Carver & Scheier, 1982). These are summarised in section 5.1.2.

5.2.6 Step 5 – Data synthesis

In Step 5, a final synthesis was conducted, integrating the preliminary understanding of the process developed in Step 3 and the relevant empirical evidence and psychological theories identified in Step 4 (Pawson et al., 2005). A theoretical framework was then developed, linking the multiple constructs (Popay et al., 2006) to map out the inter and intra personal mechanistic processes through which PROMs might influence outcomes. The conceptual diagram developed from Step 3 was then refined, considering the formal psychological theories and empirical evidence, and how these may explain the themes and the order of concepts. Several iterations of this framework were developed, with input from four academic supervisors during this process, to ensure that no elements were missing and the framework was coherent. Textual descriptions summarising the literature are provided for each element of the theory with supporting empirical evidence, with examples and verbatim quotes presented to describe the findings. The study has been written up according to the RAMSES guidance for reporting realist syntheses (Wong, Greenhalgh, Westhorp, Buckingham, & Pawson, 2013).

5.3 Results

Seventy-one relevant papers were identified (see Table 5.2). The majority (n=50) focused on the general use of PROMs in clinical practice. Nine papers focused on patients with non-malignant pain, and 12 papers examined non-malignant pain settings (e.g., rheumatology). An additional fifteen empirical studies were incorporated in Step 4. For full details of the empirical literature, see Section 4.3.1.

Several theoretical mechanisms by which PROMs can influence outcomes were identified in Step 3 (Table 5.1). Integrating the themes of the realist synthesis with empirical and theoretical literature resulted in a novel theoretical framework: Patient-Reported Outcome Measures Pathway Theory - PROMPT (see Figure 5.11). PROMPT visually depicts the act of using PROMs, potential mechanisms of action and subsequent outcomes. PROMPT comprises of three pathways: the patient-clinician interaction pathway, the threat appraisal pathway, and the coping appraisal pathway.

Table 5.1 – Themes derived from the literature synthesis

Higher-level themes	Themes
Use of PROMs in clinical practice	• Increasing clinician knowledge • Facilitating patient-doctor interaction • Provision of patient-centred care • Monitoring • Informing strategies to improve care
Influencing patient and clinician behaviour	• The therapeutic relationship • Consultation efficiency • Patient satisfaction • Patient behaviour
Outcomes	• Patient outcomes • Reducing cost
Moderators	• Factors which influence patient reporting • Factors which influence clinicians' use of PROMs

Table 5.2 – Included non-empirical papers by setting

General setting		Patients with non-malignant pain	Non-malignant pain settings
Aaronson and Snyder (2008)	Kroll, Wyke, Jahagirdar, and Ritchie (2014)	Andrasik, Lipchik, McCrory, and Wittrock (2005)	Ayers, Zheng, and Franklin (2013)
Alonso et al. (2013)			
Basch, Torda, and Adams (2013)	Lavallee et al. (2016)	Cheung and Gossec (2014)	Beattie (2001)
Bingham et al. (2017)	Lewis (2011)	Daul and Grisanti (2009)	Christensen et al. (2018)
Bitton, Onega, Tosteson, and Haas (2014)	Lohr and Zebrack (2009)	Dua, Touma, Toloza, and Jolly (2013)	Davis and Bryan (2015)
	Marshall et al. (2006)		Evans and Lam (2011)
Black (2013)	McHorney and Tarlov (1995) Meadows (2011)	El Miedany (2013)	Friedly, Akuthota, Amtmann, and Patrick (2014)
Boyce and Browne (2013)		Fautrel et al. (2018)	
Boyce et al. (2014a)	Noonan et al. (2017)	Palmer and El Miedany (2012)	Guillemin (2003)
Breitscheidel and Stamenitis (2009)	Osoba (2007)	Phillips (2007)	Johnson (2008)
Calvert et al. (2019)	Palfreyman (2011)	Solari (2005)	Michener (2011)
Chang (2007)	Porter et al. (2016)		Michener and Snyder (2008)
Coon and McLeod (2013)	Santana and Feeny (2014)		Richter, Chehab, and Schneider (2016)
Dawson et al. (2010)	Snyder and Aaronson (2009)		
Detmar (2003)	Snyder et al. (2012)		Spiegel (2013)
El Miedany (2014)	Snyder, Jensen, Segal, and Wu (2013)		
Espallargues et al. (2000)			
Feldman-Stewart and Brundage (2009)	Trujols and Portella (2013)		
	Valderas, Alonso, and Guyatt (2008)		
Fitzpatrick et al. (1992)			
Forrest (2013)	Valderas, Kotzeva, et al. (2008).		
Fung and Hays (2008)	Vallance-Owen (2013)		
Ghosh, Ghosh, and Ganguly (2010)	Wolpert (2013)		
Greenfield and Nelson (1992)	Wright (2000)		
Greenhalgh (2009)	Wu and Snyder (2011)		
Greenhalgh et al. (2005)			
Greenhalgh et al. (2017)			
Greenhalgh and Meadows (1999)			
Guyatt et al. (2007)			
Higginson and Carr (2001)			

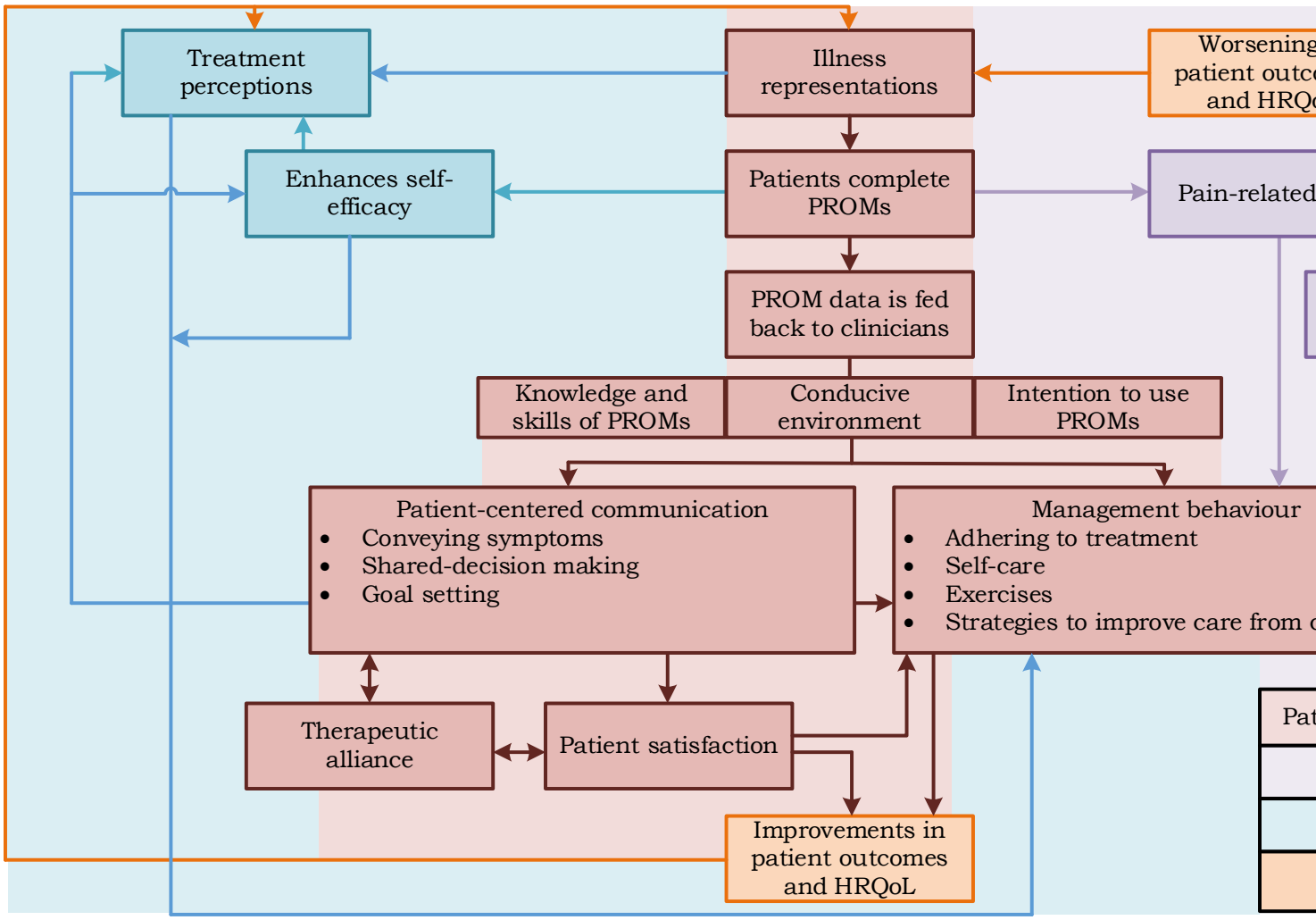


Figure 5.11 – Patient Reported Outcome Measures Pathway Theory: a theoretical framework of the process and outcomes of PROM use in clinical practice for non-malignant pain

5.3.1 Patient-clinician interaction pathway

The patient-clinician interaction pathway is based on a series of constructs around using PROMs (completion of PROMs and feedback to clinicians) and change mechanisms (patient-centred communication, management behaviour, therapeutic alliance, patient satisfaction, and clinician behaviour). PROMPT suggests that patient and clinician engagement with PROMs may influence the care of the patient and improve patient outcomes in the following ways (see Figure 5.11).

Completion of PROMs

Patients complete PROMs as part of routine clinical practice; for an initial patient assessment, individualised screening, monitoring of patient status and disease progression, or for monitoring response to treatment. Thirty of the non-empirical sources discussed using PROMs to provide a baseline assessment of a patients' health status, to assess the impact of disease, injury or specific symptoms from the patient's perspective.

"*The ultimate aim of measuring HRQOL is to provide a comprehensive assessment of patients' health status, to serve as a baseline from which to tailor interventions, pharmacological or otherwise*" (Solari, 2005, p. 2).

The synthesis of empirical literature suggested with moderate confidence that a prominent use of PROMs was to assess patients' pain, with clinicians feeling PROMs had an impact on patient assessment and medical history taking (Chapter 4).

The ways in which patients formulate answers to PROMs when used in clinical practice have not been investigated. However, the answers patients give on PROMs are grounded by their illness representations. Illness representations, as discussed in the common-sense model of self-regulation, are patients' individual perceptions of health and illness that guide their action (Diefenbach & Leventhal, 1996). PROMs may influence these illness representations, as an external stimulus provoking an individual to think differently about their health, and their self-management, which in turn may determine how patients complete PROMs. For example, selecting a numerical score on a PROM that assesses symptom severity might change a patient's representations of their illness if they identify that their pain is more severe than first anticipated or limits their ability

to function. Negative illness perceptions are thought to contribute to adverse health outcomes. Previous research in patients with low back pain demonstrated that individuals who perceived severe consequences, long duration of pain, and weak beliefs in the controllability of their pain were more likely to have poor health outcomes subsequently (Foster et al., 2008).

Feedback to clinicians

PROMs can increase clinician knowledge of their patients' perceptions of health and illness. Thirty-two non-empirical sources discussed how PROMs improve clinicians' understanding of patients' problems. Data from PROMs may describe the burden of disease and the impact of disease on patients' physical, emotional and social wellbeing. PROMs highlight concerns and needs of individual patients in a structured format, and examine domains not routinely assessed but important to patients, for example psychological distress.

"Whilst clinicians focus on disease activity scores, patients prioritize treatment outcomes that are not routinely measured by the clinician, such as well-being, fatigue, work ability, and sleep" (El Miedany, 2013, p. 736).

PROMs can minimise discrepancy between clinician and patient assessment, and help clinicians to avoid overlooking complaints that are meaningful to patients. Qualitative empirical literature suggested that PROMs could provide a positive method to gather essential information on the patient, with clinicians finding PROMs helpful for viewing pain within the context of a patient's life (Chapter 4).

Patient-centred communication – conveying symptoms

Thirty-nine non-empirical sources suggested PROMs affect communication in the initial patient-clinician encounter by providing a springboard for discussion, although no empirical studies tested this hypothesis. Clinicians can formulate questions based on PROMs scores, probing to identify patients' key concerns, and allowing for a greater understanding of the impact of a patient's condition on their daily life through the common language that PROMs provide. Clinicians can then prescribe specific support, tailored education or counselling from the first clinical encounter.

"*The use of standardized quality of life information in facilitating communication between physicians and patients can be seen as a first step toward its use in the care process, in that the form, content and quality of such*

communication may influence decisions regarding treatment" (Detmar, 2003, p. 215).

Feldman-Stewart and Brundage (2009) theorised that the use of PROMs in clinical practice would alter the communication process. They suggest PROMs may address a patient's need to be cared for and alter patients' beliefs surrounding treatment benefits. PROMs may aid the development of patients' skills in articulating problems and symptoms, and lead patients to change their values or beliefs, for example that certain symptoms should not be discussed (Feldman-Stewart & Brundage, 2009).

Patient-centred communication – shared-decision making

Twenty-five non-empirical sources suggested PROMs may improve shared decision-making by making clinicians more aware of issues and patients' ideas. Patients may feel empowered by the process of completing PROMs. This might motivate them to begin a dialogue about their care and treatment options. Thirty-eight non-empirical sources argued that PROM data enable clinicians to tailor treatment for patients, providing individualised patient-centred care. Within the empirical literature, there was high confidence that PROMs were involved in the decision-making process surrounding care for patients with pain (Chapter 4); clinicians felt PROMs provided them with information to develop an individualised treatment plan.

"The potential benefit to patients of using these measures in clinical practice is that their problems are identified and dealt with and that treatment decisions are based on their priorities and preferences" (Higginson & Carr, 2001, p. 1299)

Patient-centred communication – goal setting

Ten non-empirical sources suggested PROMs may influence goal setting. Clinicians may become more aware of patients' desired outcomes and treatment goals, prompting a discussion over expectations and realistic collaborative goal setting. Two case series and a case report examined how PROMs were used for goal setting, with PROMs providing baseline data on the patients' current situation, enabling clinicians to anticipate realistic change and set functional goals with patients (Chapter 4).

"PROMs have a powerful potential role over time in facilitating shared identification of goals and priorities between health professional and patient faced with complex, evolving and multifaceted problems" (Marshall et al., 2006, p. 565).

Self-regulation control theory suggests behaviour is regulated by identifying and attaining goals and monitoring discrepancies between one's current and desired states (Carver & Scheier, 1982; Scheier & Carver, 2003). PROMs help patients to compare their perception of their current health with their goals to see discrepancies, and subsequently induce action to resolve them (Carver & Scheier, 1982). A meta-analysis of 85 papers found evidence to support the associations between goal setting, operating, and monitoring predicted by self-regulation control theory (Burnette, O'Boyle, VanEpps, Pollack, & Finkel, 2013).

Management behaviour

Forty-four non-empirical sources suggested PROMs could be used to monitor changes over time or monitor response to treatment. Patients may need to be routinely monitored to observe symptom severity and disease progression, while repeated screening can be used to identify emergent risk factors and co-morbidities. PROM scores provide the means to assess the effect of treatment, understand patients' progress, and consider the appropriateness of the treatment plan and need for changes. Clinicians may change treatment, prescribe, change or reduce medication, order further tests, or provide additional self-management advice, in response to PROM data.

"PROs [PROMs] *can be important in this research area to monitor symptom severity and functioning, to measure quality-adjusted life-years (where necessary), to monitor changes in HRQoL domains due to treatment changes or quality of care, and to evaluate the impact of adverse events"* (Coon & McLeod, 2013, p. 400).

The effect PROMs have on managing treatment is unclear for patients with pain. In the empirical literature, clinicians' views were mixed on whether PROMs were meaningful to track patient progress, evaluate and change treatment (Chapter 4). Additionally, there were conflicting reports as to the impact PROMs may have on referrals and medication use.

Therapeutic alliance

Nine non-empirical sources reported that using PROMs in clinical practice may influence the therapeutic alliance, as shared-decision making promotes partnership between patients and clinicians. Patients may feel that clinicians are more interested and involved in their care, because they are using PROMs to get their perspective on their health and treatment. PROMs may thus aid rapport

and goal-setting, with the potential for these effects to enhance the therapeutic alliance and influence outcome (McGuire, McCabe, & Priebe, 2001).

In a survey of doctors in arthritis centres, the majority of doctors felt that PROMs contributed to the doctor-patient relationship (Kazis et al., 1990). Within the empirical evidence on patients with pain, there were mixed views from clinicians and patients as to whether PROMs affected the patient-clinician relationship (Chapter 4). Qualitative literature suggests that PROMs may facilitate interactions, aid communication, and promote individualised care, and through these processes it is suggested that PROMs impact the therapeutic alliance (Chapter 4).

Patient satisfaction

Improvements in the therapeutic alliance and communication may positively impact patient satisfaction (Fitzpatrick, 1997). PROMs enable discussions about patient expectations, and the identification of achievable goals which may reduce dissatisfaction from not meeting unattainable treatment goals. If patient and clinician concordance improves, patient satisfaction with care is also likely to be enhanced. Increased patient satisfaction may in turn trigger other positive outcomes. Patients who are dissatisfied with the care they receive may not adhere to treatment (Fitzpatrick, 1997). Improving patient satisfaction should improve adherence to treatment, medication use, and appointments (Williams, 1994). More satisfied patients are more likely to adhere to treatment or advice, or undertake a change in behaviour, which may be linked to improvements in HRQoL. Patient satisfaction and HRQoL are also thought to be positively correlated (Fitzpatrick, 1997). Fourteen non-empirical studies suggested PROMs may improve patient satisfaction. Two empirical studies examined the impact of PROMs on patient satisfaction within arthritis and surgical settings, but there were no significant differences were between the intervention and control groups (Kazis et al., 1990; Ravaud et al., 2004). However these studies were methodologically flawed, and therefore the results should be treated with caution (Chapter 4).

Clinician behaviour

Twenty-six non-empirical sources included discussions on how clinicians' knowledge, beliefs, and behaviour may influence the use of PROMs within clinical practice. This was supported by empirical literature, with clinicians having mixed feelings about PROMs, with variations in their use (Chapter 4). Despite potentially useful information from patients' PROMs, if clinicians are sceptical about PROMs they may not use them as vehicles to improve communication, care, and treatment decisions.

"Practicing physicians tend to be both skeptical (sic) of and possibly irritated by pressures to use HRQOL instruments in daily practice. The skepticism (sic) pertains, in part, to whether formulaic and standardized instruments provide any added value in eliciting information about their patients" (Lohr & Zebrack, 2009, p. 100).

Clinicians may be put off using PROMs by concerns about the validity of PROMs, their psychometric properties, and whether they are sensitive or accurate enough to detect change, or provide clinically meaningful results. Literature also indicates that clinicians lack knowledge about using PROMs. This includes: having little or no training on PROMs, perceiving them as difficult to administer and interpret, and lacking skills needed to engage patients with the process. Furthermore, some clinicians were unwilling to engage with using PROMs and the feedback they engender.

The integrated model of behaviour (Fishbein, 2000; Yzer, 2012), suggests three factors might moderate clinicians' use of PROMs: knowledge and skills, a conducive environment, and intention to use PROMs. It is essential that clinicians have the skills and knowledge to appropriately engage with patients through PROMs, analyse the data, and act on the information. Additionally, they must feel there are adequate resources for the administration of PROMs in practice (technology, administrative time, and information systems for data collection and analysis). Finally, they must have the intention to use PROMs; the integrated model of behaviour suggests that the following factors influence clinicians' intentions to use PROMS in clinical practice: a) a positive attitude towards PROMs; b) the view that using PROMs in clinical practice is a normal behaviour, and c) a belief that they have the ability and resources to use PROMs effectively. Clinicians must be engaged with PROMs for them to have a role in communicating with patients, monitoring patient status, monitoring treatment, decision-making, and changing clinical practice.

5.3.2 Threat appraisal pathway

The threat appraisal pathway is based on two theories surrounding patients' fear of pain, stemming from five non-empirical sources suggesting that PROMs may stimulate a change in patient behaviour. The fear-avoidance model suggests that through the experience of pain and associated behaviour, individuals may become dissociated from the sensation of pain and patients may avoid activities based on their fear of pain (Lethem et al., 1983; Vlaeyen & Linton, 2000). However, within protection motivation theory, fear is characterised as a motivational intervening variable that can trigger an individual to change their behaviour in an adaptive manner if that fear is accompanied by high response efficacy, i.e., believing that making the behaviour change will reduce the chances of the feared outcome occurring (Rogers, 1975). PROMPT theorises that the act of completing PROMs may increase patients' fear of pain (by focusing patients' attention on pain) which could then stimulate a positive or negative response (See threat appraisal pathway in Figure 5.11).

<u>Pain catastrophising and fear-avoidance</u>

From the empirical literature, clinicians voiced concerns that PROMs may increase a patient's awareness of pain (Ahluwalia et al., 2018). If this awareness is associated with pain catastrophising, patients may enter the negative cycle of fear-avoidance for anticipated pain, where individuals magnify the pain threat and are unable to inhibit thoughts of pain (Quartana, Campbell, & Edwards, 2009). Pain catastrophising is associated with increased hypervigilance; the use of PROMs and sudden awareness of symptoms might increase patients' concerns over symptom severity. Pain catastrophising may stimulate avoidance behaviours, which can be effective in the short term, but can lead to feelings of depression and frustration, and negatively impact on patients' HRQoL (Vlaeyen & Linton, 2000). A previous review found evidence to support the concepts in the fear-avoidance model; fear was associated with catastrophic thoughts of pain, hypervigilance and behaviour-avoidance (Leeuw et al., 2007). Worsening HRQoL can then affect illness representations and subsequent completion of PROMs.

"the use of these measures might cause unintended harm, even if from a theoretical perspective only. Physical or psychological problems that might otherwise be overlooked may make them more of a concern for the patient." (Valderas, Kotzeva, et al., 2008, p. 180).

Fear and management behaviour

According to protection motivation theory, after the perception of pain, individuals appraise the threat and the unfavourable consequences that may result if no change is made, and aim to eliminate any behaviour that may produce adverse effects (Prentice-Dunn & Rogers, 1986; Rogers, 1975). Fear of pain may trigger an individual to change their behaviour if associated with high self-efficacy for that behaviour and the perception that the new behaviour(s) will be effective.

"*For many patients, being able to track their own therapeutic changes in term of their 'score' will also motivate them to continue their therapy and healthcare regimen*" (Daul & Grisanti, 2009, p. 238).

5.3.3 Coping appraisal pathway

The coping appraisal pathway is based on themes of monitoring, and patient behaviour from Step 3 (identifying common mechanisms) with insights from the extended common-sense model of self-regulation (Horne, 2003), self-efficacy (Bandura, 1988), and self-regulation control theory (Carver & Scheier, 1982). PROMPT suggests that PROMs may engender positive treatment perceptions and improve patients' self-efficacy so they are more likely to undertake positive self-management behaviour (See coping appraisal pathway in Figure 5.11).

Self-efficacy

Five non-empirical sources suggested that through enhanced communication, patients' self-efficacy for self-management is improved, increasing their actual ability to self-manage their health. Shared decision-making may also influence patients' self-efficacy, helping patients to become more motivated and empowered to achieve goals.

"*The enhancement of communication helps to develop treatment goals with patients. Patients feel more involved in their care; patients are more engaged and activated. The discussion of treatment goals and management changes empower patient*" (Santana & Feeny, 2014, p. 1509).

Six non-empirical sources introduced the idea that through PROMs, patients feel they have the appropriate knowledge, skills and resources to undertake self-management behaviours. Enhancing patients' self-efficacy for a

specific behaviour should positively correlate with an individual's intention to perform that behaviour and actual performance of the behaviour (Bandura, 1988). Research highlights the role self-efficacy beliefs have when experiencing pain. For example, one study examined the role of self-efficacy to complete daily living activities in the treatment of chronic pain. At follow up, Altmaier et al. (1993) found associations between improvements in self-efficacy for these activities and lower pain scores. The results suggest that self-efficacy beliefs may play a role in the control of pain. Additionally, research has shown that manipulation of self-efficacy has a positive impact on perceived and sustained effort (Hutchinson, Sherman, Martinovic, & Tenenbaum, 2008). Patients' intentions and performance of self-management activities may thus improve by enhancing their self-efficacy to self-manage their pain, improving patient outcomes.

Treatment perceptions

Thirty-nine non-empirical sources suggested PROMs can improve patient-clinician communication, and according to the extended common-sense model (Horne, 2003), information and communication may influence treatment beliefs. Treatment perceptions may be specific to treatment or medication, such as concerns about potential adverse effects and beliefs surrounding the necessity of treatment. Individuals may also have general beliefs surrounding medications, such as suspicion of medicines or concerns about chemicals (Horne et al., 2005). Although most of the research on this framework has focused on adherence to medication, this theory can be applied to adherence to treatment regimens, self-care advice, and self-management behaviours (Yardley, Sharples, Beech, & Lewith, 2001). Yardley et al. (2001) conducted a qualitative study exploring patients' perceptions of chiropractic treatment. The resulting model depicted how illness beliefs and experiences of treatments, and personal and cultural global beliefs, influenced patients' perceptions of treatment. Experiences of therapy and the therapist also influenced patient treatment perceptions. Additionally, patients were influenced by perceptions of therapist competence and perceived changes in symptoms (Yardley et al., 2001). A study exploring adherence to complementary therapies found that illness perceptions, appraisals of treatment and treatment beliefs independently predicted adherence (Bishop, Yardley, & Lewith, 2008). Clinicians may use the information from PROMs to educate patients, or explain how a treatment plan may help the patient and reduce their pain (suggested by

11 non-empirical sources). Three non-empirical sources suggested PROMs may also help patients voice their beliefs about treatment and raise any concerns.

Appraisal

When PROMs are used by clinicians at follow-up points for monitoring treatment this can be conceptualised as a form of appraisal for patients. According to the common-sense model of self-regulation, once patients undertake a change in their behaviour or undertake treatment, they will appraise the efficacy of the treatment (Diefenbach & Leventhal, 1996). PROMs can inform such appraisals. The self-reporting of changes in patient outcomes (such as reduced pain), can influence treatment perceptions and illness representations and subsequent adherence to and engagement with ongoing treatment. Two non-empirical sources discussed the concept of patient appraisal, with empirical literature focusing on clinician evaluation.

"*the patient typically wants to know if he or she is improving or is getting closer to his/her health care goals. If part of the healing process includes self-awareness and the patient's desire for wellness, then outcome measures can provide the patient with the information necessary that lets him or her know where they are on the path to health.*" (Johnson, 2008, p. 329).

5.4 Discussion

In this realist review of theoretical literature, 71 non-empirical papers were examined and integrated with 15 empirical studies and seven established psychological theories. The aim was to identify and synthesise processes underpinning the possible clinical outcomes associated with PROM use for non-malignant pain. This synthesis suggests that PROMs may operate through several theoretical mechanisms to influence outcomes of non-malignant pain. These mechanisms can be depicted in three pathways within a theoretical framework, PROMPT: the patient-clinician interaction pathway, the threat appraisal patient pathway, and a coping appraisal patient pathway (Figure 5.11).

The mechanisms suggested in PROMPT are theoretical, and each may independently achieve changes in patient outcomes but as a whole they are likely to interact and have cumulative effects. There are inherent difficulties when trying to create a one-model fits all approach. Individual differences and contextual boundaries must be acknowledged. Each of the mechanisms and pathways discussed all seem plausible when explored individually and integrating these all together in one model allows future research to identify the most important determinants and examine how factors may influence each other.

Two necessary conditions are suggested for the hypothesised processes to impact health outcomes. One, PROMs should be used from the first consultation and be discussed within the first session to establish an improved therapeutic alliance. PROMs formalise the process for getting information from patients and are theorised as a mechanism to enhance communication. Two, the use of PROMs should continue throughout the patient's care, and not just be used at the end of care for audit purposes. PROMPT also makes assumptions about the patient in the context of the clinician-patient relationship, viewing patients as active problem solvers with emotional and cognitive illness representations (Diefenbach & Leventhal, 1996; Leventhal et al., 2003).

PROMPT reflects not only the results of our synthesis but is also broadly consistent and extends three previously developed models (Greenhalgh et al., 2017; Greenhalgh et al., 2005; Santana & Feeny, 2014). All four models suggest that using PROMs encourages discussion between clinicians and patients by improving communication and enhancing patient engagement, which may lead to changes in patient behaviour. Previous reviews also suggest that using PROMs may facilitate communication between clinicians and patients (Espallargues et al., 2000; Greenhalgh & Meadows, 1999).

Further building on the models proposed by Greenhalgh (2005) and Greenhalgh et al. (2017), PROMPT incorporates psychological theory and mechanisms concerning how using PROMs to monitor treatment response may change patient behaviour. PROMPT also builds on the conditions set out by Greenhalgh (2005). Although Greenhalgh's (2005) model states clinicians must feel the data is appropriate and issues are clinically meaningful, PROMPT proposes that clinicians must also have the knowledge, skills, and a conducive environment to use PROMs and not just the intention to do so. PROMPT also incorporates the possibility for patients to be negatively impacted by the use of PROMs. Greenhalgh et al. (2017) briefly acknowledge that PROMs may distress patients, reminding them of their condition and its impact on daily functioning. Despite current knowledge that external information may influence hypervigilance, and the negative implications this may have (Eccleston & Crombez, 1999), this has not previously been included in any theoretical frameworks for using PROMs in clinical practice.

Although the systematic review in Chapter 4 suggests PROMs may have an impact in the treatment of non-malignant pain, there is a limited amount of research in this area. Additionally, many studies do not examine the potential mechanisms for PROM use or have not been conducted within theoretical frameworks that would allow for the impact of PROMs to be fully understood. PROMPT can provide this theoretical framework. PROMPT suggests people who complete PROMs will have: 1) a difference in patient outcomes, 2) an improvement in outcomes (mediated by improvements in communication, self-efficacy, treatment perceptions, therapeutic alliance, patient satisfaction, and self-management behaviours), and 3) an increase in pain-related fear mediating a change in outcomes (moderated by an increase in pain catastrophising). It is acknowledged that the complexity of the framework is a potential weakness, which may make it difficult to evaluate within a single research design. However, it is argued that a comprehensive theoretical framework is needed to fully understand the process by which PROMs may influence health outcomes (Moore et al., 2015; Pawson et al., 2004).

Identifying the potential mechanisms of PROM use in the context of non-malignant pain has implications for understanding how PROMs may be used within clinical practice. PROMPT highlights how patients and clinicians may interact with PROMs, and how this may influence the patients' illness, self-care and the patient-clinician relationship. Future research will be needed to test the hypotheses derived from PROMPT. This may allow us to integrate PROMs more

appropriately within clinical practice, and in doing so, improve patient care and develop patient-centered consultations, improving the management of non-malignant pain.

In line with the focus of this review, PROMPT has been developed in the context of the clinical treatment of non-malignant pain. Although the review included theoretical literature which was based on the general use of PROMs, this was integrated with empirical evidence on non-malignant pain and non-empirical articles focused on a pain population or within a pain setting. The underlying psychological theory was also considered in relation to patients with non-malignant pain, such as the threat appraisal pathway, and therefore may be specific to patients with non-malignant pain. However, as the majority of the theoretical literature was based on the general use of PROMs, PROMPT may be developed and adapted for use in other clinical populations.

5.4.1 Strengths and limitations

The search generated a lack of pain-specific programme theories, however literature within a pain context was included. Furthermore, some of the mechanisms are generic hypotheses or were derived from formal theories and have not been explicitly tested within this intervention. These mechanisms (namely patient-centred communication, patient satisfaction, and fear of pain) could be prioritised for empirical investigation. There was also substantial heterogeneity across the included empirical literature, limiting the generalisability of the results, and there were key methodological limitations, reducing the reliability of the results and increasing risk of bias. Within the review of empirical literature (Chapter 4) CIS was used as a method of triangulation for the empirical literature, using the different studies to improve the accuracy of the synthesis, despite heterogeneous data. Although only one reviewer undertook the initial search and conducted formal screening to generate a list of potential studies, this was later checked by two supervisors. Data interpretation and refinement of the constructs and theory was conducted in discussion with two supervisors.

5.5 Chapter summary

Using the key concepts from psychological theories, theoretical and empirical literature, the findings of this realist review highlight a series of processes by which PROMs may influence patient outcomes within the context of treating non-malignant pain. The theoretical framework proposed in this chapter (PROMPT) suggests there are three pathways that underpin how PROMs can influence health outcomes: patient-clinician interaction, threat appraisal, and coping appraisal. The literature on these constructs is mainly theoretical, with no current empirical studies examining some of the constructs identified in this review. However, this comprehensive theoretical framework provides a valuable foundation to guide future research on the use of PROMs and the processes by which PROMs, as a complex intervention, may influence health outcomes. PROMPT and the identified potential outcomes will aid the generation of study hypotheses for testing the consequences of using PROMs in specialist musculoskeletal care for low back pain (Chapters 7 and 8).

Chapter 6 PROMs in specialist musculoskeletal care settings: a feasibility study

6.1 Introduction

There have been no comprehensive studies examining the impact of using PROMs in the clinical treatment of low back pain. The empirical and theoretical literature to date has produced a general picture of the processes (Chapter 5) and impact (Chapter 4) of using PROMs in clinical practice. However, further research is needed to explore the influence of PROMs on patient outcomes and the optimum use of PROMs in specialist musculoskeletal care. A feasibility study is required to identify the achievability and practicality of undertaking future studies (Craig et al., 2008). This chapter reports a feasibility study aimed to assist the development of a PROMs as an intervention and explore the design requirements for future evaluation studies (see Chapter 3).

There is currently little research on the use of PROMs in musculoskeletal care. Existing literature examining the barriers and facilitators to successful PROM use has mainly focused on oncology, palliative care, or mental health settings. One systematic review examined the use of PROMs by allied health professionals and identified four potential factors affecting their use: clinician knowledge and perceived value of PROMs, organisational support, practical barriers, and clinician concerns and consideration of patient benefit (Duncan & Murray, 2012). From reviewing patients' and clinicians' views and experiences of using PROMs within mental health and palliative care settings, Greenhalgh et al. (2017) recommended that future research in PROMs should explicitly focus on perceptions of PROMs and professional constraints in specific clinical remits. Greenhalgh et al. (2017) proposed that further research is required to examine: how PROMs are supported in different healthcare professions, the needs of healthcare professionals to aid their use of PROMs in clinical practice, and the role of training on utilising PROMs data.

It is necessary to explore the barriers and facilitators of using PROMs within the specific context of chiropractic care for low back pain patients to ensure successful utilisation. Patients with low back pain and chiropractors are likely to face different challenges to those previously explored. A feasibility study

can examine the acceptability of the proposed intervention (Feeley & Cossette, 2015). It is essential for the main evaluative study that intervention delivery is reliable; feasibility studies provide understanding on ensuring appropriate and achievable intervention delivery. Additionally, feasibility studies can explore implementation, to identify the process of embedding the intervention into routine healthcare, and strategies to integrate it successfully in future evaluations.

Feasibility studies can also examine the practicality and acceptability of conducting an evaluation trial (Giangregorio & Thabane, 2015). It is important to test the methodology and procedures proposed for a full-scale trial and identify any issues in recruitment and retention (Taylor, Ukoumunne, & Warren, 2015; Treweek, 2015). Despite some research having taken place to assess impact of PROMs in clinical practice for non-malignant pain, some of these studies had inappropriate methods to evaluate PROMs, such as lack of randomisation and blinding (see Chapter 4). Additionally, there was a lack of information surrounding participant characteristics and recruitment. The poor methodological reporting limits the ability to replicate the study design and understand the practicality of undertaking such a study to evaluate PROMs in clinical practice.

The purpose of this study was to explore the feasibility of conducting a RCT exploring the impact of PROMs in chiropractic clinics for low back pain patients.

The aims of this mixed-methods study were to:

1. Explore patients' and practitioners' experiences of taking part in a trial.
2. Assess recruitment and retention rates, and participants' acceptance of randomisation.
3. Evaluate the measurement tools and their appropriateness and usability within a larger study.
4. Identify any barriers and facilitators to implementing PROMs in chiropractic care.
5. Identify the training needs of chiropractors regarding the use of PROMs.

6.2 Methods

6.2.1 Study design

Feasibility studies can help clarify the design of a larger study and assess practicalities of conducting future research (Arain et al., 2010). Feasibility studies can have many different designs. Although some feasibility studies may include a pilot, where parts of the future study are conducted on a smaller scale to see whether it can be achieved, others do not include a pilot (Eldridge et al., 2016; O'Cathain et al., 2015). This feasibility study used a mixed-methods approach. The rationale for this sequential study design is that two phases provide data from two different perspectives and enhance the interpretation of the data collected (Brannen, 2008; Creswell & Clark, 2011). Qualitative data can explore separate objectives to quantitative components, but also help explain the results.

Mixed-methods design

Qualitative methods can be used to explore many components that are important for designing RCTs, for example: the intervention, the design and processes of the trial, outcomes and outcome measures (O'Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013; O'Cathain et al., 2015). There are a number of practices for using a mixed-methods approach within feasibility studies. Within health sciences, it is becoming more common to see qualitative research embedded within RCTs (Plano Clark et al., 2013). However, another method is to embed an RCT or parts of the RCT into a qualitative study. Embedding parts of a trial into a larger qualitative study allows for understanding of the recruitment process and exploration of the content and delivery of information (Donovan et al., 2002). This can positively impact future trials by providing in-depth detail on trial processes, to ensure future studies are conducted efficiently and effectively (Donovan et al., 2002).

This current study used an embedded mixed-methods study design. Embedded study designs do not normally have equal weighting between the qualitative and quantitative components, but rather have a main focus of data collection, with supporting data collected concurrently or sequentially (Creswell & Clark, 2011). This study focused on the qualitative component, with an embedded quantitative trial which occurred prior to qualitative interviews. Within

this study design, embedded trials provide a framework for more substantive qualitative work. For example, Palmer et al. (2016) used a qualitative evaluation of a physiotherapy intervention for joint hypermobility, with secondary aims to explore eligibility and recruitment rates, before a larger trial.

Weighting of mixed-methods components

The weight of the quantitative and qualitative components were based on the research question and study aims (Morgan, 1998), and the weighting of components is depicted by capitals in Figure 6.1. The data collected were primarily qualitative. Therefore, the qualitative component had more weighting, with all the aims being answered by qualitative data collection, with the exception of one aim (assess recruitment and retention rates) which had a quantitative component. The embedded trial provided a necessary framework for the qualitative interviews that followed. Questions within the qualitative interviews were informed by the recruitment and retention data of the RCT to generate explanations of the quantitative findings through in depth discussions with participants (Creswell & Clark, 2011).

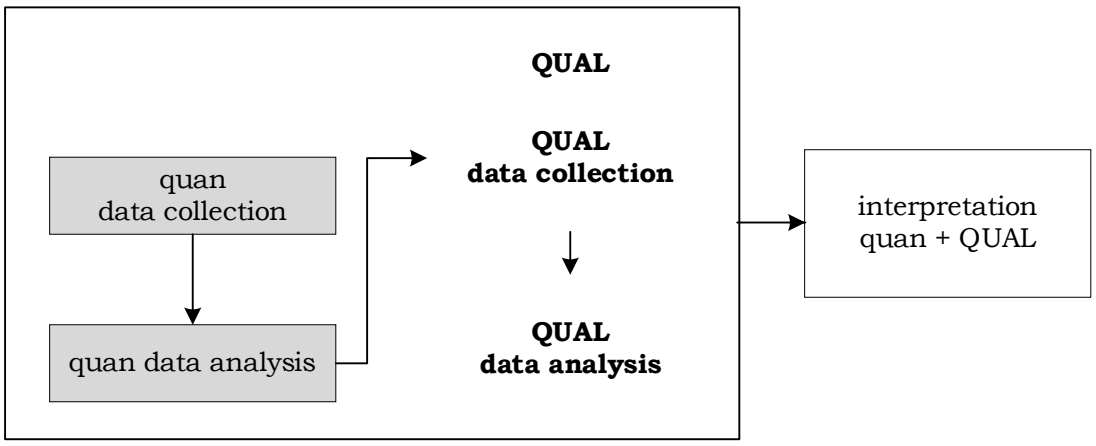


Figure 6.1 – Mixed-methods study design

Adapted from: Bishop and Holmes (2013); Creswell and Clark (2011); Morse (1991).

Capitals depict more emphasis is placed on the qualitative component.

This mixed-method approach is growing within health sciences across different settings (Plano Clark et al., 2013). Previous feasibility studies have utilised this study design, with a focus and weighting on the qualitative component of a mixed-method approach, for different conditions and specialist care (Hughes et al., 2020). Crawley et al. (2013) explored the feasibility of a trial of a specialist intervention (developed from osteopathy, neurolinguistic programming, and coaching) for children with chronic fatigue syndrome. Descriptive statistics were included to describe recruitment and retention rates

and acceptance of treatment. However, the trial was embedded into a larger qualitative methodology, enabling in-depth exploration of the acceptability of the recruitment methods, the interventions, and the burden of the study. This study design and mixed-method weighting has also been utilised within a feasibility study to explore a trial of specialist musculoskeletal care for chronic low back pain (Alhowimel, Alotiabi, Coulson, & Radford, 2020).

6.2.2 Randomised-controlled trial

Study design

The RCT used a cluster design; cluster RCTs randomise groups of patients rather than individuals (Fayers, Jordhøy, & Kaasa, 2002). The chiropractors recruited into the study were randomised to three groups: control group, routine PROMs, and intensive PROMs. Patients who consented to the study were allocated to their chiropractors' group in the trial. The groups differentiated in how often PROMs were sent to patients (see Table 6.1). Routine PROMs were sent with the standard reporting of PROMs within the chiropractic profession. A further intensive intervention was developed, as chiropractors can commonly see patients once or twice a week for treatment. At each of the time points, patients were asked to fill out the PROMs with the data fed back to clinicians.

Table 6.1 – Intervention groups

Control group	Routine PROMs	Intensive PROMs
No PROMs	• Baseline • 14 days • 30 days	• Baseline • 4 days • 9 days • 14 days • 19 days • 25 days • 30 days

Intervention

The intervention involved the completion of the Bournemouth Questionnaire and the Patient Global Impression of Change Scale (PGIC). These questionnaires are used as part of standard practice in the musculoskeletal healthcare practice, as agreed as part of the NHS Commissioning Board contract. PROMs were sent via Care Response, an online system which collects patient outcome scores (Newell et al., 2016).

The Bournemouth Questionnaire is a comprehensive outcome measure developed based on the conceptual model of back pain for use in chiropractic outpatient settings. The questionnaire assesses seven domains (pain, daily activities, social activities, anxiety, depression, fear avoidance, and pain control) (Bolton & Breen, 1999). Each question is scored on an eleven-point numerical rating scale (0-10). All points are labelled with a written description of the score, assigning a meaning to the score. Total scores can vary from 0-70, with higher scores reflecting the impact of pain on a patient. Through psychometric testing, the Bournemouth Questionnaire was found to have high internal consistency, (Cronbach's alpha - 0.9) and good reliability (ICC - 0.95) (Bolton & Breen, 1999; Perillo & Bulbulian, 2003).

The PGIC is a global rating scale and is used to aggregate several components of a patient's experience into one overall measure of their treatment (Dworkin et al., 2005). The PGIC scale has two sections; the first asks the patient to name a chief complaint or the presenting problem. Following this, the patient must assess their current health status and recall their health status from the last week and then calculate the difference; this is marked on a 7-point numerical analogue scale. All points are labelled with a written description of the score, assigning a meaning to the scale (e.g. 'very much improved' to 'worse than ever'). There has been limited psychometric testing examining the 7-point numerical analogue scales, however global rating scales have been found to have significant correlations with established measures of back pain and pain rating scales. It has also been demonstrated to have good reliability (ICC - 0.90) on an 11-point scale, and high face validity (Pearson's r - 0.72-0.90) on a 15-point scale (Kamper, Maher, & Mackay, 2009).

Audio-recordings

Patients could opt in or opt out of having their treatment sessions audio-recorded. Following consent into the study, consent to the audio-recording was recorded in the patient notes. Inclusion of audio-recordings in the feasibility study allowed for researchers to explore and understand the acceptability and achievability of using audio-recordings within a larger study. Examining use of PROMs in patient-clinician encounters allows for accurate descriptions and exploration on the behaviour and activities of participants as they naturally occur, rather than relying on self-report (Bowling, 2009; Polgar & Thomas, 2013).

Sampling

In February 2016, chiropractors from a musculoskeletal healthcare practice were invited by email to participate in the feasibility study. I visited chiropractors who expressed an interest to explain the study, provide written information regarding the study (Appendix D.1) and take informed consent (Appendix E.1). Chiropractors were sampled with a simple random sampling procedure using a random number table. Each chiropractor was allocated a number (based on date of interest in the study) and then three numbers were selected from the random number table. The table was read from left to right, selecting the first chiropractor participant numbers that appeared. This ensures that each chiropractor had the same probability of being selected (Bowling, 2009). As normal practice activity, new patients who contacted the practice for an appointment were signed up to Care Response by reception staff (see Appendix F for an overview of Care Response). Patients were emailed with links to Care Response to fill in a series of required forms prior to their first appointment (see Figure 6.2).

Randomisation: sequence generation and type

After inclusion, I randomised chiropractors to one of the three groups, using an online randomisation generator. This was simple randomisation at the individual level of the chiropractor to one of three treatment groups, with no blocking and no restrictions.

Randomisation: allocation concealment mechanism

Individuals were randomised by a computer-generated list. Group allocation was assigned after completion of consent of the chiropractor. The allocation of patients was completely automated through Care Response, with patients allocated according to the randomisation of the chiropractor.

Randomisation: implementation

I generated the random allocation sequence using the online tool, with the allocation of chiropractors and enrolment of participations to the intervention groups recorded in Care Response by a member of the supervisory team (JF).

Blinding

It was impossible to blind the chiropractors to the group to which they had been allocated, as with the patients, due to the nature of the intervention. I was aware of the randomisation status for chiropractors, however chiropractors were given ID numbers for the purpose of analysis, to ensure blinding of the patient allocation to the three groups.

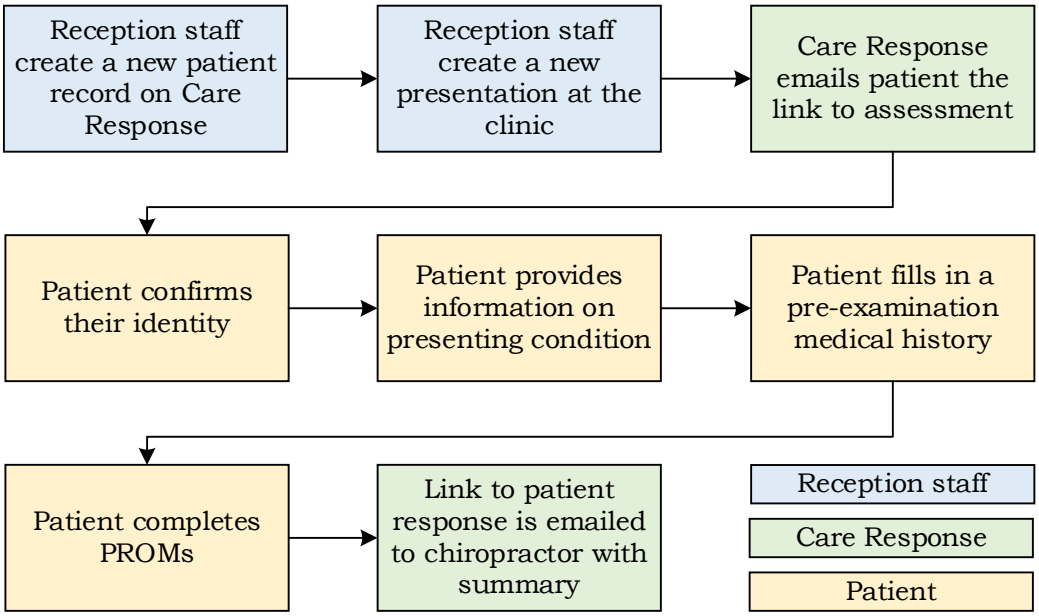


Figure 6.2 – Example scenario of reception staff and patient involvement in Care Response system

Recruitment

Recruitment of patients ran from March to May 2016. Following completion of the routine Care Response assessment, patients were screened by the system for inclusion into the study. Patients aged 16 and older, who were new to the clinic, and identified as having back pain, were directed to an online information page inviting them to be part of the study (Appendix D.2). The randomisation of patients was completely automated through Care Response, as they were already randomised by chiropractor to one of the three groups. Patients were then given three options: to participate in all components of the study, to participate with the PROMs and interviews but opt out of having their treatment sessions audio-recorded, or decline participation. Patients who were

happy to participate were directed to an online consent form (Appendix E.2 and E.3).

Data collection

Recruitment data for eligible and interested patients were collected through the Care Response system. This included: age, gender, presenting condition, and STarT Back score. Scores from the STarT Back tool are used to categorise patients' risk for developing persisting back pain with disability (see Section 2.5.1) (Hill et al., 2008).

The primary outcome measure was also collected through Care Response. The PROMPT model (Chapter 5) does not specify an outcome of completing PROMs, however this was conceptualised within the literature as outcomes specific to patients' presenting condition. Therefore, the primary outcome measure for this feasibility study was the Bournemouth Questionnaire (Bolton & Breen, 1999), measuring the biopsychosocial impact of pain.

Data analysis

The quantitative data collected was input into the statistical software SPSS (version 21) (IBM Corp, 2012). Descriptive statistics were calculated to report recruitment, participant characteristics, intervention fidelity, and follow up.

6.2.3 Qualitative interviews

Sampling and recruitment

Qualitative interviews were conducted with stakeholders who were involved with PROMs (patients, chiropractors, and reception staff) including participants (chiropractors and patients) who had taken part in the trial. Within one month following the trial, all chiropractors and patients were invited to take part in an interview. Additionally, patients previously attending the chiropractic clinics were screened by the Care Response system for recruitment into the study. Patients who had agreed to be contacted about research, were aged 16 and older, and identified as having back pain received an email invitation to the study, explaining the study (Appendix G.1) and directions to complete an online consent form (Appendix H.1).

As well as interviews with chiropractors who participated in the trial, additional chiropractors were recruited using convenience sampling. Three

different chiropractic clinics were approached to participate. These were identified by members of the supervisory team (DN, JF) via professional networks and groups, as clinics currently using PROMs. All chiropractors working within these practices were invited for interview. Chiropractors received an email invitation to the study explaining the study (Appendix G.2), and a link to an online consent form (Appendix H.2).

Following interviews with chiropractors it was noted that reception staff have an important role when employing PROMs in practice. Reception staff at clinics who agreed to participate in other aspects of the feasibility study received an email invitation to participate in a qualitative interview (Appendix G.3), which explained the study and directed them to an online consent form (Appendix H.3).

Data collection

Qualitative interviews were conducted after the trial. Interviews allow for participants to express themselves, giving individuals a chance to tell the story of their experiences (Bowling, 2009; Wilkinson, Joffe, & Yardley, 2004). Using qualitative interviews allowed for exploration into stakeholders' subjective evaluations of participating in a trial and using PROMs in clinical practice (Denzin & Lincoln, 2011; Mason, 2002). Semi-structured interviews were conducted, following an interview guide (Appendix I). However, the flexible nature of semi-structured interviews allows for changes to be made throughout the interviewing process and encourages a discussion-like feel to the interview. Topics for the interviews can be seen in Table 6.2.

Table 6.2 – Interview topics

Patients	Chiropractors	Reception staff
• Completing PROMs • Study documents • Randomisation • Study procedures (audio-recordings, process measures)	• Use of PROMs in clinical practice • PROMs training • Study documents • Randomisation • Study feasibility and improvement	• Use of PROMs in clinical practice • Study feasibility and improvement

The interviews with patients were conducted over the telephone. Telephone interviews are a convenient method of data collection for participants, as they can be contacted at a suitable time, in a comfortable environment, without having to invite a researcher into their home or travel into the study site (Taylor, 2013). Chiropractor and reception staff interviews were conducted face-

to-face at their workplace to better facilitate discussions of their experiences with PROMs.

Prior to the interviews, patients were sent a series of PROMs and an information sheet for a future evaluation study. The results of the theoretical review in Chapter 5 suggested a series of concepts which should be measured in a larger trial to evaluate PROMs; potential measures of these concepts were sent to patients prior to their interviews (see Table 6.3). Patients were sent copies of the PROMs used in the trial, the Bournemouth Questionnaire (Bolton & Breen, 1999) and the PGIC (Dworkin et al., 2005). They were also sent two alternative PROMs, the Measure Yourself Medical Outcome Profile – MYMOP (Paterson, 1996), and the Back Pain Functional Scale (Stratford & Binkley, 2000).

Table 6.3 – Potential measures for subsequent trial

Concepts	Potential measure
Patient-centered communication	Patient perception of patient centeredness questionnaire (Stewart, Meredith, Ryan, & Brown, 2004).
Self-efficacy	Self-efficacy beliefs in patients within chronic pain subscale – self-efficacy for pain management (Anderson, Dowds, Pelletz, Edwards, & Peeters-Asdourian, 1995).
Treatment beliefs	Four-item lower back pain – treatment beliefs questionnaire (Dima et al., 2015).
Self-management behaviour	The maintenance subscale of the pain stages of change questionnaire (PSOCQ) (Kerns, Rosenberg, Jamison, Caudill, & Haythornthwaite, 1997).
	Short form of the patient activation measure (Hibbard, Mahoney, Stockard, & Tusler, 2005)
Therapeutic alliance	Working alliance inventory – short-revised (Hatcher & Gillaspy, 2006).
Patient satisfaction	One-item question: “Over the course of chiropractic treatment for your low back pain how would you rate your overall care?”.
Fear of pain	Fear subscale of the Pain Anxiety Symptoms Scale (McCracken & Dhingra, 2002).
	Numerical rating scale – 0 – 10 (0 being not at all worried and 10 being extremely worried) about low back pain
	Numerical rating scale – 0 – 10 (0 being not at all concerned and 10 being extremely concerned) about low back pain
	Visual analogue scale – not at all concerned – extremely concerned about low back pain
Pain catastrophising	Catastrophising Subscale of the Coping Strategies Questionnaire (Hirsh, George, Riley, & Robinson, 2007).
Fear-avoidance beliefs	Fear-avoidance beliefs questionnaire physical activity subscale (Waddell, Newton, Henderson, Somerville, & Main, 1993).

Data analysis

The interviews and relevant data from the treatment session audio-recordings were transcribed verbatim. All text was input into the computer-assisted qualitative software NVivo (version 10) for analysis (QSR International, 2010). The data was analysed using thematic analysis following the steps set out in Braun and Clarke (2006): 1) the data was coded inductively, 2) codes were examined for patterns and refined, 3) relationships and refined patterns between codes were identified and themes were developed, and 4) themes were described with representative data to support the theme. The analysis allowed for a thorough exploration and detailed description of stakeholders' experiences of using PROMs and being involved in a research study (Braun & Clarke, 2006; Vaismoradi, Turunen, & Bondas, 2013). Quotes were selected from the arising themes to best illustrate the findings, with pseudonyms given to participants.

6.2.4 Sample size

As a feasibility study, power calculations were not necessary to calculate a sample size (Arain et al., 2010). However, as feasibility studies may take a variety of study designs (Section 6.2.1), there is variability in recommendations on sample size in the literature. For example, based on sample size recommendations for pilot studies, 36 participants would be required (Julious, 2005). However, this is based on the precision around estimates that will be used for a sample size calculation for a future study.

The focus on the qualitative component (Section 6.2.1) guided the recruitment of participants and sample size. Literature on qualitative sample sizes ranges from one participant to 60 participants, depending on the research aim (Baker & Edwards, 2012; Mason, 2010). The research aimed to explore patients' and practitioners' experiences of taking part in a trial. To achieve the aims, the study recruited participants until data saturation was reached. Therefore recruitment, data collection, and data analysis was conducted simultaneously, to assess code and theme development throughout the recruitment process (Baker & Edwards, 2012; Guest, Bunce, & Johnson, 2016). The study aimed to recruit 12 patients, as a sample size of 12 participants was identified from previous literature surrounding data collection and analysis, to potentially reach data saturation and be adequate to achieve the research aims (Baker & Edwards, 2012; Guest et

al., 2016). No target number of participants were given per arm, as the qualitative analysis did not aim to explore the experiences per group.

As per the iterative nature of qualitative research, individuals were recruited throughout the study. In addition, to assess recruitment and retention rates, participants were recruited into the trial throughout the qualitative data collection and analysis process to assess how many participants would be recruited and remain in the study over this time period.

6.2.5 Ethical considerations

This study received ethical and research governance approval (University of Southampton, ref: 16880; Berkshire Research Ethics Committee, ref: 16/SC/0025). All participants provided informed consent to participate in the trial and interviews. Additionally, the data collected fit with the Data Protection Act of 1988 and the Data Policy of the University of Southampton (UK Public General Acts, 1998; University of Southampton, 2013). The General Data Protection Regulation did not come into effect until after study completion. The Care Response system passed the Information Governance Toolkit to Level 2. The Information Governance Toolkit is a Department of Health Policy that draws together the legal rules of information handling. Passing at Level 2 provides assurance that NHS patient data are handled appropriately. All data were fully encrypted when stored and sent with data anonymised when extracted.

6.3 Results

Three chiropractors and eight patients took part in the trial and all participants were invited to take part in an interview. Additionally, 74 stakeholders who were involved with PROMs (patients, chiropractors, and reception staff) were invited for interview. A total of 26 consented to participate, however after consent, seven patients did not respond to communication to arrange the interview. Eighteen interviews were conducted, nine face-to-face and nine via telephone. Chiropractors were based at four different clinics for the purposes of the trial, however many worked in more than one practice. Table 6.4 provides details of the participants and recruitment for interviews.

Table 6.4 – Participant recruitment for interviews

Participant	Invited	Consented	Participated	Characteristics
Past patients	40	7	4	Mean age = 56.5 1 male, 3 females
Trial patients	9	9	4	Mean age = 50.5 1 male, 3 females
Trial chiropractors	4	4	3	1 male, 2 females
Chiropractors	32	5	5	3 males, 2 females
Reception staff	2	2	2	2 females

The qualitative interviews focused around two topics: the use of PROMs within clinical practice and the feasibility of conducting a trial in a chiropractic clinic. Table 6.5 depicts the two findings and related themes. The following sections describe each theme with example quotes from participants and quantitative data from the trial.

Table 6.5 – Qualitative findings and themes

Use of PROMs within clinical practice	Feasibility of conducting a trial in a chiropractic clinic
• Clinician knowledge and engagement with PROMs • Organisational barriers and facilitators • Patient engagement with PROMs • Appropriateness of PROMs • Use of PROMs for individual patients	• Recruitment • Intervention • Data collection • Retention

6.3.1 Use of PROMs with individual patients in clinical practice

Clinician knowledge and engagement with PROMs

Chiropractors and reception staff discussed clinician knowledge and engagement with PROMs. All chiropractors had used PROMs at some point during their practice. Half of the chiropractors used PROMs routinely within their practice, with half rarely using PROMs. Use of PROMs was varied amongst the chiropractors, some used electronic systems where PROMs were completed by patients before their clinical appointment, with others using a paper system filled in by patients at each visit. PROMs specifically mentioned included the Bournemouth Questionnaire (Bolton & Breen, 1999), Patient Specific Functional Scale (Sterling, 2007), Roland-Morris Questionnaire (Roland & Morris, 1983) and the Disabilities of the Arm, Shoulder and Hand (DASH) Outcome Questionnaire (Gummesson, Atroshi, & Ekdahl, 2003). Choice of PROMs and process was also influenced by their clinic, for example the PROMs procedures within the clinic they were employed at differed from their practices as an individual practitioner.

Most of the chiropractors were positive about using PROMs, stating many reasons and benefits for using PROMs in their practice. Chiropractors spoke about using PROMs for audits and feedback: to understand personal and clinic performance, to compare practitioners and practices, and to improve practice. PROMs were thought to be useful to understand overall patient progress and satisfaction for groups of patients: *"it helps you to see how you're doing, as well, overall, across lots of different patients. And.. yeah sort of how your clinic is performing so it's just making sure the patients are happy with other aspects of their care."* (Trial chiropractor – Gemma). Chiropractors also thought PROMs were necessary to collect for research purposes, to legitimise their practice and was important for the profession. However, one chiropractor cautioned that valid reasons to collect data are required: *"what you don't want to be doing is just gathering loads of data. So you can say how wonderful you are. There is an element of that.. so as a profession we can say how wonderful we are. And we are doing for it ourselves, we aren't really doing it for the patients in that case"* (Chiropractor – Henrik).

Chiropractors were concerned over patient engagement, some believed that PROMs were only meaningful if all patients completed them, needing to significantly improve completion rates to be able to benefit from collecting data. Some chiropractors and a receptionist felt that patients would not report feeling

dissatisfied and thus were concerned that the data they received was positively skewed. Chiropractors suggested that patients might not want to offend their chiropractor, or disappoint them, and therefore report improvement. *"My gut feeling is that people that don't complete are the people that aren't happy with what you've done. So it's immediately biased."* (Chiropractor – Andrei)

There were mixed responses to using PROMs within every day clinical practice. Some chiropractors thought it was beneficial to them, progressing as a chiropractor and improving their practice. Some chiropractors used PROMs as a tool, in combination with discussion and physical examination, to make a clinical decision: "*I have looked at data and then changed my practice, possibly because I was thinking that.. 'that patient is not getting any better, what is happening?' err.. looked at the data to see if that could help me at all, tried a completely different approach with the patient*" (Trial chiropractor – Anja). Others did not use it within their practice, preferring to ask their patients personalised questions within the clinic to build rapport with patients: *"I'm too old to be that interested in learning new things from questionnaires, I've had a lot of experience in practice, and if I want to learn something it won't be by using questionnaires."* (Chiropractor – Henrik).

Some chiropractors lacked clarity on the details of their clinic's procedures relating to PROMs, especially when completed via an electronic system. For example, there was uncertainty on the timing of follow-up PROMs: *"I think they get it at three months, or do they get it at four weeks? I think they get it at four weeks"* (Chiropractor – Andrei). Others did not know whether the PROMs they used had been validated or empirically tested and therefore appropriate for use in practice, or were unclear over the populations the PROMs were validated for. Many chiropractors perceived the subjective nature of PROMs as a weakness, voicing concerns that PROMs are open to interpretation and questioning the value of the data in clinical practice: *"It's even more subjective and open to interpretation. I mean the BQ* [Bournemouth Questionnaire] *and getting them to grade things on 1 – 10 is fairly subjective anyway. When you say 'how do you feel, are you very much improved or just much improved?' You know you can go to a smiley face system can't you."* (Chiropractor – James).

Organisational barriers and facilitators

Chiropractors and reception staff discussed the barriers and facilitators of using PROMs within routine clinical practice. Chiropractors voiced concerns about practicalities and human error; they forgot to look at PROMs, feeling they

did not come to mind easily, and it was an additional task to remember to use PROMs during follow-up treatments. Chiropractors expressed trying to be timely and efficient, so as not to keep patients waiting, which restricted their use of PROMs within treatment sessions. "*I do think time pressure, is a big limitation, forgetting and then sometimes you think.. 'oh I forgot on that one patient, or no I'm just going to leave that one patient out, I need to get on to the next one' – that's the challenge*." (Trial chiropractor – Anja).

One debate was the best medium to use for PROMs collection (paper or via an electronic system). Receptionists stated the benefit of using electronic systems is automatically generated follow-ups. One chiropractor highlighted that results were easier to use when electronic, the system generated patients' results into a graph, which would be time consuming to do if PROMs were paper-based. However, some chiropractors had difficulties with using electronic systems *"You can sit there for ages trying to figure out"* (Chiropractor – Rachel). One chiropractor had issues with the electronic system not functioning correctly. However, using a paper version often required more administrative time for both the reception staff and the chiropractor. Reception staff reported that patients without email or IT access receive a paper version in the clinic, which the reception staff upload onto a computerised-system. One key message was that all data should be on the same medium. One practice used paper clinic notes and an electronic system for PROMs, which was deemed inconvenient. Chiropractors within this clinic spoke about the difficulties switching between the two systems when the clinic is busy, and PROMs were often forgotten.

One key facilitator in the collection of PROMs was reception staff. All chiropractors spoke very highly of their reception teams. Some chiropractors noted PROMs were a joint effort, with reception staff explaining the importance of PROMs to patients and chasing patients for follow-ups. One chiropractor, who did not have the support of a reception team, noted that this would improve data collection. Other chiropractors saw PROMs as mainly an administrative task that they did not get involved with: "*I just leave it to the receptionist to do all that*" (Chiropractor - Andrei).

Patient engagement with PROMs

Chiropractors and reception staff voiced views on patient engagement with PROMs, and patients commented on barriers and acceptability of completing them. Charlotte (chiropractor) felt that for patients: *"This is just a pain, literally"*; she, along with other chiropractors, expressed that PROMs were bothersome for

patients, stating that patients do not enjoy completing a large volume of paperwork. Some chiropractors reported patients asking them to stop sending the questionnaires, although one chiropractor stated this was a minority of patients. Chiropractors and reception staff also had concerns that it might put off patients coming back to the practice, due to the paperwork involved *"I mean the more questionnaires you give people, the more annoyed they are going to be with questionnaires*" (Chiropractor – Andrei). However, no patients reported PROMs being burdensome, and all found PROMs to be an acceptable and appropriate part of their care. *"The feedback was necessary to understand whether the treatment was being good for my back, my pain was recorded adequately and understanding between the practitioner and I that we were going forward and not backwards"* (Trial patient – Katja).

Participants did acknowledge some barriers to patients completing PROMs, such as: email and computer access, IT skills, literacy, age, and time. *"You can usually tell quite quickly whether they are going to respond to the follow-ups. A fair amount don't*" (Reception staff – Leanne). Chiropractors stated that some patients might be too busy to fill them in.

Some chiropractors and reception staff believed that you could not change patient engagement with PROMs: *"there's a small minority that kind of just can't be bothered to do it, and are just not interested"* (Trial Chiropractor – Gemma). However, many participants had ideas to improve patient engagement. Chiropractors explained that most patients come in for treatment and are not necessarily expecting to fill out a form, and they do not understand why they are completing PROMs. One method recommended to improve engagement was to explain to patients that completing PROMs is a component of their care and explain its inherent value, for example: *"this is a positive thing as part of your management plan, which gives us information about how you are improving"* (Chiropractor – James). Chiropractors also suggested reception staff may have to explain this to patients, as they take the initial details from patients for PROMs to be sent. *"I think it totally hinges on how you explain it to the patient and the way that they.. that initial conversation and how it's explained initially will probably determine whether that patient stays with that or not. The better it's explained and the more they understand it, the better their compliance will be."* (Chiropractor – Rachel).

Appropriateness of constructs within PROMs

Patients and chiropractors discussed some of the PROMs currently used in clinical practice for low back pain. Chiropractors often chose to focus on functional outcomes, changing the focus to a patient's abilities rather than their pain. *"I work both here and in a private practice, tried different things in both places, and really ended up with, the same thing overall, going with measures of what they feel they can achieve and do. In my opinion I feel that's what matters in the end."* (Trial chiropractor – Anja). Although chiropractors acknowledged the need to know how much pain patients are in, several expressed concerns about getting patients to routinely quantify their pain, noting it might remind patients of their pain. *"I always think 'we keep going back to the pain' and really we don't want them to focus on the pain."* (Trial chiropractor – Gemma). Several chiropractors commented that these pain scores might have a negative effect for the patient. *"By always focusing on how much things hurt, and how difficult it is to do things, and how bad it's been, for that kind of patient.. you're perhaps, kind of, maintaining them in that, sort of, slightly negative spiral."* (Chiropractor – Rachel).

Additionally, patients and chiropractors spoke about the relevance of PROMs. Overall, most patients found the PROMs used were relevant, although some found the questions were not appropriate for their condition. *"I can see it was relevant various different issues, you know, I think the problem is.. mine is intermittent. So it's.. one day I can be filling in this questionnaire and I can be scoring 0 and then the next day I can be scoring 7 or 8."* (Trial patient – Jana). Some chiropractors also had concerns about questionnaires that used the word 'depressed', noting that although this was pertinent for some patients, this may not always be appropriate. *"It says something about.. yeah.. 'how depressed have you been feeling?' and she was like 'I didn't think I was supposed to be depressed with back pain'. And it hadn't even crossed her mind".* (Chiropractor – Rachel).

Although many chiropractors used the same PROMs for all patients, regardless of condition, patients expressed that some of the time this was not relevant for them. This was acknowledged both in the content and timing of PROMs. *"One of the questions was about involving my activity, if I'm running around, and doing things, up and about, I'm fine, but my actually hobbies are sitting down, doing the computer, or needlework, erm, sit and cross-stitching, and things like that, and that's where for me the pain affects me"* (Trial patient – Katja).

"the questionnaires that I filled in, during and immediately after the treatment, that was fine. But what there wasn't was something like.. six months later.. 'is it still okay?' you know.. and to give you the chance to say, 'well, no, it didn't last that long'." (Past patient – Marius).

Use of PROMs for individual patients

Chiropractors discussed their use of PROMs throughout the treatment process with patients. PROMs were used from the first consultation to look at the patients' story. They identified that sometimes the information they received from PROMs differed from patients reporting during the initial visit. One chiropractor stated PROMs enabled chiropractors to see things from the patient's perspective: *"I do think the longer you're out in practice, either the more you pick up on things and use it, or the more settled to your routines you become and maybe forget the importance about the psychological aspect of the care, because you get so.. so sort of swaddled in your own routine, that you forget about renewing yourself. I think this sort of feedback is useful for renewing us, if we choose to use it actively."* (Trial chiropractor – Anja).

Chiropractors also talked about being able to identify 'yellow flags' by using PROMs. This triggered chiropractors to reassure the patient, educate them about recovery, and discuss self-management. One chiropractor stated that PROMs affected the management plans of his patients: *"For me it's about identifying those that are at risk of not.. not responding as you would expect them to and then being able to intervene a lot earlier"* (Chiropractor – James).

Chiropractors also used PROMs at follow up to track patients, identifying both improvements and patients who were not progressing. One chiropractor discussed how they used the PROMs to follow up a patient: *"I think they'd put that it hadn't improved. So I phoned and err.. yeah we had a discussion about it, and they just started coming back."* (Chiropractor – Charlotte). Chiropractors also mentioned discussing PROMs with patients and visually showing them their progress: *"I pinged up his little graph and said 'look, there you are' and he went 'oh, yeah, that's loads better isn't it' so for him, it was really neat."* (Chiropractor – Andrei).

This visual depiction, and showing patients their improvement after a change in behaviour, was seen as positive reinforcement "*cos they can physically.. go.. 'oh last time I remember the last time I filled that in I was 8 and now it's only a 4'"* (Chiropractor – James). Chiropractors also believed that

PROMs improved patient adherence for treatment and self-care exercises: "*for patient compliance.. if a patient is.. that is the advantage if the patient sees or remembers what they've done, then they themselves can see improvement*" (Chiropractor – James). Chiropractors also thought that PROMs may improve the patient-clinician relationship. *"So for the majority of patients I feel like it makes them feel like we are really interested, like we want to know everything. Especially if they can fill it out at home, and then when they come in for the initial like consultation, I've already looked at it, and have some insight into their pain. I think it's really good, and I think they feel.. kind of reassured by it."* (Trial chiropractor – Gemma). Chiropractors also identified using PROMs to change treatment for their patients: *"I know I've ended care for patients because it hasn't seemed to be helping, but I've continued care but in a different way. Erm.. because maybe it was maybe more appropriate to.. to refer to someone else"* (Trial chiropractor – Anja).

Despite chiropractors identifying how they might discuss PROMs, all trial patients reported that chiropractors did not discuss the questionnaires during their treatment. However, one patient identified that perhaps they talked about it indirectly, because it was obvious that the chiropractor had read her answers and understood the problem. Other chiropractors reported using the PROMs to check in with patients: *"with that I see time-to-time before the patient comes in, sort of have an overview, to see whether it matches with what the patient tells me. Sometimes it does and other times it doesn't and if it doesn't, then I try and find out why. And a lot of times I find that it's because they've got other things going on as well. It's not only regarding what they the problem they come and see me for, and we need to see whether the bigger aspect of things is affecting the back pain, or whatever I see them for, or whether it's completely different."* (Trial chiropractor – Anja).

Many chiropractors reported not discussing PROMs with their patients, often in cases where patients were improving. Chiropractors also would not talk to patients about anxiety and depression unless they scored highly. Several chiropractors thought discussing PROMs may only be beneficial for certain patients, such as chronic patients. *"it gives me a handle on the psychosocial stuff and the barriers, and the chronic ones. And therefore I might tweak them more psychosocially, or more in terms of exercise and something different, from just treating.*" (Chiropractor – Andrei). One chiropractor also said discussion was down to their personal rapport with the patient: *"if I've got a builder in, who's talking about football, or rugby, I'm not going to ask him.. I'm not going to start talk about emotions and stuff like that"* (Trial Chiropractor – Sven).

6.3.2 Feasibility of conducting a trial in a chiropractic clinic

Recruitment

This study also aimed to assess recruitment rates and participants' acceptance of randomisation. The trial aimed to recruit three chiropractors in the South of England. Emails were sent to five chiropractors working with a musculoskeletal healthcare practice. Reasons for non-participation are unknown as chiropractors failed to respond. Four chiropractors expressed an interest to participate in the study. Using a random number table, three of these chiropractors were selected and randomised to take part.

Patient recruitment was open for 9 weeks beginning in March 2016 and finishing in May 2016. Table 6.6 shows recruitment over the nine weeks.

Table 6.6 – Patient recruitment by week

Week	1	2	3	4	5	6	7	8	9
Participants	-	1	2	2	2	1	1	-	-

Figure 6.3 presents the flowchart of patient participation for the trial. Twenty-three eligible participants declined to participate (42%) and another twenty-three registered interest (42%) but did not complete the consent form for the trial. It is unknown why the patients declined to participate. Additionally, despite nine patients consenting to take part in the study, a technical error meant only eight patients received the intervention. The technical fault occurred after obtaining consent, with the reception staff not enrolling the patient into the study on Care Response.

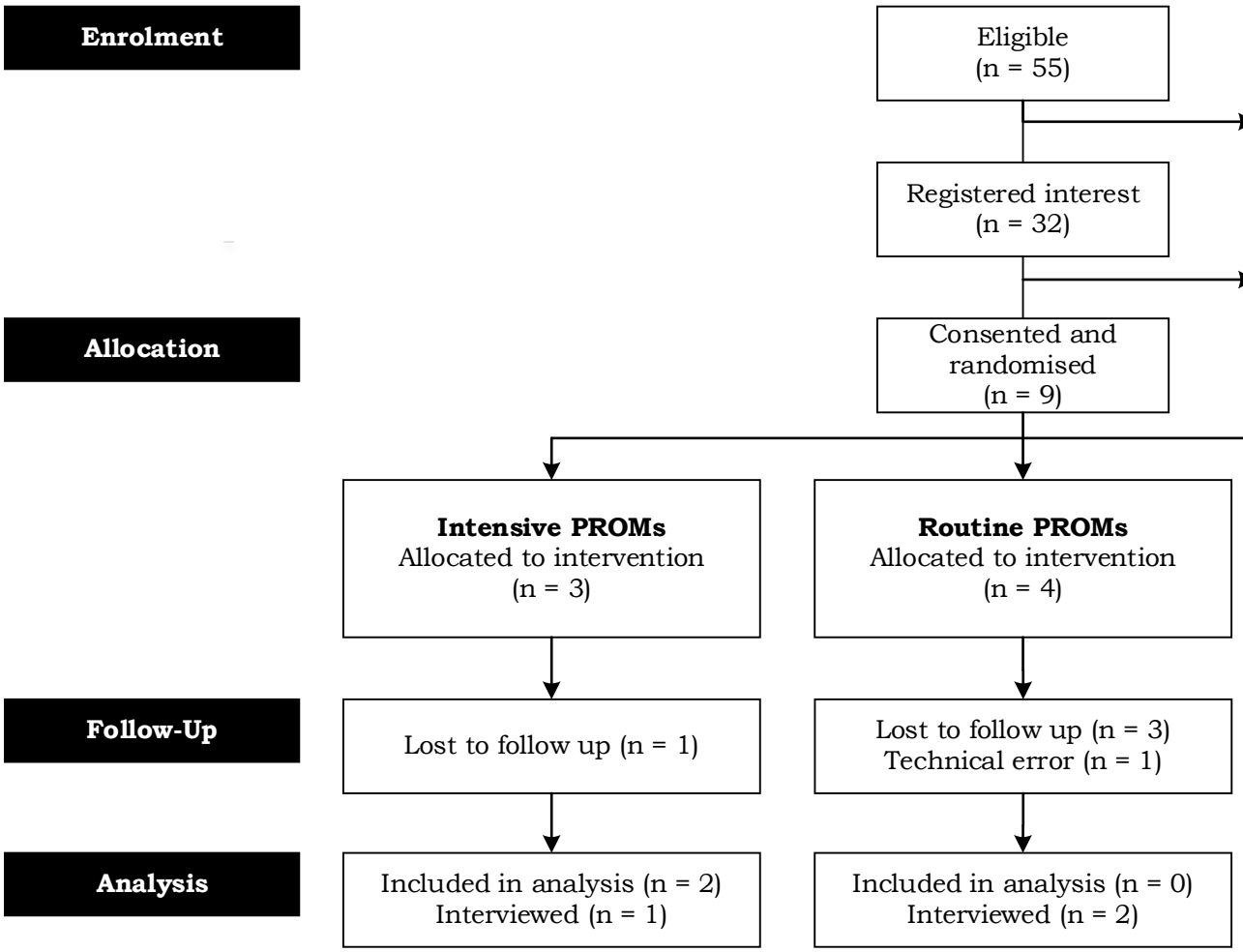


Figure 6.3 – Flowchart of patient participation

Table 6.7 shows baseline characteristics for each group. The mean age of patients recruited to the trial was 57.3 (SD 11.8, range 36-71) and all patients were women. All reported back pain, with 50% reporting other pain (neck pain, shoulder pain, arm pain, leg pain), 75% had pain over 30 days, and 62.5% reported this being a reoccurring problem. Median pain scores at baseline were 6.0 (range 5-8) and functioning 30.5 (range 23-49).

Table 6.7 – Baseline characteristics for trial patients

	Intensive (n = 3)	**Routine (n = 3)**	**Control (n = 2)**	**Overall sample (n = 8)**
Age				
mean (SD)	58.0 (11.1)	56.3 (18.2)	57.5 (7.8)	57.3 (11.8)
Back pain-related quality-of-life				
mean (SD)	37.3 (11.5)	32 (4.4)	23.5 (0.7)	31.9 (1.8)
Other pain				
n (%)	0 (0%)	2 (66.7%)	2 (100%)	4 (50%)
Pain over 30 days				
n (%)	1 (33.3%)	3 (100%)	2 (100%)	6 (75%)
Recurring problem				
n (%)	2 (66.7%)	2 (66.7%)	1 (50%)	5 (62.5%)

Interview participants expressed being generally happy to participate in research. Patients did not object to any part of the proposed study and did not raise concerns with the study design, including randomisation, as it was all "*part of research*" (Trial patient – Katja), *"Well obviously you're taking part in the study, so you expect the, you know, to be put in different groups"* (Past patient – Joanne). Participants were generally appreciative of the value of research, expressing that research is important to advance treatments and improve patient care. *"I'm quite keen on research. And if it helps somebody else understand, you know, the problems or the interaction between the patient and the medical professional or clinician, then I think that's a good thing.*" (Trial patient – Alison). Chiropractors were receptive to participating in research, believing it was important to contribute to research to improve practice.

Participants overall had positive comments about the research topic. Chiropractors were generally interested in the research, to understand how PROMs affected their treatment and how the results of the research could

improve their clinical practice. "*I think it's a good study, cos otherwise we are wasting time.. if all of this* [PROMs] *doesn't.. if it's not improving care"* (Chiropractor – Andrei). One chiropractor had concerns about using PROMs within the clinic, worried about becoming obsessed with measurements and targets, wanting to focus more on treating the patient.

The feasibility study aimed to explore participants' views on recruitment processes for the subsequent trial. Reception staff and chiropractors also had no concerns about recruitment processes. Most patients were happy with the study documents and information sheet, stating that they used plain language and were easy to understand. Patients did not have any additional questions about the study.

Intervention

Patients found PROMs self-explanatory and easy to complete. However, no participants in either treatment group fully completed the intervention, one participant did not complete at all, and five participants only partially completed the PROMs intervention (see Figure 6.4 for completion across groups). One patient taking part in the trial, who had partially completed, thought they had completed all the questionnaires. Interview participants reported no concerns about completing the PROMs for the study: *"I hadn't got a problem with any of the questions that was there, cos it was erm.. like my progress sheet really."* (Trial patient – Katja).

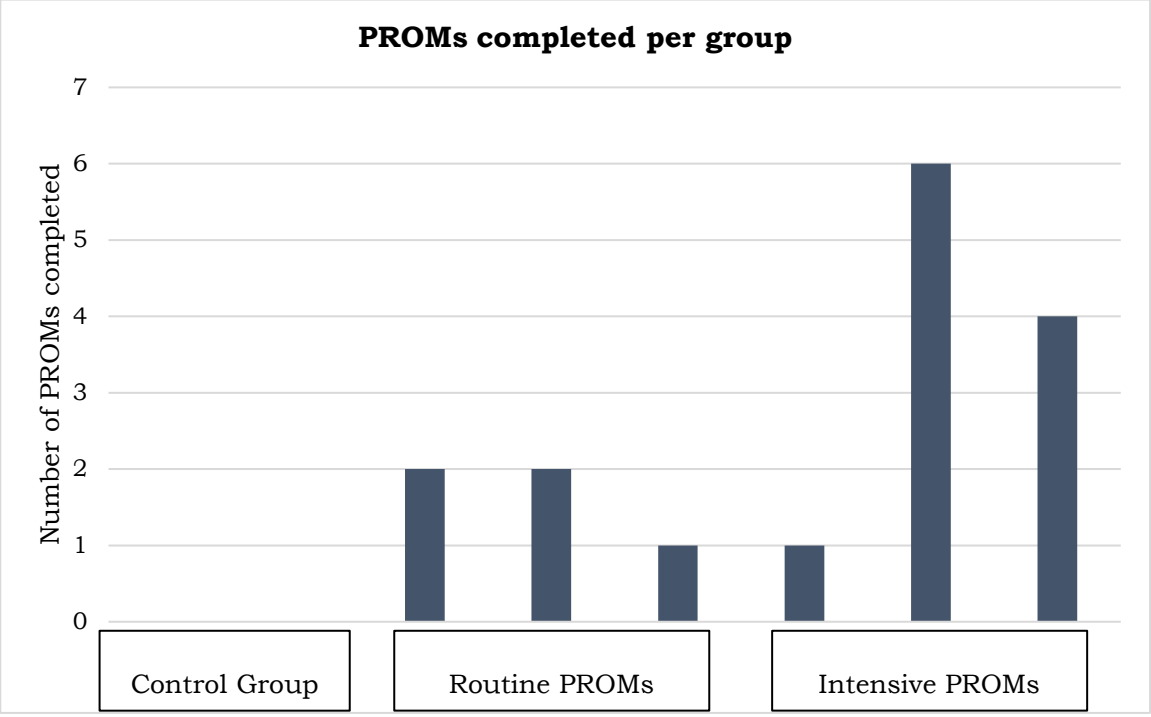


Figure 6.4 – Completion of intervention (per participant)

Patients discussed some of the PROMs currently used in clinical practice for low back pain. One trial patient (Katja), who had back pain, reviewed four different questionnaires (Bournemouth Questionnaire, PGIC, MYMOP, and the Back Pain Functional Scale). Two questionnaires were seen as straightforward: for the Bournemouth Questionnaire, Katja stated she had "*no problems filling it in and I understood it all*", and the PGIC was also simple: "*To me it was pretty much straightforward. You know.. you either was.. if it was really bad to begin with and now'it's improved or not improved*". Katja found MYMOP slightly more difficult "*I found that a bit wordy. To be honest. Erm, I had to read it several times, to make sure what I was understanding it to be.*" Katja's preference was the Back Pain Functional Scale as it "*was more relevant".* Katja's views were typical compared to other patients who were interviewed, finding the PGIC simple and the MYMOP more difficult to understand. Patients comparing the Bournemouth Questionnaire and the Back Pain Functional Scale preferred a functional scale.

Specific PROMs were not discussed with reception staff but the intervention as a whole was seen as feasible by reception staff and chiropractors. Chiropractors commented that reception staff would need to be engaged for the intervention to be feasible. "*whenever you've got surveys to patients it's their engagement with it. And all that comes down to is your clinician or reception staff to keep pushing it and reminding them, without it becoming a barrier and a nuisance"* (Chiropractor - James). Reception staff are the first interaction the patient has with the chiropractic clinic. Thus, they are the first to explain PROMs to patients, and take their email/contact information, for the PROMs to be sent to the patient in advance of their first session. Reception staff explained that often patients do not volunteer an email address until the chiropractor has explained to the patient why it is required.

Chiropractors believed that, in general, chiropractors might not have any previous knowledge on PROMs. In the interviews, chiropractors were asked about training on PROMs, as within a full RCT training on PROMs may improve intervention implementation. They suggested highlighting the benefits of using PROMs and the simplicity of the process: "*So assuming everybody knows absolutely nothing about them and saying 'this is what they are, this is why they are useful, this is how it can help you' erm.. is probably the way to go.*" (Chiropractor – James). Training on PROMs delivered via the internet, with electronic resources and a physical guide was seen as acceptable by chiropractors. Chiropractors requested to make the training undemanding as possible, due to their busy practices and limited time.

Data collection

The feasibility study sought to investigate the acceptability of process measures for the full RCT and audio-recording of treatment sessions. Chiropractors believed patients would be unhappy to have their treatment sessions audio-recorded, feeling it might prohibit patients from talking freely. However, patients stated they were happy to be audio-recorded, seeing it as part of the study and unobtrusive. Although patients had the option to opt out of being audio-recorded, all patients consented to have their treatment sessions audio-recorded. *"It didn't bother me. It was just like talking to somebody directly, I just ignored it.*" (Trial patient - Katja). Despite chiropractors reporting no concerns or issues with using the recorders, they sometimes forgot to record sessions or did not record the information required for the researcher to match the recording with the participant. It was suggested that reception staff might also be the interface to remind chiropractors which patients are in the study for audio-recording sessions.

Patients were asked their opinions on the data collection tools for a full RCT. Patients commented that completing nine process measures at the end of the study would be acceptable and were a manageable length. They could complete them quickly and it was easy to do and understand. Patients on average said it would take them about 10 minutes to complete, maximum 20 minutes. Some participants had comments on specific questions with some concerns over the subjectivity of the questions. Patients preferred measures with a clear layout, lay language, and measures with verbal descriptions of each rating rather than answering on a numerical scale without context. However, there were no questionnaires that patients objected to. Patients looked specifically at the acceptability of two measures for self-management. Patients preferred the Maintenance Subscale of the Pain Stages of Change Questionnaire (Kerns et al., 1997) over the Patient Activation Measure (Short-Form) (Hibbard et al., 2005). Patients preferred the length and clear layout, and the content was felt to be more relevant for their conditions. Patients also preferred the Fear Subscale in the Pain Anxiety Symptoms Scale (McCracken & Dhingra, 2002) rather than a visual analogue scale or numerical scale to measure fear of pain. Patients felt that the fear subscale was easier to understand and complete.

Patients had mixed preferences of completing the process measures online or on paper. Whilst most patients preferred to complete them online, rationalising that it was easier and avoided them needing to remember to post

them, one patient felt that she would prefer a paper copy and some patients stated that older patients might prefer a paper copy. Patients suggested that giving people the option might improve compliance of filling them in.

Retention

The feasibility study also aimed to assess retention in the study and completion of follow-up measures. Chiropractors had concerns about getting complete data from patient. "*Loss to follow up is rampant in research, especially with chiropractic research*" (Chiropractor - Henrik). Of the nine patients registered to take part in the trial, five were lost to follow up (see Figure 6.1). Follow-ups with patients were 90 days after their first visit to the chiropractor (June 2016 – July 2016). Only half the participants completed the 90-day outcome scores (n = 4) and were included in the final analysis. Changes for individual patients' pain scores and the biopsychosocial impact of pain from baseline to 90 days can be seen in Figures 6.5 and 6.6. Effect sizes were not calculated, given that it would be inappropriate for the aims of this feasibility study.

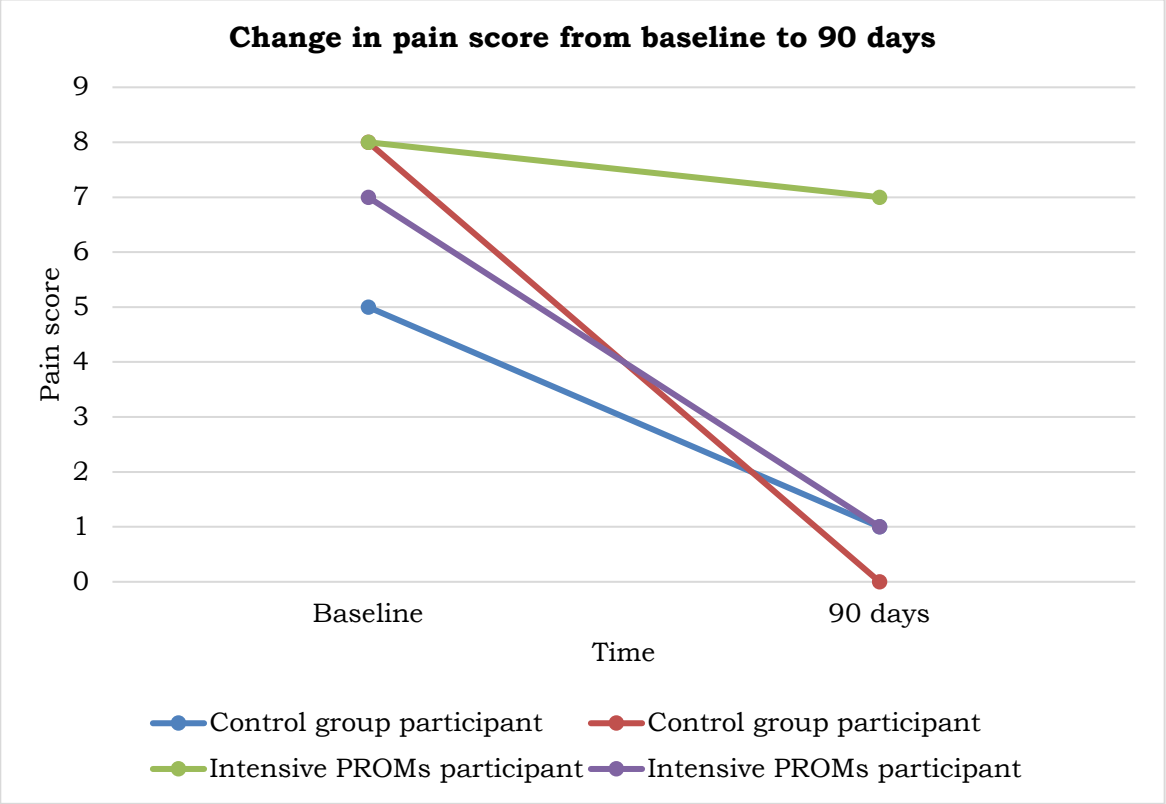


Figure 6.5 – Changes in pain score for individual participants

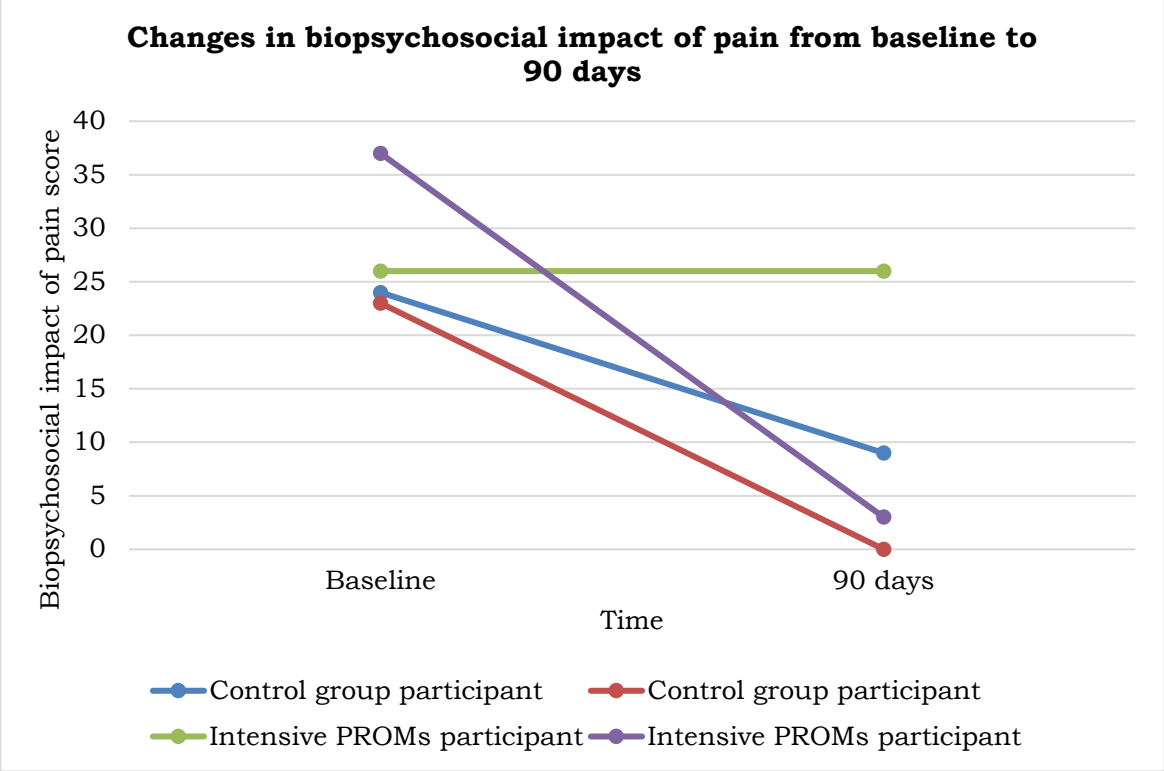


Figure 6.6 – Changes in biopsychosocial impact of pain for individual participants

There was no observed harm or unintended effects in each group. Whilst dropout was higher in one group, one receptionist stated that it was common to have a lack of patients filling in PROMs at 90 days within their clinic. *"We don't very often get.. don't get as far as the fourth one. They tend to.. If they are going to do it they do the first three..it's unlikely that they'll do the fourth one."* (Reception staff - Leanne).

Patients in the trial commented that the emails from the Care Response system to complete the PROMs were good reminders. Two trial patients interviewed had completed the 90-day outcome assessment. The other two patients both thought they had completed the intervention, but one later commented that sometimes the emails went to her junk mail and she might have missed a questionnaire. She also suggested some of the headings might be a bit dubious and thus she missed the emails. Participants had no other suggestions, other than email reminders, for getting complete data and retaining patients in the study. *"I really don't understand why people say yes they're going to take part in the study and then not carry on. That doesn't make sense to me"* (Trial patient - Jana).

6.4 Discussion

This study aimed to investigate the feasibility of conducting an RCT on PROMs in specialist musculoskeletal care for patients with low back pain. The study explored patients' and chiropractors' experiences and views on participating in a trial. The findings identified a series of issues and informed recommendations relating to the evaluation of PROMs for subsequent studies, in both the development of PROMs as an intervention and the study design and procedures for evaluation (See Table 6.8 for an overview).

6.4.1 Development of PROMs as an intervention

Despite PROMs being routinely used in chiropractic settings, no participants completed the intervention with no single factor impacting completion. Overall, participants felt that patient engagement with PROMs was low due to patients' lack of knowledge about PROMs and beliefs about completing them. Previous reviews have identified that staff encouragement facilitated patient engagement with PROMs (Antunes et al., 2014; Duncan & Murray, 2012). Chiropractors suggested that reception staff could explain to patients that PROMs are a valuable part of their care, which may increase fidelity to PROMs.

A systematic review of the barriers and facilitators of using PROMs in palliative care settings suggested a series of steps that need to be taken prior to using PROMs in clinical practice. This included selection of outcome measure, decision of application of measure, and clinician education (Antunes et al., 2014). Each of these steps are considered below in the context of employing PROMs in specialist musculoskeletal care.

<u>Selection of PROMs</u>

Two systematic reviews identified that PROMs must be appropriate for successful use in clinical practice, and be clinically meaningful for clinician engagement (Duncan & Murray, 2012; Greenhalgh et al., 2017). A cross-sectional study exploring the barriers and facilitators of Australian chiropractors utilising PROMs found that 72.5% of the survey respondents used PROMs in their clinical practice, which included pain specific PROMs (e.g. Pain Diagram, Numeric Rating Scale, Visual Analogue Scale), functional PROMs (e.g. Oswestry Disability Index, Functional Rating Scale, Roland Morris Questionnaire), and

generic health PROMs (e.g. Health Status Questionnaire, RAND-36) (Clohesy & Schneiders, 2018). Within this current study, the trial used the Bournemouth Questionnaire and PGIC. However, in the interviews patients and clinicians stated a preference for functional scales, which focus on a patient's functioning rather than pain levels. Patients felt functional PROMs were relevant for their conditions, with chiropractors finding them meaningful for their clinical practice. These preferences will need to be addressed for PROMs to be successful as an intervention.

Application of PROMs

In a survey of 558 Australian chiropractors (11% of the registered chiropractors in Australia), PROMs were mostly administered via paper format by the chiropractor (47.4%) or paper format administered by other staff (39.5%). Only 8.2% of participants used PROMs in an online format (Clohesy & Schneiders, 2018). Chiropractors felt that time to administer and assess PROMs was a significant barrier to using PROMs in practice, noting the increase in practitioner and admin workload. Chiropractors felt utilisation of PROMs should be easy and simple to administer (Clohesy & Schneiders, 2018).

Within the current study, two chiropractors identified issues with an electronic PROM system, however, overall this was preferred over a paper-based system. Greenhalgh et al. (2017) identifies that the practicalities of collecting PROMs to be fed back to clinicians within the consultation can be challenging with the administrative time affecting workflow. Therefore, electronic PROMs are recommended, making PROMs more accessible within clinics and reducing the time-burden. A commentary by Chang (2007) identified that unfamiliarity with electronic PROM software is a barrier to successful use. This could be addressed by ensuring the computerised PROMs are designed to be easily used by clinicians in busy practice settings and with training to ensure clinicians are confident with the system.

During the feasibility study interviews, IT skills, literacy, age, and time were suggested as barriers to completion, however only one trial patient experienced problems with her email provider filtering the PROM reminders. In a study assessing the feasibility and acceptability of PROMs with patients with rheumatoid arthritis, patients' perceived a web-based PROM as easy, and reported willingness to fill in the questionnaires at home (Koevoets et al., 2013).

Clinician education

The qualitative interviews identified that chiropractors often had a lack of knowledge and engagement with PROMs, despite using them in clinical practice. In a survey of PROM use, chiropractors who were not using PROMs felt they needed further understanding of which PROMs to use and why they should use them in order to employ them in their practice (Clohesy & Schneiders, 2018). Antunes et al. (2014) and Duncan and Murray (2012) also identified clinicians' lack of knowledge and education as a significant barrier to PROM use. Greenhalgh et al. (2017) also reported concerns on clinicians' ability to interpret data and understand the potential utility in clinical practice.

Literature suggests that educating clinicians on the purposes of PROMs and the benefits of using them may be beneficial (Antunes et al., 2014; Callaly, 2001; Duncan & Murray, 2012). Santana et al. (2015) described the development and execution of training on PROMs for clinicians in three areas: adult oncology, lung transplant, and paediatrics. From these case studies, they recommended using a framework to guide the planning, content creation, and delivery of training. Work should be conducted to identify the local issues which need to be addressed, and training should be timed to fit with clinical practice (Santana et al., 2015). In the qualitative interviews, chiropractors indicated that training on PROMs would be acceptable to others and would improve knowledge and engagement with PROMs in clinical practice. They recommended an online format for training with a physical guide as support.

6.4.2 Evaluation of PROMs

Recruitment and response rates

Although there was little difficulty in identifying chiropractors and potential patients with a significant interest in the study, only nine patients consented to take part (16% of eligible patients). This finding highlights difficulties for future research, as a large sample will be required to adequately test the hypotheses derived from PROMPT (see Chapter 5). Although patients were generally accepting of the study design and participating in the proposed study, those interviewed had already agreed to take part in a study. Therefore, the sample interviewed is not representative of the population of patients with back pain. Improvements are necessary to encourage more patients who register an interest in the study to consent to taking part. Additionally, many patients

were lost to follow-up (50%). This reflects the need to improve the study processes to ensure participants remain engaged with the study (see Table 6.8).

Data collection

Chiropractors discussed their use of PROMs, which often matched the patient-clinician interaction pathway in PROMPT (see Chapter 5). Chiropractors thought PROMs improved: clinician's understanding of the patient's perspective, individualised advice to patients, and discussion of patient's progress. Additionally, chiropractors believed PROMs could improve patient adherence for self-management and improve the patient-clinician relationship. These are also reflective of elements identified by the theoretical review (Chapter 5).

Potential measures to evaluate PROMs were sent to patients prior to their interviews. The measurement tools were seen as appropriate and patients thought it was acceptable to complete the measures, on average taking 10 minutes to complete. Although many patients preferred to complete the measures online, participants valued being given the choice of versions, which could improve completion rates. All patients consented to have their treatment sessions audio-recorded, however, in some cases, chiropractors did not audio-record sessions, or did not record the data needed to cross-tabulate the recordings to the patient. Chiropractors may need administrative support in managing audio-recordings.

6.4.3 Strengths and limitations

This feasibility aimed to look at the acceptability of study procedures to evaluate PROMs in clinical practice. However, the sampling of participants may limit the transferability of the results. Socioeconomic region of the clinics and details on the experience and training of the chiropractors were not collected. It is therefore not possible to compare the chiropractors to the wider profession. Additionally, there is no insight from the qualitative data into why patients declined to take part. The findings represent the views of patients and clinicians who have volunteered to take part in research and therefore may not be representative of the population. While this sampling may limit the transferability, this study provides an insight into PROMs as an intervention and the process of evaluation.

In addition, this study could have utilised a different mixed-methods approach (Creswell & Clark, 2011), for example, a quantitative feasibility study

with an embedded qualitative component (Plano Clark et al., 2013). This alternative design, with a focus and weighting on the quantitative component, has been beneficial for previous feasibility studies within specialist musculoskeletal care (Stuber, Langweiler, Mior, & McCarthy, 2018), research on back pain in primary care settings (Geraghty et al., 2018), and studies examining PROMs (Appleyard, Larkin, Stewart, Minton, & Gilbert, 2021).

This type of feasibility study would have allowed for exploration of different primary research questions (Plano Clark et al., 2013). Mixed-methods studies with a quantitative focus can explore differences in outcomes; a mixed-methods feasibility study with a more quantitative focus, provided preliminary findings on patient-centredness within chiropractic settings (Stuber et al., 2018), as well as recruitment and retention rates. This study design also provides an opportunity to explore participant characteristics during recruitment; in exploring the feasibility of PROMs in men with prostate cancer, Appleyard et al. (2021) classified participants on their familiarity with computers, which is important for future studies using this intervention. A focus on the quantitative component can lead to data for future sample size calculations; the findings from a feasibility study on self-management of back pain (Geraghty et al., 2018) were used in estimating variance for a future trial (Geraghty et al., 2020). This current feasibility study did not explore differences in outcomes, difference in participant characteristics, or estimate variance for a future sample size calculation.

Table 6.8 – Implications for subsequent research

Area of Study	Issue	Recommendations
Recruitment	Low recruitment rate	• Refine the information sheet aims to provide clear and simple information about the consequences of participating • Streamline the information and consent process to improve accessibility for patients
Intervention	Preference for different PROMs	• Change the PROMs for an appropriate and meaningful measure (both functional and psychological items) to align the intervention to patients' and clinicians' values and needs
	Lack of patient engagement with PROMs	• Reception staff to explain to patients that PROMs are part of their care, improving patient awareness of PROMs and understanding the role they play within their treatment
	Lack of clinician knowledge and education on PROMs	• Improve clinician knowledge on PROMs including the value of PROMs in clinical practice and procedural knowledge on interpreting the data • Conduct training for chiropractors to improve their knowledge, beliefs about consequences, and self-efficacy for using PROMs with patients
Data collection	Preference for paper version	• Offer patients the option of paper or online completion of outcome and process measures providing the appropriate resource for patients needs
	Few audio-recordings	• Reminders for chiropractors to audio-record treatment sessions of patients in the study
Response and retention	Low response and retention	• Remind patients about the study by sending email reminders routinely throughout the trial • Personalise email reminders to patients from the lead researcher to make an interpersonal connection with the participant

6.5 Chapter summary

The aim of this feasibility study was to examine the practicality and acceptability of conducting an evaluation trial and test the methodology and procedures proposed for a full-scale trial. Using patients', chiropractors', and reception staff' views of PROMs, the study identified barriers and facilitators to using PROMs in chiropractic care, and the training needs of chiropractors regarding PROMs. The results from the study have demonstrated further development of PROMs as an intervention is necessary for the next phase of the research to ensure PROMs are meaningful to patients and chiropractors and improve engagement.

The study also provided an opportunity to assess recruitment and retention rates, participants' acceptance of randomisation, and evaluate the measurement tools and their appropriateness and usability within a larger study. The results of this feasibility study will be used with the theoretical framework proposed in Chapter 5 to design a mixed-method evaluation of PROMs in clinical practice for low back pain (Chapters 7-10).

Chapter 7 A cluster-randomised controlled trial evaluating the effects of PROMs in routine treatment for back pain

7.1 Introduction

This chapter reports a cluster-RCT that examined the effects of using different frequencies of PROMs in chiropractic care for low back pain. Previous systematic reviews have identified that PROMs may improve patients' health, functional status and influence diagnosis and use of health services, with improvements in patient-clinician communication and patient satisfaction (Espallargues et al., 2000; Marshall et al., 2006; Valderas, Kotzeva, et al., 2008). In addition to reviews exploring the overall impact of using PROMs, other reviews have focused on the impact of using PROMs within certain conditions, such as cancer, which identified that the utilisation of PROMs may improve patient-communication and satisfaction with care (Chen, Ou, & Hollis, 2013; Luckett, Butow, & King, 2009).

There has been very little published research in the context of low back pain and PROMs, with just one case series demonstrating how PROMs can aid decision making in clinical practice (Stratford & Binkley, 1999). The feasibility study (Chapter 6) highlighted chiropractors' support for using PROMs in clinical practice. Chiropractors used PROMs throughout the treatment process, assessing patients at their initial consultation, discussing concerns and self-management plans, and tracking and identifying improvements in patients. This reflected empirical (Chapter 4) and theoretical literature (Chapter 5) on PROMs for non-malignant pain.

Whilst systematic reviews suggest that PROMs may improve the process and outcome of care, there is little research on effective utilisation and optimum use of PROMs to achieve these benefits. Chiropractors who regularly use PROMs have standardised reporting times of three times within 30 days. However, chiropractors can see patients once or twice a week for treatment, suggesting intensive PROMs (every five days) may be clinically useful for chiropractors.

Due to the aims of the feasibility study, small number of participants, and with no participants completing the intervention, no preliminary findings could

be drawn about the effect of PROMs on patients with low back pain. However, the results supported the feasibility of conducting an RCT and process evaluation to answer the following research question: what are the clinical and psychosocial consequences of using PROMs in specialist musculoskeletal care for low back pain, and through what mechanisms?

Based on the theoretical review (Chapter 5), a hypothesis was derived from PROMPT, and it was predicted there will be a difference in back pain-related disability at 90 days between those who complete PROMs routinely, those who complete PROMs intensively, and those who do not complete PROMs. The current study aimed to test this hypothesis and evaluate the clinical effects of using different frequencies of PROMs in routine treatment of low back pain.

7.2 Methods

7.2.1 Study design

This study used a cluster-RCT design. A cluster-RCT randomises patients by groups rather than randomising individuals (Fayers et al., 2002). A cluster trial was chosen to avoid contamination between the three groups in this trial. If chiropractors were treating patients completing PROMs at different times and were not systematic in the delivery of PROMs as an intervention, it would be unrealistic to expect the effect of care to be limited to each patient. This may distort the study results. Chiropractors were randomly assigned to one of three groups: intensive PROMs, routine PROMs, or a control group. Patients booking to see participating chiropractors were asked if they would like to take part in the study. Patients who consented to the study were allocated to that chiropractor's group in the trial. The trial was registered with ISRCTN (ISRCTN82172279; date assigned 22/03/2018).

7.2.2 Sampling and recruitment

Chiropractors

Recruitment of chiropractors to the study ran from 25th July 2018 to the 29th February 2020. Emails were sent to all chiropractors registered with the Royal College of Chiropractors and the British Chiropractic Association, with follow-up emails periodically sent, reminders on association social media pages, and advertisement at national conferences. Additionally, chiropractors currently using Care Response, an online system which collects patient outcome scores, were invited to participate. The study was also advertised on Care Response social media pages. The inclusion criteria were: (a) be registered with the General Chiropractic Council, (b) speak and read English fluently; as the PROM used within this study has not been translated into other languages and independently assessed for validity and reliability, and (c) be able to comply with all study procedures. Following interest in the study, chiropractors were sent study information (Appendix J.1) and provided consent online (Appendix J.2).

Patients with back pain

A consecutive sample of patients consulting each participating chiropractor was recruited. A consecutive sample is made up of all eligible individuals who meet the inclusion criteria and agree to participate (Maxwell & Satake, 2006). The inclusion criteria were set to be as inclusive as possible, aiming for the study to be generalisable to the larger population of patients who receive chiropractic treatment for back pain. The inclusion criteria were: (a) be at least 16 years old. Due to the biological and psychological differences between children, adolescents and adults, children and adolescents were excluded from this project, (b) speak and read English fluently. As with the chiropractors, the inclusion criterion of speaking and reading English fluently was set so study participants could coherently understand the questions in the PROMs used in the study, (c) be a paying patient presenting to the musculoskeletal clinic, rather than a state-funded patient, and (d) present to the clinic with self-reported low back pain.

The recruitment procedure was the same as the feasibility study (described in Section 6.2.2) and ran from April 2019 to March 2020. As per normal practice activity, new patients who contacted chiropractors for an appointment were signed up to Care Response with consent verbally obtained by reception staff during the booking phone call (Appendix K). Patients were emailed links to Care Response to complete a health assessment prior to their first appointment (see Appendix D for overview of Care Response). Following completion of the routine Care Response assessment, patients were screened by the system for inclusion into this study. Patients eligible to participate were directed to an information sheet and consent form for the study (Appendix L).

Randomisation: sequence generation and type

After consenting to the study, chiropractors were randomised to one of the three groups, using an online randomisation generator. This was simple randomisation at the individual level of the chiropractor after recruitment to one of three treatment groups, with no blocking. There were no restrictions.

Randomisation: allocation concealment mechanism

Individuals were randomised by a computer-generated list. Group allocation was assigned after completion of consent of the chiropractor. The allocation of

patients was completely automated through Care Response, with patients allocated according to the randomisation of the chiropractor.

Randomisation: implementation

I generated the random allocation sequence using the online tool, with the allocation of chiropractors and enrolment of participations to the intervention groups recorded in Care Response by a member of the supervisory team (JF).

Blinding

It was impossible to blind the chiropractors to the group to which they had been allocated, as with the patients, due to the nature of the intervention. I was aware of the randomisation status for chiropractors, however chiropractors were given ID numbers for the purpose of analysis, to ensure blinding of the patient allocation to the three groups.

Sample size

The statistical program G*Power (version 3.1) was used to conduct power analysis to determine the appropriate sample size (Faul, Erdfelder, Lang, & Buchner, 2007). Under individual randomisation, power calculations indicated that 369 patients (assuming an alpha of 0.05, 80% power) is sufficient to detect an effect size (f = 0.15), which is clinically meaningful on the Roland-Morris Questionnaire (Geraghty et al., 2020). This equates to 123 participants in each group (12 participants per cluster). To account for the design effect of cluster trials, the intra-cluster correlation coefficient was proposed as 0.03 for a moderate estimate appropriate for primary care trials (Adams et al., 2004), estimating 15 patients per cluster would be required with 30 clusters estimated to be recruited (equating to ten chiropractors per arm). This would overall require 450 patients, 150 in each group. To allow for 50% attrition, based on the feasibility study (Chapter 6), it was estimated 900 patients would be required.

7.2.3 Intervention

The intervention PROMs were the Musculoskeletal Health Questionnaire (MSK-HQ) and the Patient Global Impression of Change Scale (PGIC). The MSK-HQ was chosen following qualitative interviews with patients and chiropractors in the feasibility study, who preferred a functional measure rather than a pain score (Chapter 6). The MSK-HQ focuses on a two-week period; some patients

interviewed had symptoms which varied from day-to-day, and stated a preference for measures which could capture this, rather than focusing on daily functioning and pain.

It was also noted in the interviews, that the variety of conditions and symptoms affecting patients influenced the relevance of PROMs. The MSK-HQ was developed to be used across patients with musculoskeletal conditions, focusing on both their pain, pain-related symptoms, and the interference pain has on their daily functioning (Ellis, Fitzpatrick, Hill, & Price, 2014). The questionnaire has 14 items assessing different domains: pain, stiffness, walking, dressing, physical activity, daily routine, social activity, needing help, sleep, fatigue, emotional wellbeing, condition understanding, symptom management, overall impact (Hill et al., 2016). Each question is scored on a five-point scale from "not at all" to "extremely" and on average the total MSK-HQ takes two minutes to complete. During development and validation, the MSK-HQ has shown to have high internal consistency (Cronbach's alpha – 0.88), and excellent reliability (ICC – 0.84) (Hill et al., 2016). The chiropractors recruited into the study were randomised to three groups: a control group, routine PROMs, and intensive PROMs. The routine and intensive PROMs groups differentiated in how often Care Response emailed to patients during their treatment (see Table 7.1). Those in the control group did not complete PROMs. Chiropractors in the routine and intensive PROM groups were asked to discuss PROMs with their patients at every session after a PROM had been completed.

Table 7.1 – Intervention groups

Control group	Routine PROMs	Intensive PROMs
No PROMs	• Baseline • 14 days • 30 days	• Baseline • 4 days • 9 days • 14 days • 19 days • 25 days • 30 days

Clinician education on PROMs

Based on the findings of the feasibility study, chiropractors often lacked knowledge and engagement with PROMs. Clinicians' lack of education surrounding PROMs is a significant barrier to their use in clinical practice (Antunes et al., 2014; Duncan & Murray, 2012). Training on the purpose, administration, benefits, and interpretation of PROMs is essential (Antunes et al., 2014; Callaly, 2001; Santana et al., 2015). Chiropractors in the routine and

intensive PROM groups received training on PROMs via a booklet (Appendix M.1) and were asked to participate in telephone training (see Appendix M.2). This was developed based on previous training on PROMs in other settings, including mental health (Improving Access to Psychological Therapies, 2011) and palliative care (Bausewein et al., 2011). The training and resources covered: (a) PROMs in musculoskeletal healthcare, (b) administration of PROMs, (c) PROM scoring and analysis, and (d) use of PROMs in clinical practice. Reception staff at the chiropractors' clinic were sent information on the administrative process of PROMs (Appendix K). Chiropractors in the control group received the training and resources after study completion.

7.2.4 Data collection

Patient demographics were collected at baseline on Care Response, this included: age, gender, other pain, length of complaint, pain over 30 days, pain of recurring problem, STarT Back score. Patients were also asked to complete the primary and secondary outcome measures at baseline and were repeated at 90 days after their first appointment. After completing baseline measures participants received an email thanking them for their participation (Appendix N.1). At 86 days after first appointment, patients received an email reminder about the study (Appendix N.2) prior to patients receiving an email at 90 days through Care Response to complete the primary and secondary outcome measures. If patients had not completed the measures within 5 days, they were sent an email reminder (Appendix N.3), follow-up phone calls were made 5 days later, and finally if the patient did not respond within two weeks of the phone call, a copy of the primary outcome and process measures was posted with a pre-paid envelope (Appendix N.4).

<u>Primary outcome measure</u>

Within the PROMPT model (Chapter 5), PROMs are hypothesised to influence patient outcomes specific to the patients' presenting condition. Within this study, back pain-related disability was measured with the Roland-Morris Questionnaire, examining the physical functioning and disability of patients with low back pain (Roland & Fairbank, 2000; Roland & Morris, 1983). The questionnaire has 24 statements with the patient selecting statements that apply on the day of completing the questionnaire. The questionnaire is scored with the sum of ticked statements. Scores range from 0 to 24, with higher scores equating

to greater back pain-related disability. Through psychometric testing, the Roland Morris was found to have good internal consistency (estimated Cronbach's alpha - 0.84 – 0.93), good reliability (ICC - 0.74), and is sensitive to change (Ostelo, de Vet, Knol, & van den Brandt, 2004; Roland & Fairbank, 2000; Stratford, Binkley, Solomon, Gill, & Finch, 1994).

Secondary outcome measure

The PROMPT model also hypothesises HRQoL as an outcome. Patients' HRQoL was measured with the EQ-5D thermometer. The EQ-5D thermometer is a visual analogue scale numbered on a 100-point scale, labelled 'best imaginable health state' to 'worst imaginable health state', with greater scores indicating higher QoL. The questionnaire asks patients to rate their own health state by marking an X on the scale which indicates their health on that day (Johnson, Coons, Ergo, & Szava-Kovats, 1998). Through psychometric testing, the EQ-5D was found to have acceptable internal consistency (estimated Cronbach's alpha - 0.82 – 0.87) and good reliability (ICC - 0.76) (Solberg, Olsen, Ingebrigtsen, Hofoss, & Nygaard, 2005).

7.2.5 Data analysis

The quantitative data on patient demographics and primary and secondary outcomes were extracted for all recruited patients and downloaded into an anonymised spreadsheet. All follow up responses on paper were manually inputted and checked for accuracy. The data were analysed using the statistical software SPSS (version 26) (IBM Corp, 2012). Descriptive statistics and frequencies were run on the data to summarise patient characteristics and baseline back pain-related disability status and health-related quality of life scores. Following the Consort statement, significance tests of baseline differences between the three groups were not conducted (Schulz, Altman, & Moher, 2010). This outdated practice shows if any significant differences in baseline are caused by chance. However, with proper randomisation procedures, any differences are already known to be caused by chance. Comparisons were made between participants who completed follow-up and those that did not.

To evaluate the effects of using different levels of PROMs in routine treatment of low back pain, outcome scores of back pain-related disability and HRQoL were compared between the three groups. The analysis aimed to test the hypothesis that there will be a difference in scores at 90 days between those who

complete PROMs routinely, those who complete PROMs intensively and those who do not complete PROMs. Before any analyses, the distribution of variables was examined to ensure the assumptions for parametric analysis were met; histograms, skewness and kurtosis were examined for each measure, with cut-off scores of +/- 2 for skewness, +/- 7 for kurtosis (Field, 2013). Preliminary analyses examined practitioner differences in patients' mean change in back pain-related disability, to identify if this was a possible confounding variable due to the cluster design. The main per protocol analysis then compared the three groups using a series of ANOVAs to test for the effects of time and group. Significant differences between group were analysed with post-hoc tests. Bonferroni correction was used to mitigate against Type I errors.

The mean difference between baseline and follow-up scores on the Roland-Morris questionnaire were calculated. These were used to create a dummy variable on whether any change of patients' back pain-related disability was clinically significant. A chi-square test was used to examine any statistically significant differences between groups. The per protocol analysis was conducted to identify the treatment effect with the data available. However, this may be biased, due to the exclusion of patients with no primary endpoint. Therefore, a sensitivity analysis was conducted using an intention-to-treat approach. This provides a more conservative estimate of the treatment effect by using the data from all participants initially randomised to the trial, whether they received or discontinued treatment (Schulz et al., 2010). This upholds the randomisation of participants, however, those who drop-out from treatment rarely complete follow-up measures, introducing missing data to the analysis. To account for this, imputation was carried out using baseline observations carried forward. This approach was used, under the assumption that participants that discontinue treatment, should be considered as a failure of treatment and therefore baseline values should be used as an estimate for the analysis (Kenward & Molenberghs, 2009). However, by using baseline values, this does not consider any deterioration or worsening of symptoms, and this method only provides an estimation (Kenward & Molenberghs, 2009). For this analysis, patients' baseline measures on the Roland-Morris questionnaire and EQ-5D were used as an estimate of their missing follow-up data.

7.2.6 Ethical considerations

Recruitment

This study received ethical and research governance approval from the University of Southampton (ref: 20133, 2017). All participants received an information sheet, explaining that participation in the study was voluntary, the use of the collected data, and the anonymity and protection of the data (Appendix J and L). All participants provided informed consent to participate in the trial. Recruited chiropractors received a certificate showing their research collaboration with the University of Southampton and Royal College of Chiropractors certificate, continuing professional development certificate. For every five patients they recruited, chiropractors were entered into a £100 raffle. Patients who completed the follow-up questionnaires received a £10 digital Love2shop voucher.

Data protection

The Care Response system passed the Information Governance Toolkit to level 2, providing assurance that patient data are handled ethically. Data were only available once patients had consented to be part of the study. In addition, all data downloaded from the Care Response system was anonymised when extracted and stored on a password-protected computer. These procedures fully comply with General Data Protection Regulation (European Parliament and Council of European Union, 2016) and the Research Data Management Policy of the University of Southampton (University of Southampton, 2019).

7.3 Results

7.3.1 Chiropractors

The study received 372 expressions of interest from chiropractors, who followed a link to a consent form from the participant information sheet. Twenty-five chiropractors then consented to take part in the study and were randomised, with 16 chiropractors responding to further correspondence regarding study procedures. Ten chiropractors registered and enrolled to participate in the study, of these, only eight chiropractors recruited patients into the study and collected data. The final practitioners involved in the study included five male and three female chiropractors, spread geographically across the U.K.

7.3.2 Sample

From the eight participating chiropractors, 323 patients were invited to participate over 12 months (April 2019 – March 2020). Of these, 158 patients met the eligibility criteria and consented to participate in the study and were randomised according to their chiropractor. Nine patients withdrew from the study. Two patients were excluded from analysis: one due to the wrong intervention being sent, and one due to the first appointment being cancelled due to COVID-19 lockdown (UK Cabinet Office, 2020). The overall response rate was 50.6% (80/158). Figure 7.1 shows the flow of participants through the trial. Total drop-out (including loss to follow-up, withdrawal, and exclusion from analysis) varied between the three groups: intensive group (54.7%, 35), routine group (48.0%, 12), control group (44.9%, 31). However, these differences were not statistically significant (Pearson's x^2 (2, n = 158) = 1.29, p = 0.525).

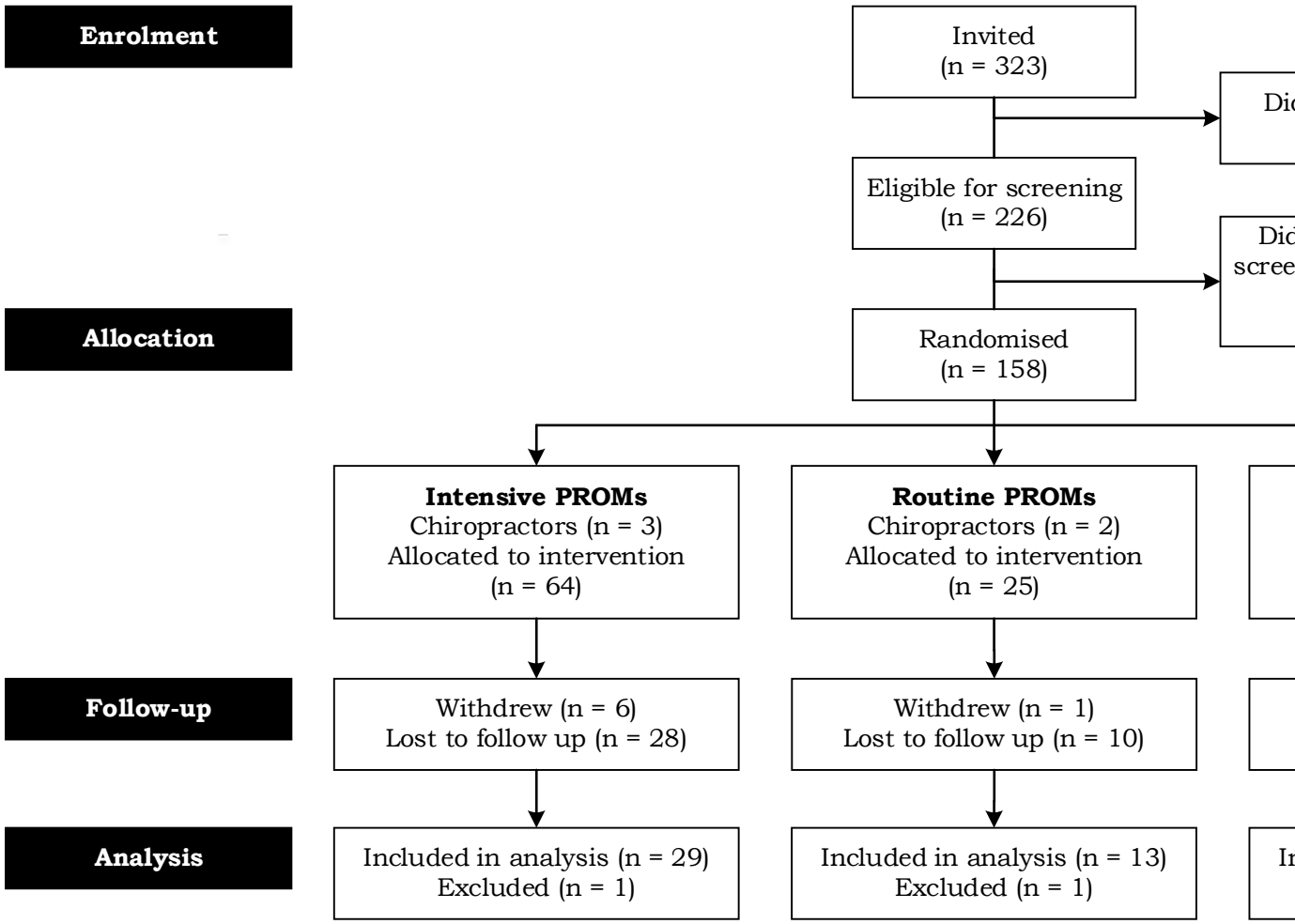


Figure 7.1 – Flowchart of patient participation

Table 7.2 gives the baseline characteristics of the 158 participants in the study. Participants had a mean age of 44.07 (SD = 16.21) with an age range of 16-82, 50.3% (79) were female. Over half the sample (65.8%) also noted an additional pain complaint other than back pain, this included: 60 (38.0%) pain in lower extremities, 51 (32.3%) pain in neck, 39 (24.7%) pain in upper extremities, 11 (7%) pain in front of body, 3 (1.9%) pain in face and head.

Table 7.2 – Baseline characteristics for trial patients

	Intensive n = 64	**Routine n = 25**	**Control n = 69**	**Overall sample n = 158**
Age				
mean (SD)	48.13 (16.74)	40.32 (13.64)	41.67 (15.97)	44.07 (16.21)
Gender				
Female - n (%)	33 (51.6%)	13 (52.0%)	32 (46.4%)	79 (50.3%)
Other pain				
n (%)	38 (59.4%)	15 (60.0%)	51(73.9%)	104 (65.8%)
Length of complaint				
<3 months n (%)	24 (37.5%)	7 (28.0%)	17 (24.6%)	48 (30.4%)
3-12 months n (%)	14 (21.9%)	2 (8.0%)	22 (31.9%)	38 (24.1%)
1-2 years n (%)	11 (17.2%)	5 (20.0%)	10 (14.5%)	26 (16.5%)
>2 years n (%)	15 (23.4%)	11 (44.0%)	20 (29.0%)	46 (29.1%)
Pain over 30 days				
n (%)	39 (60.9%)	17 (68.0%)	54 (78.3%)	100 (63.3%)
Recurring problem				
n (%)	36 (56.3%)	16 (64.0%)	48 (69.6%)	110 (69.6%)
STarT Back				
Low n (%)	31 (48.4%)	15 (60.0%)	31 (44.9%)	77 (48.7%)
Medium n (%)	22 (34.4%)	6 (24.0%)	28 (40.6%)	56 (35.4%)
High n (%)	11 (17.2%)	4 (16.0%)	10 (14.5%)	25 (15.8%)

Baseline differences between participants who completed the follow-up and those who did not can be seen in Table 7.3. There were no significant differences in the full recruited sample and those who had completed follow-up in terms of age, gender, other pain, length of complaint, recurring problem, and baseline back pain-related disability scores and HRQoL. There were significant differences in baseline scores on the STarT Back tool, with those with lower risk scores more likely to drop out.

Table 7.3 – Baseline characteristics for those who completed all assessments compared to those who did not

	Participants who completed all assessments (n = 80)	Participants who did not complete all assessments (n = 79)	p-value of chi-squared test/t-test for difference
Age			
mean (SD)	45.13 (16.92)	42.99 (15.49)	t (156) = -.828 p = 0.409
Gender			
Female - n (%)	44 (55.0%)	34 (43.6%)	x^2 (1) = 2.30 p = 0.129
Other pain			
n (%)	55 (68.8%)	49 (62.8%)	x^2 (1) = 0.62 p = 0.432
Length of complaint			
<3 months n (%) 3-12 months n (%) 1-2 years n (%) >2 years n (%)	25 (31.3%) 18 (22.5%) 13 (16.3%) 24 (30.0%)	23 (29.5%) 20 (25.6%) 13 (16.7%) 22 (28.2%)	x^2 (3) = 0.25 p = 0.969
Pain over 30 days			
n (%)	54 (67.5%)	56 (71.8%)	x^2 (1) = 0.34 p = 0.557
Recurring problem			
n (%)	45 (56.3%)	55 (70.5%)	x^2 (1) = 3.46 p = 0.063
STarT Back			
Low n (%) Medium n (%) High n (%)	32 (40.0%) 31 (38.8%) 17 (21.3%)	45 (57.7%) 25 (32.1%) 8 (10.3%)	x^2 (2) = 6.05 p = 0.048*
Back pain-related disability			
mean (SD)	7.54 (5.78)	6.77 (5.92)	t (156) = -0.83, p = 0.411
HRQoL			
mean (SD)	66.09 (22.13)	66.94 (18.44)	t (156) = 0.26, p = 0.794

Significance level: * = $p < 0.05$

7.3.3 *Outcomes*

Table 7.4 summarises the change in primary and secondary outcome measures change over time for the three groups. All three groups had a statistically significant reduction of back pain-related disability between baseline and follow-up. An initial ANOVA showed no significant differences between practitioners on the mean change in back pain-related disability ($F(7) = 0.84$, $p = 0.562$). Therefore, practitioner effect was not controlled for in further analysis. Table 7.5 provides comparisons of the three groups. Participants in the control group achieved slightly greater reductions in back pain-related disability (shown in Figure 7.2). However, there was no significant differences between the scores on the Roland-Morris questionnaire across the three groups ($F(2) = 0.29$, $p = 0.752$).

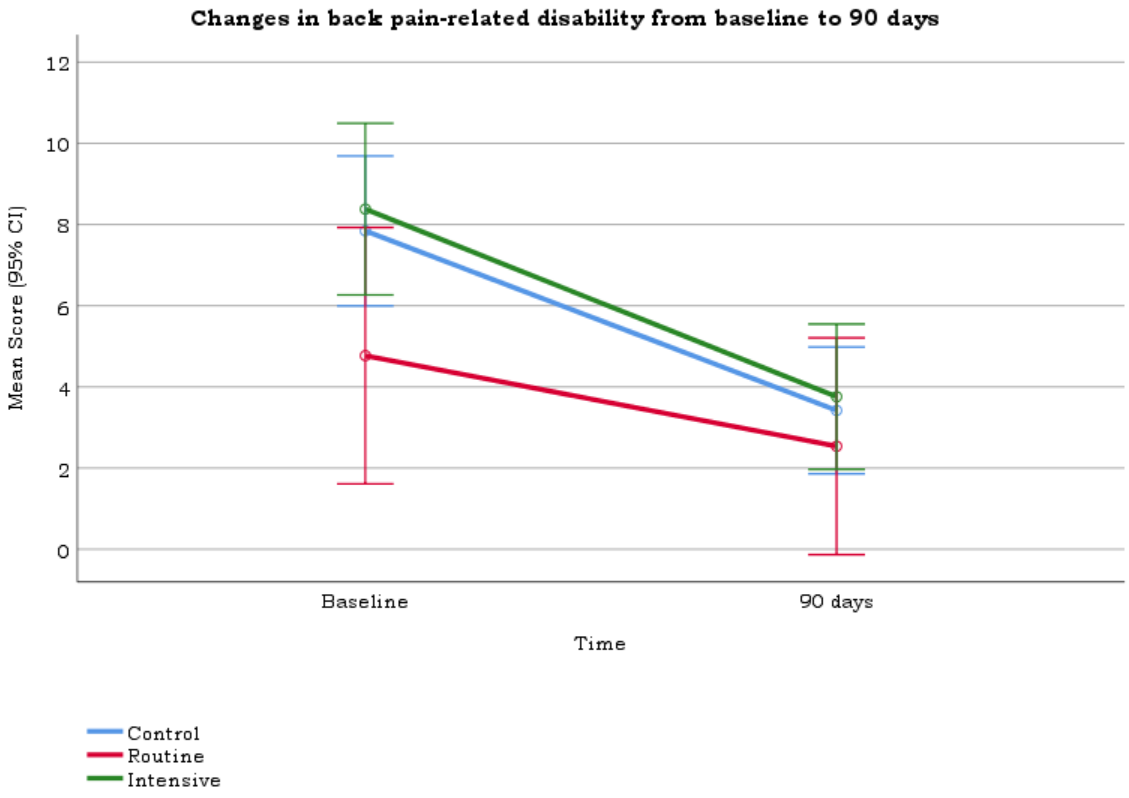


Figure 7.2 – Back pain-related disability mean change by group

Of the 80 participants that completed follow-up, 63.7% had a clinically meaningful change on the Roland-Morris questionnaire. There were higher proportions of participants achieving a clinically important change in the intensive intervention (72.4%), than the control group (63.2%), and the routine group (46.2%). However, this was not significantly different x^2 (2) = 2.69, p = 0.261 between the three groups.

Table 7.4 – Back pain-related disability and health-related quality of life at baseline and follow-up, including mean difference

	Baseline mean (SD)	Follow-up mean (SD)	Mean difference (95% CI)	Significance
Back pain-related disability				
Intensive	8.38 (5.75)	3.76 (5.55)	-4.62 (-6.57, - 2.67)	t (28) = -4.85, p < 0.001*)
Routine	4.77 (4.29)	2.54 (3.60)	-2.23 (-4.44, -.022)	t (12) = -2.20, p = 0.048*
Control	7.84 (6.08)	3.42 (4.60)	-4.42 (-5.96, -2.88)	t (37) = -5.83, p < 0.001*
HRQoL				
Intensive	70.34 (22.01)	77.17 (21.62)	6.83 (-2.33, 15.99)	t (28) = 1.53, p = 0.138
Routine	65.77 (19.57)	65.92 (27.73)	.15 (-17.53, 17.84)	t (12) = 0.02, p = 0.985
Control	62.95 (23.02)	73.71 (24.21)	10.76 (0.77, 20.75)	t (37) = -2.18, p = 0.350

Significance level: * = p < 0.05

The EQ-5D is also shown in Table 7.4. There were some improvements in all three arms from baseline to follow-up, although all changes were non-significant. There were also no significant differences between groups, (F (2) = .99, p = 0.375), see Table 7.5 for comparisons.

Table 7.5 – Formal comparisons between intervention groups

	Difference	95% CI	Significance
Back pain-related disability			
Intensive vs. Control	0.44	(-1.46, 6.29)	p = 1.000
Routine vs. Control	-1.98	(-5.71, 1.75)	p = 0.594
Intensive vs. Routine	2.42	(-1.46, 6.29)	p = 0.393
HRQoL			
Intensive vs. Control	5.43	(-5.60, 16.46)	p = 0.696
Routine vs. Control	-2.48	(-16.85, 11.89)	p = 1.00
Intensive vs. Routine	7.91	(-7.01, 22.84)	p = 0.595

Significance level: * = p < 0.05

7.3.4 Sensitivity analysis – intention-to-treat

Repeating the analysis with an intention-to-treat approach as a sensitivity analysis resulted in slight differences. Participants in the intensive group had a greater difference in back pain-related disability (3.75, 95% CI 0.55 – 6.59, p = 0.014) compared to the routine group. All other sensitivity analyses were non-significant (see Table 7.6).

Table 7.6 – Formal comparisons between intensive, routine, and control groups using baseline observation carried forward approach

	Difference	95% CI	Significance
Back pain-related disability			
Intensive vs. Control	0.99	(-1.23, 3.21)	p = 0.841
Routine vs. Control	-2.58	(-5.56, 0.41)	p = 0.115
Intensive vs. Routine	3.75	(0.55, 6.59)	p = 0.014*
HRQoL			
Intensive vs. Control	4.77	(-2.93, 12.47)	p = 0.407
Routine vs. Control	4.68	(-5.68, 15.04)	p = 0.828
Intensive vs. Routine	0.09	(-10.37, 10.56)	p = 1.000

Significance level: * = p < 0.05

7.4 Discussion

This study aimed to evaluate the clinical effects of using different levels of PROMs in routine treatment of low back pain. This was the first RCT to examine PROMs in specialist musculoskeletal care for low back pain. Overall, there was a significant improvement in patients' back pain-related disability in all three groups, three months after their initial visit. However, there were no significant differences between the three intervention groups. This may be due to the small sample size, limiting the power within the study to detect a clinically meaningful effect size on the Roland-Morris Questionnaire. Overall, 63.7% of participants had a clinically meaningful change on the Roland-Morris questionnaire. Higher proportions of participants in intensive PROMs group had a clinically meaningful improvements on their back pain-related disability compared to the control group and the routine group, although this was not significantly different. With the sensitivity analysis, the intensive group had significantly larger reduction in back-pain related disability compared to the routine group.

The results of this study showed limited to no improvement in back pain-related disability when using PROMs for low back pain. However, the lack of statistical power within the study, means the hypotheses cannot be refuted. Previous research has shown PROMs to be beneficial in reducing pain for patients on a surgical ward (Ravaud et al., 2004). Patients completing PROMs also had lower pain intensity at rest and coughing after cardiac surgery (dos Santos Silva et al., 2013). Seniors in general practice completing PROMs also reported less pain related to strenuous activity compared to a control group (Hadjistavropoulos et al., 2009). dos Santos Silva et al. (2013) found no significant difference between intervention and control groups on pain levels when deep breathing, and Hadjistavropoulos et al. (2009) found no differences on overall pain levels. However, due to the wide variation in pain conditions and pain settings, these may not be directly comparable.

There was no significant difference in numbers of participants who had a reduction in back pain-related disability and those with no change or increase in back pain-related disability. These results indicate that there is no clinical harm in PROMs. All three groups had an improvement on HRQoL, over 3 months, as measured by the EQ-5D, however, these changes were not significant. There were also no significant differences between the three groups. In patients with rheumatoid arthritis, PROMs were found to have no significant impact on overall health status (Kazis et al., 1990). This current study only focused on the clinical

effect of using PROMs. As per the systematic review (Chapter 4) and theoretical review (Chapter 5), it is hypothesised that PROMs may have an impact on other psychosocial aspects of care. Further exploration of the psychosocial impact of using PROMs for low back pain is reported in Chapter 8.

Intervention fidelity is a concern with the use of PROMs. In a study examining web-based PROMs for multiple sclerosis, there were declining adherence and completion rates after initial engagement over a six month period (Engelhard, Patek, Sheridan, Lach, & Goldman, 2017). The theoretical assumptions of utilising PROMs suggest that PROMs must be thoroughly integrated into routine clinical practice to influence patient care and outcomes, and include a discussion of PROMs between patients and clinicians (Catarinella & Bos, 2016; Jongen et al., 2013; Lalloo et al., 2014). Intervention fidelity in both patient completion of PROMs, and chiropractor discussion of PROMs may be a factor in intervention delivery and outcome. Within a further process evaluation (Chapter 10), fidelity will be explored to identify if completion of PROMs varied between the three groups, and whether adherence to completing PROMs and discussion with their chiropractor is correlated to changes in back pain-related disability.

7.4.1 Strengths and limitations

This study was the first RCT to explore PROMs for low back pain. However, several methodological challenges arose that need to be acknowledged. Despite having many expressions of interest, only 25 chiropractors were recruited. However, nine chiropractors did not then respond to further correspondence regarding the training for the study. This resulted in low numbers of participating chiropractors. Chiropractors were randomised into the study as they consented, to allow for appropriate training, this caused an uneven distribution of chiropractors randomised when they did not respond to communication about employing PROMs in their practice. This resulted in having uneven numbers of patients in the intervention groups. Future studies should consider block randomisation, to ensure randomisation is equal.

The main limitation of this study is the sample size and power to detect a clinically meaningful effect size on the Roland-Morris Questionnaire. The study had 80 participants; however a priori sample size calculations estimated 450 participants would be required. The small sample size is problematic as it can lead to type II errors (VanVoorhis & Morgan, 2007). The lack of statistical power

in this study means that caution must be taken when interpreting the results. Hypotheses cannot be refuted, as this study is at risk of not identifying significant effects.

The study had a 48.9% recruitment rate. Although this was an improvement from the feasibility study, which only had a 16.4% recruitment rate, patient recruitment posed its own difficulties. The research team cannot inform patients of the study until they have signed up to Care Response but must consent to the study before their first visit to the chiropractor. Therefore, recruitment relies on individuals signing up with limited contact from the researcher or chiropractor. Despite these challenges, several recommendations from the feasibility study were used that improved engagement and recruitment. The study sign-up process was refined and simplified, with a one-page website for patient information and consent, to improve accessibility for the consent processes.

Although many patients did not complete outcomes at 90 days, there was a marginal improvement from 44% retention rate in the feasibility study to 50.6% retention rate with the RCT. Several activities were planned and used where possible to keep participants engaged with the study, for example, any participants with outstanding follow-ups were planned to be contacted via telephone or sent a paper copy of the questionnaires. However, several participants did not have these contact details in the Care Response system. Chiropractors had separate systems which contained the participants' details. This was not foreseen as an issue within the feasibility study. Therefore, many of the reminders regarding the follow-up questionnaires were sent via email rather than using any other methods. At follow-up, there was no significant difference in participant characteristics, other than the STarT Back score. Those with lower STarT Back scores were more likely to not complete the 90 day follow-up. This might be explained by chiropractors using STarT Back to stratify patients, with patients identifying as low risk patients having only one treatment or fewer number of visits.

7.5 Chapter summary

This study was the first RCT examining the impact of different frequencies of PROMs for low back pain. All groups demonstrated significant reductions in back pain-related disability, with many patients showing a clinically significant improvement. However, there were no significant differences between groups receiving PROMs. Due to the sample size, there was not sufficient power to detect a clinically meaningful effect, and additional studies are needed to explore the impact on back pain-related disability. Further quantitative analysis on the effect of varied PROM collection on psychosocial mediators will be explored in more detail in Chapter 8. The results of the RCT and quantitative analysis will be combined with qualitative findings from a subset of patients' and chiropractors' experiences of using PROMs (Chapter 9) to form a mixed-methods process evaluation on PROM collection in specialist care for low back pain (Chapter 10).

Chapter 8 The mechanisms of action when using PROMs in the treatment of low back pain: mediation analysis

8.1 Introduction

8.1.1 Overview

Despite existing theoretical frameworks modelling the mechanisms through which PROMs might influence patient outcomes in clinical practice (Greenhalgh et al., 2017; Greenhalgh et al., 2005; Santana & Feeny, 2014), there is limited research examining the proposed mechanisms of action. Further, there is no research examining the mechanisms of PROMs within the context of low back pain. Identifying the potential mechanisms of PROMs in the context of low back pain highlights the important components of PROMs and has implications for understanding how PROMs may be used within clinical practice. This chapter reports a quantitative analysis exploring the direct, mediating, and moderated effects of PROMs on back pain-related disability, captured as part of the RCT (Chapter 7).

8.1.2 Mechanisms

Through reviewing previous empirical and theoretical literature (Chapters 4 and 5), the Patient Reported Outcome Measures Pathway Theory (PROMPT) was developed (see Figure 5.11), highlighting a series of processes by which PROMs may influence patient outcomes within the context of treating non-malignant pain. PROMPT hypothesises that PROMs can impact several elements of care. This includes increasing clinicians' knowledge of patients, facilitating patient-clinician interactions, enabling patient-centred care, monitoring symptoms, informing strategies to improve care, enhancing therapeutic relationships, improving patient satisfaction, and encouraging self-management behaviours. Additionally, it suggests that PROMs may increase peoples' pain-related fear, mediating a change in their health (moderated by pain catastrophising).

PROMPT depicts the multiple components of PROMs within clinical practice and specifies hypothesised outcomes, mechanisms, and parameters. This theoretical framework can be used to explore how patients and clinicians may interact with PROMs, and how this may influence patient outcomes, self-care, and the patient-clinician relationship. PROMPT suggests three pathways that underpin how PROMs might influence health outcomes: coping appraisal, patient-clinician interaction, and threat appraisal. These are discussed below.

Coping appraisal pathway

The coping appraisal pathway in PROMPT suggests that completion of PROMs may influence patient outcomes, and changes may be mediated by patient-centred communication, coping beliefs and self-management behaviours. It is theorised that the completion of PROMs may positively influence patient-centred communication (Greenhalgh et al., 2017; Santana & Feeny, 2014). Through enhanced communication between patients and clinicians, patients' self-efficacy for self-management is said to improve; patient-centred communication is also reported to positively influence patients' treatment beliefs. Self-efficacy and treatment beliefs form part of a patients' appraisal of coping; by influencing treatment beliefs and improving self-efficacy, patients are more likely to undertake positive self-management behaviours (Bandura, 1988; Carver & Scheier, 1982; Horne, 2003). Finally, PROMPT suggests that patients' self-efficacy for self-management, treatment beliefs around back pain, and performance of self-management behaviours may improve outcomes.

Patient-clinician interaction pathway

PROMPT theorises that PROMs are a potential mechanism to enhance communication between patients and clinicians, providing a formal process of information exchange. Clinicians from various healthcare backgrounds use PROMs to monitor patients and evaluate treatment (Bottega & Fontana, 2010; Boyce et al., 2014b; Schorn et al., 2014; Stratford & Binkley, 1999). Clinicians may use the information gathered to modify treatment, prescribe or change medication, make referrals, or provide self-management advice. Through this monitoring and discussion of treatment, patients may change self-management strategies, such as seeking further treatment, adhering to advice, or changing unhelpful thoughts and behaviours regarding pain. As a result of improving patient-centred communication, PROMs may also influence therapeutic alliance.

PROMs are thought to provide a mechanism for shared decision-making, increasing feelings that clinicians are interested in patients' care, and improving rapport (McGuire et al., 2001). Good patient-centred communication and therapeutic alliance may positively impact on patient satisfaction (Fitzpatrick, 1997). Patients who are satisfied with their care are thought to be more likely to adhere to treatment or advice, resulting in a change in self-management. Patient satisfaction is also thought to be positively correlated with health outcomes (Fitzpatrick, 1997).

Threat appraisal pathway

Considering the use of PROMs in the context of back pain, it is important to consider patients' fear of pain. PROMPT theorises that completion of PROMs, and any associated discussion between patients and clinicians, may increase patients' awareness of their pain; this could stimulate a positive or negative response. Fear of pain could trigger patients to change their behaviour (Rogers, 1975). Positive self-management strategies and adherence to healthcare professionals' advice, could occur if associated with high self-efficacy for that behaviour and the perception that the change will be effective. However, if fear of pain is associated with pain catastrophising, where individuals magnify the pain and are unable to inhibit thoughts of pain, this may increase fear-avoidance beliefs (such as reducing physical activity) (Lethem et al., 1983; Rogers, 1975; Vlaeyen & Linton, 2000). Avoiding or reducing physical activity is contradictory to current guidelines regarding low back pain (Maher et al., 2017), and may increase patients' back pain-related disability.

8.1.3 Research question and objectives

Chapter 7 reported an RCT which examined the impact of using different frequencies of PROMs on back pain-related disability and HRQoL. The study did not examine the psychosocial effects, nor any mechanisms of action when utilising PROMs in the routine treatment of low back pain. Whereas, the current study examined potential mechanisms of PROM use in routine clinical practice for low back pain, by comparing those who completed PROMs to those who did not. The aim of this study was to clarify mechanisms of PROMs by testing hypotheses derived from the PROMPT model. It was hypothesised that:

1. Those who complete PROMs will have higher scores in patient-centred communication, therapeutic alliance, patient satisfaction, self-efficacy for pain management, and self-management behaviours, compared to those who do not complete PROMs.
2. Those who complete PROMs will have a reduction in back pain-related disability mediated by improvements in patient-centred communication, self-efficacy for self-management, treatment perceptions, and self-management behaviours (coping appraisal pathway).
3. Those who complete PROMs will have a reduction in back pain-related disability mediated by improvements in patient-centred communication, therapeutic alliance, patient satisfaction, and self-management behaviours (patient-clinician interaction pathway).
4. Those who complete PROMs will have a change in back pain-related disability mediated by increased pain-related fear and fear-avoidance beliefs, impacting on self-efficacy for pain management and self-management behaviours. With the relationship between pain-related fear, fear-avoidance beliefs and self-management behaviours moderated by pain catastrophising (threat appraisal pathway).

8.2 Methods

8.2.1 Study design

Data for this mediation analysis were collected alongside the RCT (Chapter 7). Ethical approval was granted by the University of Southampton (ref: 20133, 2017). Within the RCT, participants were assigned to receive PROMs seven times over 30 days (intensive PROMs), three times over 30 days (routine PROMs), or not at all (control group). Demographic data, PROMs, and outcomes were collected using Care Response, an online software for collecting patient outcomes. Patients were followed-up 90-days after their first appointment, with the primary measure (back pain-related disability) measured using the Roland-Morris questionnaire.

8.2.2 Sampling and recruitment

The RCT recruited 158 participants to the study (see section 7.2.2. for sampling and recruitment details). Eighty participants (50.6%) completed the study and were included in the final analysis (mean age = 45.13, SD = 16.92). The majority had back pain over 30 days (67.5%), with back pain as a recurring problem (56.3%), and also reported an additional pain complaint other than back pain (68.8%). Twenty-nine (36.3%) participants were randomised to the intensive group, 13 (16.3%) to the routine group, and 38 (47.5%) to the control group. Data from these 80 participants were used in this current analysis. Fritz and MacKinnon (2007) provide recommendations on sample size for mediation analysis. Using simulations, they note that sample sizes can vary from 34 to 462 when using a bias-corrected bootstrap approach for multiple mediation (See section 8.2.4) depending on the effect size. Although other approaches can be used to compute sample size and power, these can be difficult to calculate *a priori* (Hayes, 2017). Using the method of Cohen, Cohen, West, and Aiken (2013) for computing power analysis for regression coefficients, simple estimations suggested a sample size of 311 participants, based on Pearson's R = 0.2 (Bradbury et al., 2016), assuming an alpha of 0.05 and 80% power.

8.2.3 Data collection

Using Care Response, all participants were sent a series of psychosocial process measures along with their primary and secondary outcome measures at 90-days after their first appointment (See Section 7.2.4). Measures were selected to assess pain-related fear, pain catastrophising, fear-avoidance behaviours, self-efficacy for self-management, self-management behaviours, treatment perceptions, patient-centered communication, therapeutic alliance, and patient satisfaction. The measures are described below and were chosen based on their theoretical basis in PROMPT, psychometric properties, and feedback received from participants in the feasibility study (Chapter 6).

Patient perception of patient centeredness questionnaire (PPPCQ)

This questionnaire focuses on patients' perceptions of clinicians exploring their illness experience and finding common ground (Stewart et al., 2004). The questionnaire has 9-items, each rated on a four-point scale, from 3 = 'completely' to 0 = 'not at all'. This includes items such as 'To what extent was your main problem(s) discussed?'. The questionnaire has a lack of ceiling effect in initial validation and good internal consistency (Cronbach's alpha – 0.8, Stewart et al., 2004).

Self-efficacy beliefs in patients within chronic pain subscale - self-efficacy for pain management (PSE)

This five item questionnaire covers self-efficacy beliefs for pain management, including resuming daily activities, sleep, and reducing pain by methods other than medication (Anderson et al., 1995). Each item is rated on a ten-point scale, ranging from 1 = 'very uncertain' to 10 = 'very certain', for example: 'How certain are you that you can decrease your pain quite a bit?'. The questionnaire has been used to predict readiness to self-management pain and has good internal consistency (Cronbach's alpha – 0.88, Anderson et al., 1995).

Four-item lower back pain – treatment beliefs questionnaire

This compact questionnaire measures treatment beliefs in primary care patients with low back pain, for four back pain treatments: medication, exercise, manual therapy, and acupuncture (Dima et al., 2015). This study used the manual therapy version. The questionnaire looks at patients' beliefs on the credibility, effectiveness, concerns and individual fit of the therapy, for example

"Using manual therapy for back pain makes a lot of sense", rated from 'strongly disagree' to 'strongly agree' on a 5 point scale. Two of the items measure negative beliefs, for example 'I think manual therapy is pretty useless for people with back pain'. These questions are reversed scored, to reflect that overall, higher scores indicate positive beliefs about manual therapy for low back pain. The questionnaire has been shown to have good internal consistency (Cronbach's alpha – 0.86, Dima et al., 2015).

The maintenance subscale of the pain stages of change questionnaire (PSOCQ)

The PSOCQ is based on the transtheoretical model of behaviour change and four stages of behaviour change (Kerns et al., 1997). This seven item subscale measures maintenance of a self-management approach to chronic pain, such as 'I am using strategies that help me better deal with my pain problem on a day-to-day basis'. Each item is rated on a scale from 0 = 'strongly disagree' to 4 = 'strongly agree'. There are no reported ceiling effects and acceptable internal consistency (Cronbach's alpha – 0.71, Kerns et al., 1997).

Working alliance inventory – short-revised (WAI_SR)

The WAI_SR is based on three principles of alliance: patient-clinician agreement on goals, patient-clinician agreement on the treatment addressing the patient's presenting issues, and the interpersonal relationship between the patient and clinician (Hatcher & Gillaspy, 2006). For example: 'I believe the way we are working with my problem is correct'. The questionnaire consists of 12 items, each item scored on a five-point scale from 1 = 'seldom' to 5 = 'always'. The questionnaire has excellent internal consistency (Cronbach's alpha – 0.9, Munder, Wilmers, Leonhart, Linster, & Barth, 2010).

Patient satisfaction – single item question

Patient satisfaction was measured using a one-item question: 'Overall how have you found the service and care you have received?'. The item is scored on a seven-point scale – from 1 = 'unacceptably poor' to 7 = 'a very high level'. A single non-validated item was used to get overall patient satisfaction, as many patient satisfaction measures are based on clinician communication or therapeutic alliance, which were measured separately within this study.

Fear subscale of the Pain Anxiety Symptoms Scale (PASS-20)

The PASS-20 was developed as a short version of the Pain Anxiety Symptoms scale, to evaluate pain anxiety and fear in patients with chronic pain conditions (McCracken & Dhingra, 2002). The fear subscale has five questions, rated on a scale from 0 = 'never' to 5 = 'always', including items such as 'I think that if my pain gets too severe, it will never decrease'. The subscale has good internal consistency (Cronbach's alpha - 0.82, McCracken & Dhingra, 2002).

Catastrophising Subscale of the Coping Strategies Questionnaire (CSQ-CAT)

Pain catastrophising was measured using the CSQ-CAT. This consists of six negative self-statements of catastrophising thoughts and ideation, such as 'It's terrible and I feel it's never going to get any better'. The measure is predictive of clinical measures of psychological distress and physical functioning (Hirsh et al., 2007). Each item is measured on a 7-point scale from 0 = 'never' to 6 = 'always' based on the degree to which participants have the thoughts and feelings about their pain. The questionnaire has good internal consistency (Cronbach's alpha – 0.84, Robinson et al., 1997).

Fear-avoidance beliefs questionnaire physical activity subscale (FABPA)

Fear-avoidance beliefs were measured by the FABPA. The subscale measures the belief that physical activity affects pain (Waddell et al., 1993). The subscale has six items, and good internal consistency (Cronbach's alpha – 0.82, Staerkle et al., 2004). Each item is a statement about their back pain, such as 'My pain was caused by physical activity' and is scored on a seven-point scale from 0 = 'completely disagree' to 6 = 'completely agree'.

8.2.4 Data analysis

Data preparation

All data were input into the statistical package SPSS version 26 (IBM Corp, 2012). Preliminary analyses were conducted to test for normality of the data. Z-scores were calculated to identify outliers, with Z-scores of +/- 3.29 classified as an outlier; skewness and kurtosis were examined for each measure, with cut-off scores of +/- 2 for skewness, +/- 7 for kurtosis (Field, 2013).

Differences in outcomes and potential mechanisms

Descriptive statistics were calculated for the process measures. Cronbach's α coefficients were calculated to examine scale reliability, with cut-off values >.9 high, >.8 good, >.7 acceptable, <.7 poor (Field, 2013). Initial analyses aimed to test hypothesis 1 and explore any differences in the process measures between those who completed PROMs (intensive and routine group combined, coded as 1) and those who did not (control group, coded as 0) using bootstrapped t-tests. Bootstrapping was used to account for the possible non-normality of the data. Bootstrapping repeatedly samples from the data for an estimation of the sampling distribution, these values are then used to estimate the limits of the confidence intervals (Field, 2013). Cohen's d was calculated as a measure of effect size alongside the t-test statistic using an online calculator (www.socscistatistics.com).

Correlations were examined for participants in the intervention groups (intensive and routine). Pearson's correlation coefficient was used to analyse the relationship between each of the process measures and back pain-related disability with bias corrected accelerated (BCa) 95% confidence intervals. These established any relationships between variables prior to further analysis. As well as prior relationships, regression analysis requires that deviation from normality is explored, checking assumptions of independence and linearity (Field, 2013). The Durbin-Watson statistic was calculated, testing for correlations between errors. Homoscedasticity was explored by visually inspecting scatterplots, plotting standardised errors against standardised predicted values. The data was checked for multicollinearity by examining individual correlations for correlations >0.8; when predictor variables are too highly correlated it becomes impossible to obtain unique estimates of the regression coefficients (Tabachnick & Fidell, 2013). Collinearity statistics (variance inflation factor and tolerance statistics) were examined. Two bootstrapped multiple regression models were conducted to examine the predictors of the back pain-related disability at the end of the trial.

Mediation analysis

Mediation analysis explores the relationship between an independent variable and dependent variable, whilst controlling for one or more potential mediators (Preacher & Hayes, 2008). Historically, the most common method of mediation analysis is Baron & Kenny causal steps strategy, which estimates the indirect effects between independent variables, mediators, and dependent variables.

However, a direct effect of the independent variable on the dependent variable is required (Preacher & Hayes, 2008). The causal steps strategy is now outdated, noting that a significant total effect is not necessary for mediation to occur (Hayes, 2017). The independent variable can exert an effect on the dependent variable through the mediators, even without the presence of a significant total effect with a hypothesis test (Hayes, 2017). The Sobel test, known as product-of-coefficients approach, is another strategy for testing mediation, which computes the ratio of indirect effects to estimated standard error (Preacher & Hayes, 2008). However, bootstrapping is currently recommended as best practice in mediation analysis. Bootstrapping repeatedly samples from the dataset, estimating the indirect effects. Therefore, bootstrapping does not require normally distributed data and is suitable for small samples. Bootstrapping is considered advantageous over other methods such as Sobel tests, as this method has higher power whilst controlling for Type I errors (Preacher & Hayes, 2008).

In the present study, multiple mediation was used to the explore the effects of psychosocial process measures, as mechanisms mediating the relationship between completing PROMs and back pain related-disability, using the bootstrapping indirect effects method in the PROCESS macro of SPSS (Hayes, 2012). One conditional process analysis was conducted, to account for both theoretical mediators and moderators (Hayes, 2017). PROCESS uses a model system, with pre-specified models estimating mediators and effects. These models can be represented in a *B* matrix, noting the antecedent (sending an effect) and consequent (receiving an effect) variables (Hayes, 2017). As none of the predeveloped models in PROCESS were appropriate for the hypotheses developed from PROMPT, *B* matrices were developed to represent the effects that are theoretically estimated (Appendix O). The models can be written into a *B* matrix statement, followed by a string of zeros and ones, which PROCESS reads as a command. For each model, the dataset was resampled 5000 times, as recommended by Hayes (2017). Direct effects and indirect effects were quantified for each model. No total effects could be generated due to paths in each of the models being fixed to zero (theorised to have no effect). Bias-corrected accelerated confidence intervals were calculated to determine significance of effects.

8.3 Results

8.3.1 Summary of data

Descriptive statistics of all the process measures, for the full sample, are presented in Table 8.1. Five variables contained outliers (PPPCQ, PSOCQ, WAISR, CSQ, and patient satisfaction). To reduce the impact of outliers, scores were changed on outlying cases to one unit next to the most extreme scores in the distribution (Tabachnick & Fidell, 2013). For two cases on patient satisfaction, the outliers were already one unit above the next outlier, therefore, raw scores were changed to be identical to last extreme score in the dataset. Patient satisfaction had a positive kurtosis, therefore further correlation and regression analyses were bootstrapped to account for possible non-normality of data. The scores of all other process measures met parametric assumptions. Internal consistency reliability analysis indicated that measures of self-efficacy, therapeutic alliance, and pain catastrophising had excellent internal consistency (>0.9), patient-centred communication, self-management behaviours, and pain-related fear had good internal consistency (>0.8), and treatment beliefs and fear-avoidance beliefs had acceptable internal consistency (>0.7) (Field, 2013).

Table 8.1 - Descriptive statistics, linearity and reliability calculations for process measures

Process measures	Mean (SD)	Skew	Kurtosis	Cronbach alpha (α)
Patient-centred communication (PPPCQ)	24.43 (3.21)	-1.44	1.45	0.81
Self-efficacy for self-management (PSE)	40.13 (10.05)	-1.32	1.07	0.95
Treatment beliefs (LBP-TBQ)	13.50 (2.36)	-0.78	0.16	0.77
Self-management behaviours (PSOCQ)	20.25 (4.32)	-0.48	0.90	0.85
Therapeutic alliance (WAI_SR)	50.62 (8.04)	-0.86	0.06	0.94
Patient satisfaction	6.53 (0.90)	-1.92	2.54	-
Pain-related fear (PASS-20)	7.75 (5.36)	0.41	-0.83	0.83
Pain catastrophising (CSQ-CAT)	7.71 (7.03)	1.30	1.72	0.91
Fear-avoidance beliefs (FABPA)	12.96 (6.57)	-0.02	4.29	0.74

Table 8.2 presents the means and standard deviations of the process measures, comparing those who completed PROMs (in the intensive and routine group) to those who did not (the control group). Although slight differences exist across the three groups, the only significant differences across all measures was for patient satisfaction. Patients in the control group had slightly higher scores of patient satisfaction. Patients who completed PROMs had lower scores of pain-

related fear, pain catastrophising, and fear-avoidance beliefs than the control group, but these were not significantly different.

Table 8.2 – Differences in process measures between groups

Process measures	Intensive and routine group	Control group	Sig	Effect size
	Mean (SD)	Mean (SD)		Cohen's d
Patient-centred communication (PPPCQ)	24.17 (3.38)	24.74 (3.06)	t (77) = 0.78, p = 0.39	0.49
Self-efficacy for self-management (PSE)	39.20 (9.47)	41.11 (9.47)	t (77) = 0.84, p = 0.405	0.20
Treatment beliefs (LBP-TBQ)	13.34 (2.09)	13.63 (2.66)	t (77) = 0.54, p = 0.622	0.12
Self-management behaviours (PSOCQ)	20.12 (4.22)	20.55 (4.40)	t (77) = 0.44, p = 0.658	0.10
Therapeutic alliance (WAI_SR)	49.22 (8.24)	52.13 (7.63)	t (77) = 1.63, p = 0.106	0.37
Patient satisfaction	6.32 (1.06)	6.76 (0.63)	t (77), = 2.29, p = 0.029*	0.50
Pain-related fear (PASS-20)	6.63 (4.93)	8.82 (5.65)	t (77) = 1.83, p = 0.080	0.41
Pain catastrophising (CSQ-CAT)	6.51 (5.77)	9.00 (8.05)	t (77) = 1.59, p = 0.136	0.36
Fear-avoidance beliefs (FABPA)	12.83 (5.40)	13.11 (7.70)	t (77) = .18, p = 0.858	0.04

Significance level: * = $p < 0.05$

8.3.2 Bivariate correlations

Correlations were calculated between process measures and back pain related disability at follow-up for both intervention groups (intensive and routine combined). Table 8.3 displays intercorrelations between these measures. Lower scores of back pain-related disability were significantly associated with higher ratings of patient-centred communication, self-efficacy for pain management, self-management behaviours, therapeutic alliance, and patient satisfaction. As expected, higher scores of pain catastrophising were significantly associated with higher levels of back pain-related disability. However, there were no significant correlations between treatment beliefs, pain-related fear, and fear-avoidance beliefs and back pain-related disability.

Table 8.3 - Pearson's Product Moment Correlations between Roland-Morris and Process Measures

Measures: 1. Roland-Morris Questionnaire, 2. Patient perception of patient centeredness questionnaire, 3. Self-efficacy for pain management subscale 4. lower back pain – treatment beliefs questionnaire, 5. maintenance subscale of the pain stages of change questionnaire, 6. Working alliance inventory – short-revised, 7. Patient satisfaction, 8. Fear subscale of the Pain Anxiety Symptoms Scale 9. Catastrophising Subscale of the Coping Strategies Questionnaire, 10. Fear-avoidance beliefs questionnaire physical activity subscale.

	1. RM	**2. PPPCQ**	**3. PSE**	**4. LBP-TBQ**	**5. PSOCQ**	**6. WAI-SR**	**7. SAT**	**8. PASS-20**	**9. CSQ-CAT**	**10. FABPA**
1. RM	-									
2. PPPCQ	-.503**	-								
3. PSE	-.676**	.570**	-							
4. LBP-TBQ	-.306	.494**	.301	-						
5. PSOCQ	-.366*	.381*	.516**	.273	-					
6. WAI-SR	-.655**	.619**	.569**	.477**	.657**	-				
7. SAT	-.379**	.509**	.345**	.581**	.405**	.682**	-			
8. PASS-20	.248	-.220	-.060	-.160	-.090	-.382*	-.327*	-		
9. CSQ-CAT	.418**	-.211	-.303	-.166	-.196	-.396*	-.420**	.649**	-	
10. FABPA	.169	-.400**	-.310*	-.176	-.117	-.251	-.283	.366*	.089	-

Significance level: * = $p < 0.05$, ** = $p < 0.01$

8.3.3 Predictors of back pain-related disability

Two bootstrapped hierarchical multiple linear regressions were conducted to examine the individual contributions of factors predicting back pain-related disability at the end of the trial before further exploration with mediation models. Within both models, baseline Roland-Morris scores were entered in step one to control for initial back pain-related disability. In the first model, process measures hypothesised to predict back pain-related disability at the end of the trial were entered in step two. This included measures of patient-centred communication, self-efficacy for pain management, self-management behaviours, therapeutic alliance, patient satisfaction, and pain catastrophising. Measures of treatment beliefs, pain-related fear, and fear-avoidance beliefs were excluded from the analysis due to their lack of significant associations in the previous bivariate correlations (Table 8.2) (Field, 2013).

The data met assumptions of linearity and normality. The Durbin-Watson test was non-significant (2.06), suggesting a slight negative correlation between errors, but not a cause for concern (Field, 2013). When checking for multicollinearity, there were no correlations >.80 (see Table 8.3). Additionally, no variance inflation factors were above 10, and no tolerance statistics below 0.1, giving no indication of collinearity in regression models.

Results of the first regression analysis can be seen in Table 8.4. Baseline scores on the Roland-Morris accounted for 35.4% of the variance in Roland-Morris scores at 90 days. The process measures of patient-centred communication, self-efficacy for pain management, self-management behaviours, therapeutic alliance, patient satisfaction, and pain catastrophising accounted for 33.4% of the total variance. Overall, the model was significant ($F(7, 33) = 10.37$, $p < 0.001$) and accounted for 68.8% of the total variance.

Table 8.4 – Bootstrapped regression analysis for back pain-related disability at 90 days after first appointment

Confidence intervals and standard errors based on 1000 samples

	B (95% CI)	SE B	β
Step 1			
Constant	-.59 (-2.03, .64)	0.65	
Initial back pain-related disability (Roland-Morris)	0.54 (0.26, 0.85)	0.15	0.60*
Step 2			
Constant	14.15 (2.68, 24.05)	6.17	
Initial back pain-related disability (Roland-Morris)	.28 (0.04, 0.59)	0.13	0.31*
Patient-centred communication (PPPCQ)	.08 (-0.48, 0.59)	0.24	0.05
Self-efficacy for self-management (PSE)	-.19 (-0.38, -0.04)	0.08	-0.40*
Self-management behaviours (PSOCQ)	.14 (-0.23, 0.59)	0.21	0.12
Therapeutic alliance (WAI_SR)	-.30 (-0.59, 0.00)	0.13	-0.49*
Patient satisfaction	.63 (-0.57, 2.08)	0.75	0.13
Pain catastrophising (CSQ-CAT)	.07 (-0.21, 0.29)	0.13	0.08
Total R^2 = 0.688, Step 1: R^2 = 0.354, F (1, 39) = 21.38 (p <0.001), Step 2: R^2 change = 0.334, F (6, 33) = 5.87 (p <0.001).			

Significance level: * = p < 0.05

Within the second model, the intervention group (intensive or routine PROMs) were entered into step two, to explore if group allocation predicted back pain-related disability at the end of the trial. Finally, all process measures from the first model were entered in step three: patient-centred communication, self-efficacy, stages of change, therapeutic alliance, satisfaction, and pain catastrophising. As with the first regression model, the Durbin-Watson test suggested a slight negative correlation between errors (2.05). There was no indication of collinearity in regression model, with no correlations >.80, no variance inflation factors were above 10, and no tolerance statistics below 0.1.

Table 8.5 – Bootstrapped regression analysis for back pain-related disability at 90 days after first appointment, including group allocation

Confidence intervals and standard errors based on 1000 samples

	B (95% CI)	SE B	β
Step 1			
Constant	-0.59 (-1.95, 0.53)	0.65	
Initial back pain-related disability (Roland-Morris)	.54 (0.26, 0.88)	0.15	.60*
Step 2			
Constant	1.73 (-4.34, 7.57)	3.06	
Initial back pain-related disability (Roland-Morris)	0.56 (0.28, 0.92)	0.16	.62*
Group	-0.93 (-3.10, 1.26)	1.15	-0.09
Step 3			
Constant	13.85 (3.14, 22.64)	6.78	
Initial back pain-related disability (Roland-Morris)	.28 (0.02, 0.53)	0.135	0.31*.
Group	.12 (-2.67, 2.85)	1.27	0.01
Patient-centred communication (PPPCQ)	.08 (-0.45, 0.64)	0.25	0.06
Self-efficacy for self-management (PSE)	-0.19 (-0.40, -0.02)	0.08	-0.40*
Self-management behaviours (PSOCQ)	0.14 (-0.31, 0.67)	0.23	0.12
Therapeutic alliance (WAI_SR)	-0.30 (-0.61, -0.03)	0.13	-0.49*
Patient satisfaction	0.64 (-1.00, 3.00)	0.79	0.13
Pain catastrophising (CSQ-CAT)	0.07 (-0.21, 0.28)	0.1	0.08
Total R^2 = 0.688, Step 1: R^2 = 0.354, F (1, 39) = 21.38 (p <.001), Step 2: R^2 change = 0.007, F (1, 38) = .40 (p = 0.530), Step 3: R^2 = 0.327, F (6, 32), = 5.58 (p <0.001).			

Significance level: * = p < 0.05

Results of the regression analysis can be seen in Table 8.5. The overall model was significant (F (8, 32) = 8.81, p <0.001) and accounted for 68.8% of the variance in Roland-Morris scores at 90 days. It was noted that group allocation (receiving either intensive or routine PROMs) did not add anything to the model, only accounting for 0.7% of the variance and was non-significant.

8.3.4 Multiple mediator models

Multiple mediation models were conducted to display the direct effects between: completing PROMs (X) and back pain-related disability (Y), completing PROMs and a series of mediators identified from the PROMPT model (M_k), the mediators and back pain-disability, and the total effect of completing PROMs on back pain-related disability. Indirect effects of completing PROMs on back pain-related disability via the mediators were also computed. Initially three models were developed, one for each of the hypotheses generated from the PROMPT pathways.

Coping appraisal

Within the coping appraisal pathway from PROMPT, it was hypothesised that those who completed PROMs would have a reduction in back pain-related disability mediated by increased scores in patient centred communication, self-efficacy, treatment perceptions and self-management. To aid interpretation, Figure 8.1, illustrates the mediation model and the proposed pathways. For the *B* matrix, see Appendix O.

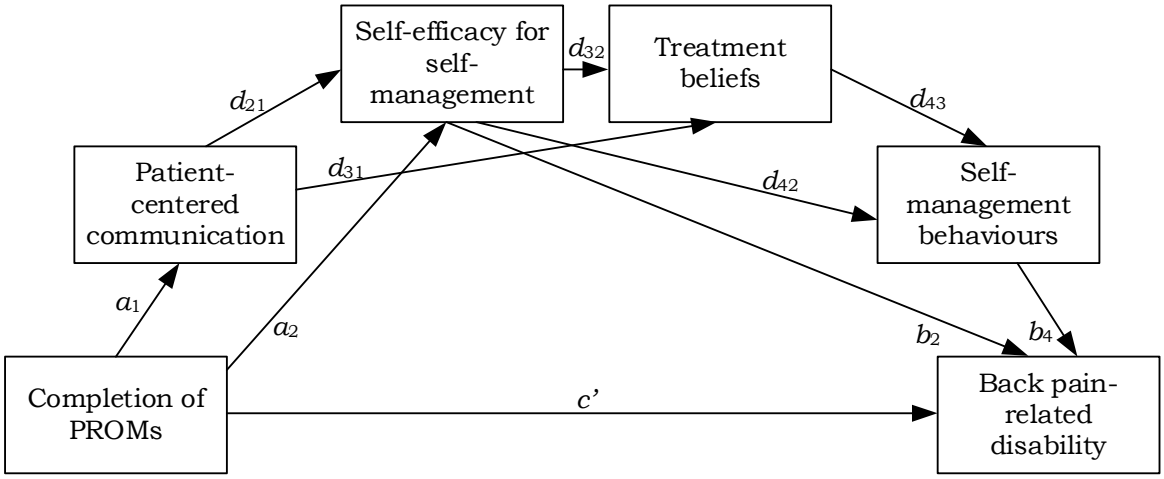


Figure 8.1 - Statistical diagram of multiple mediation model of direct and indirect effects of completion of PROMs on back pain-related disability mediated by patient-centred communication, self-efficacy for self-management, treatment beliefs, and self-management behaviours

The results of the mediation analysis for the coping appraisal pathway are shown in Table 8.6. This model was significant, F (3, 76) = 22.16, p<.0001, explaining 46.7% of the variance in back pain-related disability. There was no direct effect of completing PROMs on back pain-related disability. There were several significant direct effects between mediators in the model. Those with

higher levels of patient-centred communication were more likely to have increased scores of self-efficacy for self-management. High scores of patient-centred communication predicted positive treatment beliefs about chiropractic for their back pain and patients with positive treatment beliefs about chiropractic for their back pain, were more likely to maintain self-management behaviours of their pain. High scores of self-efficacy for self-management also predicted positive self-management behaviours.

However, several hypothesised direct effects were not significant. There were no significant direct effects of completing PROMs on participants' ratings of patient-centred communication or self-efficacy for self-management. There was no evidence that self-efficacy had a direct effect on treatment beliefs, and self-management behaviours had no significant direct effects on back pain-related disability. All estimated indirect effects were also non-significant (Table 8.6).

Table 8.6 – Direct and indirect effects of completion of PROMs on back pain-related disability mediated by coping appraisal

Bias-corrected confidence intervals that do not pass through zero, indicating significant effects, are bolded

Direct effects	B	S.E	95% CI
a_1: effect of completing PROMs on patient-centred communication	-0.5940	0.7190	-2.0255, 0.8375
a_2: effect of completing PROMs on self-efficacy for self-management	-0.8648	1.9214	-4.6909, 2.9613
d_{21}: effect of patient-centred communication on self-efficacy for self-management	1.6873	0.3013	**1.0876, 2.2874**
d_{31}: effect of patient-centred communication on treatment beliefs	0.2479	0.0884	**0.0719, 0.4238**
d_{32}: effect of self-efficacy for self-management on treatment beliefs	0.0441	0.0282	-0.0120, 0.1002
d_{42}: effects of self-efficacy for self-management on self-management behaviours	0.1095	0.0447	**0.0205, 0.1986**
d_{43}: effect of treatment beliefs on self-management behaviours	0.6931	0.1905	**0.3139, 1.0724**
b_2: effect of self-efficacy for self-management on back pain-related disability	-0.3275	0.0436	**-0.4143, -0.2407**
b_4: effect of self-management behaviours on back pain-related disability	0.0030	0.1012	-0.1986, 0.2047
c': effect of completion of PROMs on back pain-related disability	-0.6498	0.8026	-2.2483, 0.9486

Indirect effects	B	S.E	95% CI
a_2b_2: Completion of PROMs → self-efficacy for pain management → back pain-related disability	0.2832	0.6179	-1.0622, 1.4321
$a_1d_{21}b_2$: Completion of PROMs → patient-centred communication → self-efficacy for pain management → back pain-related disability	0.3283	0.4113	-0.5095, 1.1522
$a_2d_{42}b_4$: Completion of PROMs → self-efficacy for pain management → self-management behaviours → back pain-related disability	-0.0003	0.0289	-0.0562, 0.0638
$a_1d_{21}d_{42}b_4$: Completion of PROMs → patient-centred communication → self-efficacy for pain management → self-management behaviours → back pain-related disability	-0.0003	0.0213	-0.0499, 0.0418
$a_1d_{31}d_{43}b_4$: Completion of PROMs → patient-centred communication → treatment beliefs → self-management behaviours → back pain-related disability	-0.0003	0.0181	-0.0388, 0.0387
$a_2d_{32}d_{43}b_4$: Completion of PROMs → self-efficacy for pain management → treatment beliefs → self-management behaviours → back pain-related disability	0.0001	0.0068	-0.0137, 0.0153
$a_1d_{21}d_{32}d_{43}b_4$: Completion of PROMs → patient-centred communication → self-efficacy for pain-management → treatment beliefs → self-management behaviours → back pain-related disability	0.0001	0.0047	-0.0115, 0.0085

Patient-clinician interaction

From the theoretical review it was theorised that the relationship between completing PROMs and a reduction in back pain-related disability would be mediated by increased scores in patient-centred communication, therapeutic alliance, self-efficacy and self-management behaviours (patient-clinician interaction pathway). This is depicted in Figure 8.2, and the *B* matrix can be seen in Appendix O.

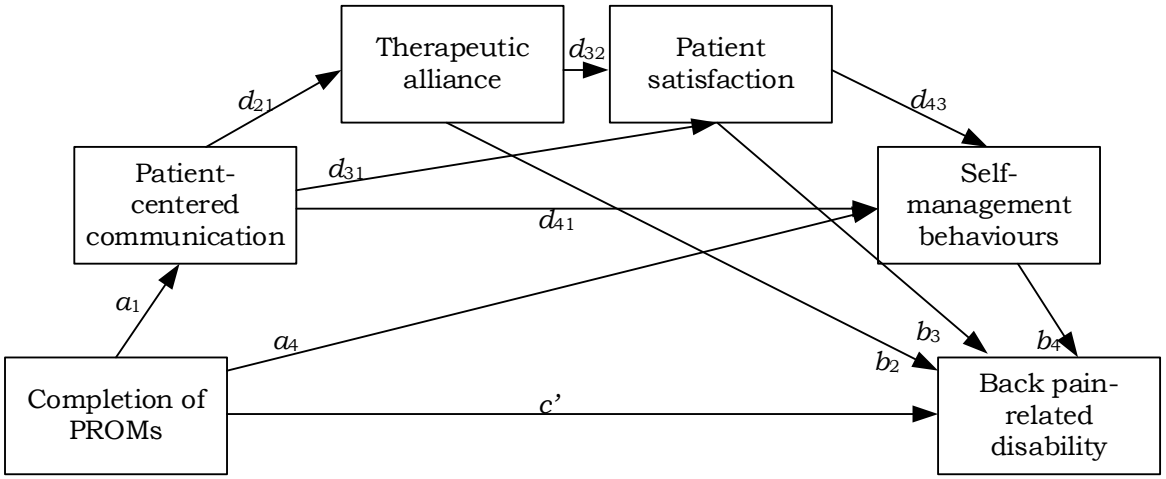


Figure 8.2 - Statistical diagram of multiple mediation model of direct and indirect effects of completion of PROMs on back pain-related disability mediated by patient-centred communication, therapeutic alliance, patient satisfaction and self-management behaviours

The model testing the link between completion of PROMs and back pain-related disability, through its effect on patient-centred communication, therapeutic alliance, patient satisfaction, and self-management behaviours, was significant, $F(4, 74) = 5.25$, $p < .001$. The model explained 22.1% of variance in back pain-related disability. As shown in Table 8.7, there was no significant direct effect of completion of PROMs on back pain-related disability. However, as hypothesised, those with higher scores of patient-centred communication also had higher ratings of therapeutic alliance with their chiropractor. Higher ratings of therapeutic alliance were associated with increased scores of patient satisfaction. Those with higher scores on satisfaction of their care were more likely to report engaging in self-management strategies for their back pain. High scores of therapeutic alliance also predicted reductions in back pain-related disability.

Conversely, there were no significant direct effects of completing PROMs on patient-centred communication or self-management behaviours. The effects of

patient-centred communication on patient satisfaction and self-management behaviours were not significant. Higher scores of self-management behaviours also did not have any significant direct effect on back pain-related disability. The estimated indirect effects of completion of PROMs on a reduction in back pain-related disability (through patient-centred communication, therapeutic alliance, patient satisfaction, and self-management behaviours) were also non-significant.

Table 8.7 - Direct and indirect effects of completion of PROMs on back pain-related disability mediated by patient-clinician interaction

Bias-corrected confidence intervals that do not pass through zero, indicating significant effects, are bolded

Direct effects	B	S.E	95% CI
a_1: effect of completing PROMs on patient-centred communication	-0.5661	0.7273	-2.0143, 0.8821
a_4: completing PROMs on self-management behaviours	0.4640	0.9029	-1.3348, 2.2628
d_{21}: effect of patient-centred communication on therapeutic alliance	1.5445	0.2232	**1.1001, 1.9890**
d_{31}: effect of patient-centred communication on patient satisfaction	0.0528	0.0296	-0.0061, 0.1116
d_{41}: effect of patient-centred communication on self-management behaviours	0.2108	0.1616	-.1110, 0.5327
d_{32}: effect of therapeutic alliance on patient satisfaction	0.0629	0.0119	**.0393, .0865**
d_{43}: effects of patient satisfaction on self-management behaviours	1.7381	0.5924	**0.5580, 2.9181**
b_2: effect of therapeutic alliance on back pain-related disability	-0.2589	0.0898	**-.4378, -.0800**
b_3: effect of patient satisfaction on back pain-related disability	-0.3428	0.7595	-1.8562, 1.1706
b_4: effect of self-management behaviours on back pain-related disability	-0.0026	0.1382	-0.2778, 1.1706
c': effect of completion on PROMs on back pain-related disability	-1.0120	1.0171	-3.0386, 1.0146

Indirect effects	B	S.E	95% CI
a_4b_4: Completion of PROMs → self-management behaviours → back pain-related disability	-0.0012	0.1299	-0.2913, 0.2821
$a_1d_{21}b_2$: Completion of PROMs → patient-centred communication → therapeutic alliance → back pain-related disability	0.2264	0.3443	-0.3503, 1.0432
$a_1d_{31}b_3$: Completion of PROMs → patient-centred communication → patient satisfaction → back pain-related disability	0.0102	0.0584	-0.1060, 0.1501
$a_1d_{41}b_4$: Completion of PROMs → patient-centred communication → self-management behaviours → back pain-related disability	-0.0003	0.0379	-0.0502, 0.0944
$a_1d_{21}d_{32}b_3$: Completion of PROMs → patient-centred communication → therapeutic alliance → patient satisfaction → back pain-related disability	0.0189	0.0929	-0.1669, 0.2336
$a_1d_{31}d_{43}b_4$: Completion of PROMs → patient-centred communication → patient satisfaction → self-management behaviours → back pain-related disability	0.001	0.0132	-0.0317, 0.0234
$a_1d_{21}d_{32}d_{43}b_4$: Completion of PROMs → patient-centred communication → therapeutic alliance → patient satisfaction → self-management behaviours → back pain-related disability	-0.0002	0.0210	-0.0510, 0.0390

Threat appraisal

Based on the threat appraisal pathway of PROMPT, several mediators were hypothesised to influence back pain-related disability. Pain-related fear, fear-avoidance beliefs and self-efficacy for pain management were hypothesised to have a direct effect on self-management behaviours. Fear-avoidance beliefs, self-efficacy for pain management, and self-management behaviours were also hypothesised to have a direct effect on back pain-related disability. Pain catastrophising was theorised to moderate the relationship between pain-related fear, fear-avoidance beliefs and self-management behaviours, with high pain catastrophising moderating an increase in fear-avoidance beliefs, and reducing self-management behaviours. This is depicted in Figure 8.3. A conditional process analysis was conducted, which can combine both mediators and moderators. The *B* matrix can be seen in Appendix O.

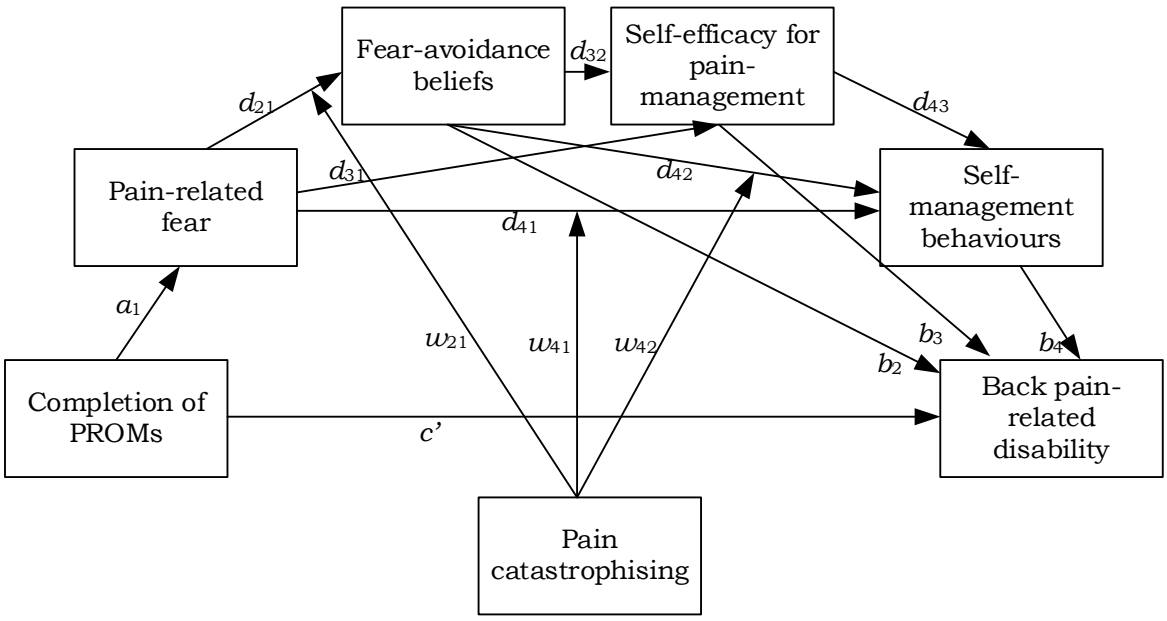


Figure 8.3 - Statistical diagram of multiple mediation model of direct and indirect effects of completion of PROMs on back pain-related disability mediated by patient-centred communication, pain-related fear, fear-avoidance beliefs, self-efficacy for pain management, self-management behaviours, and moderated by pain catastrophising

The conditional process model testing the completion of PROMs on back pain-related disability, with pain-related fear, fear-avoidance beliefs, self-efficacy for pain-management, and self-management behaviours as mediators, and pain catastrophising as a moderator was significant, $F(4, 74) = 16.48$, $p<.001$. The model explained 47.12% of the variance in back pain-related disability.

There was no significant direct effect of completion of PROMs on back pain-related disability. However, the mediation analysis showed several significant direct effects (see Table 8.8). As expected, pain-related fear increased fear-avoidance beliefs and fear-avoidance beliefs reduced patients' self-efficacy for pain management. However, self-efficacy for pain-management positively and significantly predicted self-management behaviours, and significantly predicted reductions in back pain-related disability.

In contrast, there were no significant direct effects of completing PROMs on pain-related fear. Pain-related fear also had no significant direct effect on self-efficacy for pain-management or self-management behaviours. Although both fear-avoidance beliefs and self-management behaviours were suggested to impact back pain-related disability, there were no significant direct effects. There was no evidence of moderated mediation, with pain catastrophising not found to moderate any effects (See w_{21}, w_{41}, w_{42} in Table 8.8). The estimated indirect effects of completion of PROMs on a reduction in back pain-related disability (pain-related fear, fear-avoidance beliefs, self-efficacy for pain-management, and self-management behaviours as mediators, and pain catastrophising as a moderator) were also non-significant.

Table 8.8 - Direct and indirect effects of completion of PROMs on back pain-related disability mediated by threat appraisal and moderation of pain catastrophising

Bias-corrected confidence intervals that do not pass through zero, indicating significant effects, are bolded

Direct effects	B	S.E	95% CI
a_1: effect of completing PROMs on pain-related fear	-2.1816	1.1902	-4.5517, 0.1884
d_{21}: effect of pain-related fear on fear-avoidance beliefs	0.5891	0.2211	**0.1487, 1.0295**
d_{31}: effect of pain-related fear on self-efficacy for pain management	-0.0312	0.2268	-4.828, 0.4205
d_{32}: effect of fear avoidance beliefs on self-efficacy for pain management	-0.4538	0.1852	**-0.8227, - 0.0849**
d_{41}: effect of pain-related fear on self-management behaviours	-0.1814	0.1763	-0.5329, 0.1701
d_{42}: effect of fear-avoidance beliefs on self-management behaviours	0.1394	0.1231	-0.1061, 0.3848
d_{43}: Effect of self-efficacy for pain-management of self-management behaviours	0.2018	0.0516	**0.0989, 0.3046**
b_2: effect of fear-avoidance beliefs on back pain-related disability	0.0173	0.0651	-0.1123, 0.1469
b_3: effect of self-efficacy for pain management on back pain-related disability	-0.3278	0.0458	**-0.4191, -0.2364**
b_4: effect of self-management behaviours on back pain-related disability	0.0207	0.1037	-0.1859, 0.2273
w_{21}: effect of pain catastrophising on pain-related fear and fear avoidance beliefs	-0.0149	0.0186	-0.0520, 0.0222
w_{41}: effect of pain catastrophising on pain-related fear and self-management behaviours	0.0103	0.0155	-0.0206, 0.0411
w_{42}: effect of pain catastrophising on fear-avoidance beliefs and self-management behaviours	-0.0191	0.0119	-0.0427, 0.0045
c': effect of completion of PROMs on back pain-related disability	-0.7164	0.8139	-2.3382, 0.9053

Indirect effects	B	S.E	95% CI
$a_1d_{21}b_2$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → back pain-related disability × pain catastrophising	0.0006	0.0044	-0.0105, 0.0084
$a_1d_{31}b_3$: Completion of PROMs → pain-related fear → self-efficacy for pain management → back pain-related disability	-0.0223	0.2220	-0.4993, 0.4993
$a_1d_{41}b_4$: Completion of PROMs → pain-related fear → self-management behaviour→ back pain-related disability × pain catastrophising	-0.0005	0.0059	-0.0107, 0.0148
$a_1d_{21}d_{32}b_3$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → self-efficacy for pain-management → back pain-related disability × pain catastrophising	0.0048	0.0089	-0.0128, 0.0243
$a_1d_{31}d_{43}b_4$: Completion of PROMs → pain-related fear → self-efficacy for pain-management → self-management behaviours → back pain-related disability	0.0003	0.0152	-0.0294, 0.0345
$a_1d_{21}d_{32}d_{43}b_4$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → self-efficacy for pain-management → self-management behaviours → back pain-related disability × pain catastrophising	-0.0001	0.0007	-0.0020, 0.0008

Pain catastrophising was theorised to moderate the relationship between pain-related fear, fear-avoidance beliefs, and self-management behaviours. However, there was no significant direct effects of moderation. Theoretically pain catastrophising could act as a mediator, mediating the relationship between pain-related fear and fear-avoidance beliefs, with a suggested direct effect on increasing back pain-related disability. Therefore, a second threat appraisal model was conducted, depicted in Figure 8.4 (see Appendix O for *B* matrix).

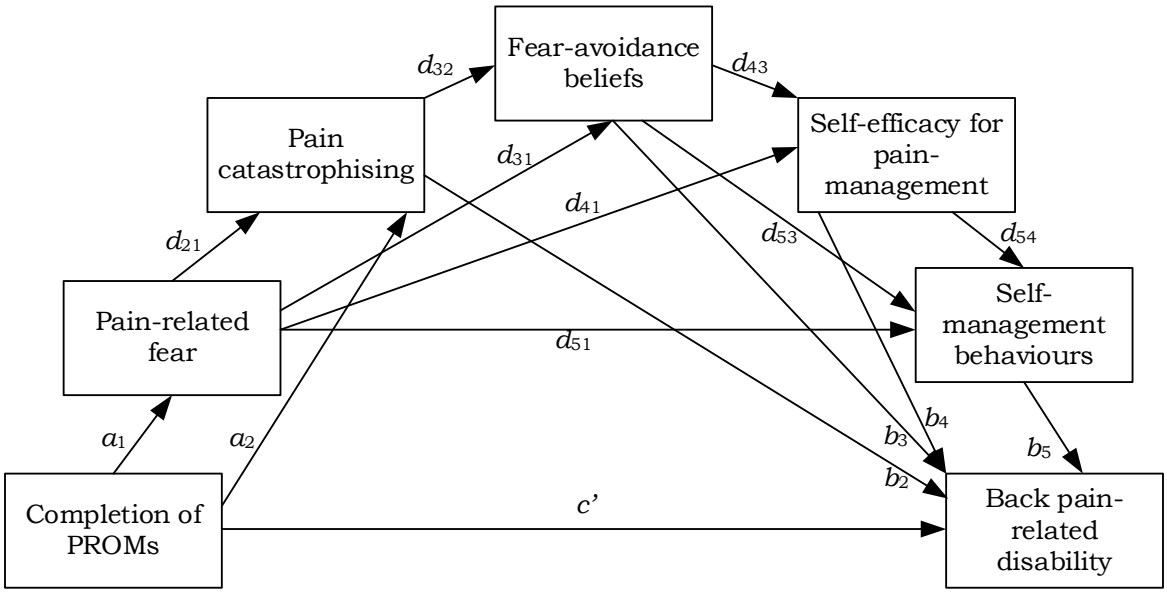


Figure 8.4 - Statistical diagram of multiple mediation model of direct and indirect effects of completion of PROMs on back pain-related disability mediated by pain-related fear, pain-catastrophising, fear-avoidance beliefs, and self-efficacy for pain management

The revised model was tested with pain catastrophising as a mediator. The model testing the completion of PROMs was significant, F (5, 73) = 16.90, p <.001, and the total model explained 53.65% of the variance in back pain-related disability. However, there was no direct effect of completion of PROMs on back pain related disability (see Table 8.9).

Exploring the direct effects, the analysis found a significant direct effect of pain-related fear increasing pain catastrophising, and pain-related fear increasing fear-avoidance beliefs. As per the earlier model, fear-avoidance beliefs reduced self-efficacy for pain management, and self-efficacy for pain-management positively predicted self-management behaviours, and reduced back pain-related disability. Additionally, as hypothesised, pain catastrophising predicted an increase in back pain-related disability.

The mediation analyses showed there was no significant effect of completing PROMs on pain-related fear and pain catastrophising. There was no significant direct effect of pain-related fear on self-efficacy for pain-management, and there was no significant direct effect of fear-avoidance beliefs on back pain-related disability. The estimated indirect effects of completion of PROMs on a reduction in back pain-related disability (through pain-related fear, pain catastrophising, fear-avoidance beliefs, self-efficacy for pain-management, and self-management behaviours as mediators) were also non-significant.

Table 8.9 - Direct and indirect effects of completion of PROMs on back pain-related disability mediated by threat appraisal

Bias-corrected confidence intervals that do not pass through zero, indicating significant effects, are bolded

Direct effects	B	S.E	95% CI
a_1: effect of completing PROMs on pain-related fear	-2.1816	1.1902	-4.5517, 0.1884
a_2: effect of completing PROMs on pain catastrophising	-0.4416	1.1312	-2.6946, 1.8114
d_{21}: effect of pain-related fear on pain catastrophising	0.9379	0.1060	**0.7268, 1.1491**
d_{31}: effect of pain-related fear on fear avoidance beliefs	0.4924	0.1847	**0.1246, 0.8602**
d_{32}: effect of pain catastrophising on fear avoidance beliefs	0.0181	0.1410	-0.2626, 0.2989
d_{41}: effect of pain-related fear on self-efficacy for pain management	-0.0312	0.2268	-0.4828, 0.4205
d_{43}: effect of fear avoidance beliefs on self-efficacy for pain management	-0.4538	0.1852	**-0.8227, -0.0849**
d_{51}: effect of pain-related fear on self-management behaviours	0.0259	0.0928	-0.1591, 0.2108
d_{53}: effect of fear avoidance beliefs on self-management behaviours	-0.0197	0.0788	-0.1766, 0.1373
d_{54}: effect of self-efficacy for pain management on self-management behaviours	0.1686	0.0470	**0.0750, 0.2621**
b_2: effect of pain catastrophising on back pain-related disability	0.2004	0.0625	**0.0758, 0.3249**
b_3: effect of fear-avoidance beliefs on back pain-related disability	-0.0269	0.0629	-0.1522, 0.0983
b_4: effect of self-efficacy for pain management on back pain-related disability	-0.2749	0.0463	**-0.3671, -0.1827**
b_5: effect of self-management behaviours on back pain-related disability	-0.0157	0.0984	-0.2118, 0.1804
c': effect of completing PROMs on back pain-related disability	-0.1449	0.7876	-1.7146, 1.4249

Indirect effects	B	S.E	95% CI
a_2b_2: Completion of PROMs → pain catastrophising → back pain-related disability	-0.0885	0.2141	-0.4838, 0.4080
$a_1d_{21}b_2$: Completion of PROMs → pain-related fear → pain catastrophising → back pain-related disability	-0.4100	0.2676	-1.0030, 0.0270
$a_1d_{31}b_3$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → back pain-related disability	0.0289	0.0779	-0.1504, 0.1816
$a_1d_{41}b_4$: Completion of PROMs → pain-related fear → self-efficacy for pain management → back pain-related disability	-0.0187	0.1857	-0.3923, 0.3899
$a_1d_{51}b_5$: Completion of PROMs → pain-related fear → self-management behaviours → back pain-related disability	0.0009	0.0204	-0.0478, 0.0388
$a_2d_{32}b_3$: Completion of PROMs → pain catastrophising → fear-avoidance beliefs → back pain-related disability	0.0002	0.0107	-0.0171, 0.0256
$a_1d_{21}d_{32}b_3$: Completion of PROMs → pain-related fear → pain catastrophising → fear-avoidance beliefs → back pain-related disability	0.0010	0.0189	-0.0395, 0.0405
$a_1d_{31}d_{43}b_4$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → self-efficacy for pain management → back pain-related disability	-0.1340	0.1152	-0.4285, 0.0102
$a_1d_{31}d_{53}b_5$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → self-management behaviours→ back pain-related disability	-0.0003	0.0117	-0.0282, 0.0203
$a_1d_{41}d_{54}b_5$: Completion of PROMs → pain-related fear → self-efficacy for pain management → self-management behaviours→ back pain-related disability	-0.0002	0.0120	-0.0215, 0.0289
$a_2d_{32}d_{43}b_4$: Completion of PROMs → pain-catastrophising → fear-avoidance beliefs → self-efficacy for pain management → back pain-related disability	-0.0010	0.0230	-0.0685, 0.0227

Indirect effects	B	S.E	95% CI
$a_2d_{32}d_{53}b_5$: Completion of PROMs → pain-catastrophising → fear-avoidance beliefs → self-management behaviours → back pain-related disability	0.0000	0.0015	-0.0025, 0.0020
$a_1d_{21}d_{32}d_{43}b_4$: Completion of PROMs → pain-related fear → pain catastrophising → fear-avoidance beliefs → self-efficacy for pain management → back pain-related disability	-0.0046	0.0418	-0.1147, 0.0618
$a_1d_{21}d_{32}d_{53}b_5$: Completion of PROMs → pain-related fear → pain catastrophising → fear-avoidance beliefs → self- management behaviours → back pain-related disability	0.0000	0.0026	-0.0047, 0.0048
$a_1d_{31}d_{43}d_{54}b_5$: Completion of PROMs → pain-related fear → fear-avoidance beliefs → self-efficacy for pain management → self- management behaviours → back pain-related disability	-0.0013	0.0121	-0.0320, 0.0159
$a_2d_{32}d_{43}d_{54}b_5$: Completion of PROMs → pain catastrophising → fear-avoidance beliefs → self-efficacy for pain management → self-management behaviours → back pain-related disability	0.0000	0.0016	-0.0029, 0.0025
$a_1d_{21}d_{32}d_{43}d_{54}b_5$: Completion of PROMs → pain-related fear → pain catastrophising → fear-avoidance beliefs → self-efficacy for pain management → self- management behaviours → back pain-related disability	0.0000	0.0030	-0.0067, 0.0047

8.4 Discussion

This study explored the psychosocial effects of using PROMs in specialist musculoskeletal care, investigating the mediating and moderated effects of completing PROMs on back pain-related disability. It further aimed to clarify mechanisms of PROMs by testing hypotheses derived from PROMPT (Chapter 5). The theory suggested that PROMs may affect patients through various processes, namely a coping appraisal pathway, patient-clinician interaction pathway, and a threat appraisal pathway. These pathways were tested using multiple mediator models.

When considering the effect of completing PROMs on back pain-related disability, all four models developed were significant. Regarding each of the pathways in PROMPT, the coping appraisal explained 46.6% of the variance in back pain-related disability, the patient-clinician interaction pathway explained 22.1% of the variance in back pain-related disability, and the threat appraisal pathway explained 53.65% of the variance in back pain-related disability. However, in all models, the direct effects of completion of PROMs on back pain-related disability were not significant. Additionally, there were no significant indirect effects of completion of PROMs on back pain-related disability via proposed mechanisms.

According to hypothesis 1, those who completed PROMs would have higher scores in patient-centred communication, therapeutic alliance, patient satisfaction, self-efficacy for pain management, and self-management behaviours, compared to those who did not complete PROMs. Contrary to this hypothesis, there were no significant differences in the process measures between those who completed PROMs and those who did not. The only exception was patient satisfaction, which was found to be slightly higher in those who did not complete PROMs.

Despite PROMs showing little to no impact on back pain-related disability in this study (hypotheses 2-4), results highlighted contextual factors that may predict changes in back pain-related disability. Contextual factors are psychosocial and environmental factors acting alongside care which are thought to influence patient outcomes (Bradbury et al., 2016). The findings suggest that patient-centred communication, self-efficacy for pain management, treatment beliefs, therapeutic alliance, and patient satisfaction may be contextual factors and have a role in predicting reduced back pain-related disability.

Patient-centred communication positively influenced patients' beliefs about chiropractic treatment for their back pain. Patient-centred communication also increased patient's self-efficacy for pain management, with self-efficacy for pain management predicting a reduction in back pain-related disability. Self-efficacy is thought to have a role in the control of pain, with associations between self-efficacy to complete daily living activities and lower pain scores (Altmaier et al., 1993). A previous study examining the effect of patient-centred communication on pain in 1027 American veterans, also found self-efficacy for managing pain as a mediating factor between patient-centred communication and pain (Ruben, Meterko, & Bokhour, 2018).

Theoretically, communication in clinical practice is based on conveying and receiving messages, shared-decision making, and goal setting (Feldman-Stewart & Brundage, 2009). Patient-centred care is also theorised to have an inherent focus on sharing power and responsibility, with mutual participation in the consultation and decision-making (Mead & Bower, 2000). In this current study, patient-centred communication increased patient perceived therapeutic alliance with their chiropractor. These findings are consistent with other literature, suggesting that positive aspects of communication, such as shared-decision making can result in positive self-management approaches, adherence to clinical advice, and can enhance the therapeutic alliance (Joosten et al., 2008; Stiggelbout, Pieterse, & De Haes, 2015). A systematic review found that facilitating patient involvement in consultations and supporting patients is associated with positive therapeutic alliance (Pinto et al., 2012).

Therapeutic alliance also had significant effects on increasing patient satisfaction and reducing back pain-related disability. This was expected, with previous work in mental health settings finding that positive relationships and interactions between patients and clinicians is thought to promote patient satisfaction (Cahill et al., 2008) and influence treatment outcomes (McGuire et al., 2001). A cross-sectional study within a pain clinic found patients' perceptions of clinicians' empathy was correlated with patient satisfaction of their care, even after a single visit (Walsh, O'Neill, Hannigan, & Harmon, 2019).

Within treatment for back pain, there are a multitude of pain management treatments and self-management activities, with treatment focusing on reducing pain rather than a cure (Maher et al., 2017). A large qualitative study examined treatment beliefs in 75 patients with low back pain (Dima et al., 2013). Patients felt treatments need to be credible, with a plausible mechanism of action and be effective in providing relief or enabling self-management. Treatments have to fit

individual needs, and be delivered by a knowledgeable, empathic and trustworthy practitioner (Dima et al., 2013). Findings of this study showed that positive treatment beliefs regarding chiropractic for their back pain had a positive influence on self-management behaviours. Further, as expected, patients' satisfaction with their care predicted positive self-management behaviour.

Although within the threat appraisal models, completion of PROMs did not directly influence the process variables, there were several direct effects which may explain patient outcomes after chiropractic care. Pain-related fear was found to increase patients' pain catastrophising and fear-avoidance beliefs. Increased fear-avoidance beliefs further reduced self-efficacy for pain management. A previous review found fear was significantly associated with catastrophic thoughts of pain, hypervigilance, and avoidance behaviours (Leeuw et al., 2007). Within the current study, pain catastrophising was found to increase back pain-related disability, although there was no direct effect of fear-avoidance beliefs on back pain-related disability. Catastrophising thoughts about pain may predict attention to pain, anticipation of pain, and create expectancies of the pain experience (Eccleston & Crombez, 1999; Vlaeyen & Linton, 2000); there is however conflicting research to support this. In a systematic review exploring psychological factors in patients with shoulder pain, high levels of pain catastrophising and fear-avoidance beliefs were associated with high levels of disability (Martinez-Calderon et al., 2018). However, a systematic review examining pain-related fear on pain levels and disability had inconsistent findings in whether fear-avoidance beliefs predicted increasing disability in patients with low back pain (Martinez-Calderon, Flores-Cortes, Morales-Asencio, & Luque-Suarez, 2019).

Overall, the results of this study showed that completing PROMs did not have direct or indirect effects on back pain-related disability or psychosocial aspects of patients' care. However, there are contextual factors that are associated with patient outcomes, in particular, this study confirmed previous findings that factors such as patient-centred communication, self-efficacy for pain management, treatment beliefs, therapeutic alliance, and patient satisfaction may have a role in predicting reduced back pain-related disability. Pain-related fear, pain catastrophising, fear-avoidance beliefs were also found to have a role in predicting an increase in back pain-related disability for low back pain patients.

8.4.1 Strengths and limitations

The main limitation of this study is the sample size and power to detect mediation and moderation effects. This study used data from the 80 RCT participants. Estimations for the number of predictors being investigated suggested a sample size of 311 participants would be required to detect a clinically meaningful effect size on the Roland-Morris questionnaire. Low power is problematic because it can lead to type II errors (VanVoorhis & Morgan, 2007). Caution must be taken when interpreting the results of underpowered studies, as they are at risk of not identifying significant effects, and hypotheses cannot be refuted.

Data collection for this study was nested within the RCT study described in Chapter 7, with all process measures collected from patients 90-days after their first appointment. There was a concern that including multiple measures at baseline, such as those around coping, and fear of pain, might negatively impact patient recruitment and completion of the baseline measures. Additionally, due to the nature of constructs such as patient-centred communication, therapeutic alliance, patient satisfaction, they cannot be measured at baseline and differences pre and post intervention cannot be explored. Measuring these concepts at 90 days also introduces the potential for significant recall bias and the large number of process measures may have led to participant response burden, impacting on study completion or affecting participants' responses.

8.5 Chapter summary

This was the first study to examine the potential mechanisms by which PROMs may impact outcomes for patients with low back pain. There were no significant effects of completing PROMs on psychosocial aspects of patient care. This study provides preliminary evidence of processes within specialist musculoskeletal care reducing back pain-related disability. These findings, in combination with the systematic review (Chapter 4) and theoretical review (Chapter 5), support a model of patient-centred communication, and reducing pain-related fear. However, completion of PROMs had no direct or indirect effects on back pain-related disability. An embedded qualitative study is reported in Chapter 9, which aimed to identify any unintended consequences of PROMs and contextual mechanisms which might moderate outcomes. Patients' and chiropractors' accounts may provide additional context and explanations of the impact of PROMs in specialist musculoskeletal care for low back pain. Further interpretation of the results of the RCT and mediation models are reported in Chapter 10, alongside the qualitative interviews, in a mixed-methods process evaluation.

Chapter 9 Using PROMs in specialist musculoskeletal care: a qualitative study of patients' and chiropractors' views

9.1 Introduction

Chapter 7 explored the use of PROMs to improve back pain-related disability and Chapter 8 considered the potential mechanisms of change. However, whilst quantitative work provides an opportunity to look at the clinical and psychosocial effects of using PROMs into clinical practice, qualitative research may provide further understanding of PROMs and can help explain any conflicting findings.

A qualitative systematic review explored the experiences of healthcare professionals' use of PROMs to improve healthcare delivery (Boyce et al., 2014a). Sixteen studies were identified from numerous healthcare settings, with the majority focused on mental health, palliative care, and oncology. Many studies focused on the barriers and facilitators of employing PROMs, including practical implications (i.e., the data collection process, administration, and workloads) and healthcare professionals' views (i.e., their understanding, appreciation of, and ability to understand and interpret PROMs). Healthcare professionals had mixed views on how PROMs impact on patient care. Some healthcare professionals suggested PROMs have the potential to impact care processes, through enhancing patient-clinician interactions, patient education, shared-decision making, treatment planning, screening, and monitoring (Boyce et al., 2014a). However, others saw no clinical value in PROMs and suggested they may negatively impact patient-clinician interactions.

There has been very little qualitative work exploring PROMs and low back pain. Interviews with chiropractors and patients from the feasibility study (Chapter 6) provided initial exploration on chiropractors' and patients' use of PROMs. The study findings reflected the broad concepts of the Boyce et al. (2014a) review regarding organisational barriers and facilitators of employing PROMs, such as choosing the appropriate PROMs, administrative tools, and

clinician knowledge. The findings from the feasibility study also demonstrated the necessity of ensuring PROMs are meaningful to patients and chiropractors.

It is clear there are differing views and degrees of engagement with PROMs within clinical practice. The aim of the current study was to consider chiropractors' and patients' views to identify any unintended consequences of PROMs and to identify contextual mechanisms that might moderate outcomes. This chapter presents a qualitative analysis of the processes involved in using PROMs in specialist musculoskeletal care, based on interviews with patients and chiropractors involved in the RCT (Chapter 7).

9.2 Methods

9.2.1 Study design

This qualitative study was embedded in a wider mixed-methods study, as part of the RCT (Chapter 7). The study followed a sequential explanatory study design, with the RCT first, followed by qualitative interviews. The qualitative phase aimed to explore separate study objectives from the RCT and to explain the results of the RCT as part of a mixed-methods analysis (reported in Chapter 10).

9.2.2 Sampling and recruitment

To provide a more complete picture of PROMs in clinical practice it was important to sample participants with a range of differing experiences (Creswell & Clark, 2011). Therefore, purposive sampling was used to recruit participants from the routine PROMs and intensive PROMs groups to include patients who showed both improvement in back pain-related disability and others who showed no improvement. Chiropractors and patients from the control group were also invited to participate, to provide a comparison of their experience of care without the use of PROMs. Purposive sampling allowed me to interview participants with a range of ages and range of baseline back pain severity, and similar numbers of participants according to their self-identified gender. The study database containing back pain-related disability scores were screened after participants completed RCT outcome measures to identify participants who met these criteria. Participants were emailed an invitation to participate in the interview (Appendix P). Recruitment, data collection, and data analysis was conducted simultaneously until data saturation was reached (Baker & Edwards, 2012; Guest et al., 2016). Data saturation refers to when collected data is routinely similar to previously collected data, and no new codes or themes are developed during the analysis (Baker & Edwards, 2012; Guest et al., 2016). Although it was felt data saturation was achieved after nine participants, additional interviews were conducted to ensure views from a wide sample of participants, acknowledging the need to sample from multiple groups and capture diverse participant characteristics.

9.2.3 Data collection

Individual interviews were conducted to allow patients and chiropractors to express their views on how PROMs may have an effect when used in the treatment of low back pain (Bowling, 2009; Denzin & Lincoln, 2011; Mason, 2002; Wilkinson et al., 2004). The interviews were conducted in a semi-structured format, following an interview guide (see Appendix Q). Topics within patient interviews included: experience of completing PROMs, how chiropractors' used PROMs, and how PROMs may influence their health. Chiropractic interview topics included: experiences of using PROMs in clinical practice, how PROMs influenced treating patients, and how PROMs may influence patients' health. Questions and prompts were developed to aid the interviewer; however, the interview guide was left flexible to encourage a discussion-like feel to the interview and allow for changes throughout the interviewing process.

All interviews were conducted over the telephone and audio-recorded with permission from participants. Telephone interviews are convenient for participants and simplify the logistics of data collection, as geographical location does not impact on obtaining data (Rohde, Lewinsohn, & Seeley, 1997; Taylor, 2013). Literature suggests participants completing telephone interviews may be more likely to give shorter and more socially-desirable answers than in face-to-face interviews (Jäckle, Roberts, & Lynn, 2006). To combat these effects, no closed ended questions were included in the interview guide and questions were worded neutrally without any positive or negative connotation to reduce any suggestive bias over a single answer.

9.2.4 Data analysis

The data from interviews was transcribed verbatim and inputted into the computer-assisted qualitative software NVivo (version 12) (QSR International, 2010). The qualitative data was analysed using thematic analysis. Thematic analysis was chosen as the best method to achieve the aims and objectives of the study, as it allows for a thorough exploration and detailed description of patients' and practitioners' experiences of using PROMs (Braun & Clarke, 2006; Vaismoradi et al., 2013). The flexibility of this approach can generate unanticipated concepts and ideas (Braun & Clarke, 2012; Joffe & Yardley, 2004) which can help identify any unintended consequences of PROMs.

The analysis was conducted following published guidance on thematic analysis, providing a systematic and transparent process of conducting qualitative data analysis (Braun & Clarke, 2006, 2012; Braun, Clarke, Hayfield, & Terry, 2019). This involved familiarisation with the data, listening to the audio-recordings, transcription, and re-reading the transcripts, with initial notes of ideas made at this stage. Initial inductive coding then followed, both describing the data and interpreting the data content. After all interviews were coded, codes were examined to identify similarity and differences. Codes were refined, including collapsing codes that were similar constructs (for example, comparisons to physiotherapy, other chiropractors, and GP consultations were grouped under comparison to other treatment). In this step, themes were generated based on broad topics in which codes were clustered, and the relationship between themes explored (for example patients' experiences of medical history, physical examination, chiropractors' questions about their pain, and thoughts on PROMs questions were all based around questioning by chiropractors). Potential themes were reviewed against coded data, exploring if themes accurately depicted the dataset. Definitions and names of themes were created, ensuring themes had a clear focus, and told a story of the data, relevant to the research question (for example, 'providing explanations and advice' was revised to 'providing explanations of pain and treatment' when finalising the themes). Quotes were selected from themes to best illustrate the dataset and describe the findings. The findings were written up, and final edits were made to codes and themes, ensuring that the interpretation was coherent and meaningful. Finally, a thematic map was developed depicting the relationships between themes.

9.2.5 Ethical considerations

Recruitment

This study received ethical and research governance approval from the University of Southampton alongside the RCT (ref: 20133, 2017). When recruiting to the RCT, all participants (chiropractors and patients) consented to take part in the trial and an audio-recorded qualitative interview (Appendix J and L). Additional verbal consent was taken at the beginning of the interview to participate and for audio-recording of the interview.

Risk

With qualitative interviews, there is often minimal risk to participants as it does not usually involve any additional risks of harm or discomfort than anticipated in everyday life. However, discussion of participants' experiences in the trial could have induced minimal psychological distress due to the context of pain. Signs of emotional and psychological distress were managed by listening for non-visual cues such as crying, voice breaking, verbal acknowledgement of being upset, or the participant becoming unresponsive or crying. No participant was identified as being distressed and all interviews were completed in full.

Data protection

Audio-recordings from interviews were transferred from a digital recorder after the interview and stored on a password-protected computer. Collected data was anonymised so participants could not be identified during analysis, with participants details being stored in a separate password-protected file. When transcribing the interviews, all identifying information was removed and replaced with pseudonyms to protect participants' anonymity. The audio recordings will be destroyed after the publication of the study and anonymised data will be archived for 10 years following study completion, in accordance with the Research Data Management Policy of the University of Southampton (University of Southampton, 2019) and compliance with General Data Protection Regulation (European Parliament and Council of European Union, 2016).

9.3 Results

9.3.1 Participants

All chiropractors from the RCT (Chapter 7) were invited to participate in an interview. Seven of the eight chiropractors from the RCT chose to participate in an interview (three female, four male). Additionally, 54 patients from the trial were invited for an interview. In total, 15 interviews were conducted with patients. Patients were interviewed from all three intervention groups, and across the different chiropractors involved in the trial. The chiropractor and patient interviews had an average duration of 25 minutes and 12 minutes, respectively. Table 9.1 provides details of the chiropractors and patients who participated in interviews.

Table 9.1 – Participant summary

Chiropractors	Patients
Intensive PROMs	
• Peter, 8 years in practice • Kristian, 9 years in practice, • Caroline, 20 years in practice	• Lauren, 25, < 3 months back pain • Patricia, 68, > 2 years back pain • Richard, 58, < 3 months back pain • Josef, 54, 1-2 years back pain
Routine PROMs	
• Mary, 19 years in practice • Tobias, 11 years in practice	• Karolina, 39, 1-2 years back pain • Margaret, 75, <3 months back pain • Michael, 27, >2 years back pain • Jessica, 26, 3-12 months back pain • Thomas, 56, < 3 months back pain • Stefanie, 33, < 3 months back pain
Control group	
• Elliott, 11 years in practice • Petra, 20 years in practice	• Lisa, 57, < 3 months back pain • Paul, 46, < 3 months back pain • Andreas, 52, < 3 months back pain • Amanda, 38, 3-12 months back pain • Hamish, 21, 3-12 months back pain

9.3.2 Overview

PROMs were viewed as a valuable tool within patient-clinician communication, with good communication key for patient-clinician interactions. Patients and chiropractors discussed how PROMs and good communication were used in their interactions regarding thorough questioning, providing explanations, and monitoring and follow-up of patients. Several benefits were discussed, including making and maintaining lifestyle changes, fostering positive views of practitioners, and building rapport and relationships. These processes are illustrated in Figure 9.1. The following sections describe each of the themes and include quotations to illustrate the main themes and provide examples from a range of participants. Three themes regarding the administration of PROMs, individual factors regarding use, and wider benefits of using PROMs are discussed in Chapter 10, alongside quantitative data around the utilisation and intervention fidelity data from the RCT (Chapter 7).

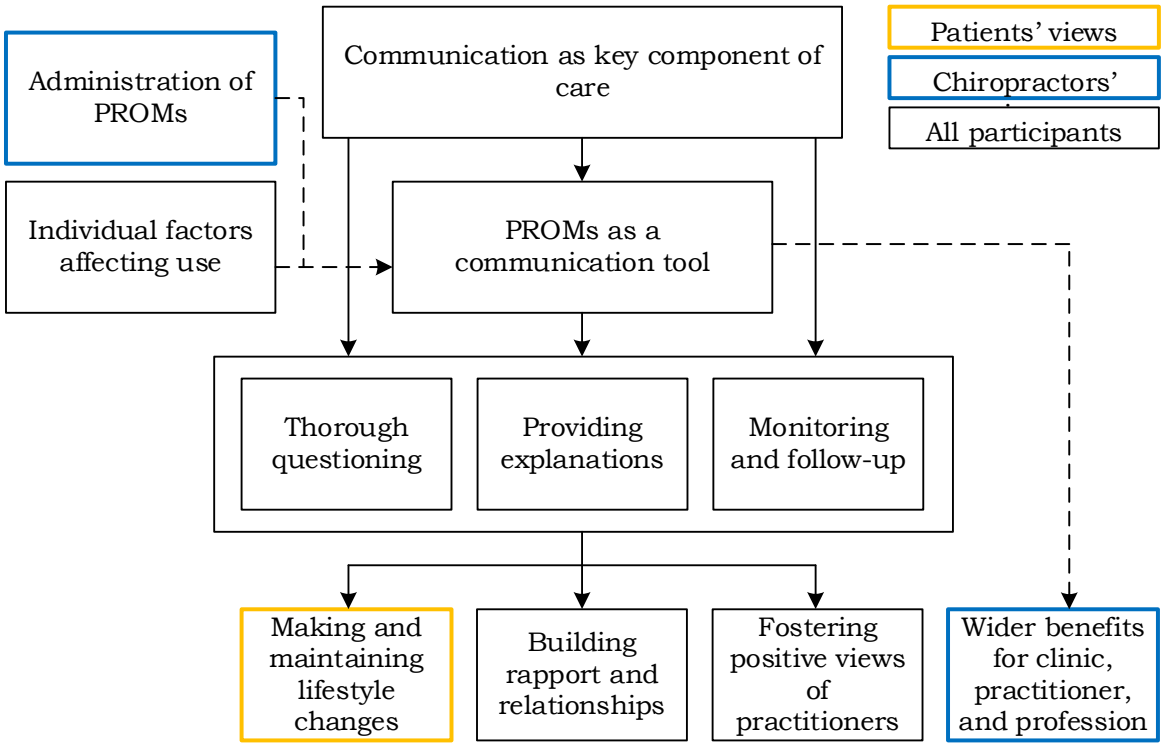


Figure 9.1 – Thematic map

9.3.3 Communication as a key component of care

Communication was viewed as a key component of care by both patients and chiropractors. Chiropractors spoke at length about their interactions with patients. They highlighted the importance of listening to patients' experiences. *"I'm always having those conversations with patients. You know I'm a kind of 'how's life?' chiropractor*." (Chiropractor – Tobias). Patients valued their chiropractor allowing them to tell their story, not just around their main complaints, but their wider medical history, concerns about their health and care, and other smaller health issues. *"the important part is having somebody to listen to you and be able to do something to help you*." (Patient - Margaret). Patients spoke positively of chiropractors' listening skills and their overall interactions with the chiropractors, *"I felt she was really on my case*". (Patient - Lauren).

Chiropractors felt that they could have good communication without the use of PROMs. "*I admit to not being a hugely numbers person. I tend to be more people focused and get on with it"* (Chiropractor - Mary). This was also reflected by chiropractors in the control group whose patients did not receive PROMs. *"They feel maybe they're listened to when they're coming up with some scores, perhaps, but I don't think we necessarily need to do it through that process of PROMs. That's just being a good clinician"* (Chiropractor - Petra). Both Elliott and Petra identified changing their conversation style when not receiving PROMs, but overall achieving the same goal of listening to patients *"I still asked them lots of questions. I still think they felt valued"* (Chiropractor - Elliott).

<u>PROMs as a communication tool</u>

PROMs were seen as having potential value by chiropractors: *"this information is super helpful for me as a clinician if I have it in front of me*" (Chiropractor - Tobias). Some felt that PROMs were an extra to their clinical practice rather than a necessary part of care: *'it's a tool that I have in the background'* (Chiropractor - Mary). This was echoed throughout the interviews with chiropractors, highlighting that PROMs were one of many tools with which to have a conversation with patients: *'maybe it formalises that to and fro between practitioner and patient?*' (Chiropractor - Petra). However, other chiropractors saw PROMs as a core part of their practice. For example, Peter discussed how PROMs were embedded into his practice, including training reception staff on PROMs, educating patients about their use, and writing PROMs into their consent policy:

"we are trying to really integrate it. It's like a core part of our practice now." (Chiropractor – Peter). Some chiropractors reported that they did not explicitly use PROMs in their discussions with patients but felt that PROMs were a prompt for conversations and further inquiries "*I would kind of get a general idea looking before where some of the issues might be, if there were any potential, you know, yellow flags or things like that. And then I would kind of just try and bring that into the consultation"* (Chiropractor - Kristian).

Patients were positive about completing PROMs before their treatment, mentioning it was a good use of time, and feeling that chiropractors were open to hearing their concerns "*I thought, you know, somebody's thinking here, about what's going on.*" (Patient – Lauren). Some patients noted they felt listened to and were given further opportunities to discuss their issues in more detail "*we discussed one of two answers that I gave"* (Patient – Jessica). Patients valued the opportunity to reflect on their health before seeing the chiropractor and were grateful that their chiropractors had considered their health and medical history before treatment. "*it was obvious from the way she was talking to me that she had read it and taken note of everything I had put down in it because of the questions she was asking me"* (Patient - Margaret).

Although chiropractors were happy with their conversations with patients, not having PROMs reduced the opportunity to use questions and data as a springboard for difficult discussions. For example, Elliott found it frustrating, that in the control group, he did not have PROMs to open up conversations about anxiety and depression: "*they state they've got like high levels of depression. So, it opens up the channel to ask them about that. And not having that, I felt like it was…it had it… an important part in my view of the case history in the treatment was taken away.*" (Chiropractor – Elliott).

9.3.4 Patient-clinician interactions

Patients and chiropractors discussed key moments of their conversations in clinical practice and noted specific moments where PROMs were used in their interactions with each other. This included within the initial consultation, with thorough questioning, providing explanations and advice, and ongoing monitoring and follow-up of their outcomes throughout their care.

Thorough questioning

Chiropractors felt PROMs acted as a prompt for patients to provide more information regarding their health, helping chiropractors to understand patients' thoughts and beliefs about their condition. Using PROMs as a prompt for questioning provided chiropractors with further insight into how patients were feeling: "*what I find the most valuable I think, is enabling patients to see that we understand how that the symptoms are affecting them"* (Chiropractor – Caroline).

PROMs were used as a baseline tool alongside their initial consultation and medical history taking, as chiropractor Mary explained: "*with the first questionnaires which records us a baseline level of how they are on day, day nothing. So I know what to expect when they come in to see me as a new patient*". Several chiropractors used PROMs to identify psychosocial factors, predictors and prognosis. Mary further explained she looked at patients scores to see: *"any sort of predictive indicators of their chronicity and things like that or poor response*".

Patients valued the thorough questioning they received from chiropractors, through the use of PROMs and the extensive initial consultation *"a lot of probing questions to try and find out as much as you possibly could before he actually administered any treatment"* (Patient – Paul). PROMs were seen as thorough, and a necessary part alongside the patients' case, and medical history, and physical examination. *"I felt very secure that she knew what she was doing because she knew all the things that happened to kind of get me to that point where I first saw her."* (Patient – Karolina).

Providing explanations of pain and treatment

Chiropractors noted that the use of PROMs, alongside their medical history taking and consultations, allowed them to provide advice to patients, and identify areas where they needed to reassure patients. *"it enables me to*

understand their challenges and their thoughts and beliefs about their complaints. And then I can then use that within our next sessions and either bring it back directly or ask them how they're feeling about certain things and then challenge their beliefs or to... or to empathize with them" (Chiropractor - Kristian). A chiropractor in the control group had previously used PROMs to identify issues and send further information to patients: "*if they put down the high anxiety on the Bournemouth questionnaire. Depending on the patient and depending what it is. I might send them some information around like some of the pain science and pain education side of things*" (Chiropractor – Elliott). However, he feared that being in the control group, he may have overlooked this for some patients "*maybe some of the psychosocial elements I might have missed, 'cause I might not have picked them up in the case history*"

Patients commented on positive aspects of their interactions with chiropractors, including chiropractors clarifying treatment goals and setting out expectations for care, and ensuring patients and chiropractors were focusing on the same issues. *"it enables him to workout what I've done and what to do and what treatment to give"* (Patient – Andreas). Patients felt that they were kept informed of treatment decisions "*she explained what she thought was wrong and what she was going to do to put it right*" (Patient – Stefanie). Amanda had a similar experience with her chiropractor: *"explained exactly what he thought it was, and what he wanted to do, and was I happy with it all.*" Some patients felt PROMs allowed them to have more input in treatment decisions, by providing information to the chiropractor: "*I think it did help me to focus on the different aspects of the treatment. So yes, rather than just turning up, letting [chiropractor] do what she did and that was the end of it. It did, did make me think, you know, is this, it made me think that* [chiropractor] *was focusing on these different aspects as well. Singing from the same hymn sheet.*" (Patient – Lauren). One chiropractor voiced the idea that PROMs could make patients feel more involved in their care. *"I try and reinforce them, it's really good because it gives us your perspective of how it's going on, rather than me asking you'. It leaves them a little bit more involved*" (Chiropractor – Peter).

Some patients noted aspects of interactions the valued, but were not directly related to PROMs. When seeking care for their back pain, they not only wanted treatment, but to understand the cause of their pain: "*He was good at explaining the parts of your back and stuff and.. and what he sort of related it too.. would be. Yeah he sat me down and explained what he was going to do and stuff like that. He was quite good in the explanation and if you ask him sort of*

questions, pretty great at giving you answers." (Patient - Richard). Patients compared their experiences of visiting a chiropractor to previous treatment with other healthcare professionals, who they felt did not provide them with adequate explanations: "*well every time that I asked the physio... 'what have I done? what.. what's the problem? Why you know? Why can't I walk walk? Why can't I put my foot to the floor?' And he just, it would just sort of, kind of, rubbing his chin, from side to side and looking at his computer screen on his laptop and evaded any answer of any description of saying what was wrong*" (Patient – Lisa).

Monitoring and follow-up

Chiropractors talked about how they used PROMs to monitor patients, through the feedback from follow-up PROMs. Kristian used PROMs in his review sessions with patients: "*when we had a review every few visits, I would kind of pull up their scores and show them, you know, 'well this is where we are at so far'*". It provided chiropractors with an opportunity to see patient improvement and any worsening of symptoms: *"it shows, you know, someone's not improving or if they've had a flare up in between things*" (Chiropractor – Mary). Chiropractors used PROMs when seeing patients in clinic and outside of the clinic, even if they had stopped coming for care. Chiropractors acknowledged PROMs were beneficial for this purpose: *"Because I think a lot of people when they're feeling worse, they don't always tell you. Whereas at least with this it's almost like just like a trigger*" (Chiropractor – Peter). Through monitoring the outcomes of his patients, this triggered Peter to open a discussion when patients' pain was worsening: *"I actually emailed them back and I said 'I've just seen on your outcome measures, you've said you've been feeling worse recently. Maybe we can book a virtual consultation where we can chat about that'"*

Chiropractors in the intervention groups talked about showing patients their outcomes from follow-up PROMs, alongside questioning patients and getting verbal updates from patients about their condition. They appreciated being able to visually show patients the progress they were making. *"I'm showing them you know, objective relatively objective data about that subjective experience. And they could see it on the graph. It wasn't me saying 'look you were telling me this, and now you are telling me that' . I would go 'here's the proof'. People really like that, especially at the review*" (Chiropractor - Kristian). Chiropractors used the information to reinforce positive changes in patients, giving them an indication of the areas that have improved. *"I also wanted to use the questionnaire there. To kind of reinforce positively her results because she had*

been quite, you know, up and down emotionally about things. And that the general trend was in a very positive direction overall, and that I was really pleased that she had recovered much better than many do with her own condition" (Chiropractor – Tobias).

Patients appreciated this aspect of monitoring within their care. Patients reported being asked improvement since previous sessions. *"I think she was thorough in the way that she would always sit me down before the next set of treatments and talk through whether things got worse or better*" (Patient – Thomas). Patients felt that PROMs and their discussion with chiropractors, allowed them to reflect on their situation, and provide an assessment over their progress and changes since treatment *"from session to session you'd be talking about the same sort of things about. Again, 'how is it feeling? When were you getting the pains? What exercises have I been doing in the meantime? Whether any different, anything different? And anything else to report?' So you know it was a consistent, you felt like it was a process that I was… it felt like I was going through a process, not just one off sessions."* (Patient - Josef).

Chiropractors in the control group had previously used follow-up PROMs within their practice. They discussed the benefits for monitoring patients, *"sometimes patients feel there's always a positive benefit by somebody keeping another eye on them by having an automated email coming through. And checking up with them so it's almost like it's another consultation almost"* (Chiropractor – Petra). Both control group chiropractors highlighted needing to change their practice to monitor patients. "*It gave me anxiety, I think. Yeah, having something that you've used in the past and you find value in it and then not getting those results. So not seeing how a patients changed or not seeing within.. within those parameters and not also having that start point*" (Chiropractor – Elliott). However, chiropractors in the control group discussed patient improvement without using PROMs. *"I might kind of do the PROMs myself away from that system, but kinda just.. just work out what would be our expectation for treatment, what do they want to change. So, I kind of do a slimmed down version of a PROM.*" (Chiropractor – Petra).

9.3.5 Benefits of communication

Patients and chiropractors highlighted several benefits of good communication within their clinical encounters. This included patients making and maintaining lifestyle changes, building rapport and relationships between patients and chiropractors, and patients fostering positive views of their chiropractor. Although participants noted how PROMs made a contribution in these areas. Participants discussed the benefits of good communication from their overall clinical experience, rather than exclusively communication that was facilitated by PROMS.

Making and maintaining lifestyle changes

Patients discussed the advice they had received from their chiropractors regarding managing their pain. Several patients commented on being given exercises to do at home and continuing to do those exercises when no longer receiving care. These changes came from their discussions with chiropractors understanding their condition, and patients commented on the tailored nature of the advice: "*He just takes his time to try to understand your sort of lifestyle and then he was very keen as I was to sort of suggest ways that would actually help me in my day-to-day*" (Patient – Paul). Patients commented on the small changes they had made in their general lifestyle, following advice from chiropractors including sleep habits, posture, manual handling, stretches etc. One patient explained making minor changes to her routines in order to try and improve her health: *"just generally trying to.. be better"* (Patient – Patricia). The communication between patients and chiropractors, including their explanations was deemed helpful in making and maintaining behaviours to self-manage their health: "*Asking* [chiropractor]'s *kind of advice on... what the musculoskeletal kind of structure is of the problem that's going on. I think that's been really helpful for me understanding kind of the reasons why we do certain rehab exercises and kind of what's going on when we're doing the manipulation and stuff like that. Which kind of helps me.. when I'm doing the rehab*" (Patient – Michael). No patients directly commented on how PROMs helped them make and maintain lifestyle changes, however these lifestyle changes came from their interactions with chiropractors, of which PROMs were noted to have a role.

Building rapport and relationships

Patients felt that the relationship with their chiropractor was an important part of their care. They talked about having faith in their chiropractors and the treatment they received. This stemmed from their chiropractors seeming knowledgeable and the thorough questioning from PROMs and in their initial consultations. *"She's so thorough. She's so well prepared in terms of the knowledge that she gets out of me being before she lays a hand on me. And that's what I think.. it boils down to trust*" (Patient - Karolina). Patients felt reassured that chiropractors were taking information from PROMs into account, they felt safe with the chiropractor, knowing they have been listened to. Patients also felt that chiropractors showed empathy for their situation.

Chiropractors felt that rapport building was important for care. They also identified that PROMs could be used to build rapport with their patients by providing chiropractors with a better perspective of patients' beliefs about their condition. *"patients can see really clearly that I've identified you know how, how they're impacted by their symptoms. Sort of building up a relationship with the patient and trust on the part in patient, and I think it gives them a sense that I'm really trying to get to the bottom of their symptoms and to understand them."* (Chiropractor – Caroline). Other chiropractors talked about how PROMs could make patients feel more connected to them. Kristian felt that by using the information from PROMs and showing patients their progress this built patients' trust in the chiropractor and the treatment plan *"it's definitely going to reinforce that rapport, it showed that we are definitely a team working on the same page and the fact that I'm showing that data. I think does help them with the trust there*" (Chiropractor – Kristian).

Fostering positive views of practitioners

Patients were very positive about their chiropractors. They expressed a lot of gratitude to their chiropractors for helping them with their pain. This was especially noted when they compared visiting a chiropractor to previous treatment from other healthcare professionals. *"I found her about the best person I've ever been to."* (Patient – Margaret). Patients valued how clever, positive, and confident their chiropractor was. For example, Lisa felt very hopeless before visiting a chiropractor: "*you are in a bit of a despair because of the amount of pain that you're in.. that nobody can help you.*" she further noted the positive attitude and confidence of her chiropractor: *"when I went to see a chiropractor, they*

understood what I was talking about and said, right, we'll sort this out. We'll do this" (Patient – Lisa). The positive views of chiropractors was not explicitly linked to the use of PROMs, however was a consequence of good communication.

Patients commented on the professional approach of the chiropractors. *"I think she had a degree of professional pride about it. You know she certainly has got very professional approach."* (Patient – Lauren). Chiropractors felt PROMs showed a level of professionalism for their practice. *"It looks quite professional as well as it's a different factor. I think it gives them confidence that you're practicing and in a professional way, especially if they've been perhaps for patients who have been to other clinics previously, and not had anything like this."* (Chiropractor – Caroline). They felt the use of PROMs mirrored other part of healthcare practice, such as NHS services, and felt this may enhance the credibility of their practice from the patients' perspective. Patients respected their chiropractor and felt they would have treatment again "*if I found myself in that position again, I wouldn't hesitate to go back to him*" (Patient – William) and many had recommended their chiropractors to family and friends *"I couldn't sort of recommend him highly enough."* (Patient – Paul).

9.4 Discussion

This study aimed to explore the use of PROMs within specialist musculoskeletal care, through qualitative interviews with chiropractors and patients. Participants, irrespective of their use of PROMs within the RCT, felt that communication was beneficial for care and patient outcomes. PROMs were seen to be a valuable tool for patient-clinician communication which enhanced their interactions. Participants highlighted aspects of good communication, both with and without the use of PROMs.

9.4.1 PROMs as a communication tool

Communication was viewed as a key component of care alongside manual therapy techniques and provision of advice and exercises. Chiropractors felt it was important to carefully listen to patients' stories, taking time to fully understand their situation. Patients valued their interactions with chiropractors, deeming this an important part of treatment. They also felt positive about completing PROMs before their first treatment, feeling that chiropractors were thinking about them, and considering their issues before their initial appointment. Chiropractors saw PROMs as a potentially valuable tool to facilitate conversations with patients. Although chiropractors did not always explicitly use PROMs in their discussions with patients they were used as a springboard for conversations. As shown in Chapter 5, it is widely theorised that PROMs may have a role within communication, with previous models emphasising how PROMs influence patient-clinician interactions (Greenhalgh et al., 2017; Greenhalgh et al., 2005; Santana & Feeny, 2014).

9.4.2 Use of PROMs within patient-clinician interactions

PROMs provided chiropractors with an insight into how patients were feeling prior to their first appointment. Alongside their case and medical history taking, and physical examinations, PROMs were used to identify psychosocial factors and prognosis. This reflected findings from the theoretical review, suggesting PROMs can be used for individualised screening of patients, show undiagnosed problems, and provide accurate prediction of patients' conditions (Chapter 5). Higginson and Carr (2001) suggested that there are common complications or symptoms which may be associated with a patient's condition, such as depression, which may go undetected by clinicians unless clinicians

specifically enquire. PROMs can provide a sensitive and specific way to screen for conditions.

Patients valued the thorough questioning they received from chiropractors with PROMs also seen as thorough and an important part of their care. This conversation and information allowed chiropractors to provide advice and reassurance to patients. This is reflective of the literature identified in the theoretical review (Chapter 5) with PROMs theorised to influence clinicians to look at the whole person and focus on the individual's experience of illness and provide explanations and reassurance to patients, enhancing patient-centred care.

The findings of this study are also reflected in other specialist musculoskeletal settings. In qualitative interviews with 21 patients attending physiotherapy for musculoskeletal health concerns in Dutch primary care settings, patients felt PROMs were used in clinical practice to support their care (Meerhoff et al., 2019). This included increasing their awareness of their own health concern, stimulating conversations with physiotherapists, and the physiotherapists using PROMs to assist with diagnosis of conditions. Overall, they felt that PROMs helped discussion over their health concerns, with some patients feeling this contributed to more patient-centred care, with PROMs providing valuable information for tailoring treatment plans (Meerhoff et al., 2019).

Chiropractors in the current study noted that they used PROMs within formal reassessment of patients, to check the effectiveness of care and review the treatment plan, which is a formal requirement noted in their professional standards of conduct (General Chiropractic Council, 2016). Chiropractors also used PROMs to monitor patients outside of treatment sessions, or once they had stopped care. They acknowledged PROMs were beneficial with patients not always verbalising worsening of their condition. Chiropractors in the control group discussed improvements with their patients without using PROMs, although commented that they would have preferred to use PROMs for this purpose. Patients valued the monitoring of their condition and discussion of their treatment and care plan. They felt that PROMs allowed chiropractors to reflect on their improvement and potentially change treatment. This mirrors the results from the systematic review (Chapter 4) and theoretical review (Chapter 5), which suggested that PROMs provide the means to assess the effect of treatment, understand patients' progress and identify if the treatment plan is appropriate. This information assists clinicians' decisions surrounding changing treatment or

providing additional treatment to patients. PROMs also allow clinicians to see meaningful improvements from care from a patient's perspective and identify any negative reactions to treatment.

9.4.3 Outcomes of patient-centred communication

Both patients and chiropractors in all three treatment groups highlighted the benefits of good communication. Although these benefits were not necessarily all explicitly linked to PROMs, PROMs were seen as an effective tool for communication. Patients were very positive and flattering about their chiropractors. Previous research has shown patients with spinal pain and back pain have higher satisfaction of chiropractic care compared to sham treatment (Walker, Hebert, Stomski, Losco, & French, 2013), and compared to medical care (Hertzman-Miller et al., 2002). Participants noted how chiropractors came across as very knowledgeable and confident, with a positive attitude towards helping them with their condition. Patients commented on feeling safe with their chiropractor, respecting their treatment decisions. From the theoretical review (Chapter 5) the use of PROMs in clinical practice is suggested to improve patient satisfaction through communication, by including the patient's opinion, identifying patients' main concerns, and increasing patient's trust of the clinician (Fitzpatrick, 1997).

Patients felt that their relationship with their chiropractor was an important part of their care. This included building trust, feeling reassured, and perceiving empathy from the chiropractor. Chiropractors suggested PROMs could be used to build rapport. This reflects findings from the systematic review (Chapter 4) and theoretical review (Chapter 5). The establishment of a therapeutic relationship occurs through the formation of goals, collaboration between patient and clinician, and the clinician providing support and guidance to the patient (Cahill et al., 2008). By improving communication between patients and clinicians, PROMs have a role in goal setting, and provide a method to enhance clinicians' knowledge of key patient concerns. Further, maintenance of the relationship is suggested to be influenced by clinicians' responsiveness to patients' concerns, needs, and behaviours (Cahill et al., 2008). PROMs provide an opportunity for clinicians to monitor patients' health status and allow for this feedback to be used when communicating with patients.

9.4.4 Strengths and limitations

This qualitative study provides contextual understanding of the use of PROMs within specialist musculoskeletal care from patients' and chiropractors' perspectives. Patients described, in their own words, their experiences of visiting a chiropractor and those within the routine and intensive groups were able to discuss their experiences of completing PROMs. Using qualitative interviews allowed chiropractors to express important information about their use of PROMs within their clinical practice, especially those experiences that had not previously been considered by researchers.

This study aimed to explore the experiences of patients and chiropractors participating in the RCT. As qualitative research, this study did not seek to be generalisable to the wider population or even represent the views of all participants in the trial, but aimed to provide further explanation and provide a more detailed understanding to the general data provided by quantitative approaches (Creswell & Clark, 2011). However, purposive sampling ensured a wide range of views were included in the study. Out of the 54 patients and eight chiropractors invited to participate in an interview, only 15 patients, and seven chiropractors took part in an interview. It is not known why individuals chose not to participate in an interview. Trial participants who had a negative experience in the trial or with chiropractic treatment may have been less likely to engage in the research process. One solution to this would be to conduct interviews concurrently with the RCT data collection, however, this poses additional challenges such as patients' concerns with confidentiality, impact on patient adherence to interventions, and comprising intervention integrity (Cooper et al., 2014).

Several interviews took place during lockdown, (the national response to COVID-19) (UK Cabinet Office, 2020). Some of the participants talked about their pain and treatment in the context of COVID-19. A few participants talked about how they had not seen their chiropractor since the lockdown began or had wished to return to care but had not been able to return due to shielding as a result of other conditions (UK Cabinet Office, 2020). Chiropractors also discussed changes they had made to their practice resulting from new rules around social distancing and telehealth consultations. As qualitative research explores participants' views in context, it is natural and expected that some of their experiences are situated within the context of this global phenomenon.

With all qualitative research, it must be acknowledged there is a level of researcher influence over data collection, analysis, and interpretations. Within the interviews, there were no prior relationship to the patients in the study, however, I had met some of the chiropractors, when recruiting to the RCT and again when delivering training for the RCT. The interviews, coding and analysis were all conducted by someone who has experienced back pain and has received chiropractic care for back pain. Therefore, the interpretations will include some level of researcher prior experience. The researcher's previous experience of back pain and chiropractic care was not disclosed to patients or chiropractors. The interview guides were developed with careful language around the questions, so participants fully shared their views and experiences, in their own words, without considering researcher experience or interpretations.

This study used thematic analysis, following the steps set out in Braun and Clarke (Braun & Clarke, 2006, 2012; Braun et al., 2019). This is a rigorous approach to qualitative analysis, and the steps have been systematically set out in a transparent way (see section 9.2.4). This study used an inductive approach to coding, with codes and later themes being derived from the data, rather than from existing theories. By using inductive analysis, this increases confidence that the themes were valid interpretations of participants' experiences rather than derived from pre-existing concepts as noted in the PROMPT model. This is reflected in the themes, which include findings not explicitly about the use of PROMs but situated in the wider context of communication in clinical practice. Additionally, although some of the findings mirrored the results of the systematic review and theoretical review, this was purposefully not explored in this analysis, to ensure that findings were faithful to participants' accounts. Further exploration of the of the data, considering prior literature and quantitative findings, were kept separate and can be seen in Chapter 10.

9.5 Chapter summary

The themes derived from this qualitative analysis of patients and chiropractors supported previous literature on PROMs in the use of non-malignant pain. The findings reflected the use of PROMs as a communication tool across the treatment process as per the systematic review (Chapter 4). These qualitative findings were specific to patients with low back pain receiving specialist musculoskeletal care, which provided additional contextual insights. Including chiropractors and patients who did not use PROMs highlighted good parts of clinical practice and allowed identification of the elements of care patients value. These findings provide insight into how PROMs can be developed as a clinical practice tool to improve care. Chiropractors and patients' accounts were analysed separately to their quantitative data, however these are used in Chapter 10 alongside the quantitative data from the RCT (Chapter 7) and mediation analysis (Chapter 8) to form a mixed-methods process evaluation on PROM collection in specialist care for low back pain.

Chapter 10 The mechanisms of action when using PROMs in the treatment of low back pain: a mixed-methods process evaluation

10.1 Introduction

Previous research has focused on the impact of using PROMs for certain conditions; for example, utilisation of PROMs within cancer settings may improve communication and patient satisfaction (Chen et al., 2013; Luckett et al., 2009). However, there has been very little research in the context of low back pain and PROMs, with scant information known about the outcomes of utilising PROMs, or the mechanisms behind any clinical or psychosocial consequences.

Existing empirical (Chapter 4) and theoretical (Chapter 5) evidence suggests that PROMs may impact clinically and psychologically on patients when used in clinical practice for non-malignant pain. The RCT (Chapter 7) tested the effect of using different frequencies of PROMs on back pain-related disability for low back pain patients. Patients completed PROMs seven times (intensive PROMs), three times (routine PROMs), or not at all (control group) whilst receiving specialist musculoskeletal care. All three groups had a reduction in back pain-related disability, with no significant differences between the three groups; 72.4% of the intensive group, 46.2% of the routine group, and 63.2% of the control group had clinically significant reduced back pain-related disability after three months.

The mechanisms of PROMs were investigated using statistical modelling (Chapter 8), exploring how PROMs may impact back pain-related disability through the hypothesised pathways of the PROMPT model developed in Chapter 5 (coping appraisal, patient-clinician interaction, and threat appraisal). None of the three mediation models showed any significant indirect effects of completion of PROMs on back pain-related disability via proposed mechanisms; although this must be cautiously interpreted due to the low power to detect mediation effects.

Despite the RCT and statistical modelling analysis concluding that PROMs do not directly or indirectly impact back pain-related disability, in qualitative

interviews with low back pain patients and chiropractors (Chapter 9), PROMs were considered a valuable tool by both parties for patient-clinician communication. Patient-centred communication was also viewed by participants as a key component of patient care, influencing outcomes including changes to lifestyle, rapport between patients and chiropractors, and patients fostering positive views of their chiropractor.

This chapter reports a mixed-methods process evaluation which aims to understand the processes by which an intervention functions, by examining its context, mechanisms, and outcomes (Moore et al., 2015). A mixed-methods approach, combining the quantitative and qualitative data, produces a more comprehensive picture of the research problem, identifying and exploring any complementary and discrepant findings (Brannen, 2008; Creswell & Clark, 2011). This study aimed to integrate the results of the RCT (Chapter 7), statistical modelling (Chapter 8), and qualitative interviews (Chapter 9), to gain a more complete picture of the outcomes and mechanisms of using PROMs in specialist musculoskeletal care.

An essential part of evaluating interventions is exploring intervention delivery, as intervention fidelity may mediate impact on patient outcomes (Hasson, 2015; Moore et al., 2015). Intervention fidelity is defined as *"the extent to which an intervention was delivered as planned"* (Steckler & Linnan, 2002, p. 12). From the theoretical review (Chapter 5), two conditions thought to be necessary for PROMs to impact health outcomes. As PROMs are theorised to formalise the process for acquiring relevant information from patients and as a mechanism to enhance communication (Greenhalgh et al., 2017; Greenhalgh et al., 2005; Santana & Feeny, 2014), PROMs should be discussed within the first session to establish and improve therapeutic alliance, and continue to be discussed by clinicians throughout the patients' care (Catarinella & Bos, 2016; Jongen et al., 2013; Lalloo et al., 2014). With PROMs hypothesised to have an effect throughout the patients' treatment (Chapter 4), patients should complete PROMs throughout their care, and not just as a baseline assessment or at the end of care for audit purposes. Within this process evaluation, it is necessary to explore intervention fidelity, to note whether PROMs were used by patients and chiropractors as intended and how this may influence outcomes.

This chapter considers the wider context of utilising PROMs including: intervention design, quality of delivery, receipt of intervention, training, frequency, and duration of delivery (Moore et al., 2015), rather than solely focusing on intervention fidelity. Literature suggests there are several barriers to successful utilisation of PROMs, including the selection of PROMs (being clinically relevant to patients and clinicians), clinician knowledge and engagement (clinicians' willingness and confidence to use PROMs), and practical barriers such as technology and administrative workflow (Chang, 2007; Duncan & Murray, 2012; Snyder et al., 2012). Exploring how PROMs are used by patients and chiropractors may identify barriers to use of PROMs in specialist musculoskeletal care.

The aims of this study were to understand the processes of utilising PROMs, by examining the context, mechanisms, and outcomes of using PROMs. By utilising a mixed-methods approach, the qualitative data provided further explanation and a more detailed understanding to the general data provided by the quantitative approaches (Creswell & Clark, 2011).

The objectives of this study were to:

1. Explore the clinical and psychosocial effects of employing PROMs.
2. Identify any unintended consequences of PROMs.
3. Assess administration and use of PROMs in specialist musculoskeletal care including intervention fidelity.
4. Identify contextual mechanisms that might moderate outcomes.

10.2 Methods

This study used the quantitative data from the RCT (Chapter 7), and mediation analysis (Chapter 8), and data from the qualitative interviews (Chapter 9). A summary of the individual study components is discussed in Section 10.2.1, with an overview of data collection and analysis procedures to provide context for this mixed-methods study.

10.2.1 Overview of individual study chapters

The studies reported in Chapters 7, 8, and 9 followed a sequential explanatory study design with the RCT conducted first, followed by qualitative interviews (Creswell & Clark, 2011). The study design is depicted in Figure 10.1.

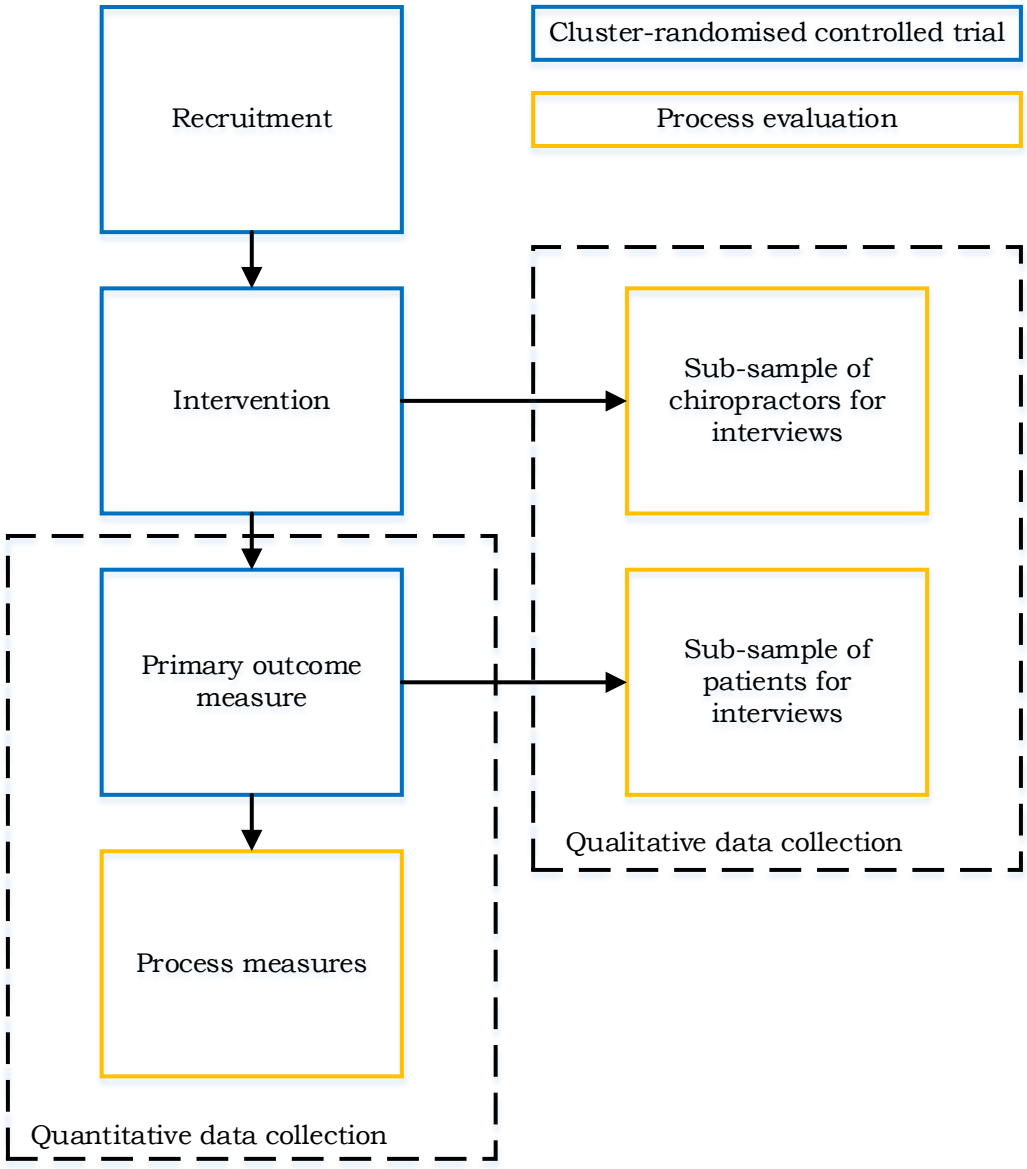


Figure 10.1 – Study design

Participants

Eight chiropractors took part in the RCT (Chapter 7). Following recruitment of chiropractors, a consecutive sample of patients consulting each participating chiropractor were recruited (see Section 7.2.2). Patients booking with recruited chiropractors were screened for inclusion into the study using the online software Care Response. For inclusion into the study, patients had to be at least 16 years old, speak and read English fluently, be a private patient presenting to the musculoskeletal clinic, with self-reported low back pain. The RCT recruited 158 participants to the study, 80 participants (50.6%) completed the study follow-up. Following the RCT, all chiropractors were invited to participate in a qualitative interview, with seven choosing to participate. Purposive sampling was used to recruit participants from the routine PROMs and intensive PROMs groups who showed improvements and no improvement in back pain-related disability to participate in a qualitative interview. Patients from the control group were also invited to participate, to provide a comparison of their experience of care without the use of PROMs. In total, 54 patients from the trial were invited for an interview, with 15 interviews conducted with patients.

Quantitative data collection and analysis

Quantitative patient-reported data was collected through Care Response. Demographic data was collected at baseline, including age, gender, presenting condition, length of complaint, additional pain complaints, and STarT Back categorisation. The primary outcome measure for the RCT was back pain-related disability, measured with the Roland-Morris Questionnaire. HRQoL was a secondary outcome, measured with the EQ-5D thermometer. Primary and secondary outcome measures were completed at baseline and repeated along with psychosocial process measures 90 days after their first appointment. The specific process measures of interest were: pain-related fear (PASS-20), pain catastrophising (CSQ-CAT), fear-avoidance behaviours (FABPA), self-efficacy for self-management (PSE), self-management behaviours (PSOCQ), treatment perceptions (LBP-TBQ), patient-centered communication (PPPCQ), therapeutic alliance (WAI_SR), and patient satisfaction. For full details on the process measures and their psychometric properties see Section 8.2.3.

All quantitative data collected was input into the statistical software SPSS (version 26) (IBM Corp, 2012). With the RCT, descriptive statistics and frequencies were run on the data to summarise patient characteristics. A series of ANOVAs were conducted to test for the effects of time and group on back pain-related disability (see section 7.2.5), a chi-square was used to examine any differences in those who improved compared with those who did not. Further data analysis on process measures were conducted by examining differences between those who completed PROMs and those who did not (Chapter 8). Multiple mediation was conducted in the PROCESS macro of SPSS (Hayes, 2012), to explore how completion of PROMs affects back pain-related disability, through the psychosocial process measures (see section 8.2.4).

Qualitative data collection and analysis

Following participants' completion of primary, secondary, and process measures 90 days after their first appointment, semi-structured interviews were conducted with a sub-sample of chiropractors and patients via telephone (see section 9.2.3 for the full process). Interview guides comprised open-ended questions and prompts to explore chiropractors' and patients' experiences of using PROMs and their views on how PROMs might influence health (see Appendix Q for interview guides). Interviews were audio-recorded and transcribed verbatim.

Data from the qualitative interviews (Chapter 9) was inputted into computer-assisted qualitative software NVivo (version 12) (QSR International, 2010). The qualitative data was analysed using thematic analysis (Braun & Clarke, 2006, 2012; Braun et al., 2019). See section 9.2.4 for full details of qualitative coding and analysis.

10.2.2 Supplementary data collection

Additional to the data collected for the studies reported in Chapters 7-9, there was a unique data collection process for this study. To assess intervention fidelity, patients' completion of PROMs was collected through Care Response. Patients were also asked an additional question at the end of the process measures 'Did you and your chiropractor discuss the questionnaires that you filled in online before, during and after your treatment?'. The item was scored on a seven-point scale from 1= 'never' to 7 = 'always'.

10.2.3 Data analysis

An overview of the data analysis steps for this study can be seen in Figure 10.2. This depicts the individual study components and how they relate to this current study analysis.

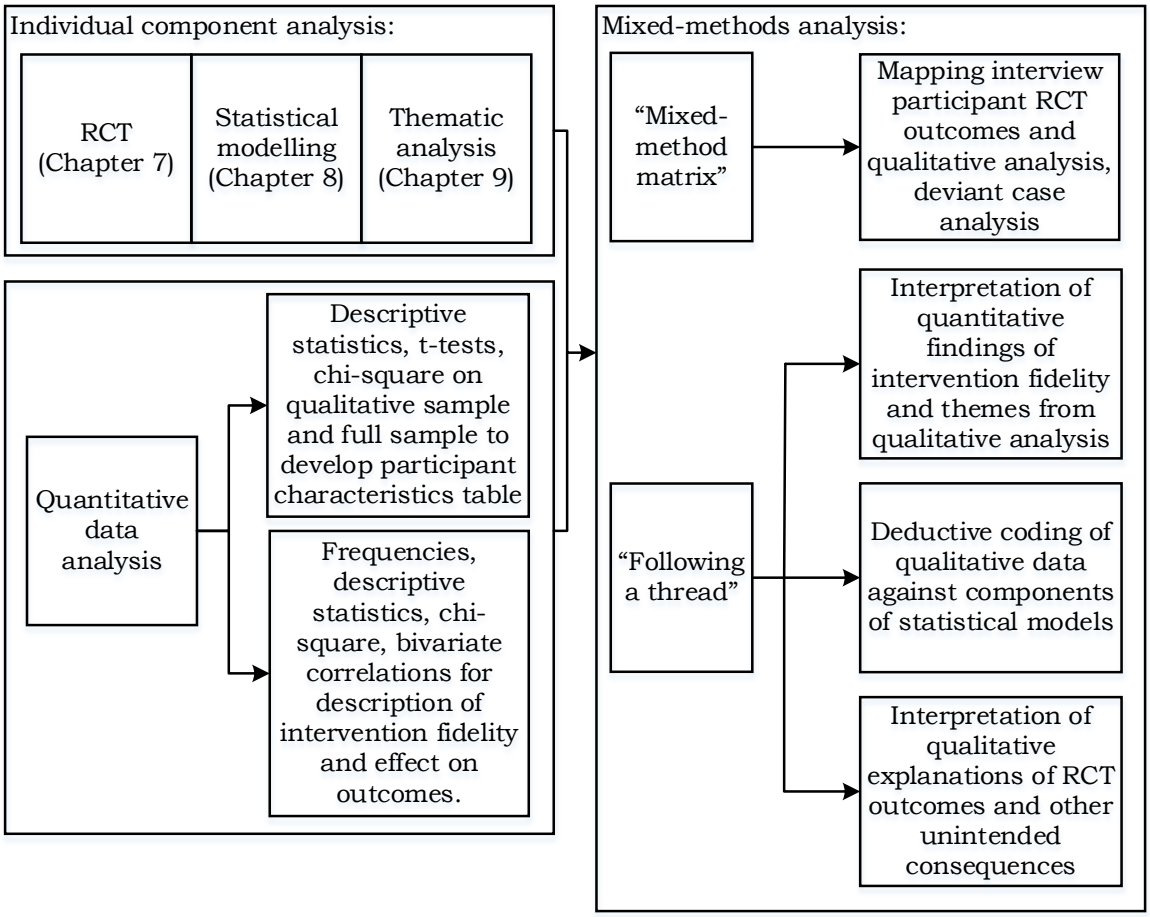


Figure 10.2 – Data analysis steps and outcomes

Quantitative data analysis

Descriptive statistics and frequencies were run on the data to compare patient characteristics of those who took part in an interview compared to the rest of the sample using the statistical software SPSS (version 26) (IBM Corp, 2012). Significant differences between the two samples were examined with t-tests and chi-square analyses to see if the patients interviewed were representative of the full RCT sample. Hedges' g was calculated alongside the t-test statistic using an online calculator (www.socscistatistics.com), as a measure of effect size accounting for different sample sizes (Lakens, 2013).

To assess intervention fidelity, descriptive statistics were conducted exploring patients' completion of PROMs and discussion of PROMs between

patients and chiropractors. T-tests were used to identify any significant differences between the intensive and routine groups. Bivariate correlations were examined, using Pearson's correlation coefficient and bias corrected accelerated (BCa) 95% confidence intervals, to analyse the relationship between completion of PROMs, discussion of PROMs, and back pain-related disability.

Mixed-methods analysis

Integration of qualitative and quantitative data requires transforming the data, and for this two techniques were used: 'mixed-methods matrix' and 'following a thread' (O'Cathain, Murphy, & Nicholl, 2010). A 'mixed-methods matrix' approach was used for objectives: 1) to explore the clinical and psychosocial effects of employing PROMs, and 2) to identify any unintended consequences of PROMs. A 'mixed-methods matrix' is a within-case analysis, which explores individual participants' experiences, by examining their quantitative and qualitative data (O'Cathain et al., 2010). Participants of the interviews were mapped against whether they had received PROMs and their levels of improvement in the RCT based on changes on the Roland-Morris Questionnaire. This was then used to examine the qualitative findings, and identify any patterns between the experiences of patients who had an improvement and those who did not, and highlight convergent and divergent findings (Creswell & Clark, 2011). Qualitative findings were interrogated to explain the statistical findings of the RCT, and deviant case analysis was used to identify examples which did not conform to the patterns identified (Silverman, 2016).

As well as examining the individual cases, a 'following a thread' approach was taken to develop themes between the statistical findings and the themes of the qualitative study, in relation to patient outcomes. The 'following a thread' technique begins after the analysis of separate study components, by identifying areas which require further explanation to be explored across the multiple components (O'Cathain et al., 2010). This approach was also used for objectives 3) assess administration and use of PROMs in specialist musculoskeletal care, and 4) identify contextual mechanisms that might moderate outcomes. The intervention fidelity statistics were analysed, with the results of the qualitative analysis then explored to consider issues of utilisation of PROMs and intervention fidelity (Creswell & Clark, 2011). To identify contextual mechanisms that might moderate outcomes, the thematic analysis of chiropractors' and patients' experiences of using PROMs were compared to the statistical analysis in

Chapter 8. Deductive coding was used to identify patients' experiences in relation to the mediation models (see Figures 8.1, 8.2, and 8.4). The codes and themes generated from the earlier thematic analysis were coded as the quantitative concepts measured as part of the mediation analysis. This allowed for merging of the two datasets and displaying of the themes in relation to the quantitative statistical results, to explore how the qualitative analysis could help explain the underlying mechanisms of PROMs (Creswell & Clark, 2011).

10.3 Results

10.3.1 Participants

Table 10.1 presents the baseline characteristics of the participants in this study. Participants had a mean age of 45.13 (SD = 16.92) with an age range of 16-82, 55.0% (44) were female. As noted in the RCT (Section 7.3.2), there were no significant differences in the follow-up sample and those who did not complete follow-up in terms of age, gender, other pain, length of complaint, recurring problem, however, there were significant differences in baseline scores on the STarT Back tool, with those categorised as low risk more likely to drop out.

Baseline differences between participants who participated in an interview and those who did not can be seen in Table 10.1. There were no significant differences in those who participated in an interview and those who did not in terms of age, gender, other pain, length of complaint, and recurring problem.

Table 10.1 – Characteristics of those who completed interviews and those who did not

	Participants who participated in an interview (n = 15)	**Participants who did not participate in an interview (n = 65)**	**All participants (n = 80)**	**p-value of chi-squared test/t-test for difference**
Age				
mean (SD)	45.00 (16.66)	45.15 (17.11)	45.13 (16.92)	t (78) = 0.03 p = 0.975, *g* = 0.009
Gender				
Female - n (%)	8 (53.3%)	36 (55.4%)	44 (55.0%)	x^2 (1) = 0.04 p= 0.838
Other pain				
n (%)	8 (53.3%)	47 (72.3%)	55 (68.8%)	x^2 (1) = 2.04 p = 0.153
Length of complaint				
<3 months n (%) 3-12 months n (%) 1-2 years n (%) >2 years n (%)	8 (53.3%) 3 (20.0%) 2 (13.3%) 2 (13.3%)	17 (26.2%) 15 (23.1%) 11 (16.9%) 22 (33.8%)	25 (31.3%) 18 (22.5%) 13 (16.3%) 24 (30.0%)	x^2 (3) = 4.74 p = 0.192
Pain over 30 days				
n (%)	7 (46.7%)	47 (72.3%)	54 (67.5%)	x^2 (1) = 3.65 p = 0.056

	Participants who participated in an interview (n = 15)	Participants who did not participate in an interview (n = 65)	All participants (n = 80)	p-value of chi-squared test/t-test for difference
Recurring problem				
n (%)	10 (66.7%)	35 (53.8%)	45 (56.3%)	x^2 (1) = 0.81 p = 0.367
STarT Back				
Low n (%) Medium n (%) High n (%)	7 (46.7%) 6 (40.0%) 2 (13.3%)	25 (38.5%) 25 (38.5%) 15 (23.1%)	32 (40.0%) 31 (38.8%) 17 (21.3%)	x^2 (2) = 0.76 p = 0.685

Significance level: * = p < 0.05

10.3.2 Context

Administration of PROMs by chiropractors

The study received 372 expressions of interest from chiropractors. However, only 25 chiropractors consented to participate. Sixteen chiropractors responded to initial correspondence regarding the study procedures. However, only ten chiropractors further enrolled to participate in the study, and only eight chiropractors recruited patients into the study and collected data. The number of chiropractors in the study reduced with every step towards recruitment, suggesting that although chiropractors showed an interest, there was a reluctance to employ PROMs into their practice. Chiropractors suggested to ensure successful utilisation and engagement with PROMs: *"making sure that it's absolutely, stupidly easy to use. Really, really simple. Really easy to implement"* (Chiropractor – Mary).

Some chiropractors felt that administration and use of PROMs via Care Response in their clinical practice was easy, because it was automatic and embedded within their clinical procedures. Several chiropractors had reception staff involvement, which significantly helped the process "*the front desk just input the data and it's sent off, and then you know the repeat sessions are done automatically and all I have to do is log in to see the current results. It's just really easy to do that."* (Chiropractor - Kristian). Some chiropractors also talked about training their reception staff to assist with the process *"a lot of clinics say 'I'd like to do these things but I don't have time for it'. Whereas, I said to people 'if you train your staff up to do it, it's not a lot of work'"* (Chiropractor – Peter).

However, other chiropractors commented there was a lot of admin involved when using PROMs in their practice *"it's not the easiest thing to do because the system is all separate, from everything else that we run, so it's a little bit laborious*" (Chiropractor – Caroline). They felt that for PROMs to be successful in their clinical practice they needed to change their routines. For example, chiropractor Tobias commented on the difficulties he had when using PROMs: *"this new thing you do, which is. You know.. it's checking your care response and discussing that on the appropriate sessions, and I think I just.. just failed to kind of secure itself and lock itself into my habit*". Overall, those who were using a paper-based note system or had no reception staff felt there was more admin involved.

Chiropractors also commented on the choice of PROM software, with some finding Care Response complex to use *"I think it's a clunky website if you ask me. I think it looks old and dated and it could do with refreshing and I find it a little confusing in places. And I'm quite tech savvy*." (Chiropractor – Tobias). Many felt that for ease PROMs should be integrated into existing clinic software, with patient electronic health records, appointments, and note-taking. They felt this would enable them to more proactively use PROMs: *"I'd love to get some kind of integration with clinic software. So, you are not having to input stuff twice*" (Chiropractor – Kristian).

Chiropractors also noted in their everyday practice, they had the additional challenge of identifying appropriate PROMs, highlighting the difficulty of balancing the clinical needs and validity of questionnaires "*guess it's a fine balance between having a 100 question questionnaire which is going to be more rigorous and more... more sensitive versus the patient can't be arsed to fill it out.*" (Chiropractor – Mary). Within the trial, chiropractors were asked to use the MSK-HQ (Hill et al., 2016), and overall chiropractors commented positively about the choice of PROM: *"I think the MSK-HQ, well there's definitely more detail, there's more sort of sort of bullet points and explanation, description of the effects in each construct on the patient, so they* [patients] *liked like that."* (Chiropractor – Caroline) and felt it was a useful tool compared to others. *"we usually use the Bournemouth questionnaire with Care Response, and I just like getting that greater depth of it* [in the MSK-HQ]. *I like the idea of it, kind of giving an more overall score, so it's not just about their current issue, you know, it's kind of, it's kind of giving a more well-rounded picture of their MSK health, which is quite a nice starting point"* (Chiropractor – Kristian).

In summary, chiropractors felt that administering and using PROMs in their clinical practice had to be simple. Chiropractors who had used PROM

software previously and those with reception staff support felt that PROMs were easy to use. However, employing PROMs was more complex and burdensome for those who needed to change administration processes. Chiropractors also had recommendations for improving the PROM software and of PROMs selection.

Intervention fidelity – patient completion of PROMs

Completion of PROMs was analysed for all participants who consented to take part in the study (n=158). Within the routine group only three out of 25 participants (12.0%) completed all three PROMs, within the intensive group, six out of 64 participants completed all seven PROMs (9.4%). Despite the intensive group being asked to complete more PROMs and more frequently, the mean completion rates of PROMs was not significantly different between the routine group (M = 54.7%, SD = 23.34) and the intensive group (M = 51.7%, SD = 29.03), t (87) = 0.45, p = 0.651.

However, there was a significant difference in mean completion rates of PROMs (t (87) = -0.39, p <.001), with participants who did not complete follow-up completing less PROMs (M = 42.7%, SD = 25.06) than those who completed follow-up (M = 63.6%, SD = 25.99). For those participants who completed follow-up, the mean completion rates of PROMs were not significantly different between those in the routine group (M = 53.9%, SD = 21.68) and the intensive group (M = 68.0%, SD 26.90), t (40) = -1.66, (p = 0.104). The number of PROMs completed (using mean completion rates) was not significantly correlated with back pain-related disability 90 days after patients' first appointment, r (40) = 0.07 BCa CI [-0.24, 0.31], p = 0.656.

In summary, patients who completed the follow-up completed more PROMs than those who dropped out, but there was no difference in mean completion rates between the routine and intensive group, despite the intensive group being asked to complete more PROMs. Completion of PROMs was also not correlated with back pain-related disability after treatment.

The qualitative data can help explain the quantitative findings, with considerable variation in intervention fidelity among patients. Within the qualitative interviews, participants explained the reasons why they chose to complete PROMs. Patient Josef felt that PROMs were a part of his care*: "I just remember thinking well if this is helping him to help me then I'm more than happy to carry on*". In contrast to the chiropractors' side of the process, patients found PROMs easy: "*They didn't take long to fill in and were quite relevant*" (Patient –

Lauren). Participants who took part in an interview on average completed 58% of PROMs. When considering why they did not complete PROMs, one person felt the PROMs were long-winded and another felt it was not appropriate to complete seven PROMs when only receiving one treatment. Although happy to complete the PROMs, some patients simply forgot about the measures, for example patient Karolina felt PROMs were simple *"They've been really easy. They've been emailed to me. It's been really clear, easy to fill in, easy to send back. No problem at all*" but when questioned on why she had not completed them all, stated: *"Oh gosh, it just slipped my mind".*

Chiropractors noted that the high intensity PROMs were not necessarily clinically useful: "*certainly with some cases everything wasn't a lot of utility in getting it like a couple of times a week for me. 'cause I wasn't looking to see the scores necessarily change that rapidly"* (Chiropractor –Kristian). Chiropractor Caroline also noted that the high intensity PROMs were not as useful as receiving fewer PROMs over the same time period: "*It's harder to see the changes and highlight them 'cause it might be quite small from week to week, so I still end up looking back at the original one".*

Chiropractors felt that not many of their patients completed PROMs, and voiced concerns that patients get too many emails from them which might have a negative impact on patient views' of their practice. Chiropractors also felt that patients could get exhausted about talking about their problems: *"I look into the reasons why they have not done it, and a lot of people they feel they haven't got time, or if they're either getting worse than they're too busy telling me about the fact that getting worse they don't want to spend their time filling in another form. A lot of people just.. just ignore it, really*" (Chiropractor – Petra). Chiropractors felt patients need to be educated about why they are asked to complete PROMs, and this would improve compliance: "*we aim to prompt the patients beforehand and also the receptionists as well when they're taking their email… the receptionist we've trained them to educate the patients… 'so you will receive an email. It's about your care, just to make sure that we can monitor your outcomes as well'"* (Chiropractor – Peter).

Overall, patients completed about half of their PROMs. Although chiropractors had concerns about asking patients to complete PROMs, patients found them easy to complete and a part of their care. However, chiropractors felt that high intensity PROMs were not clinically useful to their practice.

Intervention fidelity – discussion of PROMs

Patients were asked to rate how often their chiropractors discussed the PROMs they completed. Chiropractors in the routine and intensive group were asked to discuss PROMs at every visit with their patient. Patient-reported discussion of PROMs was not significantly different between the routine group (M = 4.46, SD = 1.56) and intensive group (M = 4.11, SD = 1.97), t (39) = 0.57, p = 0.572. Most participants in the routine group reported that they 'often' discussed PROMs with their practitioner, whereas the intensive group reported only 'sometimes' discussing the PROMs. As expected, the control group commonly reported 'never' discussing PROMs with their chiropractors. Discussion of PROMs was also not significantly correlated with back pain-related disability, r (77) = 0.03 BCa CI [-0.17, 0.24], p = 0.766.

The qualitative interviews can help provide further context to the quantitative data, noting examples of discussing PROMs and identifying where PROMs were not discussed. Some patients said their chiropractors did not discuss PROMs, however, others said they did: *"She sent me one about a week, a few days before my appointment was and I filled the one in and sent it to her before I went to see her. So we went through that at, you know, quite some length that in the first day I saw her."* (Patient – Margaret). Chiropractors felt they used PROMs within consultations and when communicating with patients, but did not discuss them explicitly with their patients. *"I would kind of get a general idea looking before were some of the issues might be, if there were any potential, you know, yellow flags or things like that. And then I would kind of just try and bring that into the consultation, try to ask around those subjects. I didn't often do it explicitly"* (Chiropractor – Kristian).

Some chiropractors said they did not look at the specific aspects of PROMs *"I wasn't going through every single question every time necessarily. But it's quite nice to get a snapshot*" (Chiropractor – Kristian), and were too busy to look at the detail of patients' responses. For example, Tobias identified the difficulties in balancing his time in the clinic: "*I don't necessarily prepare in advance for each session with every patient. You know.. I'm coming in. I've got full afternoon and sometimes I've only skimmed through the last sessions notes in advance of this patient. Uhm, just before they come in"*. He felt he did not have time to go looking for the information to discuss it with patients: *"I am not necessarily inherently lazy, but I am definitely too busy to do that."* (Chiropractor – Tobias).

Despite their patients not being sent PROMs, chiropractors in the control group asked additional questions similar to PROMs as part of the routine clinical practice. *"I mean, I still asked them in their review. I still ask them the PGIC* [Patient Global Impression of Change*]. 'Overall, rate your improvement' sort of maybe not specifically the wording of the PGIC. So I'm not if it's like invalidated or anything but just I'll get a global overall impression of how they've been.. their improvement"* (Chiropractor – Elliott).

In summary, although the chiropractors in the intervention groups were asked to discuss the PROMs, patients noted that chiropractors did not always do so. However, chiropractors felt they did discuss the responses, although not explicitly. Chiropractors in the control group were asked not to complete PROMs, however they asked ad hoc questions about improvement.

10.3.3 Outcomes

As previously reported in Chapter 7, the RCT found no significant differences in back pain-related disability or HRQoL at follow-up between the three groups, although this may be due to a lack of statistical power. Table 10.2 summarises the changes between those who completed PROMs (intensive and routine group combined) and those who did not complete PROMs (control group). There were no significant differences in follow-up back pain-related disability between those who completed PROMs compared to those who did not (t (78) = 0.04, p = 0.970). There were also no significant differences in HRQoL after treatment between those who completed PROMs and those who did not (t (78) = 0.004, p = 0.997). Overall, there was no significant difference in patient numbers in those who improved after treatment (x^2 (1) = 0.21, p = 0.647).

Table 10.2 – Back pain-related disability, health-related quality of life, and overall improvement at follow-up

Back-pain related disability and overall improvement measured by Roland-Morris questionnaire [0-24], health-related quality of life measured by EQ-5D thermometer [0-100].

	Completed PROMs (n = 42)	**Did not complete PROMs (n = 38)**
Back pain-related disability		
Baseline mean (SD) Follow-up mean (SD)	7.26 (5.55) 3.38 (5.01)	7.84 (6.08) 3.42 (4.60)
HRQoL		
Baseline mean (SD) Follow-up mean (SD)	68.93 (21.15) 73.69 (23.92)	62.95 (23.02) 73.71 (23.51)
Improvement		
Improved (n) No improvement (n)	27 15	24 14

The qualitative interviews explored patients' experiences of seeing a chiropractor, adding to the quantitative data. All patients interviewed discussed their pain before they saw their chiropractor. This included severe incidents such as passing out because of pain, and an ambulance being called out, *"I did something into my back and couldn't move for a couple of days"* (Patient - Stefanie) to maintenance care and *"regular check-ups with the chiropractor"* (Patient - Paul). From the subset of participants who took part in a qualitative interview (n = 15), 11 had an improvement in back pain-related disability (see Table 10.3). Despite this, all four patients with no improvement in back pain-related disability, described having experienced some kind of pain relief: *"it helped a lot."* (Patient – Patricia), "*did help to be honest, unbelievably*" (Patient - Andreas). Two patients who did not show improvement on the Roland-Morris questionnaire felt their conditions had completely resolved: "*I don't have issues anymore."* (Patient – Jessica), *"Like it made a huge difference and I haven't had any problems since my.. I had five sessions with him. I haven't had a problem since then."* (Patient – Hamish). This suggests that quantitative scores may not completely capture patient improvement.

Table 10.3 – Summary of qualitative interview participants and improvement of back pain-related disability
Improvement in back pain-related disability measured by the Roland-Morris Questionnaire

	Improvement in back pain-related disability	**No improvement in back pain-related disability**
Completed PROMs	• Lauren (25, < 3 months back pain) • Karolina (39, 1-2 years back pain), • Margaret (75, <3 months back pain), • Thomas (56, < 3 months back pain), • Stefanie (33, < 3 months back pain), • Michael (27, >2 years back pain), • Richard (58, < 3 months back pain), • Josef (54, 1-2 years back pain)	• Patricia (68, > 2 years back pain), • Jessica (26, 3-12 months back pain)
Did not complete PROMs	• Amanda (38, 3-12 months back pain) • Paul (46, < 3 months back pain) • Lisa (57, < 3 months back pain)	• Hamish (21, 3-12 months back pain) • Andreas (52, < 3 months back pain)

Conversely, two patients who had significant reductions in their back pain, identified ongoing symptoms: "*It feels at the moment like there's not been a massive improvement because I'm not able to sit in chairs for more than 10 minutes and occasionally when I bend down the lower back does still flare up as well. So. I mean, as I say we've changed the routine now. But yeah, I was feeling quite positive about it before and I'm feeling less positive about it now.*" (Patient – Michael). One patient reduced by 14 points on the Roland-Morris questionnaire, however, commented on lasting symptoms of back pain after care: "*I'm not in that much pain that I have to take any painkillers anymore. It's just the discomfort now*" (Patient – Lisa).

The statistical modelling in Chapter 8 also explored patient satisfaction between groups. Overall, when comparing those who completed PROMs to those who did not, there was a significant difference (t (66), = 2.29, p = .03) in patient satisfaction, with patients in the control group having higher levels of patient satisfaction (M = 6.76, SD = .63) than those in intervention groups (M = 6.32, SD = 1.06). In the qualitative interviews, those in all three intervention groups talked positively about their chiropractor and the treatment they received. Patient Richard, from the intensive group, commented: *"I think he seems to be good enough at doing his job".* Patients Karolina (routine group) and Amanda (control group) were highly complimentary of their chiropractors and the care they received: *"she was recommended and has been a joy. Has been brilliant"* (Patient – Karolina), *"he was just like a magical wizard. It was amazing"* (Patient – Amanda).

The qualitative data also provided insights into the additional impact of PROMs that were not captured by the primary outcome measures in the quantitative components of the RCT. Within the qualitative interviews, patients also discussed changes in their lifestyle and management of their pain stemming from their care, including integrating rehabilitative and regular exercises into their routines. For example, Patient Paul highlighted the changes he made to manage his pain: *"Just some general stretching exercises every morning, etc. So I've kept them up as best as I can*" (Patient – Paul).

No quantitative data was collected on the benefit of PROMs for chiropractors, however, within the qualitative interviews, chiropractors also noted the wider benefits of using PROMs beyond individual patient care. Chiropractor Mary summarised the benefits of PROMs: *"it works at all levels say the doctor patient interaction on the one to one level, your clinic level, you know your reputation, your professionalism, the patient's perspective of what you do,*

and GP healthcare perspectives of what you do. And also from a business point of view". Several chiropractors commented on using PROMs to improve their overall practice, identifying areas for improvement. For example, Tobias felt that PROMs allowed him to reflect and question assumptions of his practice: *"it made me reflect on my part on my practice and see the areas that maybe I want... may want to be better at*". Chiropractors noted that collecting PROMs provided validity and credibility for their practice, both advertising to patients, but also as part of the wider healthcare community. *"I found them* [PROMs] *really good when contacting GPs. So normally when I sent them a letter, I'll send them a copy, of their outcome measures"* (Peter). Chiropractors also believed that collecting PROMs in routine practice helped the chiropractic profession to understand patient outcomes on a large scale *"I think that globally collecting data to show positive outcomes is really helpful for be able for being able to communicate that to other health care professionals"* (Chiropractor - Petra). However, it was noted that this required certain level of utilisation and adherence, consistent use *"you need to have clinicians using it correctly to be using that big data*" (Chiropractor - Mary).

10.3.4 Mechanisms

Patient-centred communication

During the qualitative interviews (Chapter 9) both patients and chiropractors highlighted communication as a key component of care. Although chiropractors saw PROMs as a communication tool, not all chiropractors used them as an explicit part of their practice, and many felt they had other skills for discussions with patients. The qualitative thematic analysis suggested that good communication could enhance patients' ability to make and maintain lifestyle changes to self-manage their pain, enable patients to build rapport and relationships with their chiropractors, and lead to patients fostering positive views of their practitioners.

Within Chapter 8, two mediator models included patient-centred communication as a mediator between PROMs to predict back pain-related disability (See Figures 8.1 and 8.2). Although neither had a significant total-effect, there were significant direct effects between mediators in the model, mirroring the findings of the qualitative interviews. Patient-centred communication predicted positive treatment beliefs, and self-efficacy for self-management. Positive treatment beliefs about chiropractic care for their back pain and high scores of self-efficacy for self-management also predicted positive

self-management behaviours. Patient-centred communication also predicted patients' therapeutic alliance with their chiropractor. Therapeutic alliance was found to have a positive direct effect on patient satisfaction and reduce back pain-related disability.

These quantitative findings were also reflected within the qualitative interviews, with patients highlighting how much they valued good communication. This was reflected in patients' praise of the chiropractors and relationships they had fostered with them: *"She definitely gave me the feeling anyway that I really mattered as the patient. That going to get to the bottom of this if she possibly could*" (Patient – Lauren). Their experience of patient-centred discussions and clinicians attempting to understanding their illness, led patients to build trust and rapport with their chiropractors. "*I just got the idea that she knew what she was doing and that I was in safe hands. She was very thorough. Her questions are very clever. And she pins information together well."* (Patient - Karolina).

Chiropractors also acknowledged the importance of communication, and how thorough questioning and making sure patients felt heard and understood, was important for building a relationship with their patients: *"patients can see really clearly that I've identified, you know, how they're impacted by their symptoms"* (Chiropractor - Caroline). Patients discussed their relationship with the chiropractor, reflecting on how much a difference their chiropractor had made on their pain and life. Overall patients showed gratitude to their chiropractors, and impressed with the level of care they received: "*you are in a bit of a despair because of the amount of pain that you're in.. that nobody can help you. And then when I went to see* [chiropractor]*, there is light at the end of the tunnel, so to speak"* (Patient - Lisa).

Patient Margaret discussed her relationship with her chiropractor and how she felt listened to within her treatment sessions "*I find her a very pleasant person as well. She's a very nice. You know she's a very pleasant person to talk to and she'll sit there and listen exactly what you've got to say*." Margaret also highlighted the value of communication within her care: "*I think the important part is having somebody to listen to you and be able to do something to help you*."

Patients reflected on the information chiropractors provided to them within consultations, they felt their explanations and associated discussions provided them with confidence in the treatment: "*he seemed to identify it very quickly and understood where I was coming from. And yeah, that gave me huge*

confidence that it.. what would work" (Patient - Hamish). For example, Patient Paul felt listened to by his chiropractor including his expectations from treatment, which led to conversations on how to make lifestyle changes in order to manage his pain "*He just takes his time to try to understand your sort of lifestyle and then he was very keen as I was to sort of suggest ways that would actually help me in my day-to-day and not anything that's really sort of obtrusive*."

Pain-related fear

Within Chapter 8, a multiple mediation analysis was conducted exploring the relationship between completion of PROMs and back pain-related disability, including mediators of pain-related fear, fear-avoidance beliefs, and pain catastrophising. The overall model was significant $F(5, 73) = 16.90$, $p < .001$, and the total model explained 53.65% of the variance in back pain-related disability, but did not provide evidence for any indirect effects of completing PROMs on back pain-disability. Within the direct effects of the model, pain-related fear increased feelings around pain catastrophising, and increased patients' fear avoidance-beliefs. Pain catastrophising also predicted an increase in back pain-related disability.

Four patients interviewed had high scores of pain related-fear. Although within the qualitative interviews, patients and chiropractors did not directly discuss pain-related fear, they did identify experiences reflective of the mediation model. In their interviews, Lisa and Richard highlighted examples where they were restricting their activity. For example, despite only being 58, Richard felt he would be a bit more careful about his activities "*I wouldn't push things probably as maybe you would if you were younger. I'm an old man now".* Lisa had quite extreme concerns and stopped engaging in her regular physical activity: *"I don't want to put it out of place again",* she was worried about increasing her disability and pain again: *"I'm scared of damaging myself again".* Additionally, Margaret, with a high score in fear avoidance beliefs, talked about avoiding activities: *"I'm being a lot more careful with what I do".* Despite having low scores of pain-related fear and fear avoidance, patient William also talked about being *"a bit more careful".* Chiropractors noted they needed to reassure their patients about pain, provide explanations of pain and activity, and build confidence in patients returning to their day-to-day activities: "*I think it just highlights for me especially, I did a [Masters degree], how important communication is.. putting people at ease, educating them and not just the physical side of manual therapy*. (Chiropractor - Peter).

10.4 Discussion

This chapter aimed to evaluate the effects of PROMs, assess utilisation and intervention fidelity, and identify mechanisms that might explain any outcomes. By exploring the context, mechanisms, and outcomes, the study aimed to identify the clinical and psychosocial consequences of using PROMs in specialist musculoskeletal care for low back pain.

10.4.1 Utilisation of PROMs

Administration and utilisation of PROMs within specialist musculoskeletal care was found to be complex. Using a web-based system for PROMs can make data more accessible and reduce the time burden of paper-based methods of collecting PROMs within consultations (Greenhalgh et al., 2017). However, employing PROMs required a change in chiropractors' practice and administrative workflow. Those who worked with other clinicians felt unable to make changes to the administration of their practice, despite wishing to participate. This may explain why, despite interest from many chiropractors, few consented to participate, and more dropped out when having to employ new software into their practice. Clinicians' familiarity and confidence with PROM software can influence successful utilisation (Chang, 2007). From the interviews, chiropractors felt Care Response was complicated to use and suggested editing the software or embedding PROMs within existing software. Despite their dislike of the software, chiropractors liked the MSK-HQ as a choice of PROM, feeling it was a useful tool compared to others they had previously used. For clinicians to engage with PROMs, PROMs must be clinically relevant and be applicable to their clinical practice (Duncan & Murray, 2012). Chiropractors felt the concepts measured within the MSK-HQ were meaningful to patients and to their practice, however some highlighted difficulty in reading and interpreting scores. Although chiropractors received training on PROMs (Appendix M), further training and support for clinicians may be required, including more on the administration of Care Response and interpretation of data, and the purpose of PROMs and their potential benefits (Antunes et al., 2014; Callaly, 2001; Santana et al., 2015).

Within the qualitative interviews, patients highlighted they were happy to complete PROMs and found the questions of the MSK-HQ relevant. Despite this, very few patients completed all PROMs. The intensive group were asked to complete the PROMs seven times over 30 days, and the routine group three times

over 30 days, with no significant differences in completion of PROMs between the groups. Chiropractors felt high intensity PROMs were a potential burden for patients, and not relevant for patients with chronic conditions, where they expected to see little change in 30 days. It was also potentially only relevant for patients who were coming frequently to the clinic (for example, those coming twice a week for an acute issue). Considering the usefulness for practice and participant burden (Gilbert, Sebag-Montefiore, Davidson, & Velikova, 2015; Philpot et al., 2018), the routine use of PROMs (three times over 30 days) may be the most appropriate use of PROMs in this context.

Chiropractors in the routine and intensive group were asked to discuss the PROMs with their patients, although discussion of PROMs was not found to be significantly correlated with back-pain disability. However, the qualitative interviews with chiropractors revealed that those in the intensive and routine groups did not explicitly discuss the PROMs, and those in the control group asked ad hoc questions about improvement. The discussion of PROMs is theorised to be an important component of PROMs (Feldman-Stewart & Brundage, 2009), however, as PROMs were not delivered as intended, there is a potential to introduce bias to the results. Although chiropractors in the control group were asked not to complete PROMs, their questioning came from their consultations and reviews with patients, and were a natural part of providing care for patients (General Chiropractic Council, 2016). Despite the issues with intervention fidelity, the differences in discussions and use of PROMs accurately reflect the communications in clinical practice.

10.4.2 Outcomes of PROMs in musculoskeletal care

There was a reduction in back pain-related disability for those who completed PROMs and those who did not, with no significant difference between groups. All participants expressed some form of pain relief when interviewed. Additionally, patients and chiropractors highlighted other outcomes to consider. Patients were extremely complimentary of their chiropractors and the care they received. Although chiropractors suggested PROMs may enhance patient satisfaction by appearing more professional, patient satisfaction was actually higher in the control group. However, given the poor intervention fidelity, with chiropractors not explicitly discussing PROMs, and those in the control group asking PROM-like questions, and caution should be taken when interpreting the results.

10.4.3 Mechanisms and process of change

Within the qualitative interviews (Chapter 9), chiropractors suggested that whilst PROMs were a potentially valuable tool, they were one of many communication strategies used. This is reflected in the poor intervention fidelity of using PROMs in their practice. The lack of fidelity may explain the results of the RCT (Chapter 7) and statistical modelling (Chapter 8) which concluded that there was limited evidence to suggest PROMs had a significant impact on back pain-related disability.

Overall, patient-centred communication was viewed as the mechanism influencing change, rather than completion of PROMs. Based on patients' and chiropractors' qualitative accounts of communication within consultations, and the results of the coping appraisal mediation model and patient-clinician interaction mediation model, it is hypothesised that patient-centred communication will impact back pain-related disability, mediated by therapeutic alliance, patient satisfaction, self-efficacy, treatment beliefs, and self-management behaviours.

During the qualitative interviews, patients also discussed making and maintaining lifestyle changes to account for their pain, and for some, this included restricting their activity. Chiropractors also highlighted the importance of explanations and reassurance of pain, and providing advice on pain management. Based on patients' and chiropractors' views, and the results of the threat appraisal mediation model, it is hypothesised that pain-related fear will increase back pain-related disability, mediated by an increase in fear-avoidance beliefs and pain catastrophising.

Overall, when examining the mechanisms and potential processes of change, this study suggests that back pain-related disability is not directly or indirectly affected by the completion of PROMs. However, patient-centred communication and pain-related fear are hypothesised to impact patient outcomes. More research is needed to explore the two hypotheses generated, and how future interventions can enhance good patient-centred communication and provide reassurance to patients who fear their pain. It is still suggested that PROMs have a role within patient-clinician interactions, and therefore further research should examine how they may be used to increase patient-centred communication and reduce pain-related fear.

10.4.4 Strengths and limitations

The mixed-methods approach allowed for exploration of a range of questions, to develop a more complete picture of utilising PROMs. Mixed-methods can provide stronger inferences than using a single quantitative or qualitative approach, and provide the opportunity to explore conflicting views to expand the understanding of the phenomenon of interest (Burke Johnson & Onwuegbuzie, 2004; Yardley & Bishop, 2008). Using mixed-methods capitalises on each method's strengths and compensates for weaknesses (Creswell & Clark, 2011). For example, RCTs are often criticised because they are undertaken in unnatural situations, however, using their findings in combination with qualitative interviews enables understanding over participants' experiences within the research context and relevance to the real world.

Reflection on the study methodology and findings must also consider the individual study components and the implications for the process evaluation. This mixed-methods analysis used data from 80 RCT participants who completed follow-up data, rather than from the 158 participants as baseline. As noted in Chapter 7, there were no significant differences in the full recruited sample and those who had completed follow-up other than baseline scores on the STarT Back tool, with those categorised as low risk more likely to drop out. However, the RCT was underpowered to detect a clinically meaningful effect size on the Roland-Morris Questionnaire. Caution must be taken when interpreting the results, due to the potential for type II errors, and the risk of not identifying significant results (VanVoorhis & Morgan, 2007). There were no significant differences in participants who took part in an interview compared to those who did not, indicating they are representative of the wider sample. This study aimed to examine the context, mechanisms, and outcomes of utilising PROMs, however the process evaluation is impacted by the high drop-out rate (49.4%). It is not known why patients dropped out of the study, this may have been due to not wanting to continue participation in the intervention, or due to improvement or worsening of their back pain. This could have implications for the acceptability of PROMs and outcomes, not identified within this study. Additionally, due to ethical implications, it was not possible to interview any of the participants who withdrew from the study. This would have provided a further opportunity to explore how patients felt about PROMs.

By exploring the intervention fidelity of PROMs, this study identified limitations regarding how chiropractors may have been influenced by their

clinical practice and use of PROMs outside of the trial. Only patients consenting to take part in the study received PROMs as per the study design (receiving the MSK-HQ either seven times, three times, or not at all). However, chiropractors had other patients receiving other PROMs as per their routine practice. Although chiropractors were aware which patients were in the study, through Care Response and the MSK-HQ being delivered as the main PROM, due to the busy nature of clinical practice, they may have been influenced by the inconsistent nature of receiving PROMs. Again, this may have implications for chiropractors' use of PROMs and patient outcomes, not identified within this process evaluation.

10.5 Chapter summary

This mixed-methods process evaluation has provided a greater understanding of the context, mechanisms, and outcomes of utilising PROMs in specialist musculoskeletal care. Overall, the findings show that PROMs cannot be removed from chiropractors' broader communication with patients, as chiropractors view PROMs as a tool within practice rather than an explicit intervention. This was particularly evident in relation to intervention fidelity, with not all chiropractors discussing PROMs explicitly but using them amongst other clinical activities within the consultation. The analysis found no difference in back pain-related disability between those who completed PROMs and those who did not at 90 days after their first appointment. However, this may be due to poor intervention fidelity. Given that PROMs were hypothesised to impact patient-centred communication and pain-related fear, further research should explore how PROMs may be used as an intervention to successfully influence these factors and impact back pain-related disability. Additionally, this study identified several barriers and facilitators to successful use of PROMs, which is important to routine clinical practice. The findings of this study will be summarised and integrated with the results of the systematic review (Chapter 4), theoretical review (Chapter 5), and other empirical studies (Chapter 6-9), and considered with reference to other literature in Chapter 11.

Chapter 11 Discussion

11.1 Introduction

PROMs are increasingly utilised in routine clinical practice in a wide range of healthcare settings. This thesis set out to explore the use of PROMs in specialist musculoskeletal care and the clinical and psychosocial effects on patients with low back pain. Although the RCT did not demonstrate a significant effect, the findings of the systematic reviews and qualitative components of this thesis suggest that the use of PROMs in clinical practice may influence the process of patient care, patient experience, and patient outcomes. This chapter summarises the studies (Chapters 4-10), integrates the findings from the three phases of the research, discusses the strengths and limitations of the research, and identifies how findings can inform clinical practice and further research.

11.1.1 Overview of thesis

The research was set out in three phases: development, feasibility, and evaluation (see Figure 11.1). The development phase consisted of three stages, a systematic review examining findings from primary research, a theoretical review exploring the underlying concepts of use of PROMs, and development of a theoretical framework. The feasibility phase assessed the study procedures and estimated recruitment. Lastly, the evaluation phase included a RCT and mixed-methods process evaluation on the role PROMs play in clinical practice.

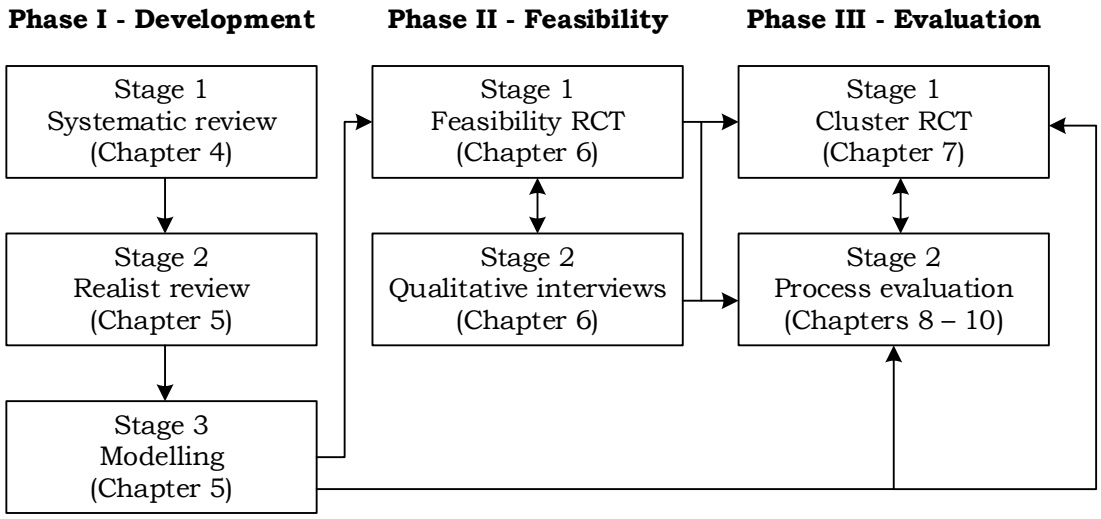


Figure 11.1 – Overview of thesis components

Phase I – Development

In Stage 1 of the development phase, a systematic review examined the potential impact of PROMs in clinical practice for non-malignant pain. This review used critical interpretive synthesis to transform the results of 15 studies (qualitative and quantitative) into a theoretical argument outlining the potential impact of utilising PROMs in routine clinical practice. Results suggested that PROMs may have an influence throughout the treatment encounter. PROMs may be used in initial consultations to assess patients, and for decision-making regarding the patients care. During the course of treatment, PROMs can be used to track progress, evaluate current treatment and change the course of care if required. The use of PROMs is also thought to influence the therapeutic relationship between patients and clinicians. Post-treatment, PROMs may also have a direct influence on other outcomes, such as pain and patient satisfaction.

In Stage 2 of the development phase, a theoretical review of 71 papers was conducted (Chapter 5) to identify the inter- and intra-personal processes through which PROMs might influence health outcomes in routine clinical practice for non-malignant pain. This review suggested that PROMs may affect patients through: increasing clinicians' knowledge of patients, facilitating patient-doctor interaction, enabling patient-centred care, monitoring, informing strategies to improve care, enhancing therapeutic relationships, improving patient satisfaction, and encouraging positive patient health behaviour.

In Stage 3, the two reviews were used to develop a novel theoretical framework, the Patient Reported Outcome Measures Pathway Theory (PROMPT), depicting the multiple components of PROMs within routine clinical practice and specifying hypothesised outcomes, mechanisms and parameters (Chapter 5).

Phase II – Feasibility

Phase II consisted of a feasibility study which examined the achievability and the practicalities of conducting a cluster-RCT using PROMs as an intervention for low back pain patients attending chiropractic clinics. The study aimed to explore patients' and practitioners' experiences of taking part in a trial, patients' acceptance of randomisation to interventions, the acceptability of completing outcome measures and the appropriateness and usability of measurement tools. The study also assessed recruitment and retention rates; only nine patients were recruited, five of whom were lost to follow up. Despite

PROMs being routinely used in chiropractic settings, no participants completed the intervention. The analysis of qualitative interviews with 18 participants proposed improvements for the development of PROMs as an intervention: a) explaining the value of PROMs within the process of patient care to patients and clinicians, b) administering PROMs in an acceptable format, and c) ensuring PROMs are meaningful to patients and chiropractors. Participants also identified several recommendations for future research aiming to evaluate PROMs, based on their experiences in a trial, such as preference for data collection methods and suggestions for improving retention.

Phase III – Evaluation

The final phase of this research was a cluster-RCT and mixed-methods process evaluation on the use PROMs in clinical practice. This three-arm RCT aimed to evaluate the clinical effects of using different frequencies of PROM delivery in routine treatment of low back pain. Eight chiropractors and 158 patients were recruited with 80 patients completing the study. All groups demonstrated significant reductions in back pain-related disability, with many showing a clinically significant improvement. However, there was no significant differences between groups receiving the different frequencies of PROMs in back pain-related disability or HRQoL.

The process evaluation used a quantitative mediation analysis to test hypotheses about mechanisms derived from PROMPT. Contrary to hypotheses, there were no significant effects of completing PROMs on psychosocial aspects of patient care. However, the study provided preliminary evidence of other potential mechanisms which may predict changes in back pain-related disability within a specialist musculoskeletal care setting.

A qualitative study was embedded in the trial, with a subset of seven chiropractors and 15 patients interviewed about their experiences. The interviews highlighted that communication was a key component of care, with PROMs as a valuable potential tool in patient-clinician interactions. Participants noted areas that they perceived to be good communication: by thorough questioning, providing explanations of pain and treatment, and monitoring and follow-up. The integration of PROMs was felt to have a positive role in their interactions. They also suggested several perceived benefits of good communication including helping patients to make and maintain lifestyle changes, building rapport

between chiropractors and patients, and fostering positive views of practitioners among patients.

The quantitative and qualitative components of the RCT were brought together in a mixed-methods process evaluation to understand the consequences of employing PROMs, assess intervention delivery, and identify contextual mechanisms that might moderate outcomes. Chiropractors had mixed views of using PROMs, with some finding the process simple and others expressing a dislike of the PROM software. The delivery of the intervention was inconsistent, with very few patients completing all the PROMs and chiropractors not discussing PROMs with patients as intended. Combining data from the RCT, mediation analysis, and qualitative interviews identified key outcomes of care, including self-management behaviours, patient satisfaction, and back pain-related disability. Triangulation of the data also suggested that communication was a key mechanism to influence change in patient outcomes.

11.2 Major findings

The findings of this thesis provide an expanded understanding of the clinical and psychosocial consequences of using PROMs in specialist musculoskeletal care for low back pain, and the context and mechanisms underlying these effects. This is summarised in Figure 11.2 and is discussed below.

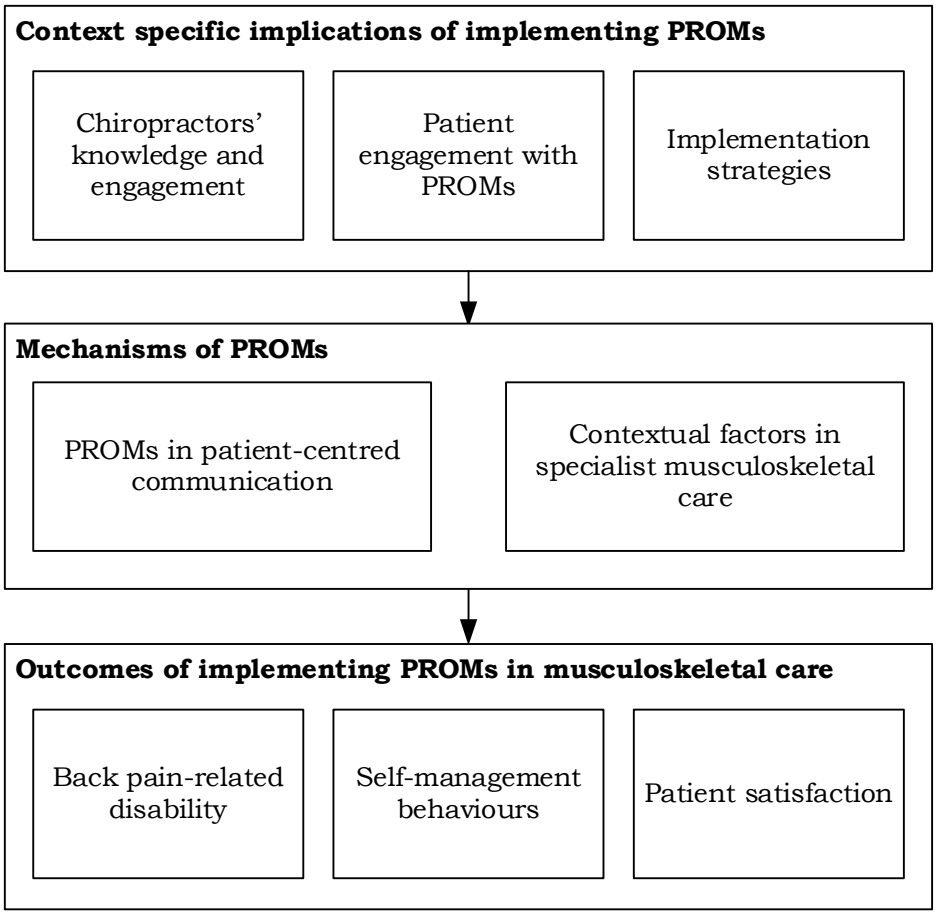


Figure 11.2 – Overview of findings

11.2.1 Mechanisms of PROMs

PROMs in patient-centred communication

This thesis aimed to explore the effects and mechanisms of using PROMs in specialist musculoskeletal care. One of the consistent findings throughout theoretical and empirical literature is that PROMs have a role in patient-clinician interactions and facilitate patient-centred communication (Greenhalgh et al., 2017; Greenhalgh et al., 2005; Santana & Feeny, 2014). This was reflected in both the qualitative components of the feasibility study and the qualitative study embedded within the RCT.

Within the systematic review and theoretical review, PROMs were suggested to have a role in the initial assessment of patients, to provide a baseline assessment of patients' health status, quantify pain, and assess impact of disease. This was also suggested by chiropractors in the qualitative interviews, who used PROMs to gather essential information alongside their medical history to identify psychosocial factors, predictors of chronicity, and prognosis. PROMs were also used by chiropractors in the feasibility study and the RCT within the first consultation to provide insight into how patients are feeling. This was noted in the theoretical review, with PROMs suggested to increase clinician's awareness of patients' perceptions of their health and the impact any illness has on their life. It was also theorised that PROMs could provide a springboard for discussion with patients. Chiropractors felt PROMs enabled them to start discussions and acted as a prompt for patients to voice issues. Patients valued chiropractors allowing them to tell their story, using thorough questioning and use of PROMs. PROMs helped patients to individually reflect on their health. Patients also felt that through PROMs, chiropractors were listening to their concerns, and valued the opportunity to use PROMs as a prompt to discuss their health in more detail.

From the qualitative interviews, patients were seen to want advice, reassurance, and explanations on the cause of their pain. Within the feasibility study and RCT, chiropractors used PROMs to identify yellow flags, triggering them to reassure patients, and educate patients about recovery. Patients felt PROMs allowed them to have more input in treatment decisions, and by providing information to the chiropractor this allowed for a tailored treatment. This was a common theme in both the systematic and theoretical reviews, with PROMs suggested to make clinicians more aware of issues and patients' ideas, aiding a discussion over expectations, realistic goal setting, and the provision of

individualised treatment. Although shared-decision making was not discussed in any of the qualitative studies, chiropractors in both studies did use PROMs to provide tailored self-management advice.

The systematic and theoretical reviews also highlighted that PROMs may be used to routinely monitor patients' progress over time, observing changes in symptom severity or response to treatment. Chiropractors in the feasibility study and RCT used PROMs to monitor patients, tracking their improvement. Chiropractors used PROMs to open discussions with patients and visually show patients their progress. Patients in the RCT felt that PROMs and associated discussion with chiropractors allowed them to reflect on their situation, provide an assessment of their progress, and identify any changes since treatment. Using PROMs as a form of self-appraisal was also noted in the theoretical review, enabling subsequent adherence and engagement with ongoing treatment and self-management advice.

Contextual factors in specialist musculoskeletal care

From reviewing empirical and theoretical literature it was hypothesised that completing PROMs would improve patient-centred communication, therapeutic alliance, patient satisfaction, self-efficacy for pain management, and self-management behaviours. These contextual factors were suggested to mediate the relationship between the completion of PROMs and reduced back pain-related disability. The hypothesised mechanisms were developed as three mediation models: patient-clinician interaction, threat appraisal, and coping appraisal. The analysis showed limited evidence to support the hypothesised pathways, with no significant differences in the process measures between those who completed PROMs and those who did not (Chapter 8). However, the statistical modelling highlighted that these contextual factors may predict changes in back pain-disability. These were further explored and are explained with the qualitative findings in Chapter 10.

Patients saw their relationship with their chiropractor as an important part of their care. There was moderate confidence from the systematic review that PROMs may improve therapeutic alliance between patients and clinicians. It was further hypothesised within the theoretical review that PROMs enable clinicians to show more interest in patients, and promote partnership, building rapport. Within the feasibility study and qualitative interviews, chiropractors also thought that PROMs could be used to improve the patient-clinician relationship, by sharing information and having a better understanding of patients' perspectives.

It was noted within the systematic review, that the therapeutic relationship may be influenced by improving communication. Within the mixed-methods process evaluation, patient-centred communication was found to have a direct effect on therapeutic alliance. Patients felt their relationship with their chiropractor was influenced by questioning, feeling listened to, providing explanations, reassurance, and empathy from the chiropractor. Therapeutic alliance was also found to directly affect patient satisfaction.

From the theoretical review, PROMs were suggested to enhance communication, improving patient's self-efficacy to self-manage their health. Within the mixed-methods process evaluation, patient-centred communication was found to directly impact self-efficacy for pain management. Self-efficacy was found to positively impact self-management behaviours and reduce back pain-related disability. Through patient-centred communication, patients feel they have the appropriate knowledge, skills, and resources to undertake self-management skills.

PROMs were also suggested to impact patients' illness and treatment beliefs. Within the feasibility study, several chiropractors expressed concerns about getting patients to routinely quantify their pain, noting this might remind patients of their pain and have a negative effect. This concern was also noted within the systematic review. Within the threat appraisal pathway of PROMPT, it was hypothesised that PROMs may focus patients' attention of pain, and which may increase patients' fear of pain. PROMs were not found to have a direct impact on pain-related fear in the mediation models, but pain-related fear was found to directly increase fear-avoidance beliefs and pain catastrophising, with pain catastrophising associated with increased back pain-related disability. One use of PROMs, from the theoretical review, was for clinicians to use PROMs to educate patients on pain and treatment plans. PROMs were also suggested to help patients voice their beliefs about treatment and raise concerns. Although PROMs did not have any impact on treatment beliefs, patient satisfaction was found to directly impact treatment beliefs, with treatment beliefs positively impacting self-management behaviours.

11.2.2 Outcomes of utilising PROMs in musculoskeletal care

Back pain-related disability

The main aim of this thesis was to evaluate the clinical and psychosocial effects of using PROMs in routine treatment of low back pain. The systematic and theoretical reviews concluded that PROMs may have the potential to influence patients' health status, pain levels, and satisfaction. However, there were no significant differences in back pain-related disability across the three groups in the RCT. There were also no significant differences in HRQoL between groups at follow-up.

It was noted within the systematic review that PROMs may increase patients' awareness of pain, which was hypothesised from the theoretical review to potentially increase back pain-related disability. This was also a concern of chiropractors within the feasibility study. However, PROMs were not found to negatively impact back pain-related disability with no significant difference in number of patients showing increased back pain-related disability between the three groups.

Self-management behaviours

Although patients commonly seek treatment for a cure, they also do this alongside self-management of their condition (Dima et al., 2013). The theoretical literature identified that through PROMs patients may feel they have the appropriate knowledge, skills, and resources to undertake self-management behaviours to manage their pain. Although there was no difference in self-management behaviours between those completing PROMs and those who did not, chiropractors in the feasibility study felt PROMs could improve patient adherence for treatment and self-care exercises. An advantage of using PROMs was for patients to see improvements after a change in behaviour, positively reinforcing the behaviour. Patients noted several changes in self-managing their pain during and after the RCT. These changes came from their discussions with their chiropractor, noting that this was because their chiropractors fully understood their condition and provided tailored explanations and advice. Patients' self-management behaviour was found to reduce back pain-related disability.

Patient satisfaction

The systematic review also suggested that PROMs may impact patient satisfaction, although there was limited evidence to support this. Examining theoretical literature, the positive impact on patient satisfaction was hypothesised through improvements in patient-centred communication and therapeutic alliance. Chiropractors felt PROMs made them seem more professional, with patients commenting positively on chiropractors' professionalism. However, PROMs did not influence patient satisfaction. Overall patients were very positive about their chiropractor, valuing chiropractors' knowledge, positive attitude and confidence, and in mediation models, therapeutic alliance was found to have a positive impact on patient satisfaction.

11.2.3 Context specific implications of utilising PROMs

There are several known barriers to employing PROMs in routine clinical practice including: appropriate technology, knowledge regarding use of PROMs, pre-existing workflows, and concerns about negative implications (Stover et al., 2020). However, the context in which PROMs are used may have context specific barriers and implications for the use of PROMs (Greenhalgh et al., 2017; Stover et al., 2020); the work in this thesis identified implications of utilising PROMs in specialist musculoskeletal care.

Chiropractors' knowledge and engagement

Within the feasibility study, some chiropractors felt that PROMs were beneficial to their practice, whilst others did not see a benefit. Those who used PROMs saw them as a tool in combination with history taking, physical examinations, and ongoing discussions with patients. However, those who did not use PROMs, preferred to ask patients personalised questions within their consultations to build rapport with patients. Despite chiropractors identifying how they might discuss PROMs, all patients in the feasibility study reported that chiropractors did not discuss the questionnaires during their treatment. However, there was improvement in intervention fidelity within the RCT. Patients reported chiropractors often discussed the PROMs, although some patients reported never discussing them. In the qualitative interviews, chiropractors confirmed they used PROMs when communicating with patients, but did not do so explicitly.

Chiropractors in the qualitative interviews also noted that it was an additional challenge in routine practice to identify which PROMs were the most appropriate to use. Chiropractors in the feasibility study often chose to focus on functional outcomes, rather than using a pain or QoL scale, shifting the focus from pain to patients' abilities. Chiropractors who took part in the RCT were positive about the MSK-HQ, finding it more useful than tools they had used previously. Within the theoretical review it was noted that clinicians need to see PROMs are valid, viewing psychometric properties, and identifying whether they are sensitive or accurate enough to detect change.

Patient engagement with PROMs

Within the qualitative interviews, patients were positive about completing PROMs before their treatment, noting this was a good use of time, and feeling that their chiropractors were open to hearing their concerns. Patients also appreciated the monitoring element of PROMs. Patients in the feasibility study and RCT found PROMs self-explanatory, easy to complete, and viewed them as a necessary part of their care. Although no patients reported PROMs being burdensome, very few participants, across both the feasibility study and RCT completed all the PROMs.

Chiropractors in the feasibility study and qualitative interviews voiced concerns about patient engagement, suggesting PROMs (and associated emails) are bothersome for patients. However, when asked in the qualitative interviews about why they did not complete the measure, patients reported they simply forgot to complete them, despite email reminders. Chiropractors recommended that, to improve engagement, patients should be educated on the value of PROMs as a component of patient care.

Administration strategies

The theoretical review reported that clinicians often have a lack of knowledge and skills surrounding PROMs. These are essential for clinicians to appropriately engage with patients through PROMs, analyse the data, and act on information provided. Additionally, they must feel there are adequate resources for the administration of PROMs in practice (technology, administrative time, and information systems for data collection and analysis). Chiropractors in the feasibility study were asked about completing training on PROMs; they felt that undemanding training (due to time constraints) could be beneficial, acknowledging chiropractors may not have any previous knowledge on PROMs.

Within the qualitative interviews, chiropractors noted that administering PROMs needs to be simple, and although there can be high administrative workload when first using them in practice, PROMs are easy once they are embedded into routine care. In the feasibility study and RCT, chiropractors noted the inconvenience of mixing paper and electronic systems. They recommended efficient systems, embedding PROMs into existing clinic workflow, with minimal deviance from patient records, appointments, and note-taking. Additionally, administrative support from reception staff significantly helped the process. Time was noted as a barrier that is difficult to overcome, for example, chiropractors in the feasibility study felt use of PROMs was affected by the practicalities of having a busy practice and trying to stay efficient.

11.3 Strengths and limitations

There are a number of specific methodological considerations for each of the studies in the thesis, which can be found in each of the corresponding chapters (Chapters 4 – 10). This section provides an overview of the general strengths and limitations which relate to the overall research findings.

The empirical research employed a mixed-methods approach; the inclusion of both qualitative and quantitative components and triangulation of the data provided a thorough evaluation of PROMs in clinical practice for low back pain. The RCT and statistical modelling examined the effectiveness and mechanisms of PROMs and the qualitative study produced an in-depth analysis with a smaller number of patients and chiropractors. The qualitative interviews provided additional insights into the results of the RCT and statistical modelling, putting the findings into context. For example, the use of PROMs was highlighted in the interviews with chiropractors, suggesting the lack of discussion of PROMs may have influenced the outcome of the trial. The RCT found there was no significant effect of using PROMs, however, within the qualitative study, chiropractors and patients valued the use of PROMs within clinical practice. Additionally, the importance of patient-centred communication was discussed by both chiropractors and patients, suggesting this is the value of PROMs, informing future research in this area. The methodological design of this thesis can be considered a strength, with a mixed-methods approach providing a comprehensive evaluation of PROMs, by addressing a range of questions and exploring conflicting views.

Although patients' views and experiences were included through qualitative interviews, in both the feasibility study and the embedded qualitative study in the RCT, there was a lack of patient and public involvement with the development and conduction of the study. Patient and public involvement would have been beneficial when developing study protocols, procedures, and materials (Blackburn et al., 2018). This would ensure that all the studies were acceptable to patients and could have contributed to increasing recruitment and retention in the study.

The sample size of the RCT is a limitation, as the study is underpowered to detect a clinically meaningful effect size on the Roland-Morris Questionnaire. The study had 80 participants; however a priori sample size calculations estimated 450 participants would be required. This further lead to low statistical power for the mediation model, and compromised the generalisability of the findings. These

results must therefore be interpreted with caution, as this study is at risk of type II errors, and ideally the study should be replicated with adequately powered studies in future research. The baseline sample of patients in the RCT were between 16 and 82 years of age (mean age = 44.07), and 49.7% were female. For ethical reasons, no data was collected on those patients who chose not to participate in the study. Therefore, it was not possible to compare demographics of patients who participated and those who did not. However, there were similarities to the wider patient population that seek chiropractic care. In a survey of 854 U.K chiropractors, most patients seen by chiropractors are between the ages of 21-60 years (General Chiropractic Council, 2004). In a large systematic review exploring the profile of chiropractic patients worldwide, females were more likely to seek chiropractic care with an average age of 43.4 years (Beliveau et al., 2017). This is a similar profile to U.K patients; in a study of 452 patients with low back pain, 53% were female, with a mean age of 41.2 years (Davies, 2013). A more recent study of 1859 patients visiting a chiropractor in the U.K, found patients had a mean age 44.6 years, and 53% were female (Newell et al., 2016). The sample that completed follow-up within this current study were 55% female, with an average age of 45.13 years. This was not significantly different to the baseline sample and was reflective of other studies that have been completed, increasing the generalisability of the findings. Additionally, only eight chiropractors took part in the RCT and no demographics were collected on chiropractors, which potentially limits the generalisability of the study findings, as they may not reflect typical clinical practice. However, a mitigating strength is that the study was conducted in multiple sites across the U.K.

11.4 Implications

11.4.1 Contributions of this thesis

This research is the first to comprehensively examine PROMs in the context of specialist musculoskeletal care for back pain. Whilst there is increasing use of PROMs within the treatment of pain, by physiotherapists, chiropractors, and osteopaths (Fawkes, 2017; McAuley et al., 2014; Newell et al., 2016), there is a paucity of research in this area. Although there is a significant amount of literature in other contexts, such as mental health and oncology settings, these are not directly comparable to primary care settings for back pain (Greenhalgh et al., 2017). This research provides a systematic exploration of PROMs for back pain following complex intervention guidance (Craig et al., 2008), including examining existing literature, evaluating effectiveness, and exploring context and mechanisms through a process evaluation.

The review of existing empirical and theoretical literature identified that PROMs have the potential to impact on the process of care and patient outcomes. No studies have previously examined this effect within the context of specialist musculoskeletal care settings, and although there was limited evidence to show an effect, this may be due to the small sample size of the research. PROMs were shown to have no adverse effect on patient outcomes, which is a noted concern from clinicians (Ahluwalia et al., 2018). The use of the PROMPT model was valuable to guide this thesis, enabling the development of specific hypotheses, drawing on both empirical literature, theoretical literature, and established psychological theories. The findings of this research indicated that PROMs may have a role within patient-centred communication, with communication identified as a key component of care. This research supports previous work on contextual factors, suggesting mechanisms for change in back pain-related disability within specialist musculoskeletal care.

In addition to further knowledge on the role PROMs may have within patient care, this research has contributed to our understanding of utilising PROMs in specialist musculoskeletal care.

11.4.2 Implications for clinical practice

Selection and application of PROMs

For utilisation of PROMs to be successful, the PROM must be appropriate to both clinicians and patients. Chiropractors and patients voiced their opinions on PROMs within the context of chiropractic care, noting that they preferred a functional measure, moving away from focusing on pain. The MSK-HQ was developed for use across patients with musculoskeletal conditions, making it relevant despite individual differences in symptoms and presentation of back pain (Ellis et al., 2014; Hill et al., 2016). The MSK-HQ was found acceptable and useful within this research, with the concepts viewed as important and meaningful to patients, and being clinically relevant and applicable for chiropractors, which is necessary for engagement (Duncan & Murray, 2012; Snyder et al., 2012).

A key question within this thesis was to identify the appropriate timing of measurements and frequency of asking patients to complete PROMs. Clinicians must balance the potential burden for patients and administrative workload against the usefulness for clinical practice (Gilbert et al., 2015; Philpot et al., 2018). It was identified that there were no significant differences between those receiving PROMs three times (as per routine practice) and those receiving high intensity PROMs (seven times). Additionally, chiropractors felt the high intensity PROMs potentially burdened patients and were not always relevant in clinical practice. Therefore, it is recommended that the MSK-HQ be sent three times over 30 days in this context.

PROM administration in specialist musculoskeletal care

Chiropractors in the feasibility study and qualitative interviews noted their high workload, feeling PROMs impacted on their time and ability to stay efficient. Administering PROMs within clinical practice has several challenges (Greenhalgh et al., 2017), with electronic PROMs recommended to make data more accessible in clinical practice and reducing time-burden for clinicians. Chiropractors and reception staff in this research preferred electronic PROMs as they require minimal administrative workload. However, technological constraints and logistical difficulties are a commonly reported barrier to successful use of electronic PROMs (Chang, 2007). Clinicians also require the appropriate hardware, software, and internet access (Lalloo et al., 2014).

PROM software needs to be conducive to clinical settings (Hans, Gray, Gill, & Tiessen, 2018). Within this research, Care Response was used (Newell et al., 2016); chiropractors in both the feasibility study and qualitative interviews identified Care Response as cumbersome, noting improvements that could be made, although they appreciated using a tool with no cost implications. The needs of chiropractors for PROM software mirrors existing literature, with clinicians requiring simplicity, ease of access, and graphical and numerical formats for data (Catarinella & Bos, 2016; Gilbert et al., 2015; Krusche et al., 2020). Chiropractors requested PROMs to be integrated with existing clinical software, alongside health records, appointments, and note-taking. Additionally, despite paper-based PROMs within consultations being time consuming and challenging (Greenhalgh et al., 2017), paper-based PROMs should be recommended for chiropractors with paper-based notes, to reduce further challenges in integrating electronic PROMs with existing administrative systems.

Patients also require a certain level of technology to use electronic PROM systems, such as computer facilities and access to the internet. Any software must be designed to produce data in a format that is easy for patients to interpret (Catarinella & Bos, 2016; Snyder, Jensen, Courtin, Wu, & Network, 2009). Previous research found some patients with long-term health conditions required assistance or had difficulties with online systems (Engelhard et al., 2017; Koevoets et al., 2013). A scoping review identified that patients do not engage with PROMs due to practical barriers including: health limiting their ability to complete PROMs, language barriers, lack of time, and difficulties using technology (Nielsen, Kidholm, & Kayser, 2020). Patient engagement with PROMs also varied due to PROMs causing emotional distress, having no symptoms to report, patients not perceiving the benefits of PROMs, and concerns regarding data security (Nielsen et al., 2020). Patients' ability to engage with PROMs is also a concern of allied health professionals (Duncan & Murray, 2012). However, electronic systems are broadly acceptable to patients, who are willing to fill in PROMs at home and show engagement with online systems (Engelhard et al., 2017; Gilbert et al., 2015; Koevoets et al., 2013; Walker et al., 2017). Chiropractors in this research also had concerns regarding patients' engagement with PROMs, however patients found Care Response simple to use and the PROMs easy to complete. Chiropractors suggested explaining the purpose of PROMs to patients to increase patient engagement; this is recommended, with patients needing to understand the purpose of PROMs, how to use any software, and the value of PROMs within their care (Koevoets et al., 2013). Chiropractors

may also need to remind patients about PROMs and provide encouragement when PROMs are completed (Antunes et al., 2014). If chiropractors are engaged with PROMs and PROMs are discussed between patients and clinicians, this is likely to facilitate patient interest in completing PROMs and increase patients' understanding of the value of PROMs within patient care (Antunes et al., 2014; Catarinella & Bos, 2016; Duncan & Murray, 2012; Jongen et al., 2013; Lalloo et al., 2014).

Clinician knowledge and engagement

The use of PROMs is only possible with active clinician engagement and willingness to integrate them into their routine clinical practice (Hans et al., 2018). Most chiropractors in this study felt PROMs had some role within healthcare, however, the wider healthcare workforce have mixed views on the usefulness and purpose of PROMs (Boyce et al., 2014a). Clinicians' lack of knowledge on PROMs can be a significant barrier to successful utilisation of PROMs (Antunes et al., 2014; Duncan & Murray, 2012).

Chiropractors in the feasibility study were positive about the idea of training to improve their knowledge and engagement with PROMs. When asked about the best approach for training, chiropractors recommended concise hard copy resources and online training for easy access to information. Chiropractors in the RCT received telephone training and a booklet on PROMs. As per recommendations on educating clinicians, the training included details on PROMs in musculoskeletal healthcare, administration, scoring and analysis, and use of PROMs in clinical practice (Antunes et al., 2014; Callaly, 2001; Santana et al., 2015). Chiropractors who were new to the Care Response software could have benefited from further training using the system. Unfamiliarity with PROM software is a known barrier to successful use, and further training must ensure clinicians feel confident in using software (Chang, 2007). Chiropractors also had difficulty in interpretation of PROM scores. Although this was included in the training, further examples may have been beneficial to show patient improvement and worsening as no chiropractors asked follow-up questions after the training or got in touch regarding difficulties. Clinicians need to be able to interpret the data, identify meaningful changes, and understand the potential usefulness of PROMs for successful use (Greenhalgh et al., 2017; Jensen et al., 2014). In a survey of 18 healthcare providers exploring use of PROMs for low back pain, participants felt that they needed knowledge and skills to be able to interpret PROM scores and use them with the management of patients with low

back pain (Eilayyan et al., 2020). Ease of access and sufficient time was also noted by healthcare providers in assisting with the use of PROMs (Eilayyan et al., 2020).

Additionally, utilisation of PROMs did not show any clinical benefit to patients compared to those not completing PROMs. A study exploring PROMs with older patients with comorbidities, also found no benefit in physical or mental health after employing PROMs in practice (Austin et al., 2019). They suggest that clinicians must discuss and engage, rather than passively use PROMs as a measurement tool only. Patient-centred communication was a key mechanism in reducing back pain-related disability and PROMs were suggested to have a role in patient-clinician interactions. Training should also include how to use the information provided by PROMs and approach discussions with patients (Gilbert et al., 2015). Recent research has focused on patient-centred communication using data from PROMs, with development of a manual and training session to help clinicians in cancer settings embedded PROMs into patient-centred discussions (Skovlund et al., 2020). Chiropractors often did not discuss PROMs with their patients, and further training should be provided to clinicians on how to use PROMs with patients.

11.4.3 Recommendations for future research

PROMs were found to be a tool for chiropractors to communicate with their patients. Although the research did not identify any differences in back pain-related disability between those who completed PROMs and those who did not, the research identified some of the contextual factors influencing back pain-related disability. This has implications for understanding how PROMs may be used within clinical practice. Further research should explore how PROMs can be used to impact patient-centred communication and pain-related fear, and how this might influence patients' back pain-related disability, self-management behaviours, and patient satisfaction.

Further qualitative research is needed to explore discussions between patients and chiropractors regarding PROMs. Recent research has explored the influence of PROMs in patient-clinician interactions in patients with epilepsy, using participant observations and qualitative interviews (Trillingsgaard Mejdahl, Schougaard, Hjollund, Riiskjær, & Lomborg, 2020). Examining conversations as they naturally occur, rather than relying on self-report, would allow researchers to understand how PROMs data is being used in clinical practice and how this may influence patient care. Audio-recordings or observations of patient-chiropractor encounters during treatment sessions would produce accurate descriptions of interactions, allowing for exploration of the nuances of patient-centred communication and the role of PROMs therein. Audio-recordings were deemed acceptable by participants in the feasibility study.

Although this research has provided some recommendations for use of PROMs, further work is needed to ensure the successful integration of PROMs into specialist musculoskeletal care. This work has identified some barriers and facilitators for use of PROMs in this context, including choosing the appropriate PROM, technological constraints, and clinician knowledge and engagement. Future research should explore these factors and link them to evidence-based change techniques for successful integration into routine clinical practice (Van Achterberg, 2015). Implementation requires long-term follow-up on an intervention, which fell out of scope of this research. However, using implementation science frameworks, further work should be conducted to explore the perception of PROMs and design and evaluate implementation strategies for PROMs in specialist musculoskeletal care (Stover et al., 2020).

11.5 Conclusion

This research set out to explore how PROM use in specialist musculoskeletal care affects patients with low back pain and through what mechanisms. Low back pain affects a third of the UK population each year, and despite PROMs being widely available and routinely used in musculoskeletal care, there was limited understanding of their clinical impact. This research was the first to examine the role PROMs play in clinical practice through identifying the clinical and psychosocial effects of using PROMs in routine treatment of low back pain and evaluating the process by which changes occur. Although there were no statistically significant effects of completing PROMs on back pain-related disability or psychosocial aspects of patient care, patients and chiropractors viewed PROMs as having a positive role in routine clinical practice. This research provides preliminary evidence of contextual factors within the treatment of low back pain, and highlighted processes by which PROMs may influence patient outcomes. PROMs may be used as a communication tool to support patient-centred communication, improving the effectiveness and delivery of existing treatments. Due to the small sample size within the RCT, it is important to conduct studies with adequate statistical power to examine the impact of PROMs on back-related disability. Further research should also explore how to integrate PROMs more appropriately within clinical practice to improve patient care and the management of low back pain.

Appendix A Search terms

PUBMED	Patient outcome assessment [thesaurus term] OR process assessment (health care) [thesaurus term] OR outcome assessment (health care) [thesaurus term] OR "patient-reported outcome*" [keyword] OR self-report [thesaurus term] OR self-assessment [thesaurus term] [thesaurus term] AND "clinical practice" [keyword] OR "clinical setting" [keyword] OR "practice setting" [keyword]
EMBASE	"patient-reported outcome*" [keyword] OR self-report [thesaurus term] OR "self-assessment" [keyword] OR self-evaluation [thesaurus term] AND Clinical practice [thesaurus term] OR "clinical setting" [keyword] OR "practice setting" [keyword]
PsycINFO	"patient-reported outcome*" [keyword] OR "self-assessment" [keyword] OR self-report [thesaurus term] OR treatment outcomes [thesaurus term] AND Clinical practice [thesaurus term] OR "clinical setting" [keyword] OR "practice setting" [keyword]
Cochrane Library	Patient outcome assessment [thesaurus term] OR process assessment (health care) [thesaurus term] OR outcome assessment (health care) [thesaurus term] OR "patient-reported outcome*" [keyword] OR self-report [thesaurus term] OR self-assessment [thesaurus term] [thesaurus term] AND "clinical practice" [keyword] OR "clinical setting" [keyword] OR "practice setting" [keyword]
Web of Science	"patient-reported outcome*" [keyword] AND "clinical practice" [keyword] OR "clinical setting" [keyword] OR "practice setting" [keyword]
PsycARTICLES	"patient-reported outcome*" [keyword] OR "self-assessment" [keyword] OR self-report [thesaurus term] OR treatment outcomes [thesaurus term] AND Clinical practice [thesaurus term] OR "clinical setting" [keyword] OR "practice setting" [keyword]

Appendix B Quality appraisal questions

(extracted from Dixon-Woods et al., 2006; Pluye et al., 2011)

Screening questions * From Dixon-Woods et al., (2006)	• Are there clear research questions (or objectives)? • Is the research question clearly specified and appropriate for the aims and objectives of research?* • Do the researchers provide a clear account of the process by which the findings were produced?* • Do the collected data address the research question (or objectives)? • Is the method of analysis appropriate and adequately explained?*
Qualitative (ethnography, phenomenology, narrative, grounded theory, case study, qualitative description)	• Are the sources of qualitative data (archives, documents, informants, observations) relevant to address the research question (objective)? • Is the process for analysing qualitative data relevant to address the research question (objective)? • Is appropriate consideration given to how findings relate to the context, e.g., the setting, in which the data were collected? • Is appropriate consideration given to how findings relate to researchers' influence, e.g. through their interactions with participants?
Quantitative randomised controlled (trials)	• Is there a clear description of the randomisation (or an appropriate sequence generation)? • Is there a clear description of the allocation concealment (or blinding when applicable)? • Are there complete outcome data (80% or above)? • Is there low withdrawal/drop-out (below 20%)?
Quantitative non-randomised (non-randomised controlled trials, cohort study, case-control study, cross-sectional analytic study)	• Are participants (organisations) recruited in a way that minimises selection bias? • Are measurements appropriate (clear origin, or validity known, or standard instrument; and absence of contamination between groups • In the groups being compared (exposed vs. non-exposed; with intervention vs. without; cases vs. controls), are the participants comparable, or do researchers take into account (control for) the difference between these groups? • Are there complete outcome data (80% or above), and, when applicable, an acceptable response rate (60% or above), or an acceptable follow-up rate for cohort studies (depending on the duration of follow-up)?
Quantitative descriptive (incidence or prevalence study, case series, case report)	• Is the sampling strategy relevant to address the quantitative research question (quantitative aspect of the mixed methods question)? • Is the sample representative of the population understudy? • Are measurements appropriate (clear origin, or validity known, or standard instrument)? • Is there an acceptable response rate (60% or above)?

Appendix C Systematic review constructs

Key
Clinicians' views
Patients' views
Trial outcomes

Construct: Assessment of Patient	Positive effect	Adverse or no effect
Quantitative	17% of clinicians felt that health status reports contributed to overall patient assessment some of the time. 21% of clinicians felt that health status reports contributed to overall patient assessment most of the time. 33% of clinicians felt that health status reports contributed to overall patient assessment all of the time (Kazis et al., 1990).	29% of clinicians felt that health status reports did not contribute to overall patient assessment (Kazis et al., 1990).
	21% of clinicians felt that health status reports contributed to medical history taking some of the time. 8% of clinicians felt that health status reports contributed to medical history taking most of the time. 29% of clinicians felt that health status reports contributed medical history taking all of the time (Kazis et al., 1990).	42% of clinicians felt that health status reports did not contribute to medical history taking (Kazis et al., 1990).
	21% of clinicians felt that health status reports contributed to physical examination some of the time. 17% of clinicians felt that health status reports contributed to physical examination most of the time (Kazis et al., 1990).	63% of clinicians felt that health status reports did not contribute to physical examination (Kazis et al., 1990).
Qualitative	The use of PROMs encourages both the clinician and patient to view illness in its biopsychosocial context (Buchi & Sensky, 1999).	Clinicians respected PROMs, but were concerned about the objectivity of the patients' ability to report pain and therefor the data was seen as subjective (Boyce et al., 2014). "Getting patients to fill out forms is grossly inaccurate in my book… the patient 9 time out of 10 wouldn't understand what hip pain is" (Boyce et al., 2014).
	The data from the PROM can be used to diagnose pain. "It is important to assess and take into account the thresholds of physical pain for each different individual on different occasions and how it is impacted by cultural and physiological factors" (Bottega & Fontana, 2010).	Clinicians were worried how patient expectation may influence PROM data, leading to either underestimation or overestimation of outcome (Boyce et al., 2014).

	PROMs are able to quantify the impact of patient injury on sport performance (Thigpen & Stanley, 2011). Positive aspects of using a pain measurement tool was to gather functional assessment information and obtain “objective data” (Schorn et al., 2014).	Participants believed that measuring pain is not important to all patients. "We don't have to have every single patients that comes in give us a pain rating on zero to ten. It's not a vital sign” (Ahluwalia et al., 2017).
	Participants felt PROMs reminded them to ask about patients' pain. “I think it’s helpful for me when it’s a patient that I’m not thinking about pain and then when I see it, I start questioning and find out maybe they are suffering from something that they didn’t even bring up because we’re dealing with other things in the visit.” (Ahluwalia et al., 2017).	Some patients regularly visiting their physiotherapist, felt PROMs did not add value as their clinician was already familiar with their problem. (Meerhoff et al., 2019)
	Some participants felt measuring pain was appropriate for ongoing and regular patients monitoring. "Well for certain populations this would be great. For the patients who come in with chronic [pain], who are on our med management list, this is a great way to go and they should be asked this before they pick up their medications… it's a good way to follow [them]" (Ahluwalia et al., 2017).	
	Participants agreed that routine pain screening through PROMS allowed for identification of patients who might not report pain. “It might help bring up something that they wouldn't talk about otherwise, you know. Like, ‘Oh, it's just old age’, ‘No, let's see what we can do with it’” (Ahluwalia et al., 2017).	
	Patients regularly visiting a physiotherapist identified PROMs had value in clarifying problems and creating self-awareness (Meerhoff et al., 2019)	

	Patients thought that the results of PROMs assisted with their diagnosis. "Obviously the benefit of using PROMs is that PTs can prepare themselves for my visit. Using the PROM results, your PT can analyze what might trigger the health problem and think about the intervention they might use." (Meerhoff et al., 2019)	
	Almost all patients felt that completing PROMs increased their self-awareness of their health and helped them discuss the severity of the problem. "I think that the questionnaires have helped me clarify my health problems, as completing the questionnaire provides me with a clearer picture of my health problems. … And when I am at the PT practice and am asked about my health problems, then I only start to think about it at that time … then you wonder at what moments during the week is the pain actually present. … the benefit of using the questionnaires is that you've already written that down. Indeed I must say that that is a real big benefit" (Meerhoff et al., 2019).	
Construct: Decision-Making	Positive effect	Adverse or no effect
Qualitative	Providers at both the US clinic and Swedish clinics both reported that the tool was valuable for follow up. (Hvitfeldt et al., 2009). "Work is smoother, it much easier to form an opinion and decisions are easier to make." (Hvitfeldt et al., 2009)	
	Measuring pain allowed for parameters to be set in order to choose the appropriate treatment and healthcare for a patient (Bottega & Fontana, 2010).	

	The assessment of pain facilitated individualised care for the patient and better planning of care. "This method is of great value in the performance / assistant of planning so we can assign a more expressive care in relation to the pathology and the patient as a whole. Thus, seeking to minimise the patient's suffering and pain" (Bottega & Fontana, 2010).	
	Using the assessment was thought to facilitate decision-making. "It is an instrument of the utmost importance and its application guides us to make important decisions in regards to the patient's pain" (Bottega & Fontana, 2010).	
	Scores from the PROMs were used to guide the treatment plan (Thigpen & Shanley, 2011).	
	Scores provided useful information in directing patient care (Thigpen & Shanley, 2011).	
	Some clinicians felt that the information from PROMs and information about clinical practice could improve decision making in the future (Boyce et al., 2014).	
	PROMs were used to set functional goals, by selecting the intervention and predicted the expected rate of change (Stratford & Binkley, 1999).	
	PROMs are used to discuss patient goals (Thigpen & Shanley, 2011).	
	PROM can be used to present the illness and anticipate change from treatment (Buchi & Sensky, 1999).	
	PROMs improved patient-centredness of their physiotherapy, helping patients to formulate problems allowing physiotherapists to make a tailored treatment plan. (Meerhoff et al., 2019).	
Construct: Therapeutic Relationship	Positive effect	Adverse or no effect
Quantitative	76.6% of clinicians felt satisfied that the tool for pain measurement helped patients	3.3% of clinicians felt dissatisfied that the tool for pain measurement helped patients

	participate in their pain management (Schorn et al., 2014).	participate in their pain management (Schorn et al., 2014).
	13% of clinicians felt that health status reports contributed to the doctor-patient relationship some of the time. 25% of clinicians felt that health status reports contributed to the doctor-patient relationship most of the time. 29% of clinicians felt that health status reports contributed the doctor-patient relationship all of the time (Kazis et al., 1990).	33% of clinicians felt that health status reports did not contribute to the doctor-patient relationship (Kazis et al., 1990).
Qualitative	It was suggested that using a PROM could increase the patient's self of control over their illness (Buchi & Sensky, 1999).	Patients regularly visiting a physiotherapist did not see PROMs having benefits in communication as they were familiar with their physiotherapist (Meerhoff et at., 2019)
	Use of a PROM made it possible to identify concerns of a patient (Buchi & Sensky, 1999).	
	Clinicians suggested that patient benefits included greater involvement in self-management (Hvitfeldt et al., 2009). "Patient gets more involved in their care –that helps the treatment" (Hvitfeldt et al., 2009).	
	The assessment of pain was thought to aid humanization of care. "I see the implementation of the pain scale as a way to humanize care, where we can stop relying on machines and turn to the patient; to what he is saying and feeling. Giving them an active voice and the right to express themselves" (Bottega & Fontana, 2010).	
	Using the PROM provides similar results to that of an interview, but is not so cumbersome and verbalising issues (Bucki and Sensky, 1999).	
	Some patients thought that the use of the PROM system changed their interaction with clinicians, comparing it to clinicians at other institutions. "The system makes it possible for the provider and I to talk about the important issues" (Hvitfeldt et al., 2009).	
	The PROM system provided a common language for patients	

	and clinicians which promoted communication. "The health questionnaire results act like a channel for communication" (Hvitfeldt et al., 2009).	
	New physiotherapy patients felt PROMs stimulated communication. "PROMs are probably useful for patients who visit their PT for the first time." (Meerhoff et al., 2019)	
Construct: Tracking Progress, Evaluating and Changing Treatment	Positive effect	Adverse or no effect
Quantitative	39.9% of clinicians felt satisfied that the tool for pain measurement helped them to visualise the effect of treatment on pain outcomes (Schorn et al., 2014).	46.6% of clinicians felt dissatisfied that the tool for pain measurement helped them to visualise the effect of treatment on pain outcomes (Schorn et al., 2014).
	53.3% of clinicians felt satisfied that the tool for pain measurement helped them to understand patient progress (Schorn et al., 2014).	36.6% of clinicians felt dissatisfied that the tool for pain measurement helped them to understand patient progress (Schorn et al., 2014).
	39.9% of clinicians felt satisfied that the tool for pain measurement helped them to modify a plan for pain treatment (Schorn et al., 2014).	30% of clinicians felt dissatisfied that the tool for pain measurement helped them to modify a plan for pain treatment (Schorn et al., 2014).
Qualitative	Information from the PROMs was used to track patient progress through treatment (Stratford et al., 1999).	Clinicians expected that the data from PROMs would be in line with that of clinicial indicators, leading to disbelief of patients whose data did not match. "Clinically, I see very very very few problems and very few dissatisfied patients… that is just wrong in my book" (Boyce et al., 2014).
	Clinicians believed that the assessment scale helped them to monitor the efficiency of the treatment. "This scale is important in the sense of monitoring the evolution of the intensification of pain and even to what point the treatment is being beneficial to the patient". "It is tool that allows us to quantify the pain our patient is feeling with more accuracy, and rethink whether or not the therapy being given is really effective in treating that individual" (Bottega & Fontana, 2010).	Five surgeons felt that the PROM data was not clinically useful and had no impact on their behaviour (Boyce et al., 2014). "I just think there is a lot of effort being put in there for not a lot of surgical gain from my perspective" (Boyce et al., 2014). "Unfortunately it does not provide me with one iota that helps me make my next score better" (Boyce et al., 2014)

	Patients who were shown a summary page from the scores appreciated it. “It is easy to see how I responded to treatment and how I felt last year” (Hvitfeldt et al., 2009).	Due to their uncertainty about the value of PROMs and a lack of knowledge of their usefulness, four clinicians were not inclined to use the data (Boyce et al., 2014)
	Clinicians compared PROMs with patient satisfaction and experience measures as together they examine the process of care (Boyce et al., 2014).	
	Clinicians reported that changes in scores aiding adjusting the treatment plan (Thigpen & Shanley, 2011).	
	Two clinicians stated that the information from PROMs had an impact by encouraging them to reflect on their clinical practice. “There have been a lot of high profile problems in recent times and maybe these kind of problems would have been spotted sooner if we were collecting this type of data” (Boyce et al., 2014).	
	Patients felt physiotherapists could use PROMs to evaluate treatment. "At a later phase, when the PROMs are completed again, they could analyze the progression did the pain decrease or is it completely resolved?” (Meerhoff et al., 2019)	
	“By administering questionnaires, the PT can optimally adjust his treatment plan, with the advantage, I presume, for the patient that a sort of a custom-fit plan arises. You’ll get more personal advice, and therefore, a more personal trajectory.” (Meerhoff et al., 2019).	
Sub-construct: Referrals	Positive effect	Adverse or no effect
Quantitative	33% of clinicians felt that health status reports contributed to patient referrals some of the time (Kazis et al., 1990).	50% of clinicians felt that health status reports did not contribute to making patient referrals (Kazis et al., 1990).
	17% of clinicians felt that health status reports contributed to patient referrals most of the time (Kazis et al., 1990).	Non-significant difference in additional treatment post-implementation of a numerical rating scale (p=.461) (Mularski et al., 2006).
		Reducing doctor visits was found to be non-significant after the use of PROMs (Kazis et al., 1990).

		Arthritis related referrals was found to be non-significant after the use of PROMs (Kazis et al., 1990).
Qualitative	Based on the scores, clinicians chose to refer the patient to another service (Thigpen & Shanley, 2011).	
Sub-construct: Medication Use	Positive effect	Adverse or no effect
Quantitative	After implementation of a new PROM form across a hospital, 17% of patients, had analgesia altered. 6% of patients had an additional dose of analgesia. And 88% of patients with scores >5 had pain management intervention after assessment (Purser et al., 2014).	54% of clinicians felt health status reports do not contribute to medication decisions (Kazis et al., 1990).
	After training of nurses and uses of a systematized assessment form, patients presented higher morphine consumption (dos Santos Silva et al., 2013).	No significant differences in changing medication post-implementation of a numeric rating scale (Mularski et al., 2006). No significant difference in pain prescription post-implementation of a numeric rating scale (Mularski et al., 2006).
	21% of clinicians felt health status reports contributes to medication decisions some of the time. 17% of clinicians felt health status reports contributes to medication decisions most of the time. 8% of clinicians felt health status reports contributes to medication decisions all of the time (Kazis et al., 1990).	Medication changes in the intervention group were non-significant after the use of PROMs (Kazis et al., 1990).
		No significant differences in medication values across intervention and control groups, after training on PROMs and PROM scores sent to clinicians (Hadjistavropoulos et al., 2009)
		No group differences in medication compliance after the use of PROMs (Kazis et al., 1990).
Qualitative		Clinicians were concerned that patients who continually score highly with pain scores may be looking to influence their prescription of opioids (Schorn et al., 2014).
Construct: Influencing Outcomes	Positive effect	Adverse or no effect
Quantitative	The pain significantly decreased in the intervention group (who completed a VAS) compared to control d = 0.1796, [0.0643-0.2949], p = 0.038 (Ravaud et al., 2004).	No differences were found between intervention and control group for pain levels (Hadjistavropoulos et al., 2009).

	Patients in the intervention group, whose nurses received training and used a systematized assessment form, presented lower pain intensity at rest and coughing (dos Santos Silva et al., 2013).	No differences were found between control and intervention groups for pain levels when deep breathing (dos Santos Silva et al., 2013).
	The intervention group, who completed PROMs and had their scores sent to clinicians, reported less pain related to strenuous activity at follow-up d = 0.4253 [0.054-0.7966] p=<0.05 (Hadjistavropoulos et al., 2009)	Health status showed no significant difference after the use of PROMs (Kazis et al., 1990).
		No significant differences in patient satisfaction after the use of PROMs(Kazis et al., 1990).
		No significant differences in patient satisfaction – across intervention and control groups. (Ravaud et al., 2004).
Sub-construct: Awareness of pain	Positive effect	Adverse or no effect
Qualitative		Participants felt that routinely measuring pain could shift the focus of the visit to an issue that was not likely to change. “If you're not careful, the pain screen is going to lead you down the road of pain when you don't need to go down that road today because that’s the same 4 out of 10 pain the patient’s had for the past fifteen years and it’s managed and they're okay with it.” (Ahluwalia et al., 2017).
		Participants felt when measuring pain, patients would report pain even if it was not a current issue. "“Like, it just didn’t come up. Does anything hurt? And then they’re like, yeah, this does, They say, oh, yeah, yeah, last year I had this and that, just went on and on and on. But maybe they don’t really care. That’s not what’s bothering them. But they’ll eventually think of something and give you a five all the time.” (Ahluwalia et al., 2017).
		Participants suggested measuring pain encouraged patients to "find" pain. "“It would just encourage them to complain, like |Participant X| said. That’s what you would have. You would have a whole clinic just related to that all day long I think. Because a lot of them sit around and just, you know…focus on the pain.” “I mean, you shouldn’t have to live with a horrible pain, but would they bring it up if they

		weren't being prompted about it?" (Ahluwalia et al., 2017).

Appendix D Feasibility trial recruitment information

D.1 Chiropractors

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16/SC/0025

REC review: South Central - Berkshire Research Ethics Committee

University of Southampton Ethics number: 16880

Version: 1.2 **Date**: 14/01/16

Please read this information carefully before deciding to take part in this research. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This research is exploring how patient outcomes are used within routine clinical practice and the effects they may have on patients.

What is the purpose of the study?

The purpose of this study is to look at the feasibility of conducting a larger research trial within the chiropractic clinic. This study is looking at chiropractors' experience of taking part in a trial. The information from this study will then be used to plan a larger research trial.

Why have I been chosen?

You have been invited to take part in this study because of you are a chiropractor working in the clinic taking part in this project. The company partner has agreed to this study being conducted in this clinic.

What will happen to me if I take part?

We will randomise you to one of three groups which will receive patients' outcome measures scores at various times during their treatment. Patients who are booked in to see you at the clinic will then be asked if they would like to be part of the study. We would like to recruit four patients for each chiropractor involved in the study. Patients may also opt to have their treatment sessions

audio recording for part of the study. If you agree to participate, we would like you to audio record your treatment sessions with these patients recruited into the study. After the completion of outcome measures (at 90 days) we will ask you to attend an interview session discussing your experience of being part of a trial.

Are there any benefits in my taking part?

The benefits of taking part include being able to share your experiences of being a chiropractor and being involved in a trial. In the long term, this study hopes to inform the development of a larger trial surrounding the use of patient reported outcome measures in clinical practice.

Are there any risks involved?

The research does not involve any additional risks of harm or discomfort than anticipated in everyday life.

Will my participation be confidential?

All data will be anonymised. Individuals may be quoted within the findings, but your names, work settings and identifiable information will be changed to protect your identity. All data use is strictly within the terms of the Data Protection Act 1998 and the Data Policy of the University of Southampton. The information will be stored on a password protected computer and all files containing any personal data will be made anonymous. No identifiable data will be published and no information will be shared with other organisations.

What happens if I change my mind?

You are free to leave the study at any time. There are no consequences for yourself if you decide you would no longer like to participate in the study.

What happens if something goes wrong?

If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.

What happens next?

If you are interested in taking part in the study, please fill in the eligibility form attached and send back to the University of Southampton in the envelope provided, you will then be contacted regarding your eligibility for the study.

Where can I get more information?

This information sheet hopes to provide all the details you need to know before deciding whether or not to take part; if you have any further queries please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 02380594719.

D.2 Patients

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16/SC/0025

REC review: South Central - Berkshire Research Ethics Committee

University of Southampton Ethics number: 16880

Version: 2.3 **Date**: 21/03/16

Invitation to enter a research study

We would like to ask you to help us with a research study we are conducting with the University of Southampton and Anglo-European College of Chiropractic.

- This research is exploring the effect of filling in the questionnaires you fill out as part of assessing your health and treatment.
- The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic and how people with low back pain experience taking part. In the long term, this study hopes to benefit patients' treatment.
- If you agree to take part you will be asked to fill in questionnaires about your health. These questionnaires are the same as those you will fill out as part of your normal treatment at the clinic. You will be asked to fill these out at various times before, during and after your treatment [up to six times].
- If you agree to participate, we would also like to audio record your treatment sessions with the chiropractor. But you can still take part in the study even if you do not want your treatment sessions audio recorded.
- The final questionnaires would be completed 90 days from now. Afterwards, we will ask you to take part in an interview, over the telephone, discussing your experience of being part of a trial.

Yes I am willing to take part

Yes I am willing to take part but I do not want my treatment sessions audio recorded

- The research does not involve any additional risks of harm or discomfort than anticipated in everyday life. All data will be anonymised. Individuals

may be quoted within the findings, but your names and any identifiable information will be changed to protect your identity. All information will be stored on a password protected computer.

- You are free to leave the study at any time. There are no consequences for yourself if you decide you would no longer like to participate in the study.
- If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.
- If you are interested in taking part in the study, please click on the link above. ; if you have any further questions please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 02380594719.

Appendix E Feasibility trial consent documentation

E.1 Consent form for chiropractors

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16880

Version: 2.1 **Date:** 14/01/16

Please initial the boxes if you agree with the following statements:

1. I have read and understood the information sheet, version 1.2, dated 14/01/16 and have been given significant opportunity to ask questions about the study.

2. I agree to take part in the above study and as part of the study I am willing to audio record treatment sessions, contact my patients who are eligible for the study and be interviewed. I agree to the recording of the interview.

3. I understand that my participation in this study is voluntary, that I can choose not to participate in part or all of the project, and that I may withdraw at any time without any questions being asked, and without being penalised or disadvantaged in any way by the University of Southampton or Back2Health.

4. I agree for my data to be used for the purpose of this study, and I understand that the information I provide will be held and processed into a report and publication related to the research. I understand that no identifiable data will be published and will not be shared with any other organisation.

E.2 Consent form for patients (full participation)

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16880

Version: 2.1 **Date:** 05/01/16

Please initial the boxes if you agree with the following statements:

1. I have read and understood the information sheet and have been given significant opportunity to ask questions about the study.

2. I agree to take part in the above study and I understand that by agreeing to take part in the study means that I am willing to have my treatment sessions audio recorded, I will be asked to fill in various questionnaires online and be interviewed over the telephone. I agree to the recording of the interview.

3. I understand that my participation in this study is voluntary, that I can choose not to participate in part or all of the project, and that I may withdraw at any time without any questions being asked, and without being penalised or disadvantaged in any way by the University of Southampton.

4. I agree for my data to be used for the purpose of this study, and I understand that the information I provide will be held and processed into a report and publication related to the research. I understand that no identifiable data will be published and will not be shared with any other organisation.

5. I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be made anonymous. I understand that the University of Southampton is complying with its duties and obligations under the Data Protection Act 1998.

Name:_____ Date: _____

Once you have completed this consent form, you will be directed to a secure form to input your contact details.

E.3 Consent form for patients (opt out of audio-recordings)

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16880

Version: 2.1 **Date:** 05/01/16

Please initial the boxes if you agree with the following statements:

1. I have read and understood the information sheet and have been given significant opportunity to ask questions about the study.

2. I agree to take part in the above study and I understand that by agreeing to take part in the study means that I will be asked to fill in various questionnaires online and be interviewed over the telephone. I agree to the recording of the interview.

3. I understand that my participation in this study is voluntary, that I can choose not to participate in part or all of the project, and that I may withdraw at any time without any questions being asked, and without being penalised or disadvantaged in any way by the University of Southampton.

4. I agree for my data to be used for the purpose of this study, and I understand that the information I provide will be held and processed into a report and publication related to the research. I understand that no identifiable data will be published and will not be shared with any other organisation.

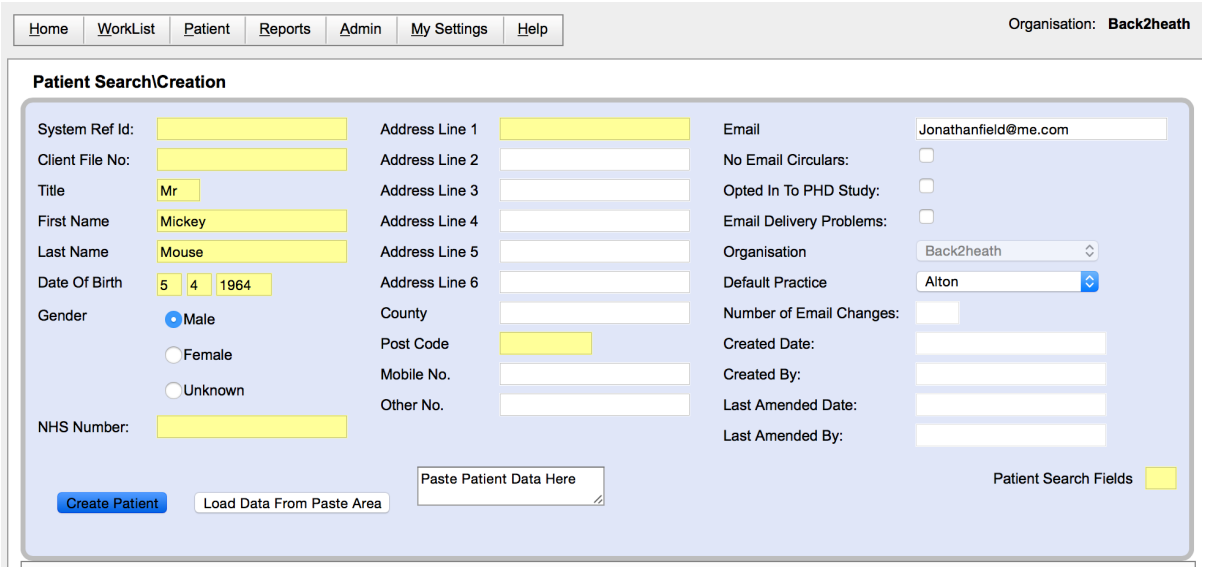
5. I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be made anonymous. I understand that the University of Southampton is complying with its duties and obligations under the Data Protection Act 1998.

Name:_____ Date: _____

Once you have completed this consent form, you will be directed to a secure form to input your contact details.

Appendix F Routine use of Care Response

Patients who ring up to book an appointment with a chiropractor in the clinic are asked to capture information from the patient before the first treatment. If the patient agrees, the receptionist creates a new patient record on the care response system. The receptionist fills in several key details, the minimum detail that is required is the patient name, date of birth and email.



After filling in these details, the receptionist creates a new presentation, including which chiropractor the patient is booked in with a date of their first appointment. The system then automatically emails assessment to the patient.

Dear Mr Patient Name,

I am writing to ask if you would please complete a short online form before your appointment. During your treatment we will ask you for personal information relevant to your care that allows us to carry out your treatment effectively. This online form gives you the opportunity to provide some of this information now which will save you time when you come into the Clinic for your first appointment.

Your clinician will email you other forms during the course of your treatment to monitor your progress and ensure you are receiving the most appropriate care. These forms will only take a few minutes to complete and will arrive 15, 30 and 90 days after your first appointment. Please complete the forms when they arrive, even if you are no longer receiving treatment. You can opt out of the online forms at any time if you wish.

Paper versions of the forms are available in Clinic if you would rather not use the online form – please remember to arrive at least 15 minutes early for your appointment so that there is time to complete them.

The initial form can be found by following the link below. By completing this assessment form you are consenting to this information being shared with the clinical staff caring for you. Some of it may also be used for clinical audit or administrative purposes and personal information will be anonymised wherever possible.

Pre-examination form for Mr Patient Name

A reminder email is sent after two days if we have not received a reply.

Yours sincerely,

Jonathan Field DC PGD FCC
Back2heath

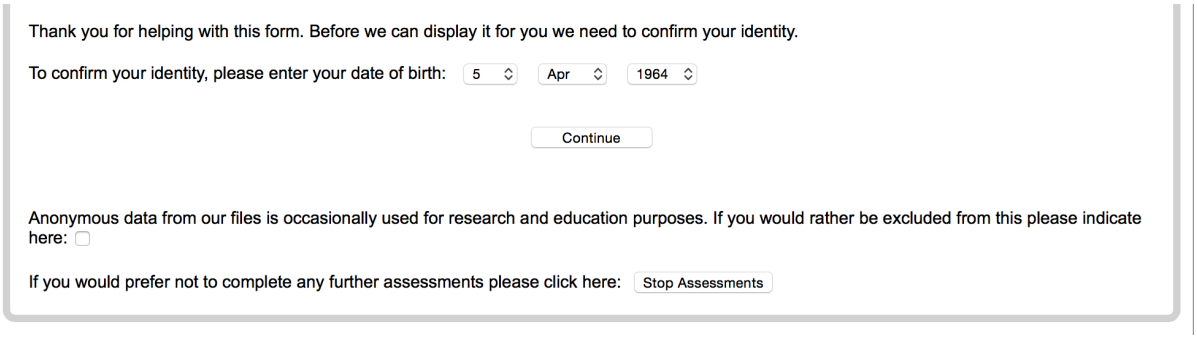
If the link does not work please copy the entire line below into the address bar of your internet browser:
http://www.care-response.com

You will be assessed and treated by: Jonathan Field DC PGD FCC
They are also responsible for supervising your overall treatment whilst with us.

Our ref {Name,Jonathan Field DC PGD FCC ,Petersfield,Back2heath}

To stop receiving assessment invitations by email please follow the link above. Enter your data of birth in the 'Checking Your Identity' window and press the 'Stop Assessments' button. You will be shown a message to confirm that you request has been received.

The patient, upon clicking on the link, is taken to the Care Response system. They are asked to confirm their identity before moving onto the next screen, at this point the patient is also able to opt out of anonymised research and has the option to not complete further assessments. They are also asked if they are willing to be contact about research. They are given two options “I consent to you contacting me” and “Please don’t contact me about research”.

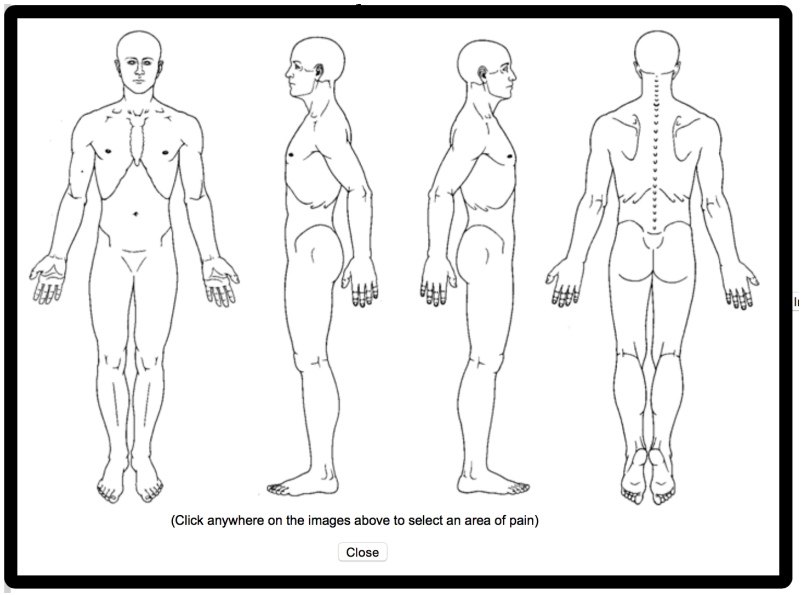


At Back2heath we regularly conduct research aimed at improving the treatment and management of musculoskeletal problems like back pain. If you are willing for a researcher to contact you to discuss a future research study that is considered relevant to you, please tick this box. (There is no obligation to participate in any study and your decision will not affect your current or future care at Back2heath)

☐ I consent to you contacting me
☐ Please don't contact me about research

Continue

Following this patients are directed to fill in clinical details. Depending on the areas of the body they select, the following questions about their condition change. Patients are asked to fill in a series of questionnaires regarding their presenting problem, and their medical history.



Information about your condition

How long has THIS PRESENT episode of your complaint lasted?

- ○ More than 10 years
- ○ 6-10 years
- ○ 3-5 years
- ○ 1-2 years
- ○ 7-12 months
- ○ 3-6 months
- ○ Less than 3 months

Have you **ever** had this problem before? ○ Yes ○ No

In total, have you had this pain for **more** than 30 days in the last year? ○ Yes ○ No

Pre-examination medical history information

As part of your first visit you will be able to discuss your problem as well as any other medical issues that may be significant. In order to use the time to the best advantage can we ask you to answer these background medical questions now.

Do you have, or have you ever had, treatment for:

Problems with circulation, blood pressure or heart	○Yes ◉No
Arthritis or orthopaedic problems	○Yes ◉No
Lung or breathing problems	○Yes ◉No
Digestive problems	○Yes ◉No
Kidney or bladder problems	○Yes ◉No
Epilepsy or neurological problems	○Yes ◉No
Anxiety, depression, stress or psychological problems	○Yes ◉No
Allergies	○Yes ◉No
Cancer or tumours	○Yes ◉No
Diabetes	○Yes ◉No

Are you currently taking any medication including contraception?	○Yes ◉No
Have you ever had any operations to date?	○Yes ◉No
Do you smoke?	○Yes ◉No
Do you drink alcohol?	○Yes ◉No
Have you suffered any significant injury as a result of an accident?	○Yes ◉No

Patients who select back pain as a problem are asked to complete the STarT Back Questionnaire and PROMs of the chiropractor's choice. Before submission patients also get space to provide more information.

Throughout and after their treatment, patients are sent an email to complete the PROMs. This is sent at 14 days, 30 days and 90 days. If they do not respond within 24 hours, patients are sent a reminder email.

Dear Mr Patient Name,
I am writing to ask if you would kindly complete a short online assessment form asking about your symptoms since you came to us
recently.

It would be helpful if you could do this now, as human nature means people who delay are often unreliable in coming back to it later. The
form can be found by following this link:
Outcome form for Mr Patient Name

We ask patients to report their progress at three intervals by sending these emails 14 days, one month and three months after they are seen with a new problem. This helps us not only see how much improvement there has been but also to assess any further changes over time. This is felt to be important as a goal of treatment is to prevent reoccurrence and ensure lasting benefit.

Information from your answers is important to me in recording your progress, positive or otherwise. Your answers will also help us help others, as anonymous information from the results of our patients is used to give us an insight into how different problems respond to the care we offer. This enables us to know if changes to the way we treat certain conditions are helpful in aiding a quicker recovery for our patients.

A reminder email is sent after 2 days if we have not received a reply.

Yours sincerely,
Jonathan Field DC PGD FCC
Back2heath

If the link does not work please copy the entire line below into the address bar of your internet browser:
http://www.care-response.com

Our ref (Name,Jonathan Field DC PGD FCC ,Petersfield,Back2heath)

To stop receiving assessment invitations by email please follow the link above. Enter your data of birth in the 'Checking Your Identity' window and press the 'Stop Assessments' button. You will be shown a message to confirm that you request has been received.

Following the link they are asked to confirm their identity, and once again can opt out of completing the assessments. At each of these time points they are asked to fill out PROMs of the chiropractor's choice. Responses to these questionnaires are emailed to the chiropractors. They are also able to log onto the Care Response system and see these results in graph form.

Hello
This is a notification email to highlight that an assessment has been completed by a patier
practitioner: Jonathan Field DC PgD FCC
Please view the practitioner worklist to view the assessment:

Click Here

If the link doesn't work, please copy the entire line below into the address bar of your inte
browser:
http://www.beta.care-response.com/beta/WorkListPractitioner.aspx

PATIENT PROGRESS SUMMARY

Date	**16/06/2015**
Practice/Practitioner:	**Petersfield/Jonathan Field DC PgD FCC**

Patient File No/Unique System ID:	**/8068**
First Appointment Date:	**18/06/2015**

	16/06/2015	**16/06/2015**
BQ	45	30
BQ Change		33.33%
Pain	7	5

Statement from PGIC
16/06/2015 : Much improved

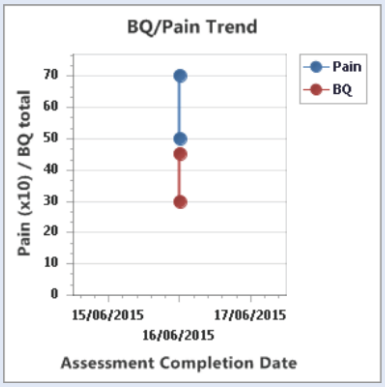
Many thanks
Back2heath

Progress
System Ref Id: **8068**

	16/06/2015	16/06/2015
BQ	45	30
BQ Change		33.33%
Pain	7	5

Statement from PGIC
16/06/2015 : Much improved

The Bournemouth Questionnaire (BQ) is a validated patient reported outcome measure. For more details see http://www.aecc.ac.uk/research



(Pain score multiplied by ten for ease of viewing)

Appendix G Feasibility study interview recruitment information

G.1 Invitation to interview (patients)

Dear _____,

We would like to ask you to help us with a research study we are conducting with the University of Southampton and Anglo-European College of Chiropractic.

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16/SC/0025

REC review: South Central - Berkshire Research Ethics Committee

University of Southampton Ethics number: 16880

Version: 1 **Date**: 21/03/16

- This research is exploring the effect of filling in the questionnaires you fill out as part of assessing your health and treatment.
- The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic and whether people with low back pain would take part. In the long term, this study hopes to benefit patients' treatment.
- If you agree to take part we will ask you to take part in an interview, over the telephone, discussing our planned study. Prior to the interview you will receive an overview of our planned study in the post, including some questionnaires and information sheets. We would then like to ask you a series of questions about our study, including your views on the questionnaires and information sheets.

Yes I am willing to take part

- The research does not involve any additional risks of harm or discomfort than anticipated in everyday life. All data will be anonymised. Individuals may be quoted within the findings, but your names and any identifiable information will be changed to protect your identity. All information will be stored on a password protected computer.

- You are free to leave the study at any time. There are no consequences for yourself if you decide you would no longer like to participate in the study.
- If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.
- If you are interested in taking part in the study, please click on the link above. If you have any further questions please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 02380594719.

G.2 Invitation to interview (chiropractors)

Dear Staff,

We would like to ask you to help us with a research study we are conducting with the University of Southampton and Anglo-European College of Chiropractic.

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16/SC/0025

REC review: South Central - Berkshire Research Ethics Committee

University of Southampton Ethics number: 16880

Version: 1 **Date**: 21/03/16

- This research is exploring the effect of patients filling in questionnaires that form the assessment of their health and treatment.
- The purpose of this study is to look at the feasibility of conducting a larger research trial within chiropractic clinics. This study is looking at chiropractors' experience of taking part in a trial. The information from this study will then be used to plan a larger research trial.
- If you agree to take part we will ask you to take part in an interview, at the Chiropractic clinic, discussing our planned study. Prior to the interview you will receive an overview of our planned study in the post, including some questionnaires and information sheets. We would then like to ask you a series of questions about our study, including your views on the questionnaires and information sheets.
- The research does not involve any additional risks of harm or discomfort than anticipated in everyday life. All data will be anonymised. Individuals may be quoted within the findings, but your names and any identifiable information will be changed to protect your identity. All information will be stored on a password protected computer.
- You are free to leave the study at any time. There are no consequences for yourself if you decide you would no longer like to participate in the study.
- If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.

- If you are interested in taking part in the study, please click on the link below. If you have any further questions please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 02380594719.

Yes I am willing to take part

G.3 Invitation to interview (reception staff)

Dear Staff,

We would like to ask you to help us with a research study we are conducting with the University of Southampton and Anglo-European College of Chiropractic.

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16/SC/0025

REC review: South Central - Berkshire Research Ethics Committee

University of Southampton Ethics number: 20715

Version: 1.1 **Date**: 12/05/16

- This research is exploring the effect of patients filling in questionnaires that form the assessment of their health and treatment.
- The purpose of this study is to look at the feasibility of conducting a larger research trial within chiropractic clinics. This study is looking at the role of clinic receptionists if we want to run a large research trial in chiropractic clinics, and the barriers of implementing patient questionnaires into clinic practice.
- If you agree to take part we will ask you to take part in an interview, at the Chiropractic clinic, discussing our planned study. Prior to the interview you will receive an overview of our planned study in the post. We would then like to ask you a series of questions about our study and the barriers to implementing patient questionnaires in your practice.
- The research does not involve any additional risks of harm or discomfort than anticipated in everyday life. All data will be anonymised. Individuals may be quoted within the findings, but your names and any identifiable information will be changed to protect your identity. All information will be stored on a password protected computer.
- You are free to leave the study at any time. There are no consequences for yourself if you decide you would no longer like to participate in the study.
- If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.

- If you have any further questions please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 02380594719.

Appendix H Feasibility study interview consent documentation

Study Title: The feasibility of conducting a pilot randomised controlled trial on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes **Ethics number:** 16880

Version: 1 **Date:** 21/03/16

Please initial the boxes if you agree with the following statements:

1. I have read and understood the information sheet and have been given significant opportunity to ask questions about the study.

2. I agree to take part in the above study and I understand that by agreeing to take part in the study means that I am willing to be interviewed over the telephone. I agree to the recording of the interview.

3. I understand that my participation in this study is voluntary, that I can choose not to participate in part or all of the project, and that I may withdraw at any time without any questions being asked, and without being penalised or disadvantaged in any way by the University of Southampton.

4. I agree for my data to be used for the purpose of this study, and I understand that the information I provide will be held and processed into a report and publication related to the research. I understand that no identifiable data will be published and will not be shared with any other organisation.

5. I understand that information collected about me during my participation in this study will be stored on a password protected computer and that this information will only be used for the purpose of this study. All files containing any personal data will be made anonymous. I understand that the University of Southampton is complying with its duties and obligations under the Data Protection Act 1998.

Name:_____ Date: _____

Once you have completed this consent form, you will be directed to a secure form to input your contact details.

Appendix I Feasibility study interview guides

I.1 Interview guide for trial patients

Preamble: To tell you a little bit about my research. The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic. The study wants to look at how people with low back pain experience taking part in a trial. I am interested in finding out about your experiences of being involved in this study. I am hoping your views will help me plan and design a larger study in the future.

- **To start with can you tell me about why you chose to take part in the study?**

Possible prompts - How does being in a study make you feel? What made you want to take part?

- **How did you feel, after you'd filled in all your details for the chiropractic clinic, to get asked straight away about taking part in the study?**

- **So I've sent you a copy of the information sheet that patients would see when they were invited to take part, I wondered if you could tell me how you would feel about taking part in the study and the overall process of the study?**

how understandable do you think the leaflet is for patients? Is there anything else you would want to know?

- **How did you feel about the questionnaires you were sent to fill in?**

Possible prompts - What made you fill in (or not fill in) the questionnaires? How did you feel about the length of the questionnaires? How did you feel about the questions that they asked?

- **You didn't fill in the questionnaires every time they were sent to you, can I ask why did you choose to fill them in sometimes and not other times?**

- **Now I've sent you a copy of the questionnaires you were asked in fill in. Do you have them with you right now?**

A) Please can you tell me what it was like filling in the Bournemouth Questionnaire?

Possible prompts - Overall how did you feel about the questions? Was there anything you specifically liked or disliked about the questionnaire? Can you tell me a bit about why that was? Is there any part of the questionnaire that seems easy or difficult?

B) Please can you tell me what it was like filling in the Patient Global Impression of Change Scale?

Possible prompts - how did you feel about the question? Did you find it particularly easy or difficult? Can you tell me a bit about why that was?

- **I've attached a couple of other questionnaires, one is the MYMOP. Can you tell me your thoughts on this questionnaire?**

How would you feel about being asked this questionnaire to complete online? Did you find it particularly easy or difficult? Do you prefer it over either of the other questionnaires? How would you feel about being asked to complete it as well as the others?

- **I've attached a couple of other questionnaires, one is the Back Pain Functional Scale. Can you tell me your thoughts on this questionnaire?**

How would you feel about being asked this questionnaire to complete online? Did you find it particularly easy or difficult? Do you prefer it over either of the other questionnaires? How would you feel about being asked to complete it as well as the others?

- **Did you and the chiropractors talk about the questionnaires at all?**

Possible prompts - What was discussed? Who brought up the topic of the conversation, you or the chiropractor? How did you feel about what was discussed?

- **Is there anything else you think you would like to be asked or the chiropractor know about before you went to the treatment session?**

Possible prompts - Was there anything you felt the chiropractor should know about you that you did not have a chance to tell him/her? Why would you have liked to be asked that? Why do you think that it is important for the chiropractor?

- **As part of the study you had to fill in the questionnaires x number of times and that was decided based on which chiropractor you booked in with. How did you feel about being placed in a group which decided how often you were sent the questionnaires to fill in?**

Possible prompts - How did that make you feel? How did that make you feel about being in the study?

- **At the beginning of the study you had the option to opt in or out of having your treatment sessions recorded, could you tell me why you chose to opt in/opt out?**

Possible prompts - What influenced you to make that decision? What were your concerns? How did that make you feel? How did you find the process of having the sessions audio recorded?

- **We are thinking about doing this study again but with more people, how do you think we should improve the study?**

Possible prompts - What would make the study more desirable? Would you take part in a similar study again, and why?

- **In advance of this interview, I sent you some other questionnaires, which we might ask patients if we do this study again. I'm keen to know what you think about them, could we have a look at them now? Overall how do you feel about filling in nine questionnaires?**

Possible prompts - is there anything there that would affect your decision to complete this questionnaire? Is there any part of this questionnaire that seems easy or difficult? How long do you think it would take you?

- **There are a couple of questionnaires we are still deciding between and it would be helpful to know which one you might prefer. So if you look at questionnaire four a and questionnaire four b, these questionnaires are assessing the same idea. Can you tell me which one you prefer and why?**

Is there a reason for that?

- **So if you look at questionnaire seven, we've got a couple which are differently worded, and differently depicted as well as a questionnaire that is similar to the previous questionnaires, these questionnaires are assessing the same idea. Can you tell me which one you prefer and why?**

Is there a reason for that?

- As part of the study, these questionnaires would come at 90 days, along with the final questionnaire sent from the chiropractor. We would really need as many people as possible to fill in all the questions, at 90 days. Can you think of anything we can do to do that?

- **Is there anything else you would like to add?**

- **Do you have any questions for me?**

I.2 Interview guide for trial chiropractors

Preamble: To tell you a little bit about my research. The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic. I am interested in finding out about your experiences of being involved in this study. I am hoping your views will help me plan and design a larger study in the future. To start with we are going to talk a bit about your past experiences when patients fill out health questionnaires, and then we will move on to specifically talking about my study.

- **As part of the study you were sent a link to view when patients have filled out the questionnaires, could you tell me about your experiences using the data provided to you?**

Possible prompts - How do you use the data? How often do you look at the data? How do you decide to look at the data? Do you discuss the data with your patients? What discussions do you have? Can you give me a specific example of that?

- **What are your views on the collection and use of these questionnaires?**

Possible prompts - Do you think there are any benefits to collecting this data? What do you think those are? Why do you think that? Do you think there are any barriers to collecting and using the data? What do you think those are? Why do you think that? Can you think of anything else that influences your decision to use the data or how you use the data?

- **I'd like to spend some time talking about the data collected from patients.**

A) So I know you use the Bournemouth Questionnaire within the clinic. What are your thoughts on this questionnaire?

Possible prompts - How do you feel about your patients filling in these questions? Do you feel like these questions are relevant to your practice?

B) I know you also use the Patient Global Impression of Change Scale. What are your thoughts on this questionnaire?

Possible prompts - How do you feel about your patients completing this? Do you feel like this is relevant to your practice?

- **How do you feel about the routine collection of this data being used in your clinical practice?**

Possible prompts - Why do you think the routine collection of this data is feasible in this practice? Can you think of anything that would facilitate your use of the data?

- **Literature suggests that collecting this data and providing it to practitioners may impact on patient care, how do you think this happens in practice?**

Possible prompts - Why do you think that is? Do you think you made any changes in your practice from the data? Are there any other ways you think the data may impact the patient and the care they receive?

Now I would like to move on to talking specifically about my study.

- **To start can you tell me about why you chose to take part in this study?**

Possible prompts - How does being in a study make you feel? What made you want to take part?

- **Was there anything you specifically liked or disliked about being in the study?**

Possible prompts - Can you give me an example of when that occurred? How did that make you feel? How did the make you feel about the study? Was there anything else you liked/disliked?

- **If we did the trial again, we would be looking at providing chiropractors with training regarding the questionnaires and the data provided to them? Can you think of anything you would like to see or know that would facilitate your use of the data?**

Possible prompts – Can you give me an example of that?

- **At the beginning of the study, patients had the option to opt in or opt out of having their treatment sessions audio recorded, can you tell me how the audio recording went?**

Possible prompts - How did you feel about audio recording the sessions? How did you feel about being audio recorded? Did you have any concerns? How did you find the process of audio recording the sessions?

- **As part of the study you were randomised to a group which decided how many times your patients had to fill in the questionnaires. How do you feel about being randomised within the study to how often you received patient outcome data?**

Possible prompts - How did that make you feel? How did that make you feel about being in the study? How do you think you would feel if you were randomised to one of the other groups?

- **We are thinking about doing this study again but with more people, how do you think we should improve the study?**

Possible prompts - What would make the study more desirable? Would you take part in a similar study again, and why?

- **Is there anything else you would like to add?**

- **Do you have any general questions for me?**

I.3 Interview guide for patients

Preamble: To tell you a little bit about my research. The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic. The study wants to look at how people with low back pain experience taking part in a trial. I am interested in finding out about how you would feel about taking part in a study. I am hoping your views will help me plan and design a larger study in the future.

- **To start with, I wondered if you could think back to when you visited the chiropractor, and you were asked to fill in questionnaires online. How did you find that experience?**

Possible prompts – What were your first thoughts? Did you fill them in? How did you feel about being asked to fill them in multiple times? If you didn't fill them in, can you tell me why you chose to not fill them in?

- **So I previously sent you an overview of our planned study, which looks at, the effect asking patients to fill in the questionnaires has on patients. Can you tell me your overall thoughts on the study?**

Possible prompts – What were your first thoughts? Would you want to take part?

- **In advance of this interview, I sent you an information sheet, which is how patients are invited to take part in the study. I'm keen to know what you think about the sheet, could we have a look at it now?**

Possible prompts – What were your first thoughts? Would you want to take part? Is there anything else you would want to know?

- **As part of the study we would ask participants to fill in the questionnaires a number of times (up to six times) and that decision would be based on which chiropractor patients booked in with. How would you feel about being placed in a group which decided how often you were sent the questionnaires to fill in?**

Possible prompts - How would that make you feel? How would that make you feel about being in the study? Would that influence your decision to take part?

- **At the beginning of the study we will give people the option to opt in or out of having their treatment sessions recorded, could you tell me if you would chose to opt in/opt out and why?**

Possible prompts - What would influence you to make that decision? What are your concerns? How would that make you feel?

- **In advance of this interview, I also sent you some other questionnaires, which we might ask patients if we do this study again. I'm keen to know what you think about them, could we have a look at them now?**

Possible prompts - is there any questionnaire that really stands out that you specifically liked or disliked? Is there any part of this questionnaire that seems easy or difficult?

- **How would you feel being asked to complete all these questionnaires online?**

Possible prompts – Do you think you would complete them all? How long do you think it would take you? Can you think of any reasons why you wouldn't complete them? What would help you complete them all? Would you prefer a paper version?

- **How do you think we should improve the study?**

Possible prompts - What would make the study more desirable?

- **Is there anything else you would like to add or do you have any questions for me?**

- **And finally, would you like a copy of this interview transcript, and would you like a copy of the findings of this study?**

I.4 Interview guide for chiropractors

Preamble: To tell you a little bit about my research. The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic. I am hoping your views will help me plan and design a larger study in the future.

- **To start with, I previously sent you an overview of our planned study, can you tell me your overall thoughts on the study?**

Possible prompts – What were your first thoughts? Would you want to take part?

- **Was there anything you specifically liked or disliked about the study?**

Possible prompts - Can you give me an example of that? How do you think that would make you feel? How did that make you feel about the study? Was there anything else you liked/disliked?

- **In advance of this interview, I sent you an information sheet, which is how chiropractors are invited to take part in the study. I'm keen to know what you think about the sheet, could we have a look at it now?**

Possible prompts – What were your first thoughts? Would you want to take part?

- **As part of the study chiropractors will be randomised to a group which decides how many times their patients have to fill in the questionnaires. How would you feel about being randomised within the study to how often you received patient outcome data?**

Possible prompts - How would that make you feel? How would that make you feel about being in the study?

- **How do you think we should improve the study?**

Possible prompts - What would make the study more desirable? Would you take part in the study?

- **I'd like to spend some time talking about the data we want to collect from patients.**

A) This is a copy of the Bournemouth Questionnaire that patients have to fill out, just take a couple of minutes to read it over. What are your thoughts on this questionnaire?

Possible prompts - How do you feel about your patients filling in these questions? Do you feel like these questions are relevant to your practice?

B) This is a copy of the Patient Global Impression of Change Scale that patients have to fill out, just take a couple of minutes to read it over. What are your thoughts on this questionnaire?

Possible prompts - How do you feel about your patients completing this? Do you feel like this is relevant to your practice?

- **As standard practice you are sent a link to view when patients have filled out the questionnaires, could you tell me about your experiences using the data provided to you?**

Possible prompts - How do you use the data? How often do you look at the data? How do you decide to look at the data? Do you discuss the data with your patients? What discussions do you have? Can you give me a specific example of that?

- **What are your views on the collection and use of these questionnaires?**

Possible prompts - Do you think there are any benefits to collecting this data? What do you think those are? Why do you think that? Do you think there are any barriers to collecting and using the data? What do you think those are? Why do you think that? Can you think of anything else that influences your decision to use the data or how you use the data?

- **How do you feel about the routine collection of this data being used in your clinical practice?**

Possible prompts - Why do you think the routine collection of this data is feasible in this practice? Can you think of anything that would facilitate your use of the data?

- **Literature suggests that collecting this data and providing it to practitioners may impact on patient care, how do you think this happens in practice?**

Possible prompts - Why do you think that is? Do you think you made any changes in your practice from the data? Are there any other ways you think the data may impact the patient and the care they receive?

- **Is there anything else you would like to add?**

- **Do you have any general questions for me?**

I.5 Interview guide for reception staff

Preamble: To tell you a little bit about my research. The purpose of this study is to look at how to conduct a large research trial within the chiropractic clinic. This study is looking at how patients till in health questionnaires. My previous interviews have suggested that your role is very important in getting patients to fill in questionnaires and I am hoping your views will help me plan and design a feasible and practical study in the future.

- **To start with, I understand you use Care Response, can you tell me a little bit about your role in using Care Response in your practice?**

Possible prompts – How does that work? Can you take me through what happens from your side of things? What is your involvement? What happens from a patients side of things?

- **If a new patient phones up to make an appointment, can you take me through what happens with that patient?**

Possible prompts – what about a returning patient?

- **What helps you to do your job?**

Possible prompts – Can you give me an example of that?

- **What impedes you?**

Possible prompts – Can you give me an example of that?

- **What helps the patients?**

Possible prompts – Can you give me an example of that?

- **What impedes the patients?**

Possible prompts – Can you give me an example of that?

- **Here is an overview of our planned study, can you tell me your overall thoughts on the study?**

Possible prompts – What were your first thoughts? Do you think this would work in this clinic? How do you think we could make the study work within your clinic?

- **What parts do you think will be difficult for you to do? What would make them easier? What could we do instead?**

Possible prompts - Can you give me an example of that? How do you think that would work/not work? How did that make you feel about the study? Was there anything else you liked/disliked?

- **How do you think we should improve the study?**

Possible prompts - What would make the study more desirable? What would enable your clinic to take part in the study?

- **Is there anything else you would like to add?**
- **Do you have any general questions for me?**

Appendix J RCT recruitment and consent documentation – chiropractors

J.1 Information sheet

We would like to ask you to help us with a research study we are conducting as part of a PhD project with the University of Southampton and AECC University College.

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

- This research is exploring how patient outcomes are used within clinical practice and their potential effects.
- This study aims to evaluate the role PROMs play in clinical practice and explore practitioners' experiences and views of using PROMs. We are hoping to improve the understanding of the role of PROMs in the treatment of back pain and the effects they may have on patient care.
- If you agree to participate we will randomise you to receive patients' outcome measures scores at various times during their treatment. This will either be three times, seven times, or not at all. Patients who are booked in to see you will then be asked if they would like to participate. We would like to recruit 20 patients per chiropractor.
- After the trial is complete we may also ask you to take part in a telephone interview discussing your experiences of using PROMs.
- Taking part in the study will count towards your continuing professional development. You will receive a CPD certificate and a certificate for your practice for research collaboration with the University of Southampton and Royal College of Chiropractors, and be entered into a raffle for £100 of

vouchers for every five patients you recruit into the study. All identifiable information will be stored on a password protected computer.

- The research does not involve any additional risks of harm or discomfort than anticipated in everyday life. Individuals who take part in an interview may be quoted anonymously in the study findings. All information will be stored on a password protected computer.
- You are free to leave the study at any time. There are no consequences for you if you decide you would no longer like to participate.
- If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.
- If you are interested in taking part in the study, please click on the link below. If you have any further questions please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 07717 209995.
- The University of Southampton conducts research to the highest standards of research integrity. The University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you only for as long as it is necessary to verify and defend, when required, the process and outcomes of the research. Any link between you and your information will be removed as quickly as is feasible, provided your research is not impacted as a result. We will only use your data/information as set out in this Participant Information Sheet and in accordance with our Data Protection Policy and our Privacy Notice for Research Participants. We will not do anything with your personal data that you would not reasonably expect.

Yes I am willing to take part

J.2 Consent form

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Please initial the boxes if you agree with the following statements:

I have read and understood the information sheet, version 3, dated 31/01/20 and have been given significant opportunity to ask questions about the study.	
I confirm I am a qualified chiropractor, registered with the General Chiropractic Council. I confirm I can speak and read English fluently.	
I agree to take part in the above study and as part of the study I am willing to be interviewed. I agree to the recording of the interview. I will report back any concerns patients may have about the study.	
I understand that my participation in this study is voluntary, and that I may withdraw at any time without any questions being asked, and without being disadvantaged in any way by the University of Southampton or any other organisation.	
I agree for my data to be used for the purpose of this study, and I understand that the information I provide will be held and processed into a report and publication related to the research. I understand that no identifiable data will be published and will not be shared with any other organisation.	

Please state full name:_____

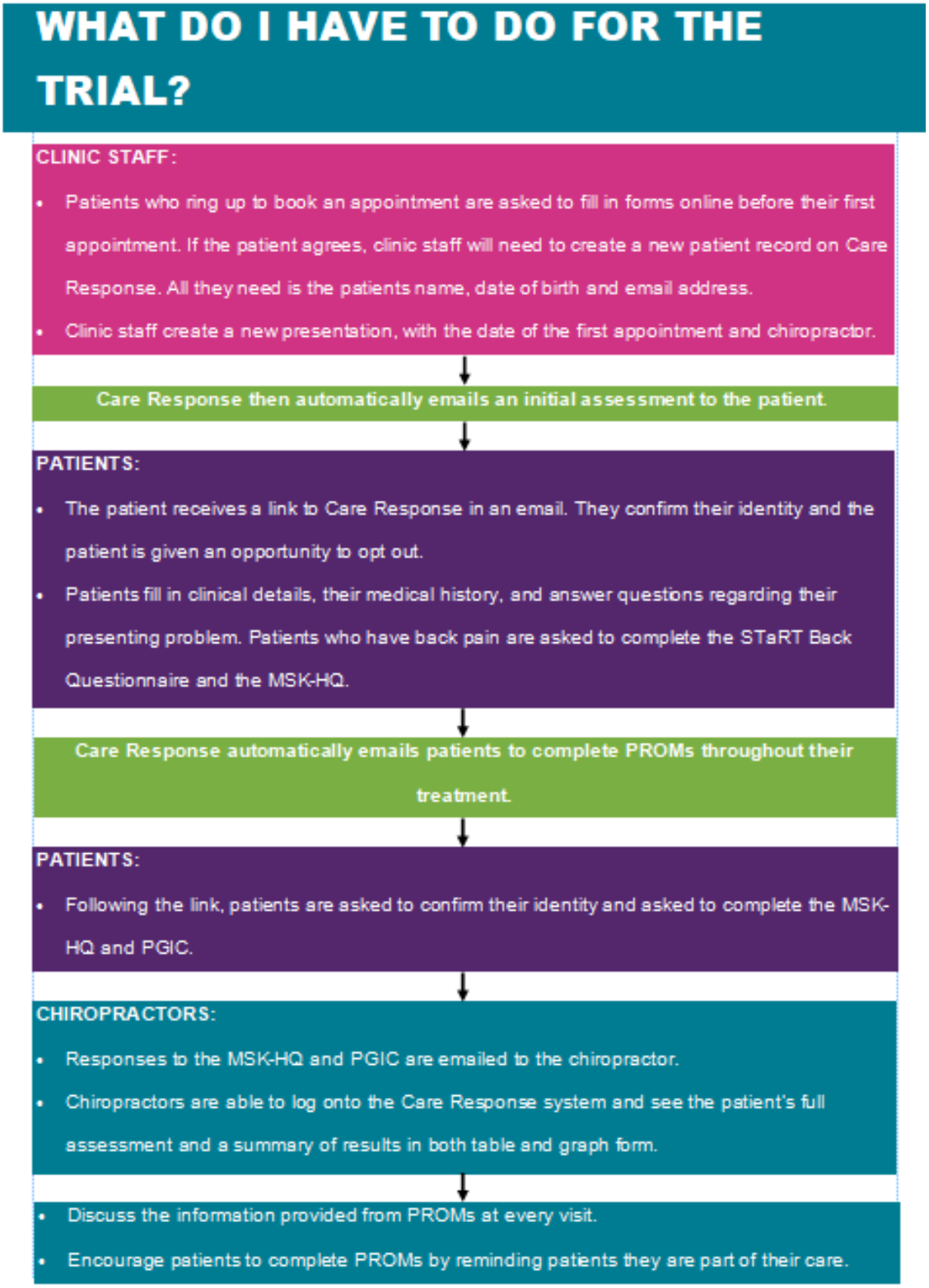
Please select today's date: _____

Practice name: _____

Practice telephone no: _____

Email: _____

Appendix K RCT documentation for reception staff



Appendix L RCT recruitment and consent documentation – patients

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 5 **Date:** 31/01/20

Invitation to enter a research study

We would like to ask you to help us with a research study we are involved with, as part of a PhD project at the University of Southampton, with AECC University College. The aim is to evaluate the role health questionnaires play in the treatment of low back pain, and to explore patients' experiences of completing health questionnaires.

- If you agree to take part you will be asked to fill in questionnaires about your health. These questionnaires are the same as those you will fill in as part of your normal treatment at the clinic. You will be asked to fill these in before, during and after your treatment [up to seven times].
- We would also like to interview some people, over the telephone, to explore their experiences of filling in the health questionnaires. If you agree to participate, you may be selected to be interviewed at the end of the study. However not all willing participants will need to be interviewed.
- We would also like you to fill in some extra questionnaires, to help us understand if you have benefited from completing the health questionnaires. You would complete one extra questionnaire today, taking two minutes. Then 90 days after your first treatment, we would ask you to complete 9 questionnaires. This will take around 20 minutes and can be done on the computer or you can request a paper copy. To thank you for filling in the questionnaires at 90 days after your first treatment, you will receive a £10 digital love2shop voucher.

- The research does not involve any additional risks of harm or discomfort than anticipated in everyday life. All data will be anonymised. What you say in an interview may be quoted in the report, but your name and any identifiable information will be changed to protect your identity. All information will be stored on a password protected computer.

- You are free to leave the study at any time without giving a reason. There are no consequences for you if you to leave. You will not be asked to complete any more questionnaires. If you have completed the questionnaires your data will be used in the final analysis. If you wish to leave the study, please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 07717 209995.

- If you have any concerns or complaints please contact the Head of Research Governance at the University of Southampton, at 02380 598848 or rgoinfo@soton.ac.uk.

- If you are interested in taking part in this study, please tick the box below; if you have any questions please contact the lead researcher, Michelle Holmes at mmh1e13@soton.ac.uk or call 07717 209995.

- The University of Southampton conducts research to the highest standards of research integrity. The University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you only for as long as it is necessary to verify and defend, when required, the process and outcomes of the research. Any link between you and your information will be removed as quickly as is feasible, provided your research is not impacted as a result. We will only use your data/information as set out in this Participant Information Sheet and in accordance with our Data Protection Policy and our Privacy Notice for Research Participants. We will not do anything with your personal data that you would not reasonably expect.

I have read and understood the information sheet, version 5, dated 31/01/20 and have been given significant opportunity to ask questions about the study. I agree to take part in the above study □

and I understand that by agreeing to take part I will be asked to fill in various questionnaires online. I may also be asked to be interviewed over the telephone. I agree to the recording of the interview.

Appendix M PROMs training for chiropractors

M.1 Training booklet

Using Patient Reported Outcome Measures in Chiropractic Care for Patients with Low Back Pain

University of Southampton

The Royal College of Chiropractors

AECC University College

RPROMs

RECONCEPTUALISING PATIENT REPORTED OUTCOME MEASURES

Working in collaboration with:

University of Southampton · The Royal College of Chiropractors · AECC University College

What is this project about?

This training was developed and written by Michelle Holmes, as part of her PhD project at the University of Southampton. Funded by the University of Southampton, AECC University College, Royal College of Chiropractors, and the Southampton Complementary Medicine Research Fund.

We are exploring how patient reported outcome measures (PROMs) are used within chiropractic practice and the potential effects of using them. We are hoping to improve the understanding of the role of PROMs in the treatment of back pain and the impact they may have on patient care.

Thank you again for being part of the RPROMs study.

PROMS PAGE 2

INTRODUCTION

Why should I read this booklet?

This booklet provides the practical PROM guidance that is needed for patient reported outcome measurement in chiropractic care for patients with back pain. The booklet introduces why we use patient reported outcome measures, and then focuses on two specific instruments, with step-by-step training on how to use them in your practice.

Michelle Holmes
Psychology, Shackleton Building
University of Southampton
University Road
Southampton
Hampshire
SO17 1BJ
m.m.holmes@soton.ac.uk

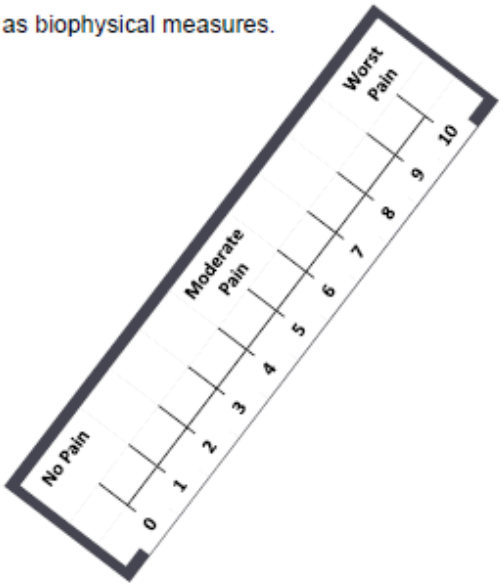
What's included?

WHAT ARE PATIENT REPORTED OUTCOME MEASURES?

What are PROMs?

'Patient reported outcome measures' (commonly abbreviated to PROMs) is an umbrella term for standardised instruments and questionnaires used to collect data on patients' perceptions and views about their health. When completed, they typically produce a numerical score.

PROMs can be used to measure constructs of health, health status, quality of life, and quality of care, as well as the processes, structures and outcomes of care. PROMs capture patient views, feelings and subjective experiences, unlike traditional methods such as biophysical measures.



Why are PROMs important?

PROMs are important in clinical practice as patients' views are valuable information that may help in evaluating health care. Initially, PROMs were used within clinical practice, to:

- increase knowledge of disease trajectories;
- evaluate the effectiveness of treatment on individual patients;
- assess the quality of the care provided; and
- inform clinicians about health management and aid the development of treatment plans.

The National Institute for Clinical Excellence (NICE) suggests that PROM data provides an insight into the effectiveness, appropriateness, acceptability of treatment; as well as the impact of a treatment on patients' physical or psychological symptoms, disability, functioning, and overall quality of life.

Within the NHS, routine measurement is used to:

- provide information on health of patients and treatment outcomes;
- allocate resources, set priorities, and planning of services.

When you think about PROMs you might typically think about their use in research studies to see if patients have improved. However we are focusing on PROMs in your clinical practice.

How are PROMs used in practice?

PROMs are typically used in clinical practice for two purposes:

HEALTHCARE EVALUATION

+

INDIVIDUALISED PATIENT CARE

The key reasons for using PROMs in clinical practice are to:

- Improve patients' experience
- Improve quality of treatment
- Support treatment planning
- Monitor delivery of services
- Define best practice treatment

HEALTH CARE EVALUATION

The NHS uses aggregated PROM data from individual patients for audit. The data is utilised to examine the effectiveness, appropriateness, quality and performance of health care.

This can be collected internally within institutions or externally as part of mandated publicly reported data; the collection of data places pressure on healthcare providers to respond and improve patient care.

PROMs are also used in clinical trials, to evaluate treatments or interventions. PROMs can also be used in economic evaluations.

EXAMPLE

Using data from PROMs with information on the costs of treatment, it is possible to estimate overall effectiveness of treatments and to quantify any health gain and the associated costs.

See: Newell, Diment and Bolton (2016)

INDIVIDUALISED PATIENT CARE

PROMs can also be used at individual patient level in routine clinical practice. PROMs can aid clinicians' provision of care for patients, by presenting patients' views of their health. This can complement medical history testing and physical examination.

PROMs can be used to:

- Screen for health problems
- Establish patients' baseline
- Assess symptoms
- Monitor health progress or disease progression
- Monitor changes in quality of life
- Select appropriate treatment for patients
- Facilitate communication with patients
- Aid clinical decision making
- Monitor the outcomes of treatment
- Evaluate the effect of treatment

Research indicates that PROMs may impact clinically and psychologically on patients when used in clinical practice.

A review of PROM research suggested that using PROMs may influence **detection of psychological problems** and **facilitate communication** between healthcare professionals and patients (Greenhalgh & Meadows, 1999).

Three reviews, examining evidence from RCTs or controlled trials, identified that PROMs may improve the process and outcome of care. This included **improvements in health status and functional status** as well as **increased diagnosis** and appropriate use of health services, with **improvements in patient-clinician communication and patient satisfaction** (Espallargues et al, 2000; Marshall et al, 2006; Valderas et al., 2008).

"The feedback was necessary to understand whether the treatment was being good for my back"

Patient story

PROMS PAGE 6

WHAT DO PROMS MEAN FOR ME?

You can look at data from patients to:

- Identify problems that may have gone unnoticed
- Track patients' outcomes over time
- Evaluate if treatment is effective
- Facilitate changing treatment as needed
- Encourage discussion with patients

"For me it's about identifying those that are at risk of not responding as you would expect them to and then being able to intervene a lot earlier"

Chiropractor's experience

KEY POINTS

- PROMs are a way of measuring a patient's health
- PROMs can measure many aspects of health
- PROMs can improve clinician knowledge over the course of care
- Can be used for health care evaluation
- Can be used within the care of individual patients
- Many ways to use PROMs in practice

HOW DO PROMS WORK IN CLINICAL PRACTICE?

How do I administer PROMs?

PROMs are self-completed, through paper questionnaires, interviews or on electronic devices. Using electronic systems to record PROMs allows the data to be presented graphically to the chiropractor and within treatment sessions with patients. Also, aggregated anonymised data can be extracted to produce local and national reports.

CareResponse

What is Care Response?

Care Response is a free web-based system to help clinical practices gather and report PROMs. It was developed by clinicians and researchers to support patient care and is promoted by the Royal College of Chiropractors.

Care Response runs on a database accessed via any internet browser. This has advantages in that there is no program to install; it works on any device capable of accessing the internet.

PROMS PAGE 8

Chiropractor's experience

"I don't have to do anything, it's easy. It just pings off. And it's lovely and I sit and see the results"

A patient's information, name, date of birth and email, is entered once and thereafter for most patients the collection of information is automatic.

Patients complete an initial assessment form from an email that the system sends to them. This includes a brief background medical history, and for those with lower back pain, the STarT Back screening questionnaire, and validated PROMs.

When a patient completes a PROM, results are delivered to their practitioner by email. Logging into Care Response allows practitioners to see detailed information for their patients.

Practitioners using Care Response may view graphs containing collated results from all of their patients. They may also compare these to results for all practitioners at their practice or all practices using the Care Response system.

How do I decide which PROM to use?

There are a huge variety of PROMs which can be used with patients. PROMs can be classified by the scope of the issue being measured, this may be generic:

- Overall health
- Wellbeing

Or they may be more specific regarding:

- Condition - i.e. Ankylosing Spondylitis
- Site - i.e. Lower Back Pain
- Dimension - i.e. Pain

PROMs may also be a summary of health, such as 'How is your health in general?', or may be individualised to allow patients to select issues that are of concern to them.

PROMs can also be classified according to three elements:

- Construct - the domain of health assessed
- Population - who the PROMs are suited for
- Measurement - how the domains are measured and scored.

	Generic Measures	Specific Measures
Advantages	• Relevant across different conditions • Large range of issues looked at	• Specifically developed • Relevant for use in specific conditions or issues
Disadvantages	• Lack of responsiveness to change • Does not identify specific problems	• Does not allow direct comparison with other groups

The number of PROMs available makes the choice of the right PROM difficult. There are a number of things to consider:

- The reason for using a PROM
- The context of collecting data
- What issues are important to patients
- If patients find the PROM suitable.

Based on research conducted with chiropractors and patients with low back pain, we recommend using the specific measures MSK-HQ and PGIC.

What is the MSK-HQ?

The MSK-HQ was developed by Arthritis UK and University of Oxford. It was developed to be used across patients with musculoskeletal conditions, focusing on both their pain, pain-related symptoms, and the interference pain has on their daily functioning.

The questionnaire has 14 questions assessing different domains:

- Pain
- Stiffness
- Walking
- Dressing
- Physical activity
- Daily routine
- Social activity
- Needing help
- Sleep
- Fatigue
- Emotional wellbeing
- Condition understanding
- Symptom management
- Overall impact.

Example questions include:
How severe was your usual joint or muscle pain and/or stiffness overall during the day in the last two weeks?
How much have your symptoms interfered with your ability to walk in the last two weeks?

Each question is scored on a five-point scale from "not at all" to "extremely" and on average the total MSK-HQ takes two minutes to complete.

Not at all	Slightly	Moderately	Fairly Severe	Very Severe
☐	☐	☐	☐	☐

Why use the MSK-HQ in chiropractic practice?

The MSK-HQ was found acceptable and useful following qualitative interviews with patients and chiropractors.
Chiropractors, although acknowledging the benefits of a pain score, preferred to use a more functional PROM, believing it improved their clinical practice. Patients also preferred a functional measure.
It was also noted in the interviews, that the variety of conditions and symptoms affecting patients influenced the relevance of PROMs.
The MSK-HQ includes various domains, but does not specify activities, allowing for an individualised response.

What is the PGIC?

The Patient Global Impression of Change Scale (PGIC) is a Global Rating Scale and is used to aggregate several components of a patient's experience into one overall measure of their treatment.

The PGIC asks patients to rate their pain or complaint and rate it compared to the past week.

They then mark this on a 7-point numerical analogue scale. All points are labelled with a written description of the score, assigning a meaning to the scale.

The PGIC

How would you describe your pain/complaint now, compared to how you were when you completed the questionnaire before your first visit to the clinic?

- ○ Very much improved
- ○ Much improved
- ○ Slightly improved
- ○ No change
- ○ Slightly worsened
- ○ Much worsened
- ○ Worse than ever

Are these tools actually useful?

To determine the usefulness of a PROM, standardised criteria, known as psychometric properties, are used to evaluate them. PROMs need to have reliability and validity.

PROMs need to be reliable, ensuring certainty over scores. PROMs must minimise the chance of random error. For example, we want to make sure that measuring pain before treatment and two weeks later, that any changes in score are true and not down to measurement error.

PROMs also need to be valid - and measure what they claim to measure. PROMs must correlate with similar measures, assess relevant domains to the subject matter, and whether the measurement measures these concepts. For example, a PROM measuring pain should be similar to other PROMs, assess relevant domains related to pain, and that the questions assess those domains.

During development and validation, the MSK-HQ and PGIC were found to be reliable and valid.

PROMS PAGE 11

HOW DO I USE PROMS IN MY PRACTICE?

- Sign up new patients in Care Response
- Care Response automatically emails an initial assessment and follow-up PROMs
- Care Response emails responses to you
- Log on to Care Response to see detailed responses, tables of results and graphs

KEY POINTS

- Electronic systems are efficient PROM data capture tools
- Many types of PROMs are available for use
- The MSK-HQ examines patients' pain, pain-related symptoms, and daily functioning
- The PGIC is a global rating scale of patients' experience
- PROMs need to be reliable and valid
- The MSK-HQ and PGIC are appropriate and acceptable to patients and useful for chiropractors

CareResponse

"It's easy. It saves a lot of time as well, when they first come in. Cos as I say, all the paperwork is done. It's just a consent form and in they go. I think it's really good."

Reception staff experience

PROMS PAGE 12

HOW DO I USE THE DATA FROM PROMS?

"Once you get into Care Response, and you actually look at the data, the data is hugely useful and really interesting"

How do I use this with my patients?

PROMs provide a method of patients providing data at a time that is convenient to them and provides clinicians with valuable information.

This ensures the patient's perspective on their pain and the impact of the pain to be heard, which enables:

- The treatment and management plan to be focused on issues important to the patient
- Clinicians to receive detailed information which provides further understanding of a patient's physical and psychological needs
- The patients to be actively involved in the treatment and management of their back pain
- The patient to see and discuss their progress, which can support self-management of their pain.

The information provided from PROMs can be used for the initial appointment and subsequent visits after a patient completes a PROM. Clinicians need to look at the data and discuss the results with patients in order to benefit from using PROMs.

"My pain was recorded adequately, and [improved] understanding between the practitioner and I that we were going forward"

Patient story

What do the scores mean?

- The MSK-HQ is scored on a range from 0 to 56. A higher score indicates better health status.
- The pain score ranges from 0-10, where 0 is *'no pain'* and 10 is *'worst pain possible'*.
- The PGIC statement has 7 options, which range from *very much improved* to *worse than ever*.

Minimally Important Change (MIC)

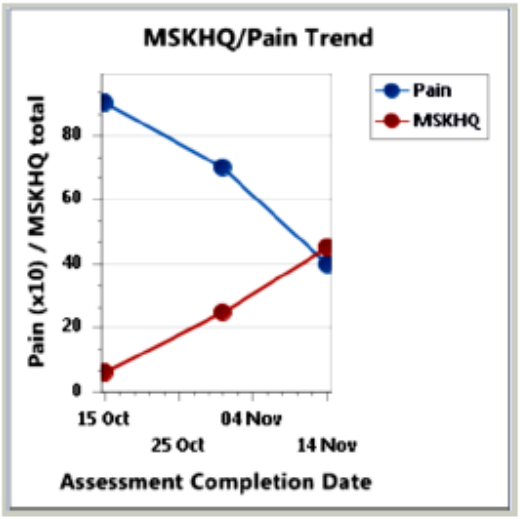
This is the smallest change on a PROM that people with the condition would identify as important.

- The MIC for the MSK-HQ has been calculated as 5.5. This means the MSK-HQ total score should change by more than 5.5 points to be clinically meaningful to patients.
- The MIC for pain has been calculated as –2.0. This means that the pain score needs to have reduced by 2 points to be clinically meaningful to patients.

Clinicians can view the full assessment by clicking on the link in the email, or by logging on to Care Response and searching for a patient.

Presentation History

Action	First Appt Date
View	15-Nov-2018



Patient Progress Graph

- The blue line represents a single item - patient's pain. The score is multiplied by ten for ease of viewing. In the above example, you can see the patient's pain has decreased.
- The red line represents the overall MSK-HQ score, with a higher score indicating better health status.

Chiropractor's experience

"I can ping that into a little graph, which I love, and you can show them the graph"

PROMS PAGE 15

WHAT DOES THIS MEAN FOR MY PRACTICE?

To help PROMs enhance your clinical practice, you need to:

- Make sure patients understand that filling in PROMs is a part of their care
- Look at the data provided by patients at the initial assessment and every time they complete a PROM
- Discuss the information provided with the patient, at the initial assessment, and every time they complete a PROM

KEY POINTS

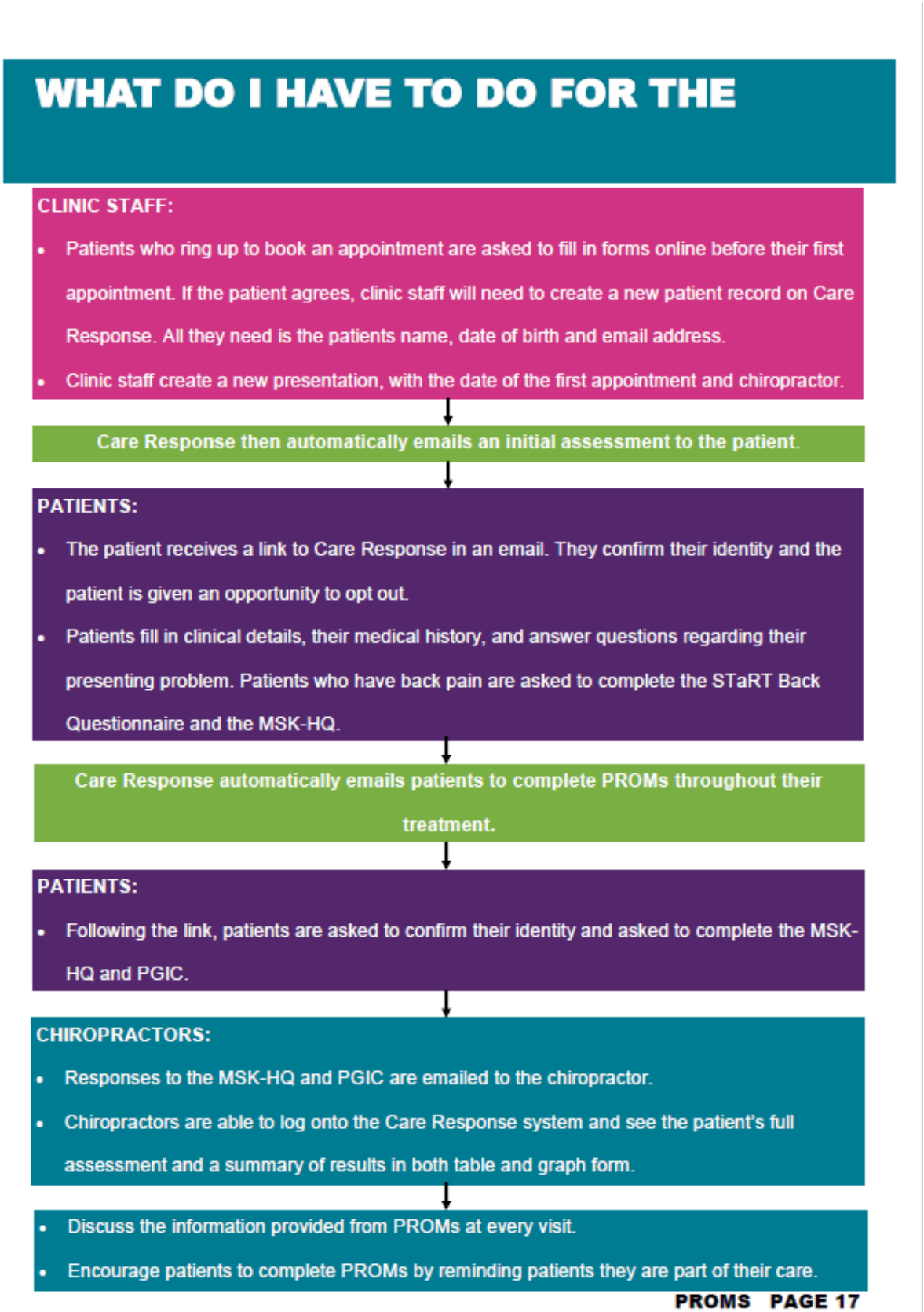
- The initial assessment provides important data on the patient's perspective of their pain
- Data from PROMs over time enables treatment to be monitored and provides information on a patient's progress
- PROMs can be viewed in table form, graph form, or the full assessment
- To enhance practice, PROMs need to be discussed with patients

PROMS PAGE 16

"If what they are telling you is they're not getting better, then obviously you can change the management plan"

"If somebody comes in, they're a 10, and then I treat them three times, and they're a 5, and you can use that as a visual tool, to say that 'your pain has reduced' so it is useful"

Chiropractors' experience


WHAT DO I HAVE TO DO FOR THE
CLINIC STAFF:
• Patients who ring up to book an appointment are asked to fill in forms online before their first appointment. If the patient agrees, clinic staff will need to create a new patient record on Care Response. All they need is the patients name, date of birth and email address.
• Clinic staff create a new presentation, with the date of the first appointment and chiropractor.
Care Response then automatically emails an initial assessment to the patient.
PATIENTS:
• The patient receives a link to Care Response in an email. They confirm their identity and the patient is given an opportunity to opt out.
• Patients fill in clinical details, their medical history, and answer questions regarding their presenting problem. Patients who have back pain are asked to complete the STaRT Back Questionnaire and the MSK-HQ.
Care Response automatically emails patients to complete PROMs throughout their treatment.
PATIENTS:
• Following the link, patients are asked to confirm their identity and asked to complete the MSK-HQ and PGIC.
CHIROPRACTORS:
• Responses to the MSK-HQ and PGIC are emailed to the chiropractor.
• Chiropractors are able to log onto the Care Response system and see the patient's full assessment and a summary of results in both table and graph form.
• Discuss the information provided from PROMs at every visit.
• Encourage patients to complete PROMs by reminding patients they are part of their care.
PROMS PAGE 17

NOTES

BARRIERS AND SOLUTIONS

You might feel it will be difficult to use PROMs in your clinical practice. Here are some things other chiropractors feel make PROMs difficult and potential solutions we have found from our previous research.

PROMs are a burden to my patients

In our previous work, no patients reported our PROMs being burdensome, taking less than 3 minutes to complete. Patients found PROMs to be an acceptable and appropriate part of their care.

Patients don't complete PROMs

It is important that it is explained to patients that completing the questionnaires is a component of their care and the answers they give play a role within their treatment.

PROMs are time consuming for clinic staff

There is minimal additional time needed for Care Response. Once the clinic and chiropractors have been set up. The processing of patients using Care Response takes less than two minutes.

Discussing PROMs with patients in clinic

It is important to look and discuss the results with patients. PROMs are part of the formal process of getting information from patients. This discussion should continue throughout their care.

PROMS PAGE 19

SELF-EVALUATION

Finish this sentence:

PROMs are important because...

See page 4

Name some of the ways PROMs can be used with individual patients:

1.
2.
3.
4.
5.

See page 6

Complete these sentences:

Care Response is a...
The MSK-HQ is a PROM which...
The PGIC is a...

See pages 8, 10-11

Phase	*Why is this important?*
Make sure patients understand PROMs	
Initial assessment	
Use PROMs throughout care	
Discuss PROMs with patients	

See page 13

If you have any questions, please note them down here to discuss at the

FURTHER READING

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RPROMs

RECONCEPTUALISING PATIENT REPORTED OUTCOME MEASURES

Working in collaboration with:

University of Southampton

The Royal College of Chiropractors

AECC University College

M.2 Guide for telephone training

- Thank you for taking part:
    - Your input will help the University of Southampton to identify the role PROMs have in the treatment of back pain. This will help us develop resources to support people with back pain and improve patient care in the future.
- Begin with I want to focus on why we are looking at PROMs:
    - Have you used PROMs before in your practice?
    - Okay so we know PROMs can be used to evaluate health services, but this study is more looking for individualised patient care
    - PROMs can measure patients' health from their view, can improve your knowledge,
- From your experience and the existing training, can you tell me a bit about how you might use PROMs in clinical practice?
    - Identify problems
    - Track patients' progress
    - Evaluate if treatment is effective
    - Facilitate changing treatment
    - Encouraging discussion with patients
- Okay, for this study we are implementing PROMs using Care Response
    - Have you used it before?
    - Confident?
    - Set up properly?
    - Can I pass your details on to…
- Using PROMs for individual patients is a bit different to healthcare evaluation, in the booklet, we talk about the different phases, I want to run through these, and your self-evaluation, thinking about why these things are important and how you will do this in your practice.
    - Making sure patients understand PROMs
    - Initial assessment
    - Use PROMs throughout care
    - Discuss PROMs with patients
- Questions
    - Barriers/solutions

Appendix N Correspondence with patients

N.1 Email to patients after recruitment

Email Subject: Study in association with University of Southampton

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Dear _____,

Thank you for agreeing to take part in our study, and completing the online consent form. Your input will help the University of Southampton to identify the role health questionnaires have in the treatment of back pain. This will help us develop resources to support people with back pain and improve patient care in the future.

I have attached a copy of the patient information sheet for your records. If you have any questions, please let me know and I will be happy to answer them by email or over the telephone (07717 209995).

Best wishes,

Michelle

Michelle M Holmes

PhD Student

School of Psychology

University of Southampton

N.2 Email to patients at 86 days after baseline

Email Subject: Study in association with University of Southampton: reminder I

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Dear _____,

Thank you for taking part in our study so far. This is just a reminder that in four days you will receive an email from your chiropractor asking you to complete a series of questionnaires for the study. It would be helpful if you could please fill out these questionnaires, **even if you have finished seeing your chiropractor** as this is important for our study. If you would prefer a paper copy, please let me know either by replying to this email, or by calling 07717 209995 and I will arrange for a paper copy to be sent to you with a pre-paid envelope for returning them to us. As a thank you for completing these questionnaires, you will receive a £10 digital love2shop voucher.

These questionnaires are very important to our study and we hope that your answers will help us improve chiropractic care in the future. Thank you again for taking part in our study so far. If you have any questions, please let me know and I will be happy to answer them by email or over the telephone.

Best wishes,

Michelle

Michelle M Holmes

PhD Student

School of Psychology

University of Southampton

N.3 Email to patients at 95 days after baseline

Email Subject: Study in association with University of Southampton: reminder II

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Dear _____,

Thank you for taking part in our study so far. This is just a reminder a few days ago you received an email from your chiropractor asking you to complete a series of questionnaires that you were asked to complete as part of the study. It would be helpful if you could please fill out these questionnaires, **even if you have finished seeing your chiropractor**. These questionnaires are very important to our study and we hope that your answers will help us improve chiropractic care in the future. If you would prefer a paper copy, please let me know either by replying to this email, or by calling 07717 209995 and I will arrange for a paper copy to be sent to you with a pre-paid envelope for returning them to us. As a thank you for completing these questionnaires, you will receive a £10 digital love2shop voucher.

Thank you again for taking part in our study so far. If you have any questions, please let me know and I will be happy to answer them by email or over the telephone.

Best wishes,

Michelle

Michelle M Holmes

PhD Student

School of Psychology

University of Southampton

N.4 Postal cover letter

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Dear _____,

Thank you for taking part in our study. Enclosed is a copy of the questionnaires you were asked to complete as part of the study. It would be helpful if you could please fill out these questionnaires. They are very important to our study and we hope that your answers will help us improve chiropractic care in the future. As a thank you for completing these questionnaires, you will receive a £10 digital love2shop voucher.

If you have any questions, please let me know and I will be happy to answer them by email (m.m.holmes@soton.ac.uk) or over the telephone (07717 209995).

Yours Sincerely,

Michelle Holmes

Appendix O Matrices for mediation analysis

Coping appraisal

X – Completion of PROMs
M_1 – Patient-centred communication
M_2 – Self-efficacy for pain management
M_3 – Treatment Beliefs
M_4 – Self-management behaviours
Y – Back pain-related disability

	X	M_1	M_2	M_3	M_4	Y
M_1	1	▪	▪	▪	▪	▪
M_2	1	1	▪	▪	▪	▪
M_3	0	1	1	▪	▪	▪
M_4	0	0	1	1	▪	▪
Y	1	0	1	0	1	▪

Patient-clinician interaction

X – Completion of PROMs
M_1 – Patient-centred communication
M_2 – Therapeutic alliance
M_3 – Patient satisfaction
M_4 – Self-management behaviours
Y – Back pain-related disability

	X	M_1	M_2	M_3	M_4	Y
M_1	1	▪	▪	▪	▪	▪
M_2	0	1	▪	▪	▪	▪
M_3	0	1	1	▪	▪	▪
M_4	1	1	0	1	▪	▪
Y	1	0	1	1	1	▪

Threat appraisal (1)
X – Completion of PROMs
M_1 – Pain-related fear
M_2 – Fear avoidance beliefs
M_3 – Self-efficacy for pain-management
M_4 – Self-management behaviours
W – Pain catastrophising
Y – Back pain-related disability

	X	M_1	M_2	M_3	M_4	Y
M_1	1	▪	▪	▪	▪	▪
M_2	0	1	▪	▪	▪	▪
M_3	0	1	1	▪	▪	▪
M_4	0	1	1	1	▪	▪
Y	1	0	1	1	1	▪

Wmatrix:

	X	M_1	M_2	M_3	M_4	Y
M_1	0	▪	▪	▪	▪	▪
M_2	0	1	▪	▪	▪	▪
M_3	0	0	0	▪	▪	▪
M_4	0	1	1	0	▪	▪
Y	0	0	0	0	0	▪

Threat appraisal 2
X – Completion of PROMs
M_1 – Pain-related fear
M_2 – Pain catastrophising
M_3 – Fear-avoidance beliefs
M_4 – Self-efficacy for pain management
M_5 – Self-management behaviours
Y – Back pain-related disability

	X	M_1	M_2	M_3	M_4	M_5	Y
M_1	1	▪	▪	▪	▪	▪	▪
M_2	1	1	▪	▪	▪	▪	▪
M_3	0	1	1	▪	▪	▪	▪
M_4	0	1	0	1	▪	▪	▪
M_5	0	1	0	1	1	▪	▪
Y	1	0	1	1	1	1	▪

Appendix P Invitation to interview

P.1 Patients

Email Subject: Study in association with University of Southampton: interview

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Dear _____,

Thank you for taking part in our study so far. We would now like to invite you to take part in the interview stage of this study. This interview will explore your experience of seeing a chiropractor. The purpose of this study is to evaluate the role health questionnaires play in the treatment of low back pain, and to explore patients' experiences of completing health questionnaires.

This interview will take place over the telephone at a time that is convenient for you. The interview will take no longer than one hour. All data from the interview will be anonymised. Individuals may be quoted within the findings, but your name and any identifiable information will be changed to protect your identity.

If you are interested in taking part in the interview, please contact me via email or telephone (07717 209995) to arrange a suitable time to conduct the interview.

Thank you again for taking part in our study so far. If you have any questions, please let me know and I will be happy to answer them by email or over the telephone.

Best wishes,

Michelle

Michelle M Holmes

Appendix P

PhD Student

School of Psychology

University of Southampton

P.2 Chiropractors

Email Subject: Study in association with University of Southampton: interview

Study Title: Reconceptualising Patient-Reported Outcome Measures (RPROMs): a cluster randomised controlled trial and process evaluation on PROMs in specialist musculoskeletal care for low back pain

Researcher: Michelle Holmes

University of Southampton ethics number: 20133

Version: 3 **Date:** 31/01/20

Dear _____,

Thank you for taking part in the RPROMs study. Taking part in the study counts towards your continuing professional development and you will receive a CPD certificate and a certificate for your practice for research collaboration with the University of Southampton and Royal College of Chiropractors.

I would like to invite you to take part in the interview stage of this study. This interview will explore your experiences of using PROMs. This study aims to evaluate the role PROMs play in clinical practice and explore practitioners' experiences and views of using PROMs. We are hoping to improve the understanding of the role of PROMs in the treatment of back pain and the effects they may have on patient care.

This interview will take place over the telephone at a time that is convenient for you. The interview will take no longer than one hour. All data from the interview will be anonymised. Individuals may be quoted within the findings, but your name and any identifiable information will be changed to protect your identity.

If you are interested in taking part in the interview, please contact me via email or text or call (07717 209995) to arrange a suitable time to conduct the interview.

Thank you again for taking part in our study so far. If you have any questions, please let me know and I will be happy to answer them by email or over the telephone.

Best wishes,

Michelle

Michelle M Holmes

PhD Student

School of Psychology

University of Southampton

Appendix Q Qualitative interview guides

Q.1 Interview guide for patients

Preamble: I'm really interested in finding out about your experiences of visiting the chiropractor and your experiences of filling in health questionnaires when you visited the chiropractor.

- **To start, please can you tell me about your experiences of going to see the chiropractor?**

- **As part of seeing [chiropractor] you were asked to complete some questionnaires online. You were sent these [three/seven] times. Please can you tell me about your experiences of completing the health questionnaires online?**

Possible prompts: What did you think about the questions you were being asked? What made you fill in/not fill in the questionnaires?

- **How did you feel about being asked to complete the questionnaire before you saw the chiropractor?**

Possible prompts: Was there anything you would have liked to be asked or the chiropractor know about that wasn't asked?

- **What happened when you first went to see the chiropractor?**

Possible prompts: did they discuss the questionnaires? what was discussed? how did that make you feel during the session? how did that make you feel afterwards?

- **How did you feel the other times you were asked to fill in the questionnaires?**

Possible prompts: What happened at subsequent visits? did they discuss the questionnaires? what was discussed? how did that make you feel during the session? how did that make you feel afterwards?

- **Do you think the questionnaires influenced your relationship with the chiropractor?**

- **If you think about the whole experience of filling in the questionnaires and discussing them with the chiropractor, what do you think is the really important part that might make a difference?**

- **Do you think you might try chiropractic treatment again?**

- **Have you changed anything in your life since you started the chiropractor that you think might have influenced your health?**

- **Is there anything else you would like to tell me about your experiences of filling in the questionnaires or visiting the chiropractor?**

- **Do you have any questions for me?**

Q.2 Interview guide for patients (control group)

Preamble: I'm really interested in finding out about your experiences of visiting the chiropractor.

- **Please can you tell me about your experiences of going to see the chiropractor?**

- **What happened when you first went to see the chiropractor?**

Possible prompts: what was discussed? how did that make you feel during the session? how did that make you feel afterwards?

- **What happened at subsequent visits?**

Possible prompts: what was discussed? how did that make you feel during the session? how did that make you feel afterwards?

- **Do you think you might try chiropractic treatment again?**

- **Have you changed anything in your life since you started the chiropractor that you think might have influenced your health?**

- **If you think about the whole experience of talking to the chiropractor, what do you think is the really important part that might make a difference on top of the treatment you received?**

- **Is there anything else you would like to tell me about your experiences of visiting the chiropractor?**

- **Do you have any questions for me?**

Q.3 Interview guide for chiropractors

Preamble: I'm really interested in finding out about your experiences of using the health questionnaires patients fill out throughout their visit to you. Please can you tell me about your experiences of using the health questionnaires in your clinical practice?

- **How do you feel about using PROMs in your clinical practice?**

Possible prompts - Why do you think the routine collection of this data is feasible in this practice? Can you think of anything that would facilitate your use of the data?

- **What do you think about the questions patients are being asked?**

- **How did you use the health questionnaires in the initial consultations with patients?**

Possible prompts: did you discuss the health questionnaires, what was discussed, what influence do you think this had on your treatment? How did what you did in the trial differ from your normal practice?

- **How did you use the health questionnaires in the following treatment sessions?**

Possible prompts: did you discuss the health questionnaires, what was discussed, what influence do you think this had on your treatment? How did what you did in the trial differ from your normal practice?

- **Do you think the questionnaires influenced your relationship with your patients?**

- **If you think about the whole experience of getting patients to complete the questionnaires and discussing them with you, what do you think is the really important part that might make a difference?**

- **What do you think about the feasibility of routinely collecting data in your practice?**

Possible prompts: Can you think of anything that would facilitate your use of the data? Do you think there are any barriers to collecting and using the data? Can you think of anything else that influences your decision to use PROMs?

- **Is there anything else you would like to tell me about your experiences of using the health questionnaires in your clinical practice?**

- **How did you find the trial?**

Possible prompts: Can you tell me about why you chose to take part in this study? Was there anything you liked or disliked about being in the study?

- **How did you find the training you received?**

- **Do you have any general questions for me?**

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