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The role of contextual factors during conservative chronic low back pain management

Bronwyn Nadine Sherriff

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Abstract

Bronwyn Nadine Sherriff: The role of contextual factors during conservative chronic low back pain management

Background: Chronic low back pain (cLBP) is a prevalent condition causing substantial disability globally, but current treatments provide moderate symptom relief. Acknowledging and targeting implicit elements within clinical encounters may enhance the quality and effectiveness of care. Contextual factors (CFs), such as the patient-practitioner relationship, beliefs/characteristics of patients and practitioners, treatment characteristics, and the therapeutic environment may affect long-term recovery, but knowledge of their role during conservative cLBP management is limited. Translational research is needed to explore ways of harnessing CFs, given patients' and practitioners' underexplored perspectives.

Methods: This research aimed to investigate the role and impact of CFs during conservative cLBP treatment through three consecutive studies: a systematic literature review, a modified Delphi-consensus survey, and semi-structured interviews with patient-practitioner dyads. The systematic review examined interventions modifying CFs and their impact on patients' clinical outcomes. Findings informed the modified two-round online Delphi-survey which measured panel consensus regarding the perceived acceptability and influence of CFs during LBP rehabilitation. To gain deeper insights into the perceived importance of CFs during LBP consultations, patient-practitioner dyads were interviewed separately.

Results: The systematic review included 21 primary studies identifying CFs which may enhance cLBP treatment. Notable CFs included addressing patients' unhelpful illness beliefs; verbal suggestions influencing recovery expectations; visual/physical cues modifying treatment expectations; and positive communication to enrich the therapeutic relationship. The Delphi panel indicated a high degree of consensus regarding CF care approaches to enhance the patient-practitioner relationship, leveraging their own characteristics/beliefs, and modify patients' beliefs. Through interviews with patient-practitioner dyads, four main themes emerged: the journey with LBP, quality of the relationship, shared recovery journey, and quality of the treatment space. Notably, the practitioner's beliefs and characteristics shaped the quality of these LBP consultations and influenced the patient's experiences of care.

Conclusions: This research highlights the potential of modifying CFs to augment conservative cLBP treatment. It may have potential implications for clinical practice, education, and theory. These insights can guide the development of targeted interventions which may improve patient outcomes. Providing supplementary training or bespoke interventions that support musculoskeletal practitioners' confidence and competence in applying contemporary knowledge could improve patients' recovery. The proposed conceptual framework may have relevance in other clinical settings. The collective findings demonstrate that actively harnessing CFs can be beneficial during cLBP management.

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This research has been an enriching learning experience, made possible by the collective efforts of supervisors, participants, reviewers, colleagues, family, and friends. Your contributions have enhanced the quality of my work and have been a source of inspiration during challenging moments. Words may not fully capture the depth of my appreciation, but I hope that this expression serves as a humble acknowledgment of the impact each of you have had on my PhD journey. Thank you for being an integral part of this transformative process. To each person who has played a role, no matter how big or small, I am grateful for your guidance, encouragement, and belief in me while striving to achieve this milestone.

I extend my utmost gratitude to Bournemouth University and AECC University College for match-funding this research. This financial support has made this research possible, and I am deeply thankful for the opportunity and privilege to pursue this PhD.

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I dedicate this research as a heartfelt tribute to three extraordinary souls who profoundly touched my life in ways beyond imagination. The bond we shared and the cherished memories we created shall forever hold a special place in my heart. In honour of:

Katie Harriet Ruth Stokol
(1921–2013)

Alexander Peter Richard Longman
(1982–2016)

Ziggy Sherriff
(2008–2017)

Their loving and passionate spirits will forever remain alive in my thoughts, an enduring acknowledgement to the impact they made on my life. May their memories continue to inspire and enrich the lives of those who remember them fondly.

Author's declaration

In this thesis, certain aspects of the research have been previously presented at academic conferences and published in a peer-reviewed journal. The initial findings from the systematic literature review were presented at Bournemouth University's (BU) postgraduate research conference and the British Pain Society's Annual Scientific Meeting. Preliminary findings from the modified Delphi-consensus survey were also presented at Bournemouth University's (BU) postgraduate research conference.

Both studies were subsequently published in Chiropractic and Manual Therapies as part of the journal's thematic series titled: *A new paradigm for musculoskeletal pain care: moving beyond structural impairments* as part of the integrated thesis format submission.

The author's individual contributions to the two publications are as follows:

Publication titled: "Impact of contextual factors on patient outcomes following conservative low back pain treatment: systematic review":
The author was involved in the review's inception, designed, and drafted the published protocol, conducted database searches, identified eligible studies, and extracted relevant data. They also conducted quality assessments and synthesised the results. Additionally, the author drafted the original manuscript and addressed the reviewers' feedback.

Publication titled: "Musculoskeletal practitioners' perceptions of contextual factors that may influence chronic low back pain outcomes: a modified Delphi study":
The author played a key role in the study's design and conception. They were responsible for drafting and piloting the surveys, as well as participant recruitment and data collection. The author conducted data analysis, drafted the original manuscript, and addressed the reviewers' feedback.

In addition to the published papers, the author's individual contributions to the unpublished manuscript include designing and conducting the semi-structured interviews, recruiting participants, analysing the qualitative data, interpreting the findings, and drafting the unpublished manuscript. Overall, the author played a substantial role in conceptualising the three studies, contributing to the recruitment, data collection, and analysis processes, and drafting the thesis chapters and manuscripts.

Chapter 1. Introduction

1.1. Chapter overview

Chapter 1 of this thesis titled *The role of contextual factors during conservative chronic low back pain management* provides an in-depth introduction to the research area, establishing the context and significance of the study. The chapter begins with an overview of the global and United Kingdom (UK) prevalence of low back pain (LBP) and its substantial impact as a public health concern. Relevant epidemiological data are presented to highlight the need for and importance of investigating effective LBP management strategies. Following the discussion on LBP, the chapter delves into the types of LBP and some of the issues with categorisation along with delineating current clinical guidelines for managing LBP. The discussion on LBP aims to establish a comprehensive understanding of the condition, acknowledging its complexity and the diverse manifestations. This sets the stage for the subsequent examination of contextual factors (CFs) in pain management.

The concept of CFs and their association with placebo-nocebo phenomenon are elucidated together with presenting useful definitions and terminology. These five main CF domains include the patient's characteristics and beliefs, the practitioner's characteristics and beliefs, the patient-practitioner relationship, treatment characteristics, and the treatment environment (Di Blasi et al., 2001). The neurological mechanisms and psychological processes that underpin placebo and nocebo effects and their role in modulating physiological responses are also explored. The chapter proceeds to elaborate on the relevance of CFs during clinical interactions and explains how each CF domain can shape patient’s pain perceptions and potentially influence clinical outcomes. By understanding the influence of CFs on pain perception, this research aims to shed light on their potential impact on treatment outcomes.

The chapter presents the research rationale by discussing the existing knowledge gaps which helps illustrate the justification for this study. To guide the investigation, the research questions, aims, and objectives are clearly outlined, providing a roadmap for the subsequent chapters. These research objectives aim to provide a structured and systematic approach to address the research questions effectively. The chapter concludes with a succinct preview of the chapters that follow.

1.2. Background to the study

1.2.1. Impact of low back pain (LBP)

Musculoskeletal (MSK) conditions, which include more than 150 diagnoses such as sporting injuries, lumbar/back pain, and autoimmune diseases like arthritis, affect the locomotor system comprising both muscles and bones, which limits mobility and dexterity (Briggs et al., 2018). MSK conditions are characterised by pain and reduced physical functioning often resulting in a decline in mental health, accompanied by increased risks for co/multi-morbidities and all-cause mortality (Briggs et al., 2018). They are a major contributor to persistent pain in various geographical locations and age groups that account for a substantial proportion of non-communicable diseases (Briggs et al., 2018). Notably, MSK conditions are the second largest cause of disability globally, with low back pain (LBP) being the leading cause (James et al., 2018). Pivotal risk factors influencing MSK health are shared with other chronic health conditions, including, but not limited to, obesity, sedentary lifestyles/inactivity, and multi-morbid health states (Maher et al., 2017). Consequently, MSK conditions pose a significant threat to health and productivity throughout the lifespan and are associated with significant direct and indirect healthcare costs. (Briggs et al., 2018; James et al., 2018).

Figures 1 to 9 below present the estimated prevalence of LBP and the corresponding rates of Years Lived with Disability (YLDs), as derived from the Global Burden of Disease Study, 2019 (Institute for Health Metrics and Evaluation [IHME], 2020). To provide a more comprehensive representation of both the global and UK prevalence of LBP, the undernoted Figures were generated using an interactive data visualisation tool accessible at https://vizhub.healthdata.org/gbd-compare/ (IHME, 2020).

Figure 1 depicts the global prevalence of LBP cases in 2019 and illustrates that LBP varies worldwide and tends to be higher in high-income countries. Similarly, Table 1 provides an overview of the epidemiological estimates for LBP, demonstrating the prevalence and disability rates of LBP in the UK and globally (IMHE, 2020). Table 1 below shows that the UK exhibits higher rates of prevalence and disability compared to the global rate (IMHE, 2020). The estimated rate of YLDs resulting from MSK conditions and LBP in the UK during 2019 were 3,016.99 (2,147.96–4,010.23) and 1,428.33 (1,004.37-1,911.91) YLDs per 100,000 individuals, whereas the global rate for MSK conditions and LBP were 1,903.49 (1,371.81-2,520.89) and 823.07 (581.58–1101.04) YLDs per 100,000 respectively (IMHE, 2020). Although the United States of America (USA) and Japan appear to have the highest

LBP prevalence overall, the UK rates are similar to other European and high-income countries.

Table 1. Overview of Global and UK LBP prevalence rates and YLDs per 100,000 for 2019

Region	Prevalent cases per 100,000	Lower Limit	Upper Limit	YLDs per 100,000
UK Female	15,163.98	13,373.12	17,192.75	1,668.97
Scotland	13,321.34	11,772.65	15,077.85	1,480.02
England	12,936.59	11,372.19	14,724.80	1,434.66
UK Overall	12,872.85	11,330.33	14,639.88	1,428.33
Wales	12,091.09	10,687.18	13,710.07	1,346.02
Northern Ireland	11,018.00	9,732.18	12,465.79	1,231.66
UK Male	10,533.07	9,202.93	12,030.41	1,182.58
Global Female	8,598.74	7,652.34	9,689.55	955.50
Global	7,346.65	6,526.69	8,279.17	823.07
Global Male	6,102.46	5,400.93	6,860.11	691.48

Table 1 shows that the highest rates of LBP and disability during 2019 were experienced by females in the UK and highlighted that Scotland had the highest rates and Northern Ireland the lowest within the UK (IMHE, 2020). Figure 2 illustrates the UK prevalence across the main regions and is accompanied by an explanatory Table with corresponding 2019 estimates (Table 2). Table 2 displays that only four regions (i.e., Wales, Northern Ireland, West Midlands, and Greater London) had lower prevalence and disability rates of compared to the overall UK rates (IMHE, 2020). However, these rates were notably higher than the corresponding global rates.

Figures 3 and 4 below show the prevalence of LBP cases by sex both globally and in the UK during 2019 respectively. In line with global trends, Figure 4 illustrates that there are fewer males experiencing LBP in the UK and that LBP tends to disproportionality affect females (IMHE, 2020). Figures 5 and 6 depict the estimated number of LBP cases by year, from 1990 until 2019 worldwide. Altogether approximately 568,444,531.93 (505,000,665.5–640,597,791.88) individuals were affected by LBP in 2019, with roughly 8,653,190.35 (7,616,297.34–9,840,996.09) residing in the UK (IMHE, 2020). The global trend suggests that cases of LBP are steadily increasing year-on-year, but this may also be a result of improved epidemiological surveillance. The UK data between 2009 and 2019 suggest that roughly between 7.4 and 9.9 million individuals are affected by LBP each year (IMHE, 2020).

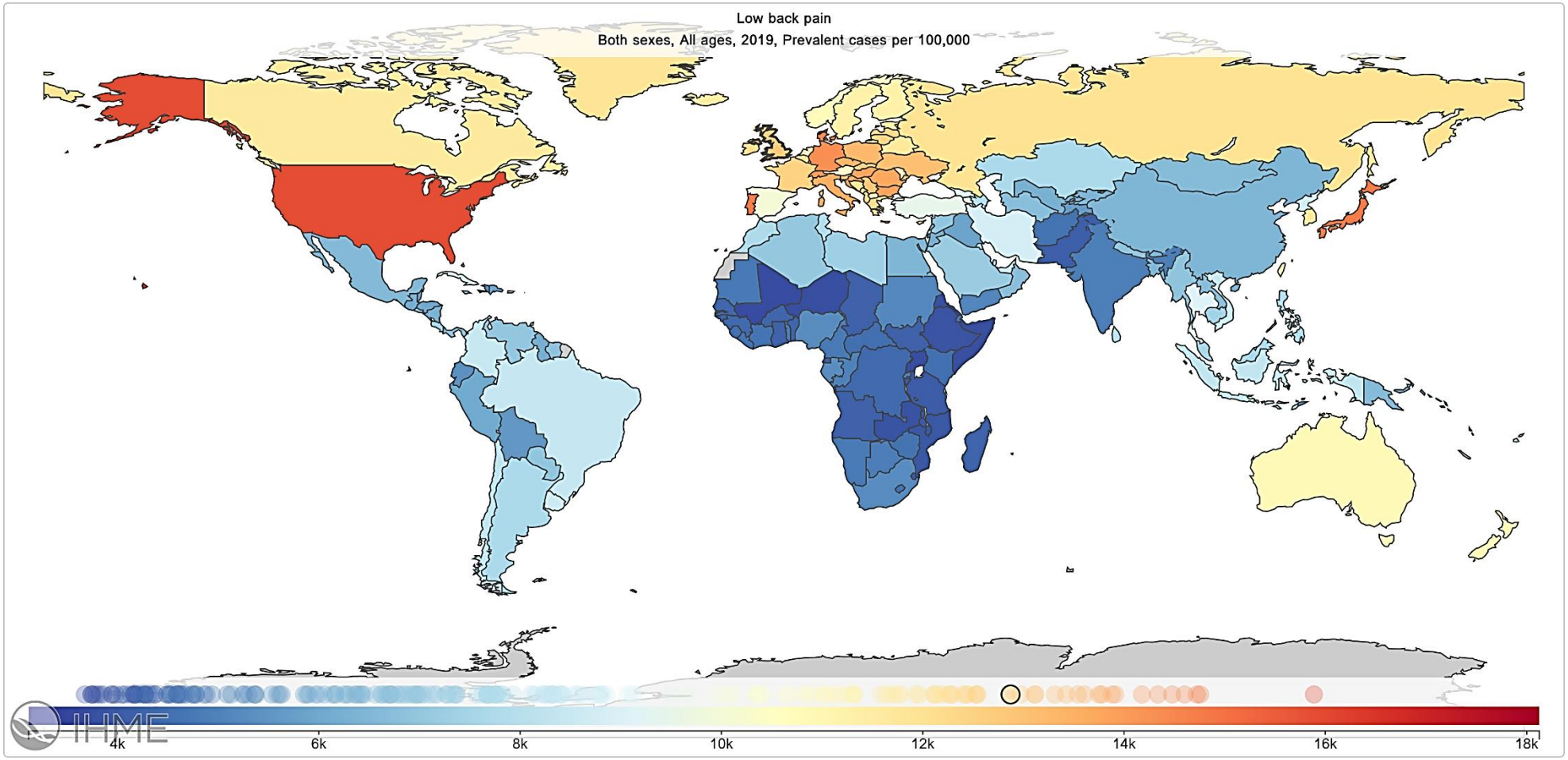


Figure 1. Global prevalence of LBP cases (per 100,000) including both sexes and all ages in 2019 (IHME, 2020)

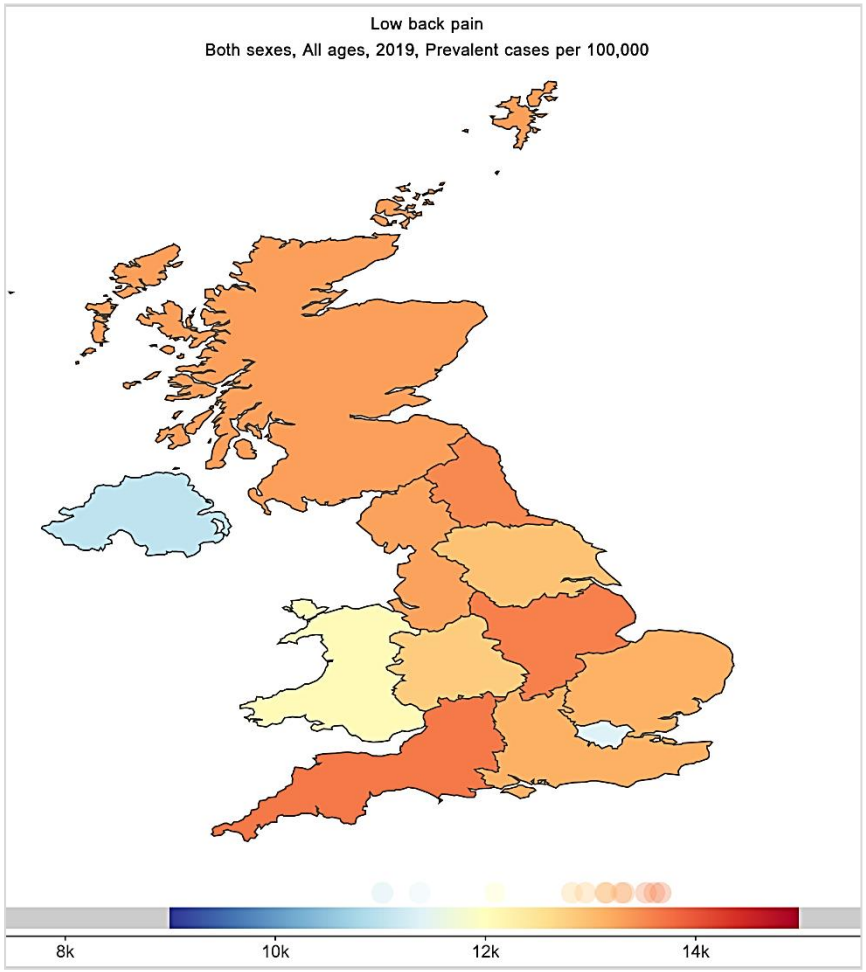


Figure 2. United Kingdom prevalence of LBP cases (per 100,000) including both sexes and all ages in 2019 (IHME, 2020)

Table 2. UK LBP prevalence rates and YLDs by region in 2019

Region	Prevalent cases per 100,000	Lower Limit	Upper Limit	YLDs per 100,000
South West England	13,666.78	12,027.24	15,578.41	1,513.02
East Midlands	13,607.35	11,965.19	15,509.11	1,508.04
North East England	13,526.84	11,901.76	15,409.02	1,489.62
Scotland	13,321.34	11,772.65	15,077.85	1,480.02
North West England	13,294.72	11,692.21	15,140.48	1,470.18
South East England	13,152.78	11,551.62	14,954.91	1,458.13
East of England	13,137.64	11,543.59	14,983.84	1,455.94
Yorkshire & the Humber	12,951.39	11,375.90	14,768.26	1,436.60
England (All regions)	12,936.59	11,372.19	14,724.80	1,434.66
UK Overall	12,872.85	11,330.33	14,639.88	1,428.33
West Midlands	12,822.47	11,288.37	14,637.47	1,423.15
Wales	12,091.09	10,687.18	13,710.07	1,346.02
Greater London	11,373.75	9,958.39	12,981.08	1,270.24
Northern Ireland	11,018.00	9,732.18	12,465.79	1,231.66

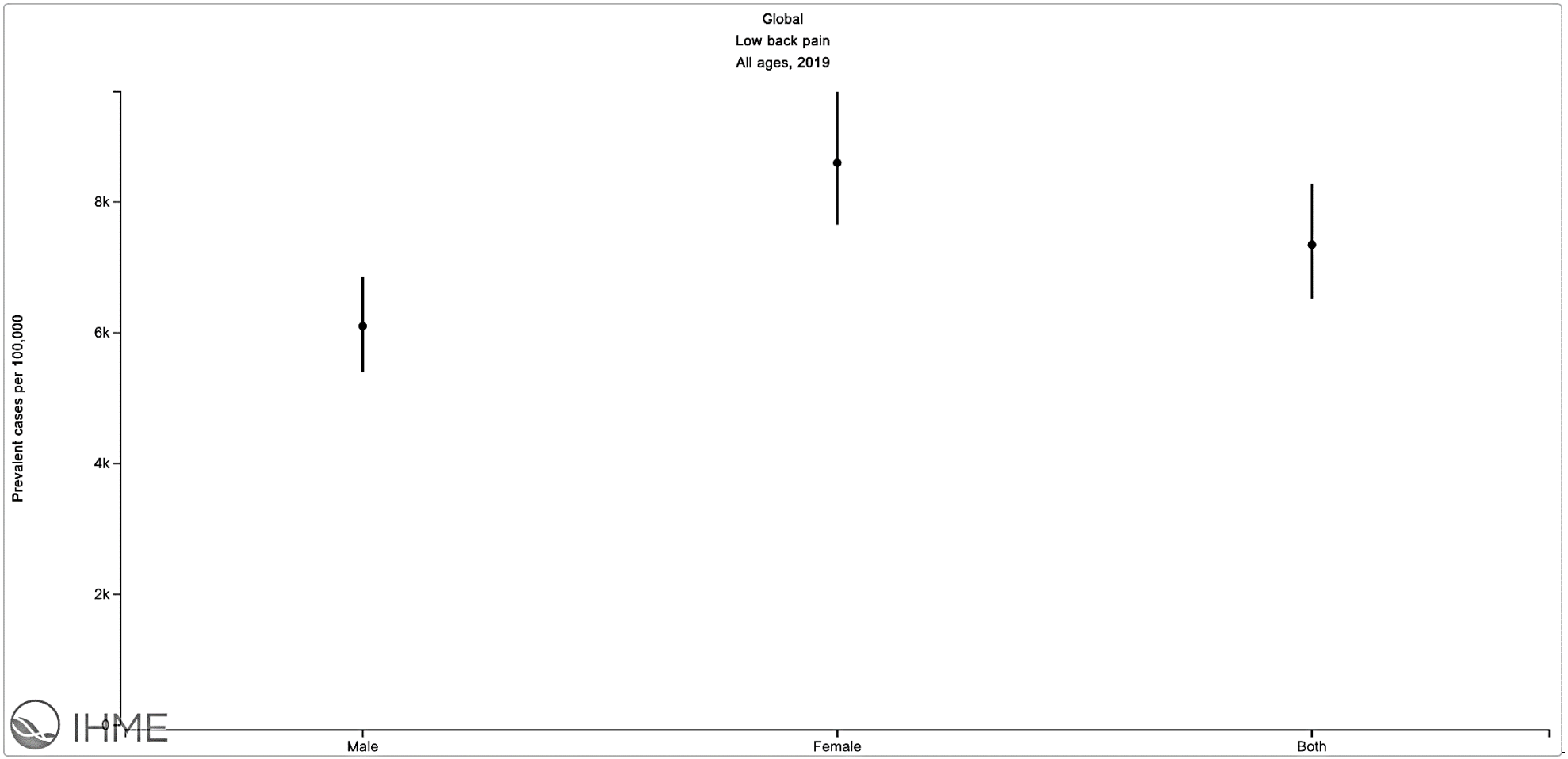


Figure 3. Global prevalence of LBP cases (per 100,000) including all ages by sex in 2019 (IHME, 2020)

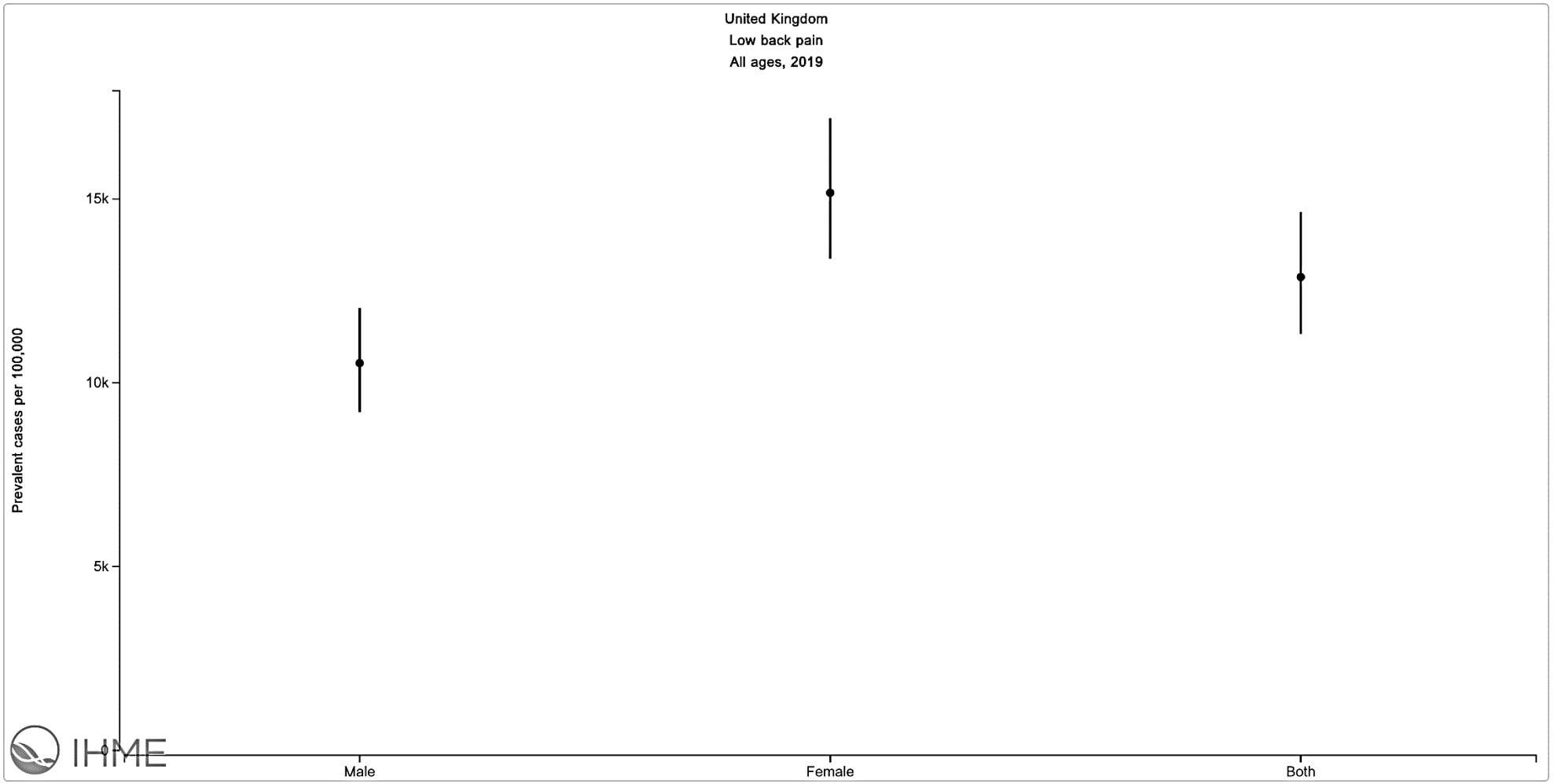


Figure 4. UK prevalence of LBP cases (per 100,000) including all ages by sex in 2019 (IHME, 2020)

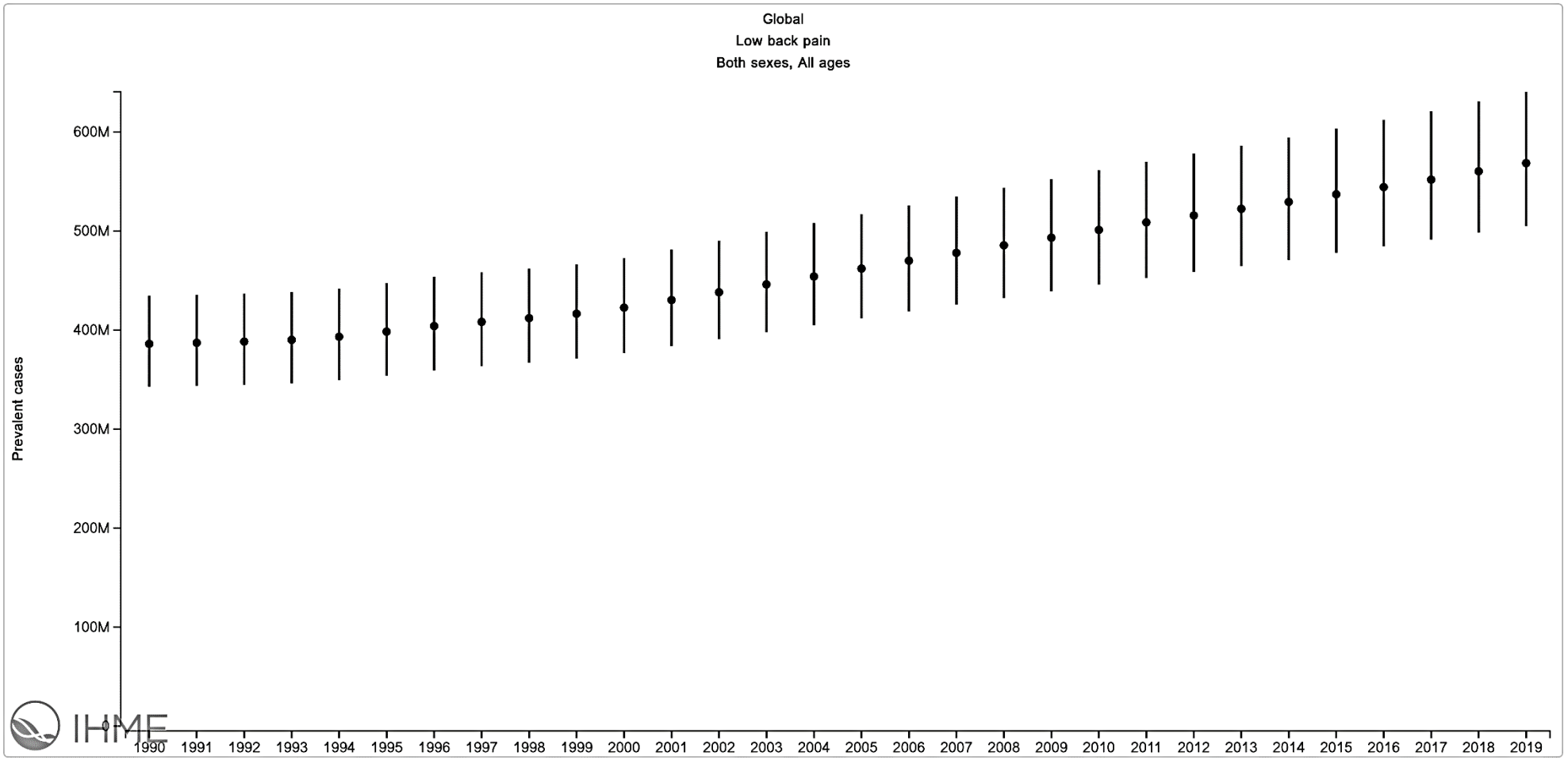


Figure 5. Estimated number of global LBP cases by year including both sexes and all ages (IHME, 2020)

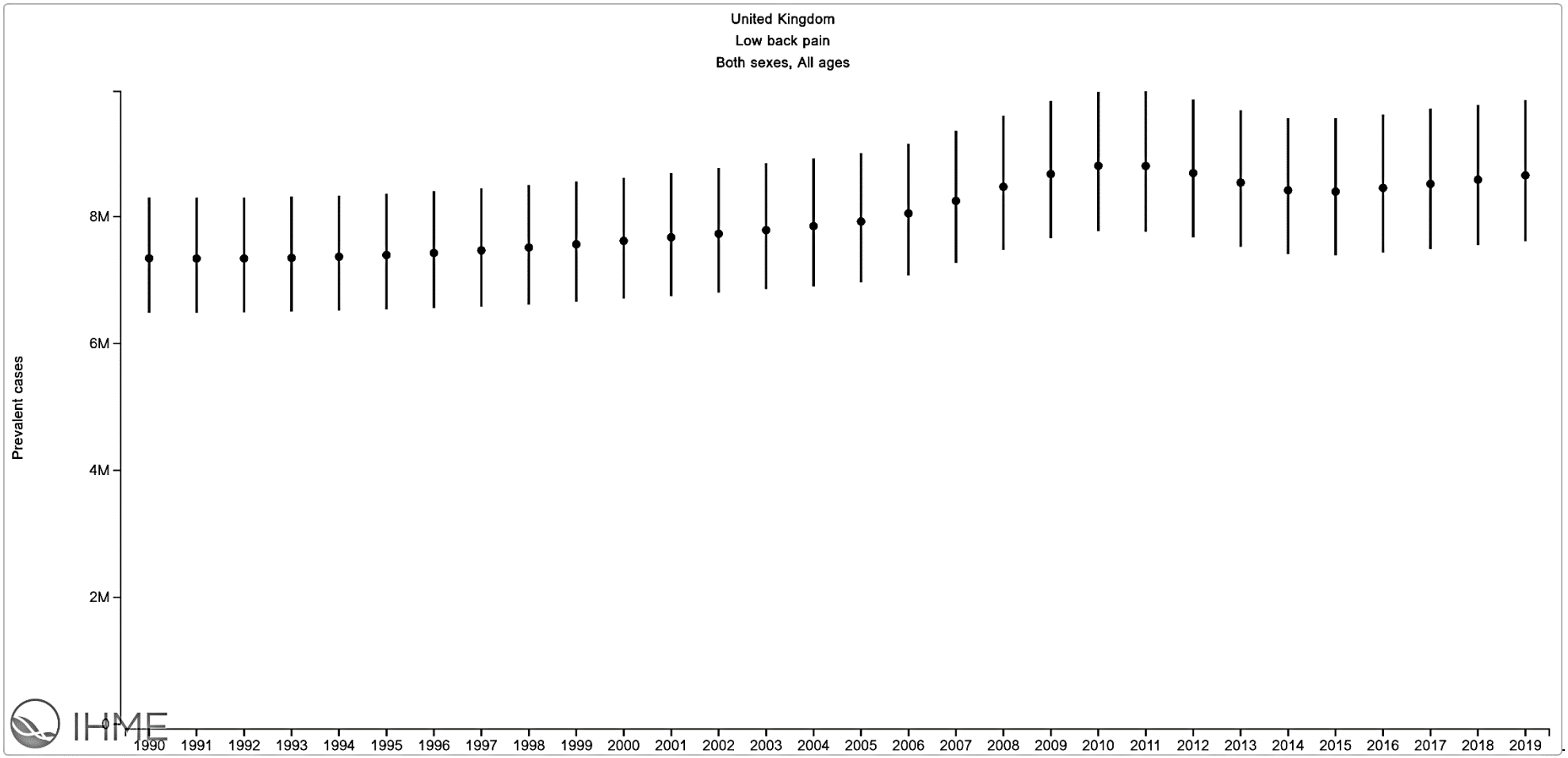


Figure 6. Estimated number of LBP cases in the UK by year including both sexes and all ages (IHME, 2020)

Figure 7 below displays the top ten health complaints in the UK ranked according to YLDs per 100,000 between 1999 and 2019 (IMHE, 2020). Notably, LBP has been the leading cause of disability in the UK for the last 20 years and this trend is unlikely to change. During 1999, the top ten causes of disability also included neck pain and other MSK conditions. However, during 2019, osteoarthritis was also listed within the top ten conditions resulting in higher levels of disability in the UK (IMHE, 2020). Similarly, Figure 8 indicates that across all four UK regions, LBP was the leading cause of disability during 2019. The prevalence of LBP in 2019 in the UK was estimated to be 12,872.85 (11,330.33–14,639.88) cases whereas the global rate was 7,346.65 (6,526.69–8,279.17) cases per 100,000 (IMHE, 2020). The UK LBP rate has shown a marginal decline since 2010, when the estimated prevalence was approximately 13,847.37 (12,228.81-15,681.67) cases per 100,000 but seems to be fairly consistent. Finally, Figure 9 shows the age distribution of LBP cases in the UK and suggests that it is a common problem affecting people of all ages with the highest prevalence amongst individuals aged between 50 and 55 years (IMHE, 2020).

Collectively, these morbidity estimates indicate that LBP is an extensive problem worldwide but particularly in the UK. It is important to note that this data does not distinguish between acute, sub-acute, and chronic LBP cases. Chronic LBP (cLBP) can be classified as a symptom rather than a disease (Maher et al., 2017). It frequently occurs in the absence of a known pathoanatomical cause, referred to as non-specific LBP, and is considered chronic when symptoms persist for at least 12 weeks (Maher et al., 2017). It has been suggested that approximately 20–30% of individuals who experience an episode of LBP continue experiencing symptoms beyond the normal recovery period (Kongsted et al., 2016). Similarly, between 10–40% of individuals with LBP may experience recurrent episodes or disabling and persistent LBP (Alihowimel et al., 2018). Risk factors associated with the development of cLBP include lifting activities, smoking, obesity, and depressive symptoms, although these factors only moderately increase the odds of developing cLBP (Maher et al., 2017). Psychological factors, such as fear of pain, anxiety, depression, and catastrophising, may lead to fear-avoidant behaviour resulting in further disability (Alihowimel et al., 2018).

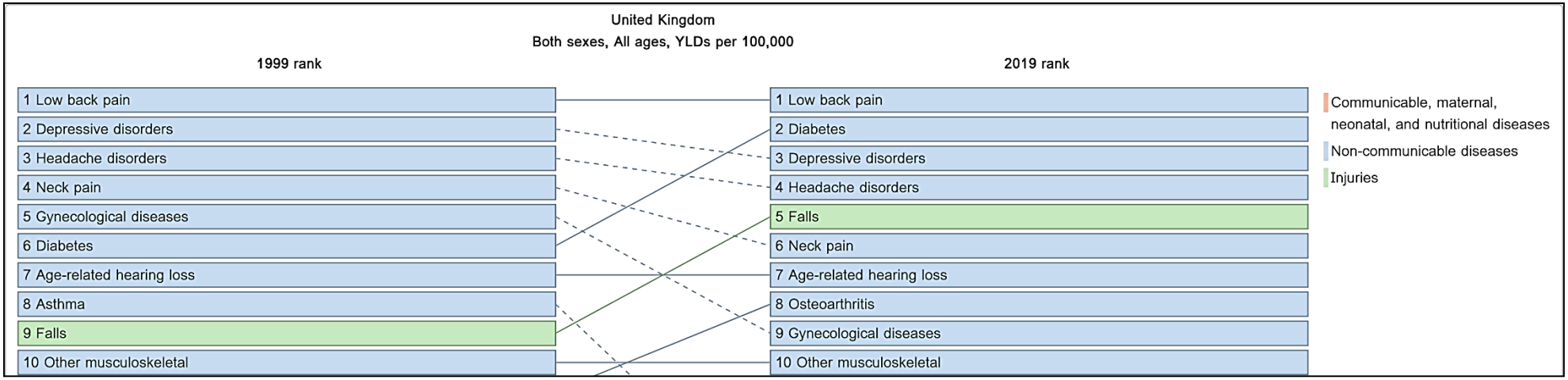


Figure 7. UK: Top ten health complaints ranked according to YLDs per 100,000 between 1999 and 2019 including both sexes and all ages (IHME, 2020)

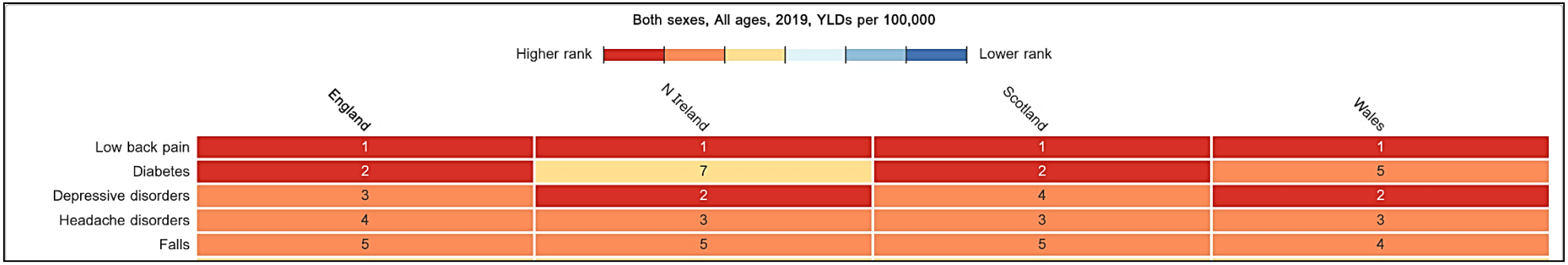


Figure 8. UK: Top five health complaints ranked according to YLDs per 100,000 by region during 2019 including both sexes and all ages (IHME, 2020)

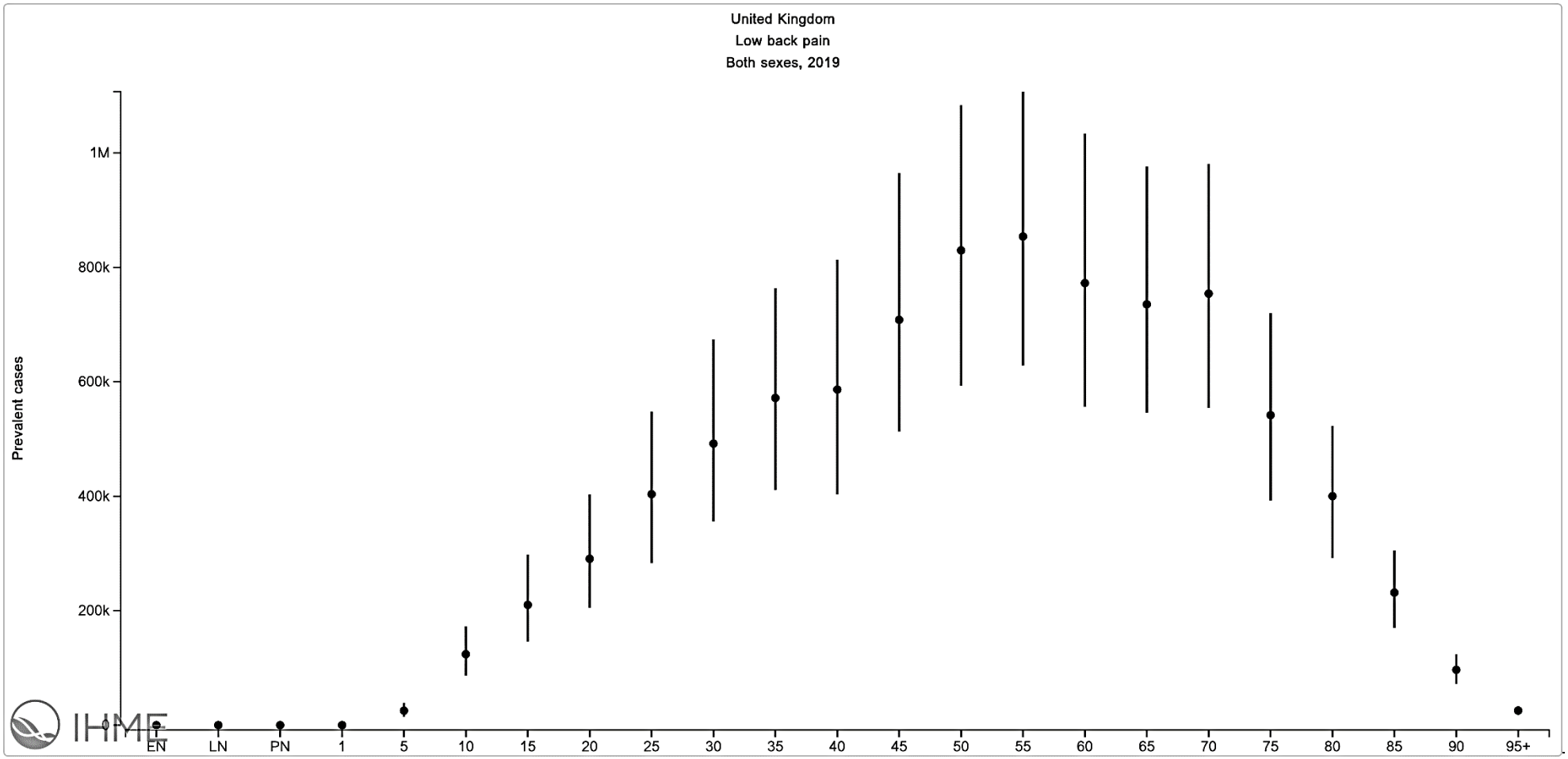


Figure 9. Estimated number of LBP cases in the UK by age groups in 2019 (IHME, 2020)

1.2.1.1. Classifying LBP

Categorising LBP as acute, sub-acute, and chronic is not especially helpful as these terms do not describe the general trajectories of persons experiencing symptoms (Kongsted et al., 2016). For example, the terms 'acute' and 'chronic' do not completely distinguish between a recent LBP episode experienced for the first time and a recent flare-up of recurrent LBP (Kongsted et al., 2016). A useful way to classify LBP has been proposed that considers the intensity, variability, and general pattern of change in symptoms over time (Kongsted et al., 2016). Figure 10 below presents common LBP trajectories proposed by Kongsted and colleagues (2016). Although these classifications are considered useful in clinical practice, they are not widely used in research and literature. Therefore, this study uses the term cLBP to describe patients who experience symptoms for three or more months. However, it recognises that patients' pain experiences may vary over time and includes individuals with both severe and milder symptoms (Kongsted et al., 2016).

Chronic LBP is an important and relevant issue to health and well-being for several reasons. Since it leads to disability and lost productivity, this can significantly impact an individual's quality of life (Buchbinder et al., 2018). Given the costs associated with treatment, lost productivity, and disability, cLBP represents a significant economic burden to individuals and society (Briggs et al., 2018). Individuals with cLBP often have higher healthcare utilisation rates putting a strain on healthcare systems and resources, which highlights the importance of effective management strategies. Additionally, cLBP can have a significant psychological impact on individuals, leading to increased psychological distress including pain-related anxiety and depression (Alihowimel et al., 2018). There is a reciprocal relationship between pain and mood – low mood is common in patients with persistent pain and can also be a trigger for pain which can prolong the recovery process (Pincus & McCracken, 2013). Depression is a significant predictor for the development of chronic pain, while chronic pain increases the likelihood of experiencing depression (Pincus & McCracken, 2013; Vadivelu et al., 2017). This bi-directional relationship highlights the intricate interplay between pain and emotions (Vadivelu et al., 2017). These psychological factors can, in turn, worsen the pain and make it more challenging to manage. Furthermore, fear of pain and movement avoidance can result in a cycle that contributes to the development and persistence of LBP (Pincus & McCracken, 2013; Alihowimel et al., 2018). Since cLBP can also affect an individual's sleep quality and limit their ability to perform daily activities, this leads to a cycle of inactivity and social isolation which may further exacerbate pain (Buchbinder et al., 2018).

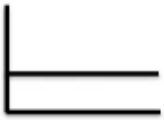
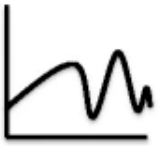
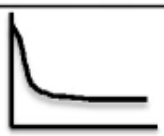
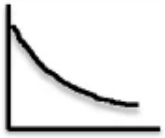
Principal pattern	Terminology for labelling	Suggested definition
INTENSITY		
	*Severe pain* *Moderate pain* *Mild pain* *Minor pain / Recovery**	Mean scores 0-10 Numeric Rating Scale 6 to 10 4 to 5 2 to 3 0 to 1
VARIABILITY		
	*Persistent pain*	An individuals' pain intensity stays within mean +/-1-point (0to 10 NRS) Pain reported >4 days per week
	*Fluctuating pain*	Variation in pain intensity exceeds 2 points, without periods of no pain (0) lasting ≥1 month**[27]
	*Episodic pain* *Single episode*	Experiencing more than one period of pain separated by periods with no pain (0) lasting ≥1 month** One period of LBP preceded and followed by periods with no pain (0) lasting ≥1 month
Change pattern **(likely to be most relevant for clinical populations)**		
	*Rapidly improving pain*	Marked decrease in pain intensity within 1 month
	*Gradually improving pain*	Marked decrease in pain intensity occurring gradually over more than 1 month
	*Progressing pain*	An overall pattern of increasing pain intensity

Figure 10. Common LBP trajectories with suggested definitions
(Kongsted et al., 2016, p.9)

Consequently, cLBP is an important health concern because of its prevalence, economic burden, as well as its physical, social, and psychological impact. These collective factors may deleteriously impact an individual's overall health and well-being. Effective interventions that address factors contributing to cLBP are essential to improve clinical outcomes. Interventions targeting both the physical and psychological aspects of the

condition may be necessary to manage cLBP more effectively. This is especially relevant in high-income settings where there is an over-emphasis on biomedical care which can result in adverse health outcomes (e.g., opioid epidemic) and unsustainable healthcare expenditure and utilisation (Briggs et al., 2018).

1.2.1.2. Recommended treatments for LBP

Clinical guidelines recommend conservative treatments for non-specific cLBP, with an initial focus on non-pharmacological and non-invasive approaches that combine a biopsychosocial approach (Foster et al., 2018). This includes treatments such as exercise, massage, cognitive behavioural therapy, and manual or physical therapies (Foster et al., 2018; Traeger et al., 2017). In addition to these treatments, it is also important to manage comorbidities such as low mood, depression, or anxiety, which are often associated with cLBP (Maher et al., 2017). Overemphasising pharmacological or biomedical care, such as solely relying on medications or surgery, can lead to poor health outcomes or iatrogenic consequences (Briggs et al., 2018). Moreover, these approaches have limited increased efficacy over conservative approaches which are recommended as initial treatments for LBP (Foster et al., 2018; Traeger et al., 2017).

Given the multifactorial nature of cLBP it is important to adopt a biopsychosocial approach to care that goes beyond the traditional biomedical model (Foster et al., 2018). There is a need for interventions that address the complex interplay between physical, psychological, and social factors contributing to patients' pain experiences (Foster et al., 2018). Despite the availability of a range of treatments for cLBP, many patients continue to experience persistent pain and disability (Foster et al., 2018; Maher et al., 2017). By focusing on treating the symptoms of pain rather than addressing the underlying factors influencing pain may help explain why treatment outcomes can vary widely between individuals (Maher et al., 2017). Accordingly, a more comprehensive approach that addresses both physical and psychosocial factors may be more effective (Foster et al., 2018; Maher et al., 2017).

Modern medicine has not been entirely successful at treating pain and psychological distress (i.e., anxiety, depression, and illness-related distress) (Wager & Atlas, 2015). According to the revised definition by the International Association for the Study of Pain (IASP), pain is described as *"An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"* (Raja et al., 2020, p.14). This definition acknowledges pain as a personal and subjective experience that can be influenced by a combination of biological, psychological, and social factors (Raja et al.,

2020). Unlike diseases where the problem is primarily located in peripheral organs, pain and distress are rooted in intricate brain functions which are strongly affected by brain pathology, internal thoughts and brain states, and perceptions of the social and environmental context (Wager & Atlas, 2015). Accordingly, there are no clear physical markers for pain and distress nor are the brain mechanisms that cause and regulate them fully understood (Wager & Atlas, 2015). There is a pressing need for effective, scalable, and low-risk strategies for pain management, especially considering the growing concerns surrounding opioid prescribing and its associated morbidity and mortality risks (Darnall & Colloca, 2018). While improving symptoms is often the main goal of treatment, there are other factors that can also affect patients' clinical outcomes (Testa & Rossettini, 2016).

1.2.2. What are contextual factors?

Effects arising from healthcare interactions encompass several elements that are typical across various treatments, including qualities like focused attention, approachable demeanour, demonstrating understanding, genuine care, kindness, hope, and enthusiasm (Di Blasi et al., 2001). Di Blasi and colleagues (2001) proposed one way of categorising common elements within therapeutic interactions referring to them as context effects or contextual factors (CFs). These CFs encompass five broad domains that are implicated in eliciting placebo/nocebo effects (Di Blasi et al., 2001; Testa & Rossettini, 2016):

1) Patient's characteristics and beliefs (e.g., age, gender, anxiety levels, expectations);
2) Practitioner's characteristics and beliefs (e.g., age, gender, appearance, professional reputation, beliefs, and behaviour);
3) Patient-practitioner relationship (e.g., trust, reassurance, empathy, communication);
4) Treatment characteristics (e.g., side effects, overt therapy, clear diagnosis, touch);
5) Treatment environment (e.g., setting, layout, interior design, décor)

Treatments are never administered in a neutral situation – it is not solely the treatment itself that holds significance, but also the manner in which it is delivered and the atmosphere surrounding the treatment (Balint, 1955) which Miller and Kaptchuk (2008) called "contextual healing". Balint (1955, p.683) notes that "*by far the most frequently used drug in general practice was the doctor himself*". Beyond natural or spontaneous recovery, CFs may play an important role during MSK treatments (Rossettini, et al., 2018a). Research suggests that CFs can have a considerable influence on clinical outcomes during healthcare interactions (Di Blasi et al., 2001; Testa & Rossettini, 2016).

While there has been increasing research on CFs different studies have used varied definitions (Cook et al.,2023; Di Blasi et al., 2001; Miciak et al., 2012; Nielsen et al., 2019). These clinical elements have been referred to as 'non-specific' factors, 'common' factors, context effects, and more recently CFs. Features of clinical interactions include the way healthcare practitioners communicate with patients, the amount of time practitioners listen to patients, patients and practitioners' beliefs and expectations about the illness or treatments, and the physical environment in which treatment takes place (Di Blasi et al., 2001; Testa & Rossettini, 2016). Accordingly, these definitions involve a range of factors, including sociodemographic and individual characteristics, patient and practitioner beliefs, relational aspects, as well as physical and social environments (Cook et al., 2023). Since there is no universally accepted definition of CFs that applies to all health-related conditions, a recent study aimed to address this issue using a virtual Nominal Group Technique (NGT) (Cook et al., 2023). Ten participants with extensive clinical and research experience regarding CFs proposed the following definition in the final NGT stage (Cook et al., 2023, pp.4–7):

> *Contextual factors (CFs) are components of all therapeutic encounters and may constitute the entirety of the perceived effects of the intervention itself or be additive to effects of interventions such as pharmacological and nonpharmacological treatments. CFs are perceived cues that affect both the patient and practitioner and can arise from previous experiences and immediate dynamics within the encounter, or a combination of both. CFs fall into broad categories that can include patient characteristics, practitioner characteristics, treatment characteristics, characteristics of the dynamic between the patient and practitioner and characteristics of the setting within which the encounter is being delivered. CFs can be complexly interwoven in the patients and practitioners experience so as to influence what patients and practitioners expect the outcome of the encounter to be. Through such conscious and unconscious expectations, involving a range of specific neurological pathways, CFs can directly influence (both positively and negatively) symptoms and characteristics associated with the presenting condition. The proportion of clinical effects observed associated with CFs can vary from large to small depending on the characteristics of the patient, practitioner, condition, and intervention.*

The NGT participants' definition is consistent with the five main CF domains that were previously identified by Di Blasi and colleagues (2001) and have informed this study. Notably, the NGT participants' definition acknowledged that CFs encompass both internal and external contexts during therapeutic interactions (Cook et al., 2023). The *internal context* encompasses memories, prior experiences, emotions, expectations, and evaluations of meaning that are pertinent to an individual's well-being and survival (Rossettini et al., 2018a; Wager & Atlas, 2015). Contrastingly, the *external context* includes treatment features, cues related to the environment of care, together with social cues (e.g., eye contact, body

language), and verbal suggestions (Wager & Atlas, 2015). Rossettini and colleagues (2018a) further differentiate the external context from the relational features of patient-practitioner interactions such as verbal and non-verbal communication.

The NGT participants' definition also recognises that CFs can function as both mediators and moderators of clinical outcomes or confounding variables (Cook et al., 2023). Mediators help explain the underlying mechanisms or processes through which an intervention or treatment affects a particular clinical outcome (MacKinnon, 2011). In other words, they provide insights into how or why a treatment leads to a specific outcome (MacKinnon, 2011). For example, if a patient perceives their practitioner as caring and empathic this is considered a mediating factor because it plays a role in the patient's response to a particular treatment. The patient's perception of the practitioner's qualities may influence their emotional state, trust, and overall satisfaction with the treatment, which can then impact the clinical outcome. As moderators, CFs may influence the strength or direction of the relationship between an intervention or treatment and a particular clinical outcome (MacKinnon, 2011). Moderating factors can include the patients' characteristics or experiences. For instance, if a patient has previously had a positive experience with a particular treatment, it is likely to influence their response to the treatment. Thus, positive prior experiences can be considered a moderating factor because it may influence how the patient responds to the treatment and subsequently impact their clinical outcomes. In both cases, understanding the role of CFs is important for developing effective interventions and improving clinical outcomes. By considering CFs, researchers or healthcare practitioners can better understand the mechanisms through which the treatment works, and how patients' experiences, perceptions, and expectations contribute to the observed outcomes.

Researchers are making progress in understanding placebo effects, which involves manipulating the context surrounding a medical treatment (Wager & Atlas, 2015). Placebos are treatments that are biologically inactive and have no direct therapeutic effects for a specific medical condition, but they are delivered in a context that includes various social and physical cues (Wager & Atlas, 2015). Regardless of whether the treatment involves an active intervention or a placebo pill/intervention, the clinical environment surrounding the treatment encompasses various types of contextual information (Wager & Atlas, 2015). This context is perceived and interpreted by the patient, which can affect health outcomes in both the brain and the body by influencing a patient's expectations, emotional states, and memories (Wager & Atlas, 2015). Responses to the context that promote health and well-being may be referred to as placebo effects, while those that increase pain, distress, and disease are termed nocebo effects (Wager & Atlas, 2015). Multidisciplinary studies are

helping researchers better understand placebo/nocebo effects and potential applications in clinical practice. Table 3 below provides useful definitions that aid in understanding important terminology and concepts.

Table 3. Proposed definitions for useful concepts/terminology

Concepts/ Terminology	Definition	Reference
Analgesia	"Pain relief, which can be caused by many factors, including medical treatments (for example, opioid analgesia), features of the treatment context (placebo analgesia) and affective states (for example, stress-induced analgesia)."	Wager & Atlas, 2015, p.407
Context	"The combination of all of the elements surrounding a given event that can be psychologically meaningful, including interpersonal dynamics, situational features owing to a place or location, memories, goals for the future and internal body or brain states."	Wager & Atlas, 2015, p.403
Placebo	"The word placebo is the Latin term for "I shall please." It is used to indicate sham treatments or inert substances such as sugar pills or saline infusions."	Schedlowski et al., 2015, p.700
Placebos	"Placebos are pills composed of inert substances (e.g., microcrystalline cellulose) or sham procedures without any direct effect on pathophysiology."	Kaptchuk, et al., 2020, p.2
Placebo analgesia	"A reduction in pain that can be attributed to the treatment context."	Wager & Atlas, 2015, p.404
Placebo effects	"Placebo effects are the salubrious clinical outcomes patients derive from participation in the rituals, symbols, and behaviours of medical treatment."	Kaptchuk, et al., 2020, p.2
Placebo response	"The placebo response refers to the outcome caused by a placebo manipulation. It reflects the neurobiological and psychophysiological response of an individual to an inert substance or sham treatment and is mediated by various factors within the treatment context. Importantly, placebo responses are not restricted to placebo treatments – they can also modulate the outcome of any active treatment."	Schedlowski et al., 2015, p.700
Placebo responses	"Outcomes detected with placebo controls in randomized clinical trials that include both genuine placebo effects and such non-specific effects as regression to the mean, spontaneous improvement, and normal fluctuations in illness. Placebo responses also accompany most clinical interventions for subjective complaints."	Kaptchuk, et al., 2020, p.2
Nocebo	"The term nocebo (I shall harm) was introduced in contrast to 'placebo' to distinguish the positive from the noxious effects of placebos, when an inert substance is given within a negative context, inducing negative expectations about the outcome."	Schedlowski et al., 2015, p.700
Nocebo effects	"Deleterious outcomes (for example, an increase in pain or an increase in negative side effects) owing to beliefs about the treatment context."	Wager & Atlas, 2015, p.404
Descending pain modulation	"Endogenous, biological mechanisms for suppressing ascending nociceptive information at the level of the spinal cord."	Wager & Atlas, 2015, p.409
Descending pain modulatory network	"The CNS mechanisms initiating and mediating placebo responses are best characterized for placebo analgesia and involve the descending pain modulatory network, which includes the dorsolateral prefrontal cortex (DLPFC), the anterior cingulate cortex (ACC), the amygdala (Am), and the periaqueductal grey (PAG). Similar regions of the brain have been shown to contribute to emotional placebo responses. The shared and distinct contributions of different brain networks in other types of placebo responses are currently unknown."	Schedlowski et al., 2015, Fig. 4., p.704

The definitions in Table 3 suggest that placebo and nocebo effects are related to CFs because they describe how the context in which a treatment is administered can influence the patient's perception of the treatment and its effectiveness (Wager & Atlas, 2015). However, it is important to note that there is a wide array of terminology used to describe placebo-nocebo phenomenon, for instance fake, dummy, and sham treatments; inert and active placebos; pure and impure placebos; placebo or nocebo effects; placebo or nocebo responses; negative placebo; context effects; contextual healing; and even the meaning response to name a few (Jakovljević, 2014). This demonstrates that there is a lack of consensus regarding placebo-nocebo terminology. Moreover, placebo effects and responses are frequently used interchangeably (Jakovljević, 2014).

This study uses the term CFs because clinical theories of placebo/nocebo effects do not simply focus on singular social, psychological, or behavioural factors but instead consider multiple elements of clinical encounters and how these influence outcomes (Kaptchuk et al., 2020). Moreover, since the placebo effect can be evoked without resorting to placebo pills or sham interventions (Miller & Kaptchuk, 2008; Zion & Crum, 2018), it may be considered a misnomer and more aptly reconceptualised as contextual healing (Miller & Kaptchuk, 2008).

It has been proposed that pain modulation can be potentially achieved by manipulating CFs (Bishop et al., 2017; Testa & Rossettini, 2016). Consequently, a promising approach to enhance MSK treatments may involve explicitly manipulating CFs during routine care. These effects influence MSK pain outcomes through descending pain modulatory systems (Rossettini et al., 2018a). Several researchers have advocated for the ethical use of placebo effects as a clinically beneficial strategy for pain relief (Miller & Kaptchuk, 2008; Rossettini et al., 2018a; Testa & Rossettini, 2016; Sagy et al., 2019), with outcomes of similar magnitude to treatment effects (Howick et al., 2013). Furthermore, deliberately leveraging the effects of CFs may be relatively low-risk and a potentially cost-effective strategy to enhance clinical outcomes (Newell et al., 2017). Zion and Crum (2018) assert that the placebo effect is an essential component of the overall treatment effect as illustrated in Figure 11 below. Accordingly, it can be effectively harnessed, maximised, and personalised during medical practice (Zion & Crum, 2018).

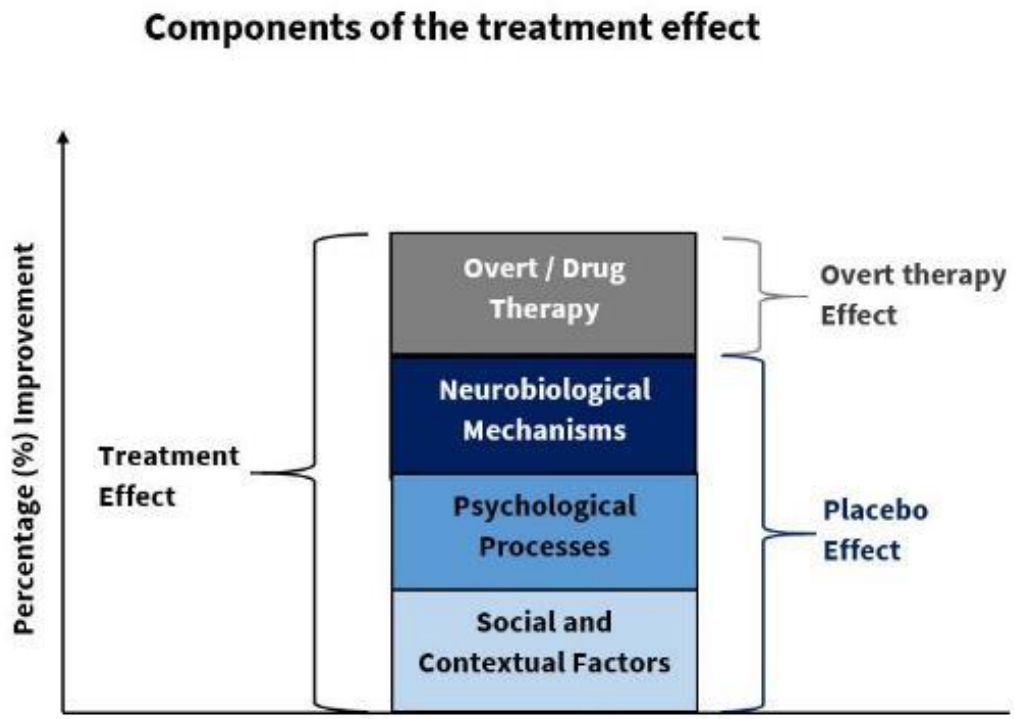


Figure 11. Components of the total treatment effect facilitating patient improvements. (Adapted from Zion & Crum, 2018 p.140. Reproduced with permission from Elsevier.)

Figure 11 shows that the total treatment effects comprise the effects of the overt/drug therapy and the placebo effect (Zion & Crum, 2018). Notably, Figure 11 above does not intend to suggest that the placebo effect is twice as large as the overt/drug therapy effect but rather to illustrate the three inter-related components that contribute to the placebo effect. It is important to briefly explain how CFs may potentially trigger placebo/nocebo effects, to provide a conceptual overview. However, it is beyond the scope of this Chapter to review the psycho-neurobiological mechanisms underpinning these effects in detail. Comprehensive reviews providing detailed neurobiological explanations have previously been discussed (see for example, Blasini et al., 2018; Carlino & Benedetti, 2016; Schedlowski et al., 2015; Wager & Atlas, 2015).

1.2.2.1. Links between CFs and placebo-nocebo phenomenon

Research has shown that placebo and nocebo effects induce physiological or biological effects through activating descending pain modulatory networks (Schedlowski et al., 2015; Wager & Atlas, 2015). This neurobiological response is triggered by specific psychological processes which are influenced and informed by social and environmental factors (Testa & Rossettini, 2016; Rossettini et al., 2018a; Zion & Crum, 2018). Figure 12 provides a conceptual flow diagram of how CFs inform psychological process and activate this innate physiological response.

Figure 12. The interconnected components underlying the placebo/nocebo effect (Adapted from Zion & Crum, 2018, p.148. Reproduced with permission from Elsevier.)

Figure 12 shows that social and CFs play a key role in informing psychological processes, which, in turn, activate neurobiological mechanisms (Testa & Rossettini, 2016; Zion & Crum, 2018). Endogenous neurobiological mechanisms are activated by both conscious and unconscious psychological processes, such as implicit learning (social and observational learning, reward-learning), expectations, and mindsets (Testa & Rossettini, 2016; Zion & Crum, 2018). The treatment context includes social interactions, cultural norms, and CFs which contribute to shaping psychological processes such as patient's beliefs, expectations, emotions, and cognitive associations and biases (Testa & Rossettini, 2016). For example, the patient-practitioner relationship plays a key role in shaping the patient's attitudes towards health, illness, and treatments, and it also impacts the quality of care the patient receives (Di Blasi et al., 2001). The patient-practitioner relationship is influenced by factors such as the practitioner's warmth and competence, along with their individual characteristics such as empathy and honesty (Di Blasi et al., 2001). Accordingly, the interplay between social and CFs and psychological processes forms the basis for the activation of placebo or nocebo effects (Zion & Crum, 2018).

Neurobiological mechanisms

Key neurotransmitters involved in placebo effects include the release of endogenous opioids, dopamine, endocannabinoids, oxytocin, and vasopressin, which are associated with pain relief and other positive outcomes (Rossettini et al., 2018a; Testa & Rossettini, 2016; Zion & Crum, 2018). On the other hand, key neurotransmitters associated with nocebo effects, which can lead to negative outcomes, include cholecystokinin (CCK), dopamine, opioid deactivation, and activation of cyclooxygenase-prostaglandins (Rossettini et al., 2018a; Testa & Rossettini, 2016). These neurochemicals play important roles in modulating pain and can either amplify or dampen pain signals within the spinal cord. Importantly, the interplay

between these neurotransmitters and corresponding brain regions contributes to the modulation of pain perception and the placebo-nocebo phenomenon.

Placebo and nocebo effects engage well-defined top-down or descending pain modulation systems (Schedlowski et al., 2015; Testa & Rossettini, 2016). These systems involve projections from the brainstem to the spinal cord and can either enhance or suppress pain signals (Testa & Rossettini, 2016). Multiple pathways and neurochemical systems contribute to these modulation processes (Testa & Rossettini, 2016; Wager & Atlas, 2015). Of particular importance is the central opioidergic pathway that extends from the midbrain periaqueductal grey (PAG) through the rostroventral medulla (RVM) and down to the spinal cord (Wager & Atlas, 2015). The PAG serves as a central hub that receives direct projections from the ventromedial prefrontal cortex (vmPFC), ventrolateral prefrontal cortex (vlPFC), amygdala (Am), nucleus accumbens (NAc), and hypothalamus, enabling prefrontal cortical and limbic control over both incoming sensory information and central pain circuitry (Wager & Atlas, 2015). It is worth noting that the PAG circuitry not only plays a critical role in regulating pain but also contributes to various motivated behaviours and is activated during emotional responses too (Wager & Atlas, 2015).

Figure 13 below summarises the main neurobiological findings regarding nocebo hyperalgesia, which is the experience of increased pain in response to negative expectations (Benedetti et al., 2020). Limited knowledge regarding nocebo hyperalgesia is primarily attributed to ethical constraints that restrict research in this area (Benedetti et al., 2020). Inducing nocebo hyperalgesia involves giving participants an inactive treatment along with verbal suggestions implying an increase in pain, which is considered a stressful and anxiety-provoking procedure (Benedetti et al., 2020).

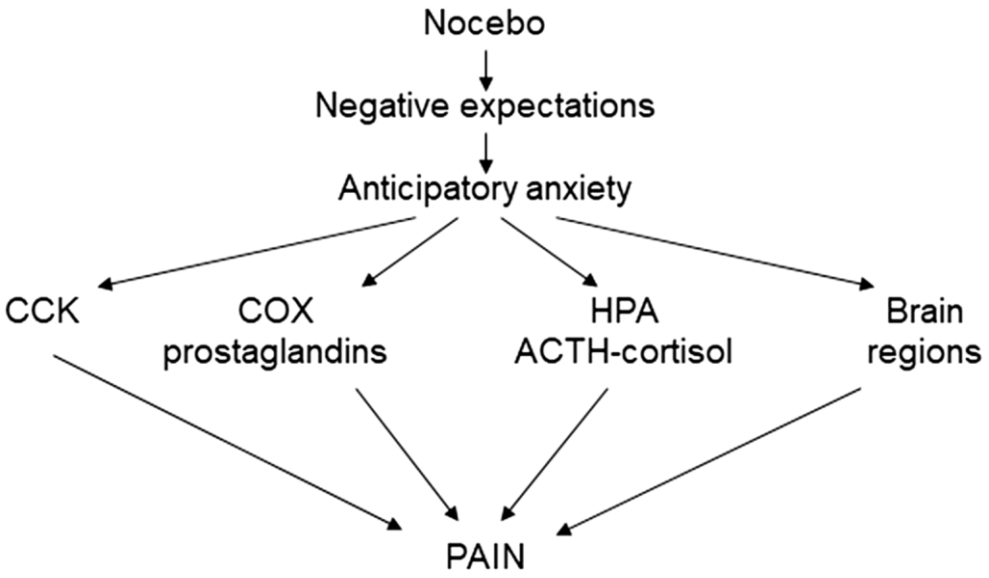


Figure 13. Sequence of events following the administration of a nocebo
(Benedetti et al., 2020, p.691. Reproduced with permission from Springer Nature.)

Figure 13 depicts the sequence of events following the administration of a nocebo, leading to pain. Negative expectations induced by the nocebo primarily affect pain perception through anticipatory anxiety (Benedetti et al., 2020). This process involves the activation of various systems, including cholecystokinin (CCK), cyclooxygenase (COX), prostaglandins, the hypothalamus-pituitary-adrenal (HPA) axis, which involves the release of adrenocorticotropic hormone (ACTH) and cortisol, and multiple regions in the brain (Benedetti et al., 2020). Anxiety-induced hyperalgesia occurs when individuals anticipate pain, resulting in heightened sensitivity to pain, with CCK systems playing a role (Benedetti et al., 2020). During the anticipation of pain arising from negative expectations, specific regions such as the anterior cingulate cortex, prefrontal cortex, and insula are activated. Nocebos have the potential to influence COX activity and the HPA axis and have also been associated with reduced dopamine and opioid activity specifically in the nucleus accumbens (Benedetti et al., 2020). Contrastingly, stress-induced analgesia occurs when a state of general arousal arises from a stressful situation in the environment, and attention is directed towards the stressor resulting in the activation of endogenous opioid systems (Benedetti et al., 2020).

Conceptual processes that may represent the treatment context can be challenging to precisely define and measure in the brain because these processes rely on the integration of information from multiple systems to form a coherent schema or conceptualisation of a situation and its implications for well-being (Wager & Atlas, 2015). In the context of placebo

effects, several cortical regions that may be implicated in these conceptual processes (Wager & Atlas, 2015). These regions include:

a) the dorsomedial prefrontal cortex (dmPFC), which is associated with inferences about social information;
b) the insula, which is involved in interoceptive assessments of one's body state;
c) the lateral orbitofrontal cortex (lOFC), which relates to expectancies; and
d) the hippocampus (Hipp), which is linked to autobiographical memories and place/context information (Wager & Atlas, 2015).

The ventromedial prefrontal cortex (vmPFC) plays a central role in integrating these elements into a coherent schema, as depicted in Figure 14 below (Wager & Atlas, 2015, p.37). Accordingly, the vmPFC serves as a hub that connects with other processing levels involved in regulating sensory, autonomic, and neuroendocrine responses. These processing levels include the amygdala (AMY), hypothalamus (HYP), nucleus accumbens (NAc), periaqueductal grey (PAG), and rostroventral medulla (RVM) (Wager & Atlas, 2015). This integrated schema allows for bidirectional information exchange and influences the responses at these processing levels, contributing to placebo effects (Wager & Atlas, 2015).

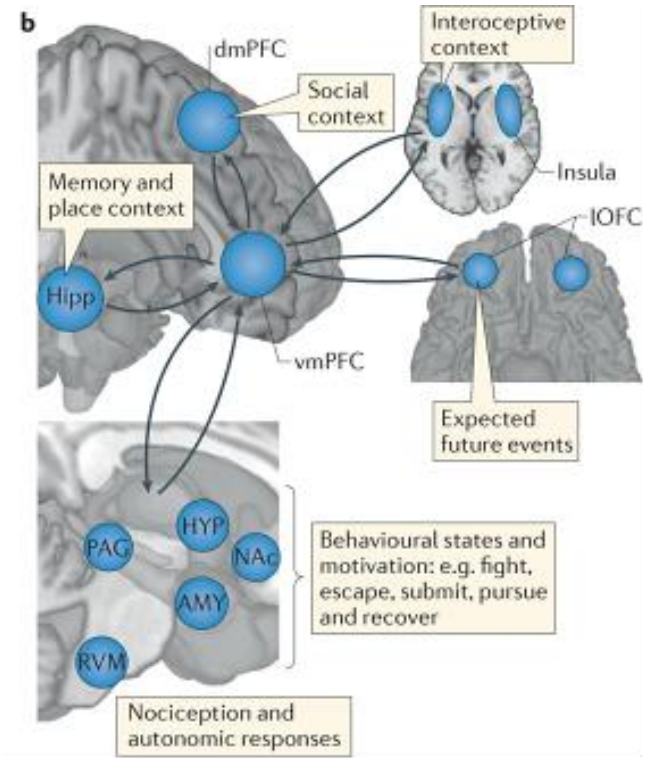


Figure 14. Cortical regions implicated in conceptualising the treatment context [1]
(Wager & Atlas, 2015, p.412. Reproduced with permission from Springer Nature.)

[1] **Abbreviations**: dorsomedial prefrontal cortex (dmPFC); lateral orbitofrontal cortex (lOFC); hippocampus (Hipp); amygdala (AMY); hypothalamus (HYP); nucleus accumbens (NAc); periaqueductal grey (PAG); rostroventral medulla (RVM)

Accordingly, the vmPFC and other prefrontal areas play central roles as hubs in the process of conceptual meaning-making (Figure 14), making them potential candidates for shared factors underlying placebo effects (Wager & Atlas, 2015). These regions are involved in integrating contextual information, social inferences, expectancies, and autobiographical memories, forming a coherent conceptualisation of the situation and its implications for well-being (Wager & Atlas, 2015). By serving as central hubs, the vmPFC and other prefrontal areas facilitate the interaction and integration of information from different processing levels and are well-positioned to contribute to the generation and modulation of placebo effects across a range of outcomes (Wager & Atlas, 2015).

Recently, computational neurobiological models have emerged which provide a unified framework to explain the diverse evidence surrounding placebos (Kaptchuk et al., 2020). Two inter-related theories, known as "predictive coding" or "predictive processing" and the "Bayesian brain" have offered new insights into placebo effects (Ongaro & Kaptchuk, 2019; Kaptchuk et al., 2020). While discussing these neurobiological models is beyond the scope of this Chapter, comprehensive reviews are available for further reference (see Ongaro & Kaptchuk, 2019; Kaptchuk et al., 2020). In essence, predictive coding is a theory proposing that the brain continuously generates predictions about the sensory inputs it expects to receive from the environment (Kaptchuk, et al., 2020). These predictions are compared to the actual sensory information, and any disparities between the predicted and actual inputs are considered prediction errors, which play a role in learning and updating the brain's internal models (Kaptchuk et al., 2020). Bayesian models propose that perception is primarily influenced by cognitive processes, often operating outside conscious awareness (Ongaro & Kaptchuk, 2019). Accordingly, perception can be understood as a process of prediction, where sensory inputs are integrated with prior experiences and contextual cues (Ongaro & Kaptchuk, 2019). In this view, the brain generates expectations about incoming sensory information and uses them to shape perception, while considering the interplay between sensory inputs, prior knowledge, and the current context (Ongaro & Kaptchuk, 2019). According to the Bayesian brain perspective, the brain continuously updates its beliefs and makes decisions by combining incoming sensory information with prior knowledge (Ongaro & Kaptchuk, 2019).

Psychological processes

The underlying psychological processes involved in triggering placebo/nocebo and context-related effects include expectations, implicit learning (social/observational/vicarious learning, classical conditioning/associative learning), reinforced expectations/operant conditioning, along with the patient's mindset, and personality traits (Colloca & Miller, 2011a; Rossettini et al., 2020; Testa & Rossettini, 2016; Zion & Crum, 2018) as depicted in Figure 15 below. These psychological mechanisms interact and contribute to the modulation of placebo/nocebo, and context-related effects in various clinical and social contexts (Rossettini et al., 2020).

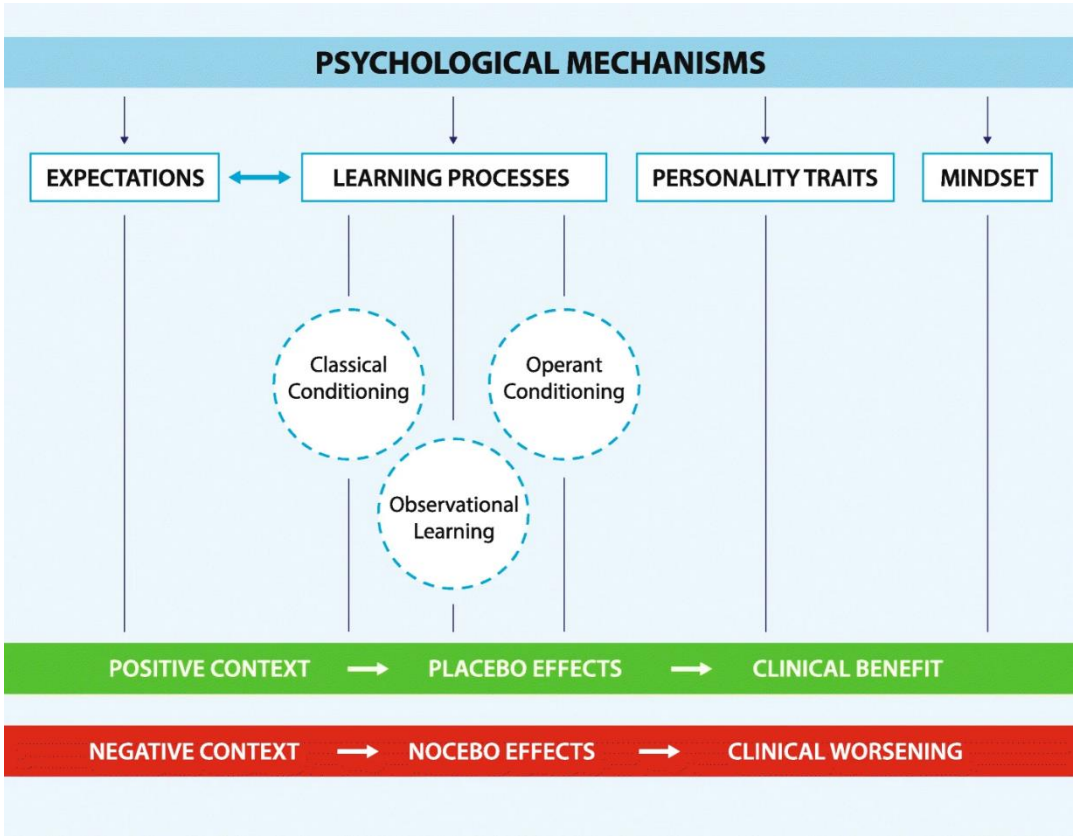


Figure 15. Psychological mechanisms involved in placebo, nocebo, and context-related effects (Rossettini et al ., 2020, p.4)

Expectancy refers to a belief about the future based on predictions of what is likely to happen next (Zion & Crum, 2018). Consequently, expectation is the cognitive process of anticipating a future event or outcome and it plays a significant role in shaping an individual's cognitive, emotional, and physical experiences (Rossettini et al., 2020). Expectations can be influenced by verbal suggestions (e.g., positive or negative outcome proposals), an individual's prior experiences, the perceived likelihood of an outcome, and emotional evaluations of a situation, such as anticipating a potentially dangerous or threatening event (Colloca & Miller, 2011a). Expectations play a role in in shaping

placebo/nocebo effects and catalyse neurobiological mechanisms (Colloca & Miller, 2011a; Zion & Crum, 2018). Expectations are dynamic and continuously influenced by the information and stimuli present in the surrounding environment. They can be modified and updated based on ongoing inputs and experiences (Rossettini et al., 2020).

Pavlovian classical conditioning originally demonstrated associative learning, which was initially understood as the pairing of two stimuli (Rossettini et al., 2020). One stimulus, initially neutral and not eliciting any response on its own, is referred to as the *conditioned stimulus* (CS e.g., bell) (Colloca & Miller, 2011a; 2011b). The other stimulus consistently elicits a response and is called the *unconditioned stimulus* (US e.g., dog food). The response that occurs as a result of pairing the CS (bell) and the US (dog food) is known as the *conditioned response* (CR e.g., salivation) (Colloca & Miller, 2011a; 2011b; Rossettini et al., 2020). In essence, classical conditioning involves pairing a neutral stimulus (CS) with an unconditioned stimulus (US) which can lead to learned associations and the elicitation of a conditioned responses (CR). This process can contribute to placebo/nocebo effects (Rossettini et al., 2020). According to classical conditioning, the nocebo effect is a learned response that is triggered by the exposure to a painful stimulus previously associated with a specific cue or context (Klinger et al., 2017). For example, the repeated pairing of a neutral CS, such as the sight of a doctor's white coat or the smell in a hospital, with an US, such as a painful intervention (e.g., injection or dental procedure) results in a conditioned response (e.g., increased pain) when the CS is presented (Klinger et al., 2017). This means that encountering the associated cues, such as the patient's interaction with the doctor or entering the hospital, or receiving a specific treatment, can elicit negative effects because of the learned associations with previous painful interventions (Klinger et al., 2017).

In a similar manner, symbols, and rituals within the medical context can become associated with healing and/or symptom improvements (Zion & Crum, 2018). For instance, actions such as being directed to the treatment room, having vital signs measured, and waiting for the practitioner can serve as situational cues that can become implicitly associated with healing experiences. Over time, these cues are consistently paired with active medical treatments. As a result, exposure to these cues alone can elicit conditioned responses in patients (Zion & Crum, 2018). Furthermore, experiences with treatments outside clinical settings, whether positive or negative, can establish associative connections between specific treatment characteristics and their outcomes (Zion & Crum, 2018). Accordingly, learning plays an important role in both placebo and nocebo effects (Blasini et al., 2018; Colloca & Miller, 2011a; Zion & Crum, 2018). Interestingly, it has been suggested that conditioning

mechanisms tend to generate more nocebo effects in women, while expectations may have a stronger influence in men (Blasini et al., 2018).

Notably, the repetition of paired associations is less influential in causing nocebo hyperalgesia compared to consolidating placebo analgesia (Blasini et al., 2018). Negative expectations induced by verbal suggestions tend to have a stronger impact in producing nocebo effects with larger effect sizes than placebo effects, which rely on first-hand experiences of positive outcomes (Blasini et al., 2018). Nocebo effects can also stem from prior unsuccessful experiences with medications or interventions, conditioning patients to experience negative effects and reduce the expected benefits of pain treatments (Blasini et al., 2018). The duration of past events involving pain exposure is also relevant to the development and persistence of nocebo-induced pain. Accordingly, positive, or negative experiences and outcomes with previous treatments can reinforce patients' expectations, influencing their response to subsequent interventions (Rossettini et al., 2020). However, since classical conditioning and expectation mechanisms both involve the processing of information where individuals anticipate future events, whether consciously or unconsciously, these psychological processes are not mutually exclusive (Colloca & Miller, 2011a). Conversely, expectations formed through communication or observation often incorporate prior experiences and may include elements of prior conditioning (Colloca & Miller, 2011a).

Expectations involve beliefs and anticipations about the outcomes of a treatment or intervention which can shape these psychobiological responses. When any treatment is administered, the information about its effects shapes the patient's expectation (Kirsch, 2018). Believing that a particular treatment makes one more or less sensitive to pain influences its effectiveness. Positive expectations about a treatment's effects can enhance its effectiveness, while negative expectations can reduce it (Kirsch, 2018). This is important because it means that the way patients are informed about painful procedures, pain medication, or other pain interventions can influence their expectations and subsequently their response to an intervention (Blasini et al., 2018). Nocebo effects can arise from negative expectations or the absence of positive expectations, and they can also be influenced by social/observational and vicarious learning (Blasini et al., 2018).

Pain perception can be affected by social interactions and can be modulated by observing others (Blasini et al., 2018). When individuals observe a particular situation and the consequences of specific actions, they acquire information about that circumstance. There is evidence suggesting that beliefs and attitudes related to pain can be influenced by observing

others in pain (Blasini et al., 2018). The expectations of both the patient receiving treatment and the beliefs held by the healthcare practitioner can influence the experience of treatment and any side effects. Therefore, the patient-practitioner relationship plays an important role in shaping the patient's treatment experiences and expectations (Blasini et al., 2018).

Additionally, expectations can be induced through verbal suggestion or written information, such as the information provided during the informed consent process regarding the treatment and its potential side effects (Blasini et al., 2018). Observing other patients interacting with healthcare practitioners and their responses to pain and pain treatments can influence patients' perceptions (Blasini et al., 2018). Observational learning involves observing the experiences and behaviours of others which can influence expectations (Colloca & Miller, 2011a). Social observation or vicarious learning plays a role in shaping placebo/nocebo effects (Colloca & Miller, 2011a). In a notable study by Colloca and Benedetti (2009), it was revealed that placebo effects can be induced through observational social learning. Participants who observed others undergoing an analgesic procedure experienced significant placebo analgesia when subjected to the same procedure (Colloca & Benedetti, 2009). Interestingly, the placebo effect induced through social observation was comparable to those induced by conditioning and even greater than those induced by verbal suggestion. Moreover, the level of empathy participants exhibited was positively correlated with the effect, highlighting the potential significance of this finding for future research (Colloca & Benedetti, 2009).

Recent evidence has also identified operant conditioning as a mechanism involved in placebo/nocebo effects (Rossettini et al., 2020). Operant conditioning is a type of learning in which behaviour is influenced by the consequences that follow (Murphy & Lupfer, 2014). Behaviours are shaped through a process of reinforcement or punishment. There are four main consequences used during operant conditioning, namely positive or negative reinforcement and positive or negative punishment (Murphy & Lupfer, 2014). Reinforcement involves providing a desirable consequence to increase the likelihood and frequency of a behaviour reoccurring. Positive reinforcement refers to the addition of a rewarding stimulus, while negative reinforcement involves the removal of an aversive stimulus (Murphy & Lupfer, 2014). Examples of positive reinforces include money, praise, and attention, or engaging in preferred activities whilst a negative reinforcer includes paying taxes to avoid fines or imprisonment. Conversely, punishment involves providing an undesirable consequence or aversive stimulus to decreases the frequency of a behavioural response (Murphy & Lupfer, 2014). Positive punishment refers to the addition of an aversive stimulus, while negative punishment involves the removal of a rewarding stimulus (e.g.,

paying a speeding fine or losing smartphone/computer gaming privileges). Through operant conditioning, individuals learn to associate specific behaviours with their consequences, leading to behaviour modification (Murphy & Lupfer, 2014).

Adamczyk and colleagues (2019) conducted an experiment to explore operant conditioning's potential to induce placebo analgesia in healthy female volunteers. Participants were divided into three groups: experimental, random-control, and colour-control. They received pain stimuli preceded by coloured cues and feedback on a computer screen as rewards or punishments. The experimental group received rewards for low pain responses (placebo) and punishments for high pain responses (non-placebo), following the coloured cues. The random-control group received feedback which was not dependent on their pain responses (i.e., rewards and punishments were non-contingent) whilst the colour-control group did not receive rewards or punishments (Adamczyk et al., 2019). The results showed that when rewards and punishments were discontinued only the experimental group experienced less pain following the placebo colour than the non-placebo colour, indicating placebo analgesia persisted throughout the study. This suggests that operant conditioning serves as a learning process that can elicit placebo and nocebo effects in healthy volunteers (Adamczyk et al., 2019).

Although there is currently no identified personality trait that reliably predicts placebo responses, certain traits like neuroticism, optimism, and openness to experience may influence outcomes (Rossettini et al., 2020). Higher levels of trait and state anxiety are associated with increased susceptibility to nocebos (Woo, 2015). Suggestibility also plays a role, as individuals can be more or less influenced by positive or negative contexts, resulting in stronger placebo or nocebo effects respectively (De Pascalis, et al., 2002). Moreover, individuals with more optimistic personalities tend to experience stronger placebo effects, while those with pessimistic personalities are more prone to nocebo effects (Geers et al., 2005).

A patient’s mindset, including their attitudes, beliefs, and cognitive biases such as pain catastrophising, can influence the response to treatments and interventions (Rossettini et al., 2020). Mindsets are mental frameworks or lenses that shape how individuals perceive and anticipate things (Zion & Crum, 2018). They simplify complex information by providing a structure for understanding oneself and the world. In the case of patients, mindsets serve as a foundation for comprehending the overall nature of illnesses and treatments (Zion & Crum, 2018). While expectations and mindsets are interconnected, they are distinct. Expectations refer to specific beliefs about future events, whereas mindsets encompass broader

psychological interpretations that align with multiple expectations. For instance, the mindset that "low back pain is a catastrophe" may give rise to several expectations such as anticipating painful treatment, feeling unable to cope, or enjoy usual activities. Mindsets are not solely oriented towards beliefs about the effectiveness of treatments (Zion & Crum, 2018). Mindsets influence patients' attention and motivation, which can impact subjective and objective health and well-being measures.

For instance, studies examining stress, diet, and exercise have revealed that mindsets have an influence on psychological well-being and physical health markers, such as blood pressure, weight loss, cortisol response, and hormone secretion (Crum & Langer, 2007; Crum et al., 2011; Crum et al., 2013). Intentional and adaptive changes in mindsets can be achieved through targeted interventions. For example, hotel employees who were taught that their work provided sufficient daily physical activity showed improvements in vital health measures, even though evidence indicated their behaviour was unchanged (Crum & Langer, 2007). This suggests that practitioners have the ability to deliberately shape their patients' mindsets (Zion & Crum, 2018). For example, assisting a patient in developing a mindset that their illness is manageable rather than catastrophic can impact patient expectations regarding the course of the illness, symptoms, and treatment efficacy. Instead of solely shaping treatment expectations, practitioners can help to cultivate more adaptive mindsets that might generate cascading effects (Zion & Crum, 2018).

Early life experiences with illness, visits to healthcare practitioners, and observations of family members and peers play a considerable role in establishing mindsets regarding health and illness (Zion & Crum, 2018). These experiences contribute to the formation of health-related mindsets, which are further shaped by cultural norms and customs. Additionally, interactions with healthcare systems and personal encounters with disease and treatment during adulthood, whether positive or negative, continue to influence and refine these mindsets (Zion & Crum, 2018). Psychological processes such as implicit learning, expectations, and mindsets are not isolated entities, and are strongly influenced by the surrounding environment (Zion & Crum, 2018). The treatment context including external factors, social, and situational cues play a role in shaping and informing these cognitive processes. The interplay between these processes and the environment is integral to understanding how individuals perceive, interpret, and respond to various situations and stimuli (Zion & Crum, 2018).

1.2.3. Relevance of CFs during clinical interactions

The clinical encounter involves a complex array of explicit behaviours and implicit non-verbal cues (Kaptchuk et al., 2020). Explicit behaviours include actions like attention, warmth, focused touch, validation, empathic witnessing, diagnostic procedures, diagnosis itself, and acts of kindness. Implicit non-verbal cues encompass elements such as voice, facial expressions, eye contact, bodily expressiveness, non-focused touch, style of conversation, proximity, and presence (Kaptchuk et al., 2020). Other important aspects of the relationship include trust and competence, which are difficult to classify. Conducting rigorous randomised controlled trials (RCTs) to reliably study the therapeutic effects of the clinical encounter is challenging because it is difficult to maintain consistency between known and unknown CFs (Kaptchuk et al., 2020). However, there is evidence to support different elements of these therapeutic interactions and how each main CF domain may influence chronic pain conditions like cLBP.

1.2.3.1. Patient's characteristics and beliefs

As previously discussed, *patient characteristics and beliefs*, including their expectations, preferences, and previous experiences, play a notable role in shaping their pain experiences and treatment outcomes (Colloca & Miller, 2011b; Testa & Rossettini, 2016; Wager & Atlas, 2015). Symptom improvement expectations can be influenced by factors such as receiving a treatment, being in a clinical setting, and verbal or non-verbal interactions with a practitioner (Rossettini et al., 2018a). Research has shown that general expectations for pain relief influence pain and disability in patients with LBP (Bishop et al., 2011). Enhancing the patient's expectations towards therapy increases the likelihood of pain relief (Rossettini et al., 2018a). Several studies have indicated that delivering a treatment with an expectation of benefiting from it has a greater effect on pain relief compared to providing a treatment without any expectation of benefit (Bishop et al., 2011; George & Robinson, 2010; Linde et al., 2007; Myers et al., 2008; Sherman et al., 2010). However, patient's expectations are often underestimated by MSK practitioners (Bialosky et al., 2010). Additionally, the patient's prior experiences can also impact the clinical outcomes (Testa & Rossettini, 2016). The patient's treatment history, including past positive or negative experiences, can impact their response to future treatments (Rossettini et al., 2018a). Patients' preferences and previous experiences can modify the therapeutic response during MSK rehabilitation (Hush et al., 2011). For instance, if a patient has previously had a negative outcome with a particular treatment, it may impact their expectations and potentially reduce the likelihood of positive experiences with that treatment (Rossettini et al., 2018a). Accordingly, neglecting, or

disregarding patient's previous experiences, preferences, and expectations can negatively influence treatment outcomes (O'Keeffe et al., 2016). Patients' perceptions of care quality can vary based on gender and age, where females tend to prioritise organisation and communication and older individuals focus on access to services and effective communication (Hush et al., 2011; Testa & Rossettini, 2016).

1.2.3.2. Practitioner's characteristics and beliefs

The *practitioner's characteristics, behaviour, beliefs, and suggestions* can have a strong influence on a patient's perception of pain (Rossettini et al., 2018a). When a practitioner demonstrates qualities such as competence, experience, professionalism, trustworthiness, and the ability to diagnose, provide a prognosis, and follow-up with the patient, it can effectively influence pain modulation (Birkhauer et al., 2017; Dieppe et al., 2016; Doherty & Dieppe, 2009; White et al., 2012). Factors such as a practitioner's professional reputation, expertise, qualifications, and appearance also contribute to modifying clinical outcomes (Hush et al., 2011; O'Keeffe et al., 2016). For example, a study conducted in a controlled medical setting emphasised the importance of practitioners' characteristics during interpersonal interactions (Howe et al., 2017). It was found that the perceived warmth and competence of the practitioner, coupled with positive expectations of treatment, had a significant impact on enhancing placebo effects. These effects led to improvements in allergic skin reactions caused by a histamine skin prick, followed by the application of a cream with no active ingredients (Howe et al., 2017).

Additionally, the practitioner's beliefs and behaviours can influence treatment outcomes such as their enthusiasm and optimism or pessimism about a treatment (Testa & Rossettini, 2016). Practitioners' expectations can serve as predictors of treatment outcomes in patients with chronic pain (Witt et al., 2012). Patients whose practitioners had anticipated a significant improvement experienced a greater reduction in pain and improved physical functioning compared to patients where only moderate improvements were expected by their practitioners (Witt et al., 2012). Contrastingly, negative behaviours such as displaying nervousness, spending excessive time reading patient charts, using too many technical terms, or appearing uncooperative or rushed should be avoided during clinical interactions (O'Keeffe et al., 2016; Testa & Rossettini, 2016). The practitioner's physical features can also influence treatment outcomes (Rossettini et al., 2018a; Testa & Rossettini, 2016). For instance, practitioners' appearance may influence patients' perception of care, where a study showed that a laboratory coat and tailored clothing were considered more professional and preferred by patients with LBP (Mercer et al., 2008). Contrastingly, formal, or casual attire

had no effect on the treatment's credibility in a RCT involving patients with acute, non-specific LBP (Traeger et al., 2017). While the practitioner's characteristics, such as their perceived likeability and credibility plays a role, they also contribute to the psychosocial factors that are essential for establishing a therapeutic relationship with patients (Blasini et al., 2018).

1.2.3.3. Patient-practitioner relationship

Miller and colleagues (2009) argue that placebo effects should be conceptualised as a form of interpersonal healing. While conventional medicine focuses mainly on the physiological aspects of disease, it often neglects the concept of illness and the potential for medical interactions to alleviate suffering. Treating an illness can be supported and facilitated through the *patient-practitioner relationship*, rather than solely relying on administering specific treatments (Miller et al., 2009). The quality of this relationship has been shown to have positive effects on various outcomes, including pain levels, disability, satisfaction, and the strength of the therapeutic alliance (Bishop et al., 2021; Ferreira et al., 2013; Hall et al., 2010). In a prospective cohort study, the therapeutic alliance and practitioner-rated expectations of the treatment response were identified as strong predictors of back-related disability (Bishop et al., 2021). These effects were however mediated by improvements in patient self-efficacy in coping with pain, a decreased perception of back pain as threatening, and reduced psychosocial distress (Bishop et al., 2021). A positive patient-practitioner relationship can lead to clinical benefits. Empathic face-to-face interactions characterised by a strong therapeutic alliance, active listening, more time spent with the patient, warmth, attention, care, encouragement, and support significantly reduces pain (Ferreira et al., 2013; Fuentes et al., 2014; Kaptchuk et al., 2020; Kelley et al., 2014; Mistiaen et al., 2016).

Clinical interactions are influenced by verbal and non-verbal communication. It has been suggested that practitioners spend approximately twice as much time engaging in conversation compared to performing hands-on treatments with patients (Roberts & Bucksey, 2007). Effective communication skills are crucial for building a strong therapeutic relationship (Parsons et al., 2007). Empathy and positive communication play a significant role in reducing pain (Howick et al., 2018). Important verbal skills include active listening, expressing support and encouragement, using humour and empathy, engaging in discussions, using partnership statements (e.g., us, we, together), paraphrasing, and seeking the patient's opinion (Hush et al., 2011; O'Keeffe et al., 2016; Testa & Rossettini, 2016). These interpersonal skills have been associated with patient satisfaction and can influence treatment outcomes. Practitioners who interrupt patients or prevent them from sharing their

story, lack empathy and friendliness, or display excessive confidence or arrogance can lead to patient dissatisfaction (O'Keeffe et al., 2016). Negative communication such as expressing anxiety and relying on closed-ended questions to gather information should therefore be avoided (Oliveira et al., 2012).

Non-verbal communication also plays a key role in therapeutic interactions (Rossettini et al., 2018a). Facial expressions and eye contact are important elements from which patients derive meaning (Benedetti, 2013; Pinto et al., 2012). Facial expressions have the ability to influence pain processing and enhance placebo analgesia (Valentini et al., 2014; Wieser et al., 2014). In a clinical setting, practitioners use non-verbal behaviours such as eye contact, smiling, and caring expressions of support and interest, which can influence outcomes (Oliveira et al., 2012; Roberts & Bucksey, 2007). Positive body language such as touch, affirmative head nodding, forward leaning, and body orientation to facilitate patient engagement can improve satisfaction with the consultation (Oliveira et al., 2012; Roberts & Bucksey, 2007). Gestures, postures, physical contact, and speech collectively convey a message full of meaning during clinical interactions (O'Keeffe et al., 2016). The practitioner's ability to interpret the patient's non-verbal body language is also an important skill during clinical interactions (Oliveira et al., 2012). Accordingly, practitioners should aim to avoid negative body language such as crossing their legs, leaning backward, excessive, or intrusive eye contact, and adopting a slanting or slouching positions (Oliveira et al., 2012; Pinto et al., 2012).

Using positive messages associated with pain relief, such as describing a treatment as a "powerful pain killer", has been found to induce placebo analgesia (Vase et al., 2002, 2009). Informing the patient that a potent treatment has been administered enhances the analgesic effect, whereas verbal suggestions regarding threatening side effects can compromise its effectiveness and trigger increased pain (Mistiaen et al., 2016; Peerdeman et al., 2016; Street et al., 2012). Combining hands-on techniques with positive verbal instructions can positively influence patients' expectations and satisfaction (Bialosky et al., 2014; Riley et al., 2015a, 2015b). Contrastingly, providing negative information such as cautioning the patient about a potential increase in pain during a leg flexion test, has been shown to exacerbate pain and hinder performance in patients with cLBP (Pfingsten et al., 2001).

Additionally, adopting a person-centred approach may enhance the effectiveness of therapy, as the patient's involvement in the overall care process has been shown to modulate pain (Rossettini et al., 2018a). A person-centred approach, which involves personalising treatment and considering the patient's opinions, has been found to influence treatment outcomes

(Hush et al., 2011; O'Keeffe et al., 2015; Oliveira et al., 2012; Pinto et al., 2012). Certain factors have been identified that negatively affect treatment outcomes, such as practitioner-centred or biomedical care approaches, lack of privacy, long waiting lists, reduced interaction times, rushed treatments, and seeing different practitioners for the same issue, leading to a lack of continuity of care (Hush et al., 2011; O'Keeffe et al., 2015; Oliveira et al., 2012). Conversely, factors that contribute to improved patient satisfaction and therapeutic outcomes include maintaining continuity of care throughout the treatment, providing sufficient consultation time, being punctual, offering appointment flexibility, ensuring timely treatment, and providing appropriate frequency, duration, and treatment follow-ups (Hush et al., 2011; O'Keeffe et al., 2015; Oliveira et al., 2012). This highlights the overlap between treatment features and the delivery of care in supporting the development of a strong therapeutic alliance.

1.2.3.4. Treatment characteristics

How a treatment is administered along with the frequency of treatment plays a role in pain perception (Rossettini et al., 2018a). Placebo effects are typically stronger when therapies are more frequent and repeated (e.g., multiple sessions instead of single session) (Zhang et al., 2008). The treatment modality is important in modulating pain (Meissner & Linde, 2018). For instance, more invasive treatments (e.g., acupuncture, injections, intravenous administration, surgery) typically induce stronger expectations and larger placebo effects than less invasive options (e.g., oral, nasal, topical, subcutaneous) (Doherty & Dieppe, 2009; Meissner & Linde, 2018; Zhang et al., 2008; Zou et al., 2016). Additionally, the colour, size, dose, price, labelling, branding/marketing features also play a role in placebo effects (see Meissner & Linde, 2018 for a detailed review). However, these effects are likely to be mediated by cultural perceptions and learning processes related to treatment characteristics and the anticipated effects arising from associated connotations (Meissner & Linde, 2018). It has been suggested that using an overt treatment that increases the patient's awareness of receiving therapy can have an impact on clinical outcomes (Testa & Rossettini, 2016). To facilitate placebo analgesia, it is important to demonstrate and inform patients that a treatment is being administered (Testa & Rossettini, 2016). For instance, patients who used mirrors to observe their back movements during exercises reported faster recovery from pain and dysfunction, suggesting it is an effective strategy for patients with LBP (Diers et al., 2013; Wand et al., 2012).

Practitioners use different forms of touch in clinical settings, including assistive touch, touch for preparation, touch for information, caring touch, touch for therapeutic intervention, and

touch for perception (Testa & Rossettini, 2016). Therapeutic touch has been shown to have a positive impact on pain experiences in patients (Lu et al., 2013; Rossettini et al., 2018a; Wardell et al., 2012; Zangrando et al., 2017). Touch plays a key role in interpersonal interactions and social bonding (Gallace & Spence, 2010), and in a therapeutic context, it can be an effective strategy for alleviating MSK pain (Monroe, 2009; So et al., 2008). Moderate pressure massage has been shown to modulate physiological parameters such as heart rate, increasing vagal activity, decreasing cortisol levels, and augmenting serotonin and dopamine levels (Field, 2014; Field et al., 2005, 2010; Mancini et al., 2015; Sefton et al., 2011). These findings highlight the potential therapeutic benefits of touch in managing pain (Rossettini et al., 2018a).

Notably, the practitioner's ability to provide positive feedback, deliver a clear diagnosis along with prognostic information, and explain the patient's illness and treatment can positively interact with patient's clinical outcomes (Hush et al., 2011; Pincus et al., 2013; Pinto et al., 2012). A clear understanding of their MSK condition can also influence patient satisfaction with the care (Hush et al., 2011). Moreover, effective cognitive reassurance (i.e., providing concrete explanations and patient education) is associated with an improvement in symptoms in patients with chronic pain (Pincus et al., 2013). During early phases of persistent LBP, cognitive reassurance combined with empathic communication supported patients' recovery (Hasenbring & Pincus, 2015).

Observing others' pain improvements through social learning can also influence the symptoms experienced by observers (Goubert et al., 2011; Yakunchikov et al., 2017). Accordingly, promoting the positive effects of a therapy by allowing patients to interact with others who have successfully undertaken the same treatment or by providing them with videos of other patients can influence placebo analgesia and prevent nocebo effects (Colloca, 2014). During MSK rehabilitation, actively observing the movements of others has been shown to improve pain and disability in patients following knee replacement (Bellelli et al., 2010; Park et al., 2014). Social learning has also been leveraged in open-label placebo (OLP) trials.

The emergence of OLP trials has been used to harness placebo effects. Prescribing an OLP has been used to treat patients with irritable bowel syndrome (Kaptchuk et al., 2010) and patients with cLBP (Carvalho et al., 2016). The open (versus hidden) paradigm means placebos are prescribed without deception (i.e., administered honestly or openly) and the patient is fully aware that the pill/intervention has no pharmacologically active ingredients but still experiences positive symptom changes (Kaptchuk et al., 2020). These OLP trials

provide evidence of proof of concept. Enrolled patients are typically receiving usual care treatments concomitantly and still report more than 50% reduction in symptoms compared to usual care controls (Kaptchuk et al., 2020). It is however important to consider that the treatment context during an OLP trial is likely to modulate these effects. For instance, who is prescribing the pill? Is social learning involved? How were these effects explained? Is the prescribing individual (i.e., scientist, practitioner) perceived as credible (e.g., white-coat effect)? How did they interact with patients (e.g., warm, cold, neutral communication and body language)? Were verbal suggestions used (e.g., "*this is a powerful treatment that is effective for your condition*")? How was the placebo pill/intervention labelled? What was the colour, size, shape, dose, label, mode of administration? Were there additional interactions and so forth. To replicate OLP trials with larger sample sizes and for longer periods, researchers will need to carefully consider and report all relevant CFs to ensure the finer details remain constant between trials and comparison groups.

1.2.3.5. Treatment environment/setting

Lastly, features of the treatment environment/setting can influence patient outcomes such as pain, stress, and anxiety which plays an important role in patient care (Ulrich et al., 2010). The environment, architecture, and interior design plays a meaningful role in creating a therapeutic context. In terms of the environment, sensory elements have a modulating effect on patient outcomes (Rossettini et al., 2020; Testa & Rossettini, 2016). Natural lighting, low noise levels, and the presence of relaxing and soft music contribute to a more desirable therapeutic environment (Cesario, 2009; Dijkstra et al., 2006; Drahota et al., 2012; Schweitzer et al., 2004; Ulrich et al., 2008). The use of pleasing aromas and maintaining an appropriate temperature are also important considerations in establishing a therapeutic context (Dijkstra et al., 2006; Schweitzer et al., 2004).

The architectural aspects of the treatment environment also influence patient perception and pain experiences (de Tommaso et al., 2013). Patients prefer environments that incorporate windows, skylights, as well as comfortable and private spaces (Cesario, 2009; Dijkstra et al., 2006; Schweitzer et al., 2004; Ulrich et al., 2008). Supportive indicators such as easily visible signs, clear directions, accessible entrances, and information desks contribute to positive experiences (Cesario, 2009). Convenient clinic hours, location, parking availability, and approachable support staff are also valued by patients (Hush et al., 2011).

Interior design elements, such as nature-themed artworks incorporating elements like green vegetation, flowers, water, and views of nature, along with the integration of plants or

garden ornaments can contribute to calming effects (Cesario, 2009; Dijkstra et al., 2006; Schweitzer et al., 2004; Ulrich et al., 2008). Colour schemes using soothing shades can contribute to patients' care experiences (Brown & Gallant, 2006). However, it is important to consider individual and cultural preferences regarding how colours are interpreted and the intended patient population (Cesario, 2009; Schweitzer et al., 2004). Notably, most of the evidence relating the environment of care is derived from in-patient or hospital settings, and there is limited evidence regarding how these CFs may influence clinical outcomes in out-patient settings or public and private MSK clinics.

An interesting double-blind, mixed-methods RCT investigated the influence of the treatment environment on an exercise therapy programme for patients with hip or knee pain (Sandal et al., 2019). Six focus group interviews with participants and individual interviews with two therapists were conducted to explore participants' experiences of the treatment environment. Participants underwent eight weeks of exercise therapy in one of three settings: a) a newly built and physically enhanced environment (n = 42); b) a standard environment (n = 40), or c) waiting list control (n = 21). Neither participants nor therapists were aware of the study's objective (Sandal et al., 2019). Interestingly, the results did not provide sufficient evidence to support the initial hypothesis that the enhanced environment would be more effective than the standard environment, but the qualitative research shed light on this outcome (Sandal et al., 2019).

Participants in the standard environment reported a greater sense of social cohesion and feeling "at home", safe, or "at ease" because the environment reminded them of familiar exercise settings such as school gyms which strongly influenced their perceptions of the space (Sandal et al., 2019). Notably, participants in both environments avoided using mirrors for visual feedback, associating them with commercial gyms and finding them inappropriate for exercise therapy (Sandal et al., 2019). While there were no significant differences in muscle strength and aerobic capacity between the two exercise groups, participants in the standard environment reported greater improvement in the Global Perceived Effect (GPE = 0.98) compared to those in the enhanced environment (GPE = 0.37). However, the between-group difference in GPE (0.61; 95% CI: -0.1–1.3) fell short of statistical significance (p = .07) and the waiting list control reported no change (GPE = -0.05) (Sandal et al., 2019). These findings suggest that the physical environment plays a role in treatment effectiveness, and designing treatment spaces based on patients' preferences may lead to better patient-reported outcomes (Sandal et al., 2019).

1.2.4. Rationale and knowledge gaps

Although progress has been made in understanding placebo/nocebo effects through clinical trials and placebo studies, there is still a lack of research and knowledge in applying CFs in clinical practice (Colloca & Miller 2011b; Rossettini et al., 2018a; 2020; Zion & Crum, 2018). The relationship between CFs and placebo/nocebo effects highlights the complex interplay between the mind and body in the experience of illness and healing (Newell et al., 2017). Deliberately leveraging CFs in an ethical manner can potentially enhance the overall effectiveness of MSK care (Bishop et al., 2017; Bradbury et al., 2016; Rossettini et al., 2020; Testa & Rossettini, 2016).

However, the existing evidence on this topic primarily stems from a diverse range of studies, which encompass healthy individuals, controlled experimental settings, clinical trials, and findings extrapolated from qualitative research (Kaptchuk et al., 2020; Klinger et al., 2018; Rossettini et al., 2018a; Testa & Rossettini, 2016). Accordingly, it is uncertain how well these findings may generalise to routine clinical practice settings. This emphasises the need for translational research, which aims to bridge the gap between research findings and practical application, in order to advance the field (Bishop et al. 2017; Colloca & Miller 2011b; Enck et al. 2013; Klinger et al., 2014). Furthermore, it is important to explore how CFs operate and impact various patient populations and settings owing to the variability of placebo/nocebo effects, which exhibit distinct mechanisms across health conditions (e.g., Parkinson's Disease versus MSK pain) and interventions (Benedetti, 2022; Frisaldi et al., 2015).

Healthcare practitioners, including Physiotherapists, Chiropractors, Osteopaths, Nurses, and General Practitioners, often lack knowledge and awareness of CFs and their potential role in enhancing placebo effects and mitigating nocebo effects (Rossettini et al., 2020). Despite CFs being integral to most complex interventions for MSK conditions, they are often overlooked and not deliberately leveraged by practitioners (Rossettini et al., 2018a). Additionally, insufficient education concerning CFs further limits practitioners' understanding and perception of their practical applicability and relevance in clinical practice (Rossettini et al., 2020).

It is important to note that existing research has predominantly focused on individual CF elements or domains, such as the patient-practitioner relationship, empathy, trust, and patient beliefs. However, CFs likely interact with each other in complex ways, emphasising the need for comprehensive studies that explore the interplay between CFs and their combined impact

on treatment outcomes. This becomes particularly important considering the ethical concerns associated with intentionally or unintentionally manipulating patient expectations or beliefs (Benedetti, 2019), necessitating further research to ensure that patients are not misled and to prevent potential harm. Although there is a growing body of evidence suggesting that CFs can impact MSK treatment outcomes, their specific influence in the management of cLBP and how they can be effectively harnessed is not well understood. Therefore, additional research is needed to fully comprehend the role and influence of CFs during cLBP treatment. By addressing these knowledge gaps, it can advance knowledge and understanding of the optimal use of CFs to improve the effectiveness of cLBP care.

Accordingly, the purpose of this study is to address the existing knowledge gaps by investigating the role of CFs in the management of cLBP. The findings of this research have the potential to contribute to the field by providing a better understanding of how CFs can be optimally utilised to improve the effectiveness of cLBP treatment. By gaining further insights into the impact of CFs, it may be possible to develop tailored and targeted treatments and interventions that address the diverse and complex needs of patients with cLBP. The integration of CFs into clinical practice has the potential to enhance treatment outcomes, minimise potential negative effects, empower MSK practitioners, and ultimately improve the overall well-being of patients.

1.3. Research aims and objectives

1.3.1. Research problem

Chronic or persistent LBP is a significant public health issue, affecting millions of individuals worldwide, that can lead to considerable disability and decreased quality of life. Although conservative treatments incorporating a biopsychosocial approach are commonly recommended for cLBP, they often offer only limited relief from symptoms. Consequently, there is a need to gain a deeper understanding of the role played by CFs in conservative management of cLBP, particularly from the perspectives of both patients and MSK practitioners. By exploring their views, valuable insights may be obtained to improve conservative interventions for cLBP that could improve patient outcomes.

1.3.2. Research aims

The overarching aim of the research is to investigate the role of CFs during conservative cLBP treatment and to explore the perspectives of both MSK practitioners' and patients' regarding CFs during care. Specifically, the study intends to examine how various CFs, such

as the beliefs and characteristics of both patients and practitioners, the patient-practitioner relationship, and the treatment features and environmental factors, influence the overall treatment process and outcomes for patients with cLBP. By exploring these key dimensions, a comprehensive understanding of the role of CFs in cLBP treatment can be achieved to provide valuable insights for improving patient care.

Furthermore, this research also aims to:

1) Review the current evidence on interventions that include potential modification of CFs following conservative cLBP treatment.
2) Draw on the opinions and knowledge of MSK practitioners to identify CF care approaches which may augment conservative cLBP care.
3) Investigate patients' and MSK practitioners' experiences and beliefs regarding the role of CFs by exploring their interpretations during LBP consultations.

The respective methods to address these aims, consists of three consecutive studies:

1) a systematic literature review;
2) a two-round modified Delphi-consensus survey; and
3) semi-structured interviews with patient-practitioner dyads.

Collectively these studies are envisaged to contribute to emerging knowledge of CFs as triggers of placebo analgesia in relation to the management of cLBP in clinical practice.

1.3.3. Research questions

The overarching research question supporting the main research aim that guided this study is:

> Which CFs have an impact on patients' outcomes during conservative cLBP management and are perceived as relevant from a clinical perspective?

Additional research questions aiming to address identified knowledge gaps included:

1) What is the impact of interventions modifying CFs during conservative cLBP care on patients' pain and physical functioning outcomes?
2) What is the extent of panel consensus amongst MSK practitioners regarding the perceived acceptability and influence of CFs during cLBP rehabilitation?
3) What are the views of patients and MSK practitioners regarding their experiences of LBP consultations and to what extent are CFs involved?

1.3.4. Research objectives

The research is situated within the pragmatism paradigm, since the overarching objective is to inform praxis (i.e., translating theory into clinical practice), whilst considering the knowledge and experience of underrepresented yet influential stakeholders. Accordingly, this research aims to address the following research objectives:

1) To examine the impact of CFs pain intensity and physical functioning outcomes during conservative cLBP management.
2) To identify which CF care approaches MSK practitioners believe are clinically relevant and influential during conservative cLBP treatment.
3) To identify potential barriers for incorporating CFs into conservative cLBP management.
4) To investigate the perceptions of patients and MSK practitioners regarding the role of CFs during LBP consultations.
5) To identify similarities and differences in patients' and MSK practitioners' perceptions regarding the role of CFs during cLBP consultations.
6) To develop initial recommendations or strategies on how to optimally incorporate CFs into conservative cLBP treatment to improve clinical outcomes and patient satisfaction.
7) To develop an initial framework for MSK practitioners to help them conceptualise how to incorporate CFs during conservative cLBP treatment.

Overall, this research aims to contribute to a better understanding of how CFs can influence conservative cLBP treatment. By exploring the role of CFs, the study seeks to provide MSK practitioners with tools and strategies to improve the effectiveness of conservative LBP treatment and ultimately improve patient outcomes.

1.4. Outline of the thesis

In conclusion, this introductory chapter has laid the foundation for this thesis. Through a comprehensive literature review, the chapter highlights the importance of understanding CFs in the context of conservative cLBP management. It has identified existing knowledge gaps, accentuating the need for further investigation into the role of CFs during clinical practice. By establishing the context and significance of this study, this chapter sets the stage for the subsequent chapters, which aim to address the research questions, aims, and objectives. A succinct preview of the subsequent chapters follows.

Chapter 2 explains the philosophical assumptions underpinning the methodology and the rationale behind the approach. It discusses the multiphase research design and explains the

data collection methods. Understanding the research process provides insights into the reliability/dependability and validity/credibility of the findings. The successive chapters may help inform future clinical practices to optimise conservative cLBP management.

Chapter 3 introduces a published research paper that presents the outcomes of a systematic literature review examining the impact of CFs on patient outcomes following conservative LBP treatment. The chapter synthesises existing evidence to identify and analyse CFs relevant to cLBP rehabilitation. It aims to shed light on influential CFs which may contribute to a better understanding of their complex interplay during LBP management.

Chapter 4 presents a published research paper that expands the investigation by delving into MSK practitioners' perceptions using a modified Delphi study. This chapter focuses on MSK practitioners' perceptions of CFs and their influence on cLBP outcomes. Understanding practitioners' perspectives may offer useful insights into the clinical context and decision-making processes that affect patient care. Their views may be beneficial for implementing CF care approaches that can enhance the effectiveness of cLBP treatment.

Chapter 5 provides a qualitative exploration of patients' and MSK practitioners' experiences of consultations for LBP. This chapter enriches the research by uncovering the nuanced aspects of CFs during clinical interactions. The rich qualitative data complements the findings from previous chapters, providing a more holistic understanding of the nature and role of CFs during conservative cLBP management.

Chapter 6 plays an important role in this thesis as it integrates the findings from the three sequential studies. By synthesising the results from the systematic literature review, the modified Delphi study, and the qualitative research, this chapter aims to provide a comprehensive understanding the multifaceted nature of CFs and their implications for patient outcomes in cLBP management. This discussion provides insights into the complexity and dynamics of CFs, opening avenues for further research and practical applications.

Lastly, **Chapter 7** presents an overarching conclusion to the thesis. Drawing on the findings in the preceding chapters, it summarises the main contributions of this research to the field of cLBP rehabilitation. It provides key insights into the role of CFs and explores potential implications for clinical practice, education, and theory. The conclusion serves as a final reflection on the journey undertaken in this thesis and considers the potential for this research to advance cLBP management through the optimal use of CFs.

Chapter 2. Methodology

2.1. Chapter overview

Chapter 2 of this thesis presents the methodology and methods utilised in this research. The chapter begins with an account of the author's research journey, outlining the experiences and developments that led to the initiation of this research project. Subsequently, it delves into the philosophical assumptions and methodological approach that have guided and shaped the research design and implementation. Brief summaries of the methods employed in each phase of the research are provided, with Chapters 3, 4, and 5 offering comprehensive explanations. Those subsequent chapters will delve into the specifics of each phase, elucidating each study's materials, methods, and research process. Additionally, this chapter explores the various types of stakeholder engagement activities conducted throughout the research, undertaken during the planning, designing, and managing of the three studies. The involvement of various stakeholders informed the research approach. By offering insights into the researcher's journey, philosophical underpinnings, and stakeholder engagements, this chapter aims to provide readers with a deeper understanding of how these factors influenced and shaped the overall research process.

2.2. Author's research journey

My interest in researching the role of CFs in conservative cLBP management stems from a deeply personal journey with persistent pain that began more than two decades ago. Living with a rare condition called idiopathic condylar resorption of the temporomandibular joints, I faced a constant battle to find effective treatment and support. Throughout the years, I encountered medical professionals who seemed to attribute my pain to some fault of my own – my personality, behaviour, or my psychological state. This lack of understanding left me feeling misunderstood, frustrated, and helpless.

I explored various treatments, some of which are considered unconventional and unscientific such as reflexology, reiki, iridology, and homeopathy even though I did not expect them to work. I was willing to try anything in my quest for relief, anything that might offer a glimmer of hope. I was also prescribed multiple analgesic medications that left me feeling dazed, unable to concentrate, and interfered with my daily life. Despite the emotional turmoil of despair, anger, sadness, anxiety, and grief, I still held onto hope that a breakthrough would occur, and new knowledge would emerge which may alleviate my

suffering. I diligently followed the latest research and surgical developments for my condition, but they often seemed too risky to consider.

My perspective began to shift during my MSc in Health Psychology at King's College London. During my studies, I was exposed to new theories and explanations that finally helped me to make sense of my own pain. Understanding pain from a psychosocial perspective, including coping responses, helped me feel more empowered and less defined by my pain. It was liberating to have plausible answers and to realise that my responses to pain were not irrational, abnormal, nor imagined. It made me feel that pain might become an intermittent part of my life instead of my life being dictated by it or revolving around it. This realisation sparked my interest in exploring “medically unexplained symptoms”, particularly chronic pain, and chronic fatigue.

During my MSc placement, I conducted an audit of a community health service that adopted a multidisciplinary approach to help patients better manage their chronic pain and chronic fatigue symptoms. The parallels in the treatment of these conditions caught my attention. I also conducted research with renal dialysis patients experiencing pain, and despite the study being quantitative, I recognised that patients were eager to share their pain experiences before I could even introduce the research properly. Patients seemed to want someone who would pay attention, listen to their stories, and express empathy. This resonated with me deeply, as I recalled similar encounters with medical professionals who often acted indifferent to my distress or dismissed my pain.

My personal encounters with medical professionals during my pain journey have been deeply impactful, shaping my understanding of the challenges individuals face when dealing with persistent pain. Unfortunately, some medical professionals I encountered appeared to view my pain with scepticism, treating me as if I were exaggerating my symptoms to seek sympathy or attention. This kind of dismissive attitude left me feeling stigmatised and dehumanised, as if my pain were not being taken seriously. At times, I was made to feel like a hypochondriac or an overly anxious person, as if my pain were merely a product of my imagination or anxiety. This invalidation added to the emotional burden of coping with persistent pain, exacerbating feelings of despair and helplessness. Moreover, there were instances where I felt as though medical professionals were suspicious of my intentions, suspecting that I was attempting to obtain prescription analgesics. I fully appreciate that medical professionals have an important duty of care and need to address issues of opioid use disorder or dependency; however, this unwarranted suspicion made me feel scrutinised and mistrusted which equally undermined my trust in them too.

I recognise that the opioid epidemic is a significant challenge to the global pain problem. I experienced the devastating impact of the opioid crisis firsthand – I lost a loved one to a suspected accidental overdose. Their struggle with persistent pain had been overshadowed by an approach to treatment that focused primarily on biomedical factors. This preventable tragedy reinforced my belief that there is a need for a more holistic, dignified, and empathetic approach to pain management, one that understands the individual's journey and prioritises their well-being.

Discovering the concept of CFs and their connection to placebo effects fascinated me, as it embodied and aligned with my beliefs about pain management. This knowledge renewed my hope for finding innovative approaches to manage persistent pain, fuelling my passion for this research. My excitement was not purely academic; it was driven by the hope that this newfound understanding could potentially revolutionise pain management. The notion that this knowledge could be leveraged to help patients like me or that open-label placebos might even assist with opioid-tapering to reduce reliance.

My own journey with pain has made me acutely aware of and empathetic towards the plight of individuals with similar distressing pain experiences. This has helped to fuel my commitment to conducting research investigating the role of CFs during cLBP management. Ultimately, my motivation to pursue this research stems from a heartfelt desire to make a meaningful difference in people's lives. I hope that my work can influence healthcare professionals to approach pain management with empathy, understanding, and open-mindedness, allowing patients to be active partners in their healing journey. My experiences have taught me the value of listening to and empathising with individuals enduring distressing pain. I aspire to contribute, however modestly, to the advancement of pain management, and to the well-being of those facing similar struggles. By sharing these cumulative experiences, I hope to provide readers with greater insight into my frame of reference and how it underpins my research on CFs.

2.3. Philosophical assumptions

Pragmatism as a philosophical movement emerged in the USA during the late 19th Century and is derived from the work of Charles Sanders Pierce, William James, George Herbert Mead, Chauncey Wright, Oliver Wendell Holmes Jr, Nicholas St. Johns Green, Arthur F. Bentley, and John Dewey (Creswell & Creswell, 2017; Kaushik & Walsh, 2019; Saunders & Bristow, 2017). The pragmatism movement emerged in response to these academics rejecting traditional positivist assumptions about the nature of reality (ontology), knowledge

(epistemology), and inquiry (Saunders & Bristow, 2017). However, pragmatism was only introduced into the American research vocabulary by Richard Rorty in 1979 (Kaushik & Walsh, 2019). One of the fundamental ontological assumptions of pragmatism is that neither reality nor the world are static. Rather actions are viewed as pivotal and play an intermediary role – the world is changed through actions and people are capable of shaping their experiences through action and intelligence (Kaushik & Walsh, 2019).

It has been argued that pragmatism avoids the ontological concepts of truth and reality by accepting that there can be single and multiple realities (Creswell & Plano, 2011; Kaushik & Walsh, 2019). Pragmatist scholars have suggested that there is an objective reality, which is grounded in the environment and can only be encountered through human experience. Accordingly, knowledge and reality are based on beliefs, and habits, which are socially constructed and some versions of those correspond with individuals' experiences more than others, but reality cannot be determined for all time since it is continually evolving (Kaushik & Walsh, 2019).

In this sense pragmatism provides one way of viewing the world by valuing both objective and subjective knowledge (James, 1908) and consequently quantitative and qualitative methods of inquiry (Cresswell & Plano, 2011). Pragmatists recognise the world can be interpreted in different ways; a single perspective is not a complete picture, but multiple realities can provide a more holistic approach (Saunders & Bristow, 2017). Pragmatism aims to reconcile the dichotomy between objectivism and subjectivism by focusing on the practical consequences of theories, concepts, ideas, hypotheses, and research within a particular context – inquiry is viewed as an instrument of thought and action instead of an abstraction (Shaw et al., 2010). On a continuum, pragmatism is situated between post-positivism, which typically supports quantitative methods, and constructivism, which favours qualitative methods (Kaushik & Walsh, 2019). Accordingly, pragmatism is observed in studies using different methods to achieve results that are meaningful and applicable to specific contexts and populations (Creswell & Plano, 2011; Shaw et al., 2010).

Pragmatism focuses on the purposes and consequences of knowledge rather than reflecting an underlying reality (Cornish & Gillespie, 2009) independent of the mind (i.e., realism) or that the mind is the basis of knowledge (i.e., rationalism). "*Truth is what works at the time*" (Creswell, 2014, p. 11). Pragmatism views knowledge as a mediator between the physical and social world rather than mirroring reality (Cornish & Gillespie, 2009). Knowledge is therefore considered a tool for action or a practical activity and should be evaluated accordingly (Cornish & Gillespie, 2009). In this sense, 'reality' involves the practical

consequences of ideas including fluctuations in processes, experiences, and practices (Saunders & Bristow, 2017). This means the underlying epistemological assumption of what is considered to be acceptable knowledge is whether it serves its intended purpose (Cornish & Gillespie, 2009). Pragmatism is orientated towards practical problem-solving for real-world social situations, with the purpose of creating knowledge to facilitate change or improvement (i.e., it has utility; Kaushik & Walsh, 2019).

Modes of inquiry may involve investigating the problem from different perspectives, favouring an independence of methods. Pragmatists focus on human experiences, recognising they are inseparable from situations and contexts (Morgan, 2014). Knowledge acquisition is viewed on a continuum, enabling the use of any suitable methodological tool (i.e., "what works" credo), rather than an absolute commitment to a paradigmatic stance or forced polarisation (Morgan, 2014). Pragmatism is not committed to one system of philosophy and reality which is compatible with mixed-methods research (Creswell, 2014). The practical effects of ideas and knowledge is valued (Saunders & Bristow, 2017). Thus, the research begins with a problem that aims to provide a sensible or pragmatic solution to inform future practice (Saunders & Bristow, 2017). A pragmatic approach does not view the epistemological differences between quantitative and qualitative paradigms as incompatible (Bishop, 2015). It aims to provide societally useful knowledge and is less concerned with the chosen methods as long as they are fit for purpose (Feizler, 2010; Saunders & Bristow, 2017). The chosen method should be credible, reliable, and relevant to advance the research problem, but pragmatists acknowledge it is possible to work with different types of knowledge and methods to address the research question (Saunders & Bristow, 2017). The focus is on the practicality – data to address the research question – which may include both biased and unbiased perspectives (Creswell & Plano, 2011). The underlying emphasis is on the nature of experience rather than the nature of reality (Kaushik & Walsh, 2019; Morgan, 2014).

Pragmatism's philosophical assumptions appear congruent with the research problem and approach. This is because when considering the implementation of health-related knowledge in the real-world, programme success depends not only on the evidence base, but also ensuring its acceptability with users, the level of required skills, as well as support and commitment from local stakeholders such as healthcare workers and managers (Cornish & Gillespie, 2009). Considering these philosophical assumptions, this research project is aligned with a pragmatist approach particularly since the overarching objective is to inform clinical practice, whilst considering the knowledge and experience of underrepresented yet influential stakeholders.

Translational research has been recognised as a key area of focus in advancing knowledge of placebo-nocebo phenomenon (Bishop et al. 2017; Colloca & Miller 2011b; Enck et al. 2013; Klinger et al. 2014). There is an increasing understanding that placebo effects are intricately intertwined with social interactions and the attribution of meaning (Colloca & Benedetti, 2009; Hardman et al., 2019; Hutchinson & Moerman, 2018), as well as embodied or enactive cognition, which focuses on the dynamic interactions between individuals and their environment (Ongaro & Ward, 2017). However, there is a disconnect between placebo studies and the public sphere, with a lack of inclusion of patients' perspectives and, to a lesser extent, practitioners' perspectives (Hardman et al., 2019).

From a pragmatist perspective, biomedical knowledge is often neither useful nor actionable particularly for individuals diagnosed with a chronic condition(s) (Cornish & Gillespie, 2009). Chronic conditions can substantially impact these individuals' lives including their work, relationships, and identities. The kind of knowledge they require extends beyond what is considered appropriate medical treatment and may include the ability to make sense of their illness, as well as strategies to manage their health or improve their quality of life (Cornish & Gillespie, 2009). It has been suggested that actionable knowledge is typically in the form of strategies and skills rather than medical facts (Cornish & Gillespie, 2009). A narrow focus on the mechanisms of disease has meant that the psychological or behavioural aspects may be misunderstood, ignored, or overlooked (Shelton, 2013). Although understanding physical mechanisms has been beneficial in advancing treatments, the drawback is a lack of understanding regarding how to treat patients using a humanistic approach (Shelton, 2013). For example, if technical procedures, laboratory tests or imaging are overemphasised and valued instead of soliciting a detailed account of the patient's clinical symptoms, important psychosocial factors may be overlooked or unaddressed including the therapeutic effects of the patient-practitioner relationship (Shelton, 2013).

The overemphasis on biomedical training, and the mind-body dichotomy has shaped modern medicine and science (Shelton, 2013). However, pragmatism, specifically John Dewey's (1859–1952) philosophy, may be an appropriate lens to reconcile this entrenched ideology in view of humanistic medicine (Shelton, 2013). Placebo effects have been historically relegated: perceived as fakery, delegitimate, purely psychological ('all in the mind'), or a scientific nuisance (Newell et al., 2017). Only recent neurobiological studies – revealing innate physiological processes – validated the phenomenon, illustrating the Cartesian legacy of mind-body dualism (Newell et al., 2017). Accordingly, placebo effects represent a potentially coherent exemplar for understanding complex phenomenon in an integrated manner. As Dewey (1928) argues, action or behaviour evolves through continual

interactions between the human organism, its social setting, and environment – an embodied conceptualisation of placebo effects mirrors this.

2.4. Methodology

Mixed methods research can be conceptualised as both a methodology and a method of inquiry (Cresswell & Plano, 2011). Methodology is generally considered an approach to research that flows from an underlying set of philosophical assumptions, whereas the method relates to a specific technique for collecting and analysing data (Cresswell & Plano, 2011). The main assumption is that mixing both quantitative and qualitative data either through a series of studies or in a single study will provide a better understanding of the research problem (Cresswell & Plano, 2011). One of the key characteristics of a pragmatic approach is that an applied research philosophy should guide the methodological choices (Cresswell & Plano, 2011). Accordingly, both quantitative and qualitative research methods can be used in a single study or a series of studies.

A multiphase design was used in the current study. A multiphase design allows for combining concurrent and/or sequential quantitative and qualitative data over a period of time (Cresswell & Plano, 2011). The purpose of this design is that multiple phases are required to address an overall objective and each study aims to focuses on a specific set of research question(s) which may evolve to address the overarching objective. Earlier findings and results are used to inform each successive phase (Cresswell & Plano, 2011). This research used three sequential studies which then informed the subsequent phases as illustrated in Figure 16 below.

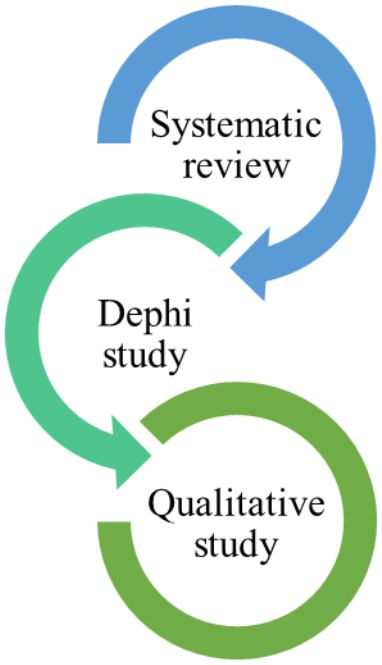


Figure 16. Overview of the multiphase research design of this study

2.5. Methods overview

The methods employed in each study are reported in detail within Chapters 3, 4, and 5, respectively. However, a brief summary of the methods used are described below. The overarching aim of this research is to systematically examine the role of CFs during conservative cLBP treatment and explore the perspectives of both MSK practitioners' and patients' regarding CFs during treatment. The respective methods and research questions to address the identified knowledge gaps are as follows:

1) **Study 1**: A systematic literature review
   Research question: What is the impact of interventions modifying CFs during conservative cLBP care on patients' pain and physical functioning outcomes?

2) **Study 2**: A two-round modified Delphi-consensus survey
   Research question: What is the extent of panel consensus amongst MSK practitioners regarding the perceived acceptability and influence of CFs during cLBP rehabilitation?

3) **Study 3**: A qualitative study with patient-practitioner dyads
   Research question: What are the views of patients and MSK practitioners regarding their experiences of LBP consultations and to what extent are CFs involved?

The research question regarding the impact of interventions targeting CFs in conservative cLBP care is effectively addressed through the systematic literature review. This method allows for the gathering and analysis of existing evidence from published studies, providing a comprehensive overview of the current state of evidence on the topic. Additionally, the Delphi-consensus survey is well-suited to investigate the acceptability and influence of CFs in cLBP rehabilitation. By gathering MSK practitioners' opinions and achieving consensus among them, this approach offers valuable insights from practitioners' perspectives in a structured and systematic manner. Furthermore, the qualitative study involving patient-practitioner dyads is appropriate for exploring the views and experiences of both patients and MSK practitioners during LBP consultations, with a specific focus on the involvement of CFs. This approach facilitates an in-depth exploration in a real-world context, offering rich insights into the perspectives and experiences of the participants. Collectively, these three phases of the research project aim to provide a comprehensive understanding of the role of CFs in cLBP treatment, which may contribute important insights for improving patient care.

The research design for the first two phases of this study were influenced by Bishop and colleagues' (2017) research. In their study, they combined a literature review and a survey to develop a taxonomy of techniques for harnessing placebo effects in non-malignant pain. Their taxonomy categorised the identified techniques based on the five main CF domains. These techniques were derived from a total of 169 studies, which were extracted from the reference lists of seven reviews (Bishop et al., 2017). Building on their work, the current study aimed to expand this approach by conducting a systematic literature review focusing on the impact of CFs on patient outcomes following conservative cLBP treatment. Additionally, the current study incorporated a modified Delphi-consensus survey.

The aim of the Delphi study was to explore MSK practitioners' perceptions of CFs and determine whether there was panel consensus regarding the acceptability and influence of CFs during cLBP rehabilitation. A notable difference from Bishop and colleagues' (2017) research lies in the design of the Delphi study. While their study involved a single survey, the Delphi approach used in this research allowed for iterative rounds of data collection, refinement, and consensus building. By involving a panel of experts in successive rounds, the research sought to provide a broad understanding of MSK practitioners' attitudes towards CFs and their perceptions regarding the influence of CFs during cLBP rehabilitation. The current study specifically considered MSK practitioners clinical experiences, whereas Bishop and colleagues' (2017) focused on the perspectives of leading placebo researchers.

By building on the foundation of Bishop and colleagues' (2017) work and refining the research methods, this study aimed to contribute to a better understanding of CF care approaches and their relevance in managing patients with cLBP. Moreover, the third phase of this study aimed to enrich the research by exploring the perspectives of both patients and MSK practitioners through semi-structured interviews which added a third dimension to the investigation.

2.5.1. Study 1: Systematic literature review

A systematic literature review protocol was registered on PROSPERO (CRD42019145157), and the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA; Page et al., 2021) checklist was followed. Four electronic databases (Medline, CINAHL, PsycINFO, and AMED) were searched from 2009 until 15th February 2022. Search strategies were tailored to each database using relevant Boolean operators, phrase searching, and Medical Subject Headings (refer to Appendix I). The search strategy focused on key concepts related to chronic low back pain, placebo effects/contextual factors, healthcare professionals, patient relationships/interactions, and patient expectations/beliefs. Searches were limited to title and abstract to maintain consistency, and duplicates were removed before screening for eligibility. Only full-text studies were included in the review to ensure a comprehensive evaluation. The study selection was limited to human studies published in English. After the initial screening, 170 full-text records were considered potentially eligible and assessed against the inclusion-exclusion criteria (refer to Chapter 3 for detailed information). These studies were then evaluated for their methodological quality using a modified Downs and Black (1998) scale. Data from the studies were extracted and synthesised using a narrative approach. The initial review findings (Sherriff et al., 2022) guided decisions regarding the Delphi survey design, and aided in identifying potentially relevant CF care approaches for patients with cLBP.

2.5.2. Study 2: Delphi study

The second study utilised a modified two-round online Delphi-consensus survey to achieve panel consensus, following the recommendations for conducting and reporting Delphi studies in palliative medicine (CREDES; Jünger et al., 2017). The number of rounds in the Delphi study were pre-determined to avoid potential attrition in successive iterations. The survey incorporated pre-determined content from literature reviews, which is an accepted modification in Delphi studies (Taylor, 2020).

Preliminary Delphi statements were derived from relevant reviews and various researchers' recommendations on harnessing placebo effects during clinical practice (Bishop et al., 2017; Dijkstra et al., 2006; Drahota et al., 2013; Hasenbring & Pincus, 2015; Iyendo et al., 2016; Klinger et al., 2017; Klinger et al., 2018; Klinger & Flor, 2014; Rossettini et al., 2018a; Stewart & Loftus, 2018; Testa & Rossettini, 2016). In addition, the initial systematic review findings (Sherriff et al., 2022) influenced the design of the Delphi survey which is discussed in more detail in Chapter 4. The between-round aims were to refine, clarify, and eliminate redundant statements while incorporating panel suggestions (Taylor, 2020). Both versions of the Delphi survey were piloted with independent/non-participating MSK practitioners who critically evaluated the survey. To review copies of each survey, and the amendments between rounds please consult Appendix II.

The Delphi study aimed to recruit 20 to 40 qualified UK MSK practitioners, accounting for a 25% drop-out rate between rounds (15–30 panellists in the final round). Convenience sampling was utilised, reaching potential participants through direct emails, social media adverts, and word-of-mouth recommendations. Panellists self-identified as MSK 'experts' proficient in cLBP rehabilitation, based on the inclusion-exclusion criteria discussed in Chapter 4.

Ethics approval was obtained from Bournemouth University's Research Ethics Panel (IDs: **28052** and **32406**) prior to data collection and recruitment. This approval ensured compliance with ethical guidelines and protected participants' rights and well-being. Participation was voluntary, with the right to withdraw at any time without penalty, and no coercion or deception was used. Data collection occurred online during two rounds: from 13th January to 11th March 2020 (round one) and from 23rd June to 23rd July 2020 (round two). Delphi panellists provided informed consent, acknowledging the study's purpose, data collection process, and use of their information.

The main analysis was conducted using SPSS version 28.0. Descriptive statistics and frequency tables were generated to summarise responses. Mean scores were computed to rank statements within the five main CF domains. Consensus was defined as ≥75% agreement, for ratings of 4 (agree) or 5 (strongly agree) on a 5-point Likert scale. Cumulative percentages indicated overall panel agreement for statements with ratings ≥4; however, disagreements or 'Not Valid' ratings indicated insufficient panel consensus.

Data management practices were carefully implemented to ensure the security and confidentiality of participants' information. Data were collected over encrypted connections,

providing an added layer of protection during transmission. Access to the survey responses were restricted and password-protected, with only the researcher having authorised access via the University-approved survey platform (JISC). Raw data were anonymised to remove any personally identifiable information. This ensured that participants' identities remained protected throughout the analysis and reporting process. The anonymised data were stored in a password protected folder, adding another level of security. To further safeguard participants' privacy, the surveys were designed to collect only the minimum necessary personal characteristics required for analysis, limiting the scope of data collected. Raw data will be securely deleted from the JISC survey platform following institutional guidelines once the degree is awarded. Anonymised data will be publicly accessible through BU's Data Repository (BORDaR). These data management practices helped to ensure the study was General Data Protection Regulation (GDPR) compliant and maintained the confidentiality and security of participants' information throughout the research process.

2.5.3. Study 3: Qualitative study

The third study utilised qualitative research as part of the multiphase research design, following the guidelines of the Consolidated Criteria for Reporting Qualitative Research (COREQ; Tong et al., 2007). Semi-structured interviews were conducted with eligible patient-practitioner dyads to investigate patients' and MSK practitioners' experiences regarding the role of CFs by exploring their interpretations during LBP consultations. The study aimed to recruit between eight and ten patient-practitioner dyads. All interviews were conducting separately and lasted approximately 25–30 minutes each. These dyads were recruited from privately-owned clinics in England, based on the preceding Delphi study's findings, which indicated that the majority of MSK practitioners expressing interest in CFs worked in private practice (Sherriff et al., 2023). Informed consent was obtained from each participant prior to their interview. Participants were also given the opportunity to complete an optional pre-interview task (5–10 minutes) via a secure online survey, where they provided basic demographic information, and their initial thoughts about their recent consultation to help minimise recall bias and ensure the eligibility criteria were met.

Ethics approval was obtained from Bournemouth University's Research Ethics Panel (ID: **33506**) prior to data collection and recruitment to ensure compliance with ethical guidelines and to protect participants' rights and well-being. Participation was voluntary, with the right to withdraw at any time without penalty, and no coercion or deception was involved. Interviews were conducted between May and November 2021, at mutually convenient dates and times. All participants provided informed consent, including express consent for audio

recording during the interview. Participant quotes were anonymised to maintain confidentiality.

Practitioner participants were recruited using various channels, including social media platforms (Facebook, Twitter, LinkedIn), email invitations, and professional networks. Research invitations and flyers were distributed through these networks, providing essential study information. Word-of-mouth referrals through snowballing also contributed to the recruitment process. Interested and eligible practitioners were requested to contact the interviewer via email. Participating practitioners played a role in patient recruitment, assisting with screening eligible patients, and promoting the study through invitations, flyers, and posters. Patient materials emphasised confidentiality and non-interference with ongoing treatment. Interested patients were able to access the information sheet and contact the interviewer through a QR code or email, ensuring that their contact information remained confidential. Importantly, none of the MSK practitioners shared any potentially eligible patient contact information with the interviewer. Participants received a £15.00 voucher as a token of appreciation for their involvement in the study.

The interview guide was developed by considering relevant literature, along with insights from the preceding systematic review (Sherriff et al., 2022) and Delphi study (Sherriff et al., 2023). These studies informed the development of the aim and research question. Data analysis followed the six phases of thematic analysis as outlined by Braun and Clarke (2006).

Braun and Clarke (2020a) argue that there is no single perfect method or methodology when choosing an appropriate qualitative analytical approach. This is because pattern-based or across-case analyses, such as Interpretative Phenomenological Analysis (IPA), Grounded Theory (GT), and (reflexive) thematic analysis (TA), often yield comparable outcomes. Both IPA and GT are methodological frameworks informed by theory, that are often perceived as more sophisticated than TA (Braun & Clarke, 2020a). IPA, rooted in phenomenology, focuses on personal experiences, small purposive samples, and qualitative interviews to elicit first-hand narratives (Braun & Clarke, 2020a). GT involves an iterative process that integrates data collection, analysis, and theory development, aiming to formulate theories rooted in empirical data (Vollstedt & Rezat, 2019). This methodology allows researchers to explore and understand complex social phenomena by systematically analysing data without pre-conceived theoretical frameworks. Suitable research questions often concern phenomena lacking theoretical foundations or insufficiently developed theories (Vollstedt & Rezat,

2019). While IPA focuses on personal experiences, GT explores complex social phenomena through inductive analysis (Braun & Clarke, 2020a).

IPA aims to understand individual experiences through a dual analytical approach, concentrating on both the unique particulars of each case (i.e., idiographic approach), and a thematic orientation across cases (Braun & Clarke, 2020a). Procedurally, IPA involves an in-depth examination of each case before progressing to the development of themes across cases. GT aims to generate new theories or refine existing ones through inductive analysis of qualitative data collected in naturalistic settings (Vollstedt & Rezat, 2019). The process involves inter-dependent data collection, analysis, and theory development, with theoretical sampling guiding case selection. Theoretical sampling ensures that new data are selected based on their potential contribution to theory development, allowing researchers to refine and validate emerging concepts and categories (Vollstedt & Rezat, 2019). Data analysis, through open, axial, and selective coding, focuses on theory development. Central to GT is theoretical sensitivity, cultivated through maintaining openness, critically evaluating data, and actively seeking novel insights that emerge from the analysis process (Vollstedt & Rezat, 2019). Conversely, TA offers greater flexibility across epistemological and ontological viewpoints and can be informed by various theories, addressing diverse research questions (Braun & Clarke, 2020a). TA concentrates on deriving themes across cases rather than accentuating the distinct characteristics of individual cases like IPA. Notably, it does not prescribe a specific sample size or data types, rendering it suitable for analysing and addressing varied research inquiries (Braun & Clarke, 2020a).

TA is often misconstrued as a singular method; however, it comprises three distinct approaches or 'schools' which can be conceptualised along a continuum (Braun & Clarke, 2020a; Braun & Clarke, 2020b; Clarke & Braun, 2018). Firstly, '*coding reliability*' approaches (or '*small q*' TA) involve early theme development using a structured coding process through a coding frame or codebook. Multiple coders work independently, and researcher subjectivity is managed through consensus-based coding procedures (e.g., inter-rater-reliability) to ensure accuracy (Braun & Clarke, 2020a; 2020b). Secondly, '*codebook*' approaches (or '*medium Q*' TA) blend qualitative research principles with structured coding and initial theme development. A codebook is used to map the analysis rather than assessing reliability, to facilitate teamwork and enhance analysis efficiency in applied settings (Braun & Clarke, 2020a; 2020b). Finally, contrasting with coding reliability, '*reflexive*' TA approaches (or '*Big Q*' TA) entail later theme development, with themes emerging organically from codes and contingent on the depth of data engagement (Clarke & Braun, 2018). Braun and Clarke (2020b) further elaborate that *'coding reliability*' TA emphasises

objective and unbiased coding, often using a deductive approach, and developing themes early in the process. In contrast, '*codebook*' TA aims for early theme development but allows themes to be refined or developed iteratively. '*Reflexive*' TA prioritises qualitative values and acknowledges researcher subjectivity during the analysis (Braun & Clarke, 2020b).

In reflexive TA, themes are understood as patterns of shared meaning, requiring significant analytic and interpretative effort by the researcher. Each theme encapsulates an 'essence' or core concept that serves as the foundation for uniting diverse observations (Clarke & Braun, 2018). Themes are actively crafted by researchers, rather than passively emerging from the data, allowing them to unify seemingly disparate information and reveal implicit meanings. Organised around central concepts, themes collectively narrate a cohesive story, allowing for the elucidation of shared meanings and contrasting perspectives more effectively than mere data summaries (Clarke & Braun, 2018). TA transcends mere data description and reduction; while it can serve these purposes if aligned with research aims, its richness lies in moving beyond summative descriptions to interpretation, ultimately telling the story of the data's significance (Clarke & Braun, 2018). Accordingly, the coding process is less structured, allowing for the evolution of codes as the researcher's comprehension deepens (Braun & Clarke, 2020a; Clarke & Braun, 2018).

The selection of an appropriate qualitative analytical approach depends on various factors, including the research's purpose, question, theoretical assumptions, and overall design (Braun & Clarke, 2020a). Given the aim of the qualitative study was to delve into patients' and MSK practitioners' experiences of consultations for cLBP, with a specific focus on CFs, the rationale for selecting TA over IPA or GT stems from several considerations. Firstly, the study extends beyond individual experiences to explore broader themes and perspectives related to CFs, aligning with TA's adaptable nature (Braun & Clarke, 2020a). IPA's focus on individual phenomenological experiences may not fully capture the breadth of experiences pertinent to the research objectives. Similarly, GT's emphasis on theory development was not deemed appropriate, given that theory development was not a primary aim of the study. Furthermore, attempting to detach IPA or GT from their methodological foundations could compromise the analytical integrity of the study (Braun & Clarke, 2020a). Moreover, the qualitative study operates within a pragmatic paradigm, emphasising practical solutions for real-world social issues to foster change or improvement (Kaushik & Walsh, 2019). Pragmatism encourages investigating problems from different perspectives and considering broader contexts (Morgan, 2014), mirroring TA's flexibility to explore diverse themes and perspectives, including those of patients and practitioners. This alignment highlights the suitability of TA for accommodating the pragmatic approach adopted in the study.

Regarding the analytical process, while semi-structured interviews were employed, the focus was on uncovering patterns, connections, and relationships in the data rather than on individual experiences or theory development. TA's approach of developing themes across the dataset resonated with this emphasis, allowing for an inductive approach to identify relevant themes based on the data's salience and relevance (Braun & Clarke, 2020a; Clarke & Braun, 2018). Consistent with this perspective, the qualitative study adopted a '*reflexive*' TA approach based on the methodology outlined by Braun and Clarke (2006), facilitating the evolution of codes and subsequent development of themes during the analysis. This iterative process facilitated the organic emergence of themes, enabling a nuanced understanding of the role of CFs in private care treatment for cLBP which is consistent with the research aim. The data from interviews with patients and practitioners were analysed separately, using an inductive approach. To ensure transparency and maintain an audit trail, qualitative data analysis software (NVivo, version 12) was utilised.

Data management practices were carefully implemented to prioritise the security and confidentiality of participants' information. Interviews were conducted and recorded using online platforms (i.e., Zoom/MS Teams), with a separate recording device serving as a backup. Audio recordings were stored on a secure BU-drive with access restriction and password-protection in place, with only the researcher having authorised access. The secondary device's audio recordings were deleted after transcription. Audio recordings were solely transcribed by the interviewer and pseudonyms were assigned to interviewees to maintain anonymity. Personally identifiable information, such as names, locations, and clinic details, were redacted from the transcripts. This ensured that participants' identities remained protected throughout the analysis process and subsequent reports. Anonymised interview transcripts will be publicly available through BU's Data Repository (BORDaR). Non-anonymised audio files will be kept for three years after the degree is awarded in a password-protected folder on BU's network by the primary BU supervisor for potential data verification or auditing purposes.

Pre-interview task data were collected over encrypted connections, using the University-approved survey platform (JISC). Only the interviewer had password-protected access to the raw data on JISC. To further safeguard participants' privacy, the pre-interview tasks and interviews only gathered the minimum necessary personal characteristics to ensure eligibility criteria were met and for the analysis, to limit the scope of data collected. Participating practitioners received a confidential email (sent from the interviewer's BU email address) which only included the consenting patient's initials, consultation date/time, and gender but excluded their name. This allowed practitioner to complete the pre-interview

task and confirm which consultation they would be reflecting on during the subsequent interview. Raw data stored on JISC will be securely deleted following institutional guidelines once the degree is awarded. These data management practices ensured GDPR compliance and maintained the confidentiality and security of participants' information throughout the research process.

2.6. Stakeholder engagement activities

Given the overarching purpose of the research involves providing recommendations for integrating CFs into clinical practice, a range of stakeholder engagement activities were undertaken during the planning, designing, and managing of the three sequential studies. These activities were documented in the researcher's field notes and included informal clinical observations, informal discussions with MSK practitioners, and Public and Patient Involvement (PPI) through targeted consultations.

2.6.1. Informal clinical observations

Since pragmatism focuses on addressing a specific problem within a social context, it was important to better understand the clinical context for which the research is intended. During the initial stages of the project, informal clinical observations were conducted at two MSK clinics to observe initial consultations with patients, following their express consent. The observations took place at a small private Chiropractic clinic in Bournemouth and a larger outpatient clinic serving private and public (NHS) patients in Basingstoke which involved two Chiropractors and one Physiotherapist. These observations aimed to better understand the clinical context in which the research would be applied, particularly as the researcher was an international student with limited exposure to the UK healthcare system.

2.6.2. Informal discussions

Throughout the research, informal discussions were held with MSK practitioners, both face-to-face, online, and via email. These discussions aimed to engage practitioners and gain valuable insights for the research project. They sought to understand the specific challenges practitioners encountered during MSK treatment and the broader context in which they worked. The aim was to foster collaborative relationships with practitioners and align the research with real-world contexts for potential application.

The MSK practitioners' input and feedback was helpful in refining various aspects of the research project. For instance, practitioners' suggestions assisted with improving the provisional design of the first round Delphi survey. During the qualitative study, these interactions focused on identifying barriers to patient involvement and recruitment, which facilitated a proactive approach to addressing potential issues.

2.6.3. Public and Patient Involvement (PPI)

INVOLVE, a government funded advisory group supporting public involvement in public health and social care research in England, defines PPI as research conducted with or by members of the public (INVOLVE, 2017). Active involvement includes consulting or collaborating with the public as well as research being led by the public. Members of the public are broadly defined to include patients, potential patients, carers, and individuals who represent the interests of those who use social and healthcare services (INVOLVE, 2017). Although there is a distinction between the perspectives of the public and those who play a professional role in health and social care services.

Hughes and Duffy (2018) provide a useful expansion of this definition using a concept analysis. Five operational definitions have been identified to clarify the nature and meaning of public involvement – specifically, undefined involvement; targeted consultation; embedded consultation; co-production and user-led research. During the planning of the qualitative interviews, targeted consultations were undertaken through Bournemouth University's *Public Involvement in Education and Research* (PIER) partners.

Targeted consultation involves approaching members of the public with relevant lived experience, to provide feedback on particular aspects of the research, but is limited to specific requests or tasks such as commenting on a research proposal or providing feedback on an information sheet (Hughes & Duffy, 2018). The reasons for using targeted consultation at this stage was because the research required adaptation owing to the impact of Covid-19. The intention was that the research would be conducted online whereas this was previously intended to occur face-to-face. Accordingly, it was important to understand patients' perspectives on how to engage prospective participants in the study and to reflect on the recruitment process as this would primarily be facilitated by healthcare practitioners instead of the researcher. Additionally, it was useful for patients to assess and comment on the appropriateness of the pre-interview task and the interview topic guide.

Three adult (≥ 18 years) PIER partners with chronic, or recurring episodes of LBP who had previously consulted with a Physiotherapist or Chiropractor for their condition were invited to engage in a 20 to 30-minute online discussion to provide input on the design and management of the qualitative study. All three PIER partners were willing to engage with the researcher online without a PIER member joining the discussion, but each one was given the option beforehand. In recognition for their involvement PIER partners were paid at the rate of £10.00 per hour in accordance with University policies. The targeted consultations with PIER partners provided important insights into patient perspectives on the study design.

The PIER partners' feedback supported the decision to use an online informed consent approach instead of traditional documents (e.g., MSWord). This was considered more accessible and user-friendly for participants who may not have software licenses or experienced difficulties accessing certain document formats. Understanding patients' perspectives on the recruitment process was also helpful, as healthcare practitioners were intended to facilitate recruitment. Their feedback validated the appropriateness of involving practitioners to invite patient participants. The PIER partners' perspectives on patient incentives were also useful. While one PIER partner thought incentives were necessary for patient recruitment, all three believed patients would be willingly to volunteer if they felt that the study would be beneficial to improving patient care. Overall, they were satisfied with the planned recruitment approach.

The PIER partners' feedback on the pre-interview task provided insights into its feasibility and acceptability from a patient's perspective. The task was perceived as worthwhile but one partner suggesting a slight change in wording. They recommended using 'up to 5' instead of 'between 3 to 5' moments to create less pressure for participants. This would allow participants to simply share a single moment to accommodate varying experiences and preferences. The partners expressed general satisfaction with the draft interview guide and confirmed it was clear and appropriate. Minor suggestions were made, such as using the term "thoughts" instead of "beliefs" and asking whether the patient would have preferred any aspect of their consultation to be different.

In addition, these stakeholder engagement activities also informed the research in the following ways.

Identifying potential implementation barriers: The informal discussions with MSK practitioners and the clinical observations aimed to identify potential barriers for implementing CFs. The observed variability of CF use among practitioners raised questions

about the acceptability and feasibility of integrating them into clinical practice. The practitioners' views regarding the use of CFs for cLBP were unclear based on the observed clinical interactions alone. This influenced the research question addressed in the Delphi study, which also considered factors such as a lack of confidence or training in implementing CF care approaches.

Ensuring participant-friendly language: Feedback from PIER partners and MSK practitioners influenced the language used in study materials and participant communication for both the Delphi and qualitative study. The goal was to incorporate their suggestions and use appropriate language that resonated with them, to ensure that the materials were clear, understandable, and accessible.

Enhancing participant engagement: Informal discussions with MSK practitioners and the involvement of PIER partners aimed to gain insights into strategies for boosting participant engagement. Understanding patient motivations for participation and their incentive preferences sought to improve recruitment and retention rates. Additionally, considering the clinical pressures on MSK practitioners influenced the length of Delphi surveys and subsequent interviews, aiming to minimise participant burden and accommodate practitioners' time constraints. The aim was to create feasible research activities to improve response rates and data quality.

Adapting to Covid-19 restrictions: The decision to transition from face-to-face to online data collection during the qualitative study was informed by both PPI and informal discussions with MSK practitioners. Understanding patients' preferences and concerns regarding the online consent process and engagement in virtual interviews facilitated this transition while adhering to Covid-19 safety measures. Moreover, MSK practitioners shared practical considerations regarding the regulations and restrictions impacting face-to-face care, further supporting the need for an online approach.

Understanding patients' and practitioners' experiences of CFs: The primary aim of the qualitative research was to gain a deeper understanding of patients' and MSK practitioners' experiences of CFs in the context of cLBP management. During the clinical observations, it was evident that directly assessing their experiences would be challenging. To address this, the subsequent qualitative interviews with patient-practitioner dyads were designed. These interviews aimed to delve deeper into their perceptions and experiences with CFs, allowing for a more comprehensive understanding.

Developing patient-practitioner relationships: Observing initial consultations allowed the researcher to witness the development of the therapeutic relationship between patients and practitioners. Understanding how practitioners established trust and communicated with their patients was beneficial for understanding how CFs may influence the treatment process.

Improving generalisability/transferability: By conducting observations in different clinics with different types of practitioners, with varying levels of clinical experience may improve the generalisability/transferability of the findings. This diversity provides a broader view of how CFs may be impactful during cLBP management in different healthcare settings.

Overall, the use of stakeholder engagement activities may have improved the study design by incorporating patient perspectives, addressing practical considerations, and validating the research approach. By actively involving relevant stakeholders, the aim was to ensure that the study was relevant, meaningful, and impactful for the healthcare community.

Chapter 3. Systematic literature review

3.1. Chapter overview

This chapter presents a published manuscript, which is the first study in the multiphase research design. The focus of this systematic literature review was examining the impact of interventions involving CFs on patients' pain and physical functioning outcomes following conservative LBP treatment. The manuscript begins with a succinct introduction and rationale for the systematic review, followed by a detailed description of the materials, methods, eligibility criteria, search procedure, study selection, quality appraisal, data extraction, and synthesis. The search results and flow chart are presented to illustrate the study selection process, followed by the quality assessment results and characteristics of the included studies to demonstrate the credibility of the evidence. The main results encompass the overall influence of CFs, within-group and between-group differences in outcomes, and the impact of CFs across the five main domains. These findings are summarised and discussed in relation to the existing literature while acknowledging and considering the study's strengths and limitations. Lastly, the chapter concludes by briefly discussing the choice of quality appraisal tool, and then explicating the link between the systematic literature review and the Delphi study by highlighting how insights from the review influenced the development of the subsequent study.

3.2. Published manuscript

The undernoted section presents the manuscript published in Chiropractic and Manual Therapies as part of the journal's thematic series titled: *A new paradigm for musculoskeletal pain care: moving beyond structural impairments* as part of the integrated thesis format submission.

See: Sherriff, B., Clark, C., Killingback, C., and Newell, D., 2022. Impact of contextual factors on patient outcomes following conservative low back pain treatment: systematic review. *Chiropractic & Manual Therapies, 30*(1), 1-29.

The following Springer Nature link provides full-text access to the PDF: https://rdcu.be/cLRyH

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Chiropractic & Manual Therapies

SYSTEMATIC REVIEW Open Access

Impact of contextual factors on patient outcomes following conservative low back pain treatment: systematic review

Bronwyn Sherriff[1,2*], Carol Clark[1†], Clare Killingback[3†] and Dave Newell[2†]

Abstract

Background and objective: Chronic low back pain is pervasive, societally impactful, and current treatments only provide moderate relief. Exploring whether therapeutic elements, either unrecognised or perceived as implicit within clinical encounters, are acknowledged and deliberately targeted may improve treatment efficacy. Contextual factors (specifically, patient's and practitioner's beliefs/characteristics; patient-practitioner relationships; the therapeutic setting/environment; and treatment characteristics) could be important, but there is limited evidence regarding their influence. This research aims to review the impact of interventions modifying contextual factors during conservative care on patient's pain and physical functioning.

Databases and data treatment: Four electronic databases (Medline, CINAHL, PsycINFO and AMED) were searched from 2009 until 15th February 2022, using tailored search strategies, and resulted in 3476 unique citations. After initial screening, 170 full-text records were potentially eligible and assessed against the inclusion–exclusion criteria. Thereafter, studies were assessed for methodological quality using a modified Downs and Black scale, data extracted, and synthesised using a narrative approach.

Results: Twenty-one primary studies ($N = 3075$ participants), were included in this review. Eight studies reported significant improvements in pain intensity, and seven in physical functioning, in favour of the contextual factor intervention(s). Notable contextual factors included: addressing maladaptive illness beliefs; verbal suggestions to influence symptom change expectations; visual or physical cues to suggest pain-relieving treatment properties; and positive communication such as empathy to enhance the therapeutic alliance.

Conclusion: This review identified influential contextual factors which may augment conservative chronic low back pain care. The heterogeneity of interventions suggests modifying more than one contextual factor may be more impactful on patients' clinical outcomes, although these findings require judicious interpretation.

Keywords: Contextual factors, Placebo effect, Chronic low back pain, Illness beliefs, Communication, Verbal suggestion, Physician–patient relations, Empathy, Therapeutic alliance

Introduction

Musculoskeletal (MSK) conditions are the second largest contributor to disability [1], with low back pain (LBP) being the single leading cause [2]. LBP is typified by pain and reduced physical functioning, often affecting mental health, and increasing risks for co-morbidities and all-cause mortality [3]. Chronic LBP (cLBP) frequently occurs in the absence of a known pathoanatomical cause

*Correspondence: bsherriff@bournemouth.ac.uk; beesherriff@gmail.com
†Carol Clark, Clare Killingback and Dave Newell have contributed equally
[1] Department of Rehabilitation and Sport Sciences, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, England
Full list of author information is available at the end of the article

(non-specific) and persists for 12 or more weeks [4]. Identified risk factors include lifting activities, smoking, obesity, and depressive symptoms, but these only increase the odds of developing cLBP by a modest amount [4]. Indirect LBP costs (e.g., carer-burden, decreased workforce participation) may exceed the direct costs [4] representing a threat to lifetime productivity and well-being [5].

Clinical guidelines recommend conservative treatments, specifically biopsychosocial approaches initially focusing on non-pharmacological treatment, [5], including exercise, massage, cognitive behavioural, and manual therapies [6] alongside comorbidity management, such a low mood, depression, or anxiety [4]. Systematic reviews support the use of non-steroidal anti-inflammatory drugs (NSAID) [7] and opioids [8] for cLBP, however, both have inherent long-term usage risks (e.g., opioid dependence; NSAID induced renal impairment). Moreover, when comparing the effectiveness of NSAIDS to placebos in studies with low risk of bias, the effect sizes were small [7]. Overemphasising biomedical or pharmacological care can result in poor health outcomes or iatrogenic consequences [3], with limited increased efficacy over conservative approaches [9]. Using ineffective, wasteful (e.g., overuse of imaging) or potentially deleterious practices exacerbates unsustainable healthcare expenditure, widening social and health inequalities [3, 10].

Beyond spontaneous or natural recovery, recent evidence suggests a considerable fraction of analgesic responses in treatments for MSK pain may be attributable to contextual factors (CFs) [11]. CFs are multidimensional (physical, social, and psychological) aspects of the clinical encounter capable of producing or inducing positive (placebo) or negative (nocebo) biological effects [12, 13]. Placebo mediated analgesia is a reduction in pain arising from features of the treatment context [12, 13] and involves defined endogenous neural pathways (e.g., dorsolateral prefrontal cortex, anterior cingulate cortex, periaqueductal grey and the dorsal horn of the spine), along with associated neurotransmitters (e.g., endogenous opioid, the endocannabinoid, and the dopaminergic systems), intrinsically linked to regions underlying conscious judgement of meaning [14–16]. Accordingly, pain modulation can potentially be induced by explicitly manipulating CFs [11, 12, 17] which Di Blasi and colleagues [18] characterised into five useful domains:

1) Patient's beliefs and characteristics (*e.g., LBP history, gender, illness and treatment beliefs, expectations, or prior experiences*);
2) Practitioner's beliefs and characteristics (*e.g., professional reputation, attire, empathy, professional training and prior experiences, and beliefs,*);
3) Patient-practitioner relationship (*e.g., therapeutic alliance, trust, verbal or non-verbal communication, reassurance*);
4) Therapeutic setting/environment (*e.g., setting, layout, décor, interior design*); and
5) Treatment characteristics (*e.g., continuity of care, labelling, visual cues, sham/dummy treatment, variations in touch or stimulus conditions*).

Although symptom improvement is a common treatment objective, other factors, such as the practitioner's communication style (e.g., demonstrating genuine empathy), time-constraints (e.g., willingness and/or ability to listen), beliefs or treatment expectations, prior training, environmental conditions (e.g., interior design, environment, setting etc.) are likely to influence patients' outcomes. Furthermore, there is a growing body of literature supporting explicit induction of placebo analgesia, as a clinically beneficial approach [11, 12, 16, 19], with outcomes similar in magnitude to treatment effects [20]. However, it remains unclear which elements of the therapeutic encounter are impactful on patient's clinical outcomes.

Accordingly, a promising adjunct to care may involve overtly manipulating CFs to enhance treatment efficacy [12, 21] but there is limited evidence examining the influence of explicit manipulation of CFs on cLBP [11]. This systematic review therefore aims to examine interventions which potentially modify known CFs during conservative cLBP care (specifically, non-pharmacological, non-surgical, and non-invasive approaches) to investigate their impact on patients' pain intensity and physical functioning outcomes. Delineating the influence and role of CFs in usual care rehabilitation settings may assist in identifying which of these CFs demonstrates potential clinical utility and ethical approaches to rehabilitation.

Materials and methods

The updated Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA; [22]) checklist was adhered to and the protocol was registered on PROSPERO (CRD42019145157).

Eligibility criteria

Table 1 presents a summary of the eligibility criteria. Only studies available in full-text were included to ensure adequate appraisal and review. The following limits were applied: human studies published in English between 2009 and 2022. The justification for this period was two-fold. The primary rationale was to ensure uniformity in conservative care approaches across potentially eligible studies. The National Institute for Health and Care Excellence (NICE) guidelines for non-invasive treatments for LBP [23] guided this decision. The secondary justification

Table 1 Summary of inclusion–exclusion criteria

	Inclusion	Exclusion
Population/Illness	Adult (≥ 18 years) with chronic low back pain (≥ 12 weeks)	Non-human subjects; human objects (e.g., tissues, fMRI, MRI, CT etc.), children and adolescents (< 18 years old); fictitious/actor patients, patients with acute, sub-acute or mixed samples of low back pain
Treatment Setting	Universally accepted/clinically recognised forms of conservative care (i.e., non-pharmacological and non-invasive) occurring in a clinical setting (in-patient or out-patient), primary or secondary healthcare (private or public) or where it was expressly articulated that the site involves regular delivery of therapeutic care (e.g., University clinic, community care centre)	Excluded if treatment related to palliative care, emergency medicine or experimental laboratory environments
Intervention	Conservative care approaches/strategies which potentially alter clinical outcomes through the explicit modulation or measurement of at least one of the five contextual factors relating to the health encounter	Excluding pharmacological or surgical interventions; acupuncture, injections, or invasive procedures; neurological experiments or imaging; interventions targeting adherence to analgesic medication, diet modification/nutritional supplements; interventions involving alternative medicine; online, app-based or telehealth interventions
Comparators	No treatment or intervention (e.g., waiting-list control or natural history group), no control group (i.e., uncontrolled study), standard/usual care, or neutral, negative, or an experimentally dosed and/or opposite or contextually comparative condition	Two-armed trial or two-group design whereby the description indicates a standard placebo-controlled trial (where the comparison group involved a "sham" condition perceived to be an "inert" placebo)
Outcomes	Validated pain or physical functioning/disability measures (e.g., used during routine clinical care)	Non-validated pain or physical functioning/disability measures or sub-scales
Study Design	Randomised Controlled Trials (RCTs); quasi-experimental designs, or prospective longitudinal studies	Retrospective/secondary analyses, qualitative studies, cross-sectional designs, n-of-1 trial; conference abstracts, dissertations, and trial protocols

is conceptual: there is a lack of definitional consensus, coupled with an array of interchangeable concepts, which are evolving in tandem with emergent knowledge, but no unified theory [24]; consequently, historical interpretations and associated research may not be wholly aligned with the CF framework.

To further clarify, an eligible intervention involved strategies designed to change or potentially modify one or more known contextual factor(s) of the health encounter/clinical consultation or experimental condition. This was guided by the review teams' understanding of the theoretical mechanisms important to generating placebo analgesia such as classical conditioning, expectancy theory, social or experiential learning, predictive coding, and the Bayesian brain (see [25]). For instance, strategies involving manipulating patients' or practitioners' expectations, beliefs, perceptions, learned associations, mindsets, aspects of their interpersonal communication, appearance/clothing, aspects of the patient-practitioner relationship, the environment (e.g., setting, décor, place, waiting time), varying packaging, patient information leaflets (e.g., drug effects, side effects, adverse events), sham devices or procedures, labels, differential pricing, warning labelling, and so forth to influence patient outcomes either before, during, after or throughout the treatment duration. Studies of both positive and negative interventions, namely, those specifically designed to induce placebo effects or nocebo effects were eligible. It is possible that there are psychological interventions that may not (currently) be known to induce placebo analgesia, such as general patient education. Such interventions were eligible if it was clear that it intended to alter the patient's expectations (e.g., influence pain perception) as this is consistent with theories of placebo mediated analgesia which assume a prediction is made (whether conscious or not) about a future health state. Such anticipatory processes are effectively based on the interpretation of both internal and external factors (which are purported to be psychological meaningful) and capable of triggering an associated neurobiological response [14].

Accordingly, eligible interventions could be simple or complex; and involve an extensive array of CFs, placebo effects, or situational elements intended to influence the design of the health encounter or the treatment of cLBP. Multimodal interventions modifying one or more CF(s) combined with usual care were included if the control group involved a well-controlled comparison condition as defined by Howick and colleagues [26]. In an experimental condition, it could involve covert (hidden design), or overt (open design) tactics expected to induce a placebo effect, or prevent a nocebo effect, such as parallel group design (e.g., three-arm trial), response conditioning design, open versus hidden design, or pharmacological conditioning designs (see [14]). Uncontrolled studies reporting on clinical outcomes which involved modification of a CF(s) (e.g., the new component was introduced as part of routine care) as well as prospective longitudinal studies where a CF(s) was pre-existing (e.g., association between outcomes after increasing consultation times or the pre-existing relationship between the patient and their healthcare provider) were also eligible. There was no limit on the length of the intervention, such as the number of sessions or time/period, provided the intervention occurred in a setting or site involving the regular delivery of therapeutic care for cLBP. Individual or group-based interventions were potentially eligible. Online, or app-based interventions were excluded because these may not be aligned with the conceptual framework of CFs since there are negligible patient-practitioner interactions and it is not a traditional clinical setting.

Search procedure

Information sources

Studies were identified using the following databases: Medline (via ProQuest); Cumulative Index to Nursing and Allied Health Literature (CINAHL via EBSCOhost); PsycINFO (via ProQuest); and Allied and Complementary Medicine (AMED via Ovid) from 2009 until the search date (15th February 2022). Additionally, named author searches (via Google scholar) and manual searches of reference lists of provisionally eligible primary studies, and the Journal of Interdisciplinary Placebo Studies (JIPS) database were conducted to identify studies potentially undetected through electronic searching.

Search

Search strategies (see Additional file 1: Search Strategy Methods S1–S4) were tailored per database using suitable Boolean operators, phrase searching, and Medical Subject Headings (exploded where appropriate) using key concepts and their alternatives (see Table 2). Key concepts included: (1) chronic low back pain; (2) placebo effects/contextual factors; (3) healthcare professionals and patient relationships/interactions; as well as (4) healthcare professionals and patient expectations/beliefs. Searches were limited to title and abstract to ensure standardisation across databases, and then screened for eligibility once duplicates were removed.

Study selection

Screening

Initially citations were screened by title and abstract based on the eligibility criteria. A conservative approach was employed—in cases of uncertainty, the record was retained for full-text screening. Thereafter, full-text papers were assessed using a standardised, pre-piloted screening

Table 2 Examples of search terms for key concepts

Key concepts	Search terms
Chronic low back pain	"back pain", "low back pain", LBP, "chronic low back pain", cLBP, "non?specific low back pain", "non?specific back pain", "lumbar pain"
Placebo effects/Contextual Factors	(placebo ADJ (effect* OR response* OR analgesi*)), (nocebo ADJ (effect* OR response*), (context* ADJ (factor* OR effect* OR response*)), (common ADJ (factor* OR effect*)), (non?specific ADJ (effect* OR factor*))
Healthcare professionals and patient relationships/interactions	alliance*, (patient ADJ (relation* OR interact*)), (empath* OR warm* OR compassion* OR kind* OR friendl*), rapport, "non?verbal communication*", "verbal communication*", "health communication*", "initial consultation", "professional-patient relation*" "physician-patient relation*"
Healthcare professionals and patient expectations/beliefs	(patient* ADJ (expect* OR belief* OR attitude*)), (practitioner* ADJ (expect* OR belief* OR attitude*)), (positive ADJ (expect* OR suggest*)), (negative ADJ (expect* OR suggest*)), illness ADJ (perception* OR belief*)

proforma, along with documenting reasons for exclusion and identifying studies reporting on the same dataset. Both screening and selection stages were carried out by the primary reviewer (BS). In addition, the entire review team also cross-checked a proportion ($n=50$; 29.4%) of potentially eligible full-text articles. Any discrepancies in opinion were resolved through discussion and a final adjudication was made using a consensus-based approach.

Quality appraisal

Eligible studies were assessed for methodological quality using a modified Downs and Black scale consisting of 27 items [27]. This tool was selected as it is appropriate for assessing both randomised and non-randomised studies, the reliability is reportedly high (internal consistency – Kuder–Richardson-20: 0.89; test–retest reliability: $r=0.88$), [27] and has previously been used in other systematic reviews [28–30]. This tool has five sub-sections, namely, quality of reporting (ten items); external validity (three items); bias (seven items); selection bias/confounding (six items); and statistical power (one item). The scoring of statistical power (item 27) was amended from five points to one (following [29, 31]), altering the total score to 28. Following O'Connor and colleagues [31], each study was graded "Excellent" (24–28 points), "Good" (19–23 points), "Fair" (14–18 points) or "Poor" (< 14 points). Owing to the inherent design of observational and single-group experiments, inapplicable questions were removed (e.g., random assignment, group allocation and concealment) and scoring adjusted accordingly.

Data extraction

The primary reviewer (BS) extracted data using a proforma, adapted from the Template of Intervention Description and Replication (TIDieR) [32] and the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) [33] data collection checklist. The following data were extracted: -

i) *Study identification features*: author(s), year of publication, title, country of origin, setting, theoretical model/basis, and aim(s).
ii) *Study features*: study design, inclusion and exclusion criteria, recruitment method, data collection method, length of follow-up, (specifically timing of measures), method of random assignment, main statistical analysis.
iii) *Sample characteristics*: intervention group (n), comparison group(s) (n), total sample size (n), description of the population (specifically gender proportions, mean/median age, mean/median duration of cLBP), mean/median baseline pain intensity and/or physical functioning scores and standard deviations.
iv) *Intervention description*: type of contextual factor(s), intervention components, delivery format, treatment frequency, treatment duration, number of session(s), length of treatment session(s), administering practitioner(s), type of comparison/control group(s), description of comparison/control conditions.
v) *Main Results*: measure(s) of pain intensity and/or physical functioning outcomes, post-treatment, and follow-up (if applicable) mean pain intensity and/or physical functioning scores, standard deviations, p-values, effect sizes, and main findings relevant to the review aim(s).

Data synthesis

A narrative synthesis was applied to the extracted data guided by the Economic and Social Research Council (ESRC) Methods Programme framework (see [34]). The synthesis process was iterative and nonsequential, rather than linear, thereby facilitating general inferences to be delineated regarding CFs and their impact on cLBP patients' pain intensity and physical functioning outcomes. Both within and between group data were tabulated to identify influential CFs in relation to these two main outcomes. Not all of the included studies investigated both within and between groups differences. The absence of such data is not a result of reporting bias but

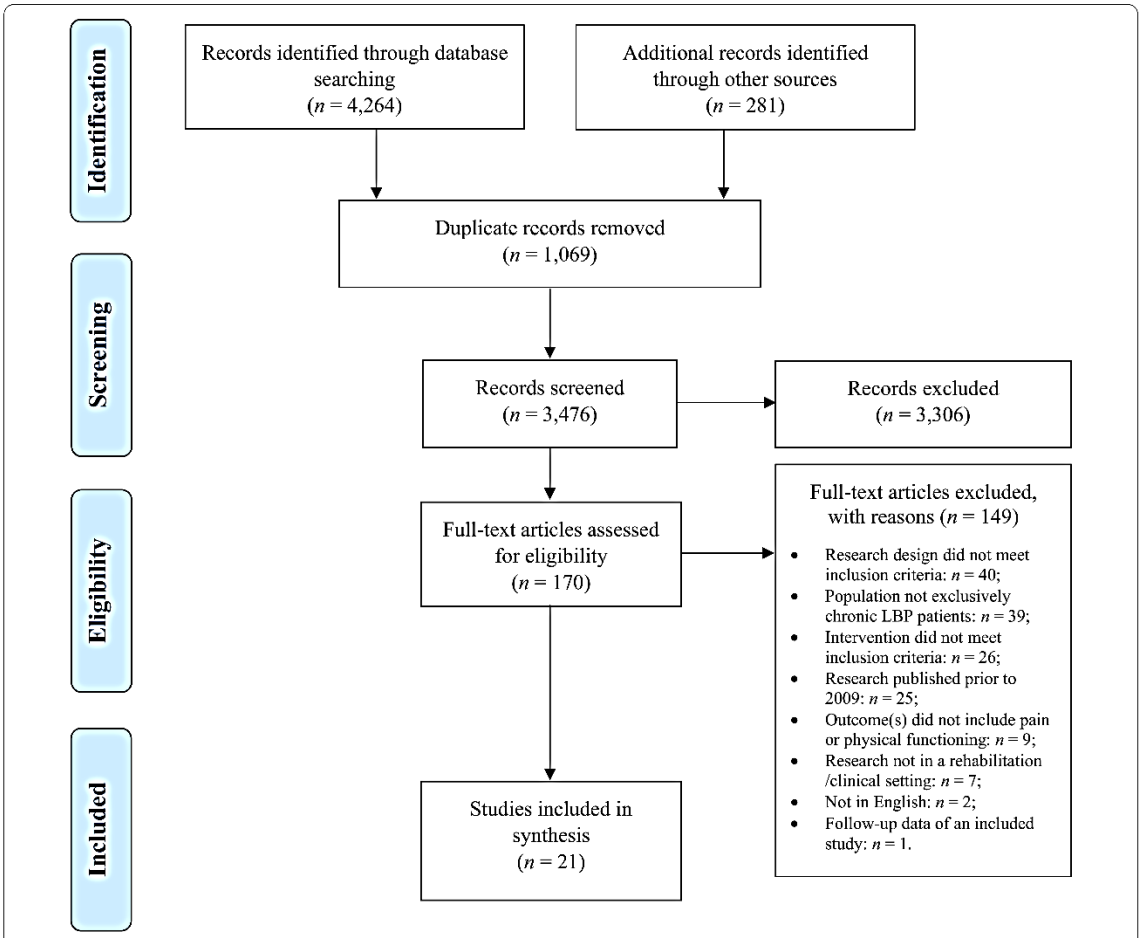

Fig. 1 Modified PRISMA flow chart diagram. This figure shows the citations through the selection process. 4545 records were identified, and after removing 1069 duplicates, the remaining 3476 titles and abstracts were screened. Out of these, 170 full-text articles were assessed for eligibility, and 21 were included in the final selection and data synthesis

rather the heterogeneity of research designs and corresponding study aims included in this review.

Results

Search results

The electronic and manual searches resulted in 3476 unique citations, of which, 21 met the eligibility criteria. Using a modified PRISMA flow chart, Fig. 1 illustrates how these studies were selected.

Quality assessment

The overall risk of bias across studies was relatively low; 13 were graded as 'Excellent' [35–41, 47, 50, 52–55], seven as 'Good', [42–46, 48, 51] and only one as 'Fair' [49]. 'Good' ratings were generally on the higher end of the scoring spectrum but the common distinction from an 'Excellent' grading related to the external validity sub-scale (items 11 and 13), and/or statistical power (item 27) where 11 (52.4%), nine (42.9%), and 11 studies (52.4%) were scored negatively respectively (see Table 3 summary).

Of 11 studies with a zero rating for statistical power (item 27), five were underpowered [36, 40, 42, 46, 48], whilst it was unclear/undetermined for the remaining six [35, 41, 50–53]. By implication, the between-group results may be understated, since four of 15 comparative studies (3 RCTs and 1 CCT) [35, 41, 42, 48] reporting non-significant differences between groups were

Table 3 Quality assessment summary clustered by research design

Reference (year)	Quality of reporting (*10 items*) Range: 0–11 points	External validity (*3 items*) Range: 0–3 points	Internal validity (*7 items*) Range: 0–7 points	Selection bias/ confounding (*6 items*) Range: 0–6 points	Statistical power (*1 modified item*) Range: 0–1 points	Total score (27 items) Range: 0–28 points	Overall grading Excellent (24–28) Good (19–23) Fair (14–18) Poor (< 14)
Randomised controlled trials (RCTs)							
[35] (2011)	11	2	7	6	0	26 (92.9%)	Excellent
[36] (2013)	10	3	7	5	0	25 (89.3%)	Excellent
[37] (2014)	11	0	7	6	1	25 (89.3%)	Excellent
[38] (2022)	11	2	6	5	1	25 (89.3%)	Excellent
[39] (2019)	11	1	6	6	1	25 (89.3%)	Excellent
[40] (2016)	10	2	6	6	0	24 (85.7%)	Excellent
[41] (2017)	10	3	7	4	0	24 (85.7%)	Excellent
[42] (2010)	10	1	6	6	0	23 (82.1%)	Good
[43] (2020)	10	2	5	5	1	23 (82.1%)	Good
[44] (2021)	10	2	4	6	1	23 (82.1%)	Good
[45] (2017)	10	0	6	5	1	22 (78.6%)	Good
[46] (2019)	9	2	6	3	0	20 (71.4%)	Good
Reference (year)	**Quality of reporting (*10 items*) Range: 0–11 points**	**External validity (*3 items*) Range: 0–3 points**	**Internal validity (*7 items*) Range: 0–7 points**	**Selection bias/ confounding (*4 items*) Range: 0–4 points**	**Statistical power (*1 modified item*) Range: 0–1 points**	**Total score (*25 items*) Range: 0–26 points**	**Overall grading Excellent (22–26) Good (18–21) Fair (13–17) Poor (< 13)**
Controlled clinical trials (CCT; non-randomised)[a]							
[47] (2017)	10	2	6	4	1	23 (88.5%)	Excellent
[48] (2012)	10	1	5	3	0	19 (73.1%)	Good
[49] (2018)	7	1	5	3	1	17 (65.4%)	Fair
Reference (year)	**Quality of reporting (*10 items*) Range: 0–11 points**	**External validity (*3 items*) Range: 0–3 points**	**Internal validity (*5 items*) Range: 0–5 points**	**Selection bias/ confounding (*2 items*) Range: 0–2 points**	**Statistical power (*1 modified item*) Range: 0–1 points**	**Total score (*21 items*) Range: 0–22 points**	**Overall grading Excellent (19–22) Good (16–18) Fair (11–15) Poor (< 11)**
Quasi-experimental (uncontrolled)[b]							
[50] (2015)	9	3	5	2	0	19 (86.4%)	Excellent
[51] (2017)	10	1	5	2	0	18 (81.8%)	Good
Reference (year)	**Quality of reporting (*9 items*) Range: 0–10 points**	**External validity (*3 items*) Range: 0–3 points**	**Internal validity (*5 items*) Range: 0–5 points**	**Selection bias/ confounding (*3 items*) Range: 0–3 points**	**Statistical power (*1 modified item*) Range: 0–1 points**	**Total score (*21 items*) Range: 0–22 points**	**Overall grading Excellent (19–22) Good (16–18) Fair (11–15) Poor (< 11)**
Observational Cohort (uncontrolled)[c]							
[52] (2013)	10	3	5	3	0	21 (95.5%)	Excellent
[53] (2013)	10	2	5	3	0	20 (90.9%)	Excellent
[54] (2011)	10	2	4	2	1	19 (86.4%)	Excellent
[55] (2019)	8	2	5	3	1	19 (86.4%)	Excellent

Table 3 (continued)

The following inapplicable items were not included in the quality assessment for this study design:

[a] Selection bias sub-scale: -Q23. Were study subjects randomised to intervention groups?; Q24. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

[b] Internal validity sub-scale:—Q14. Was an attempt made to blind study subjects to the intervention they have received?; Q15. Was an attempt made to blind those measuring the main outcomes of the intervention? Selection bias sub-scale:—Q22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?; Q23. Were study subjects randomised to intervention groups?; Q24: Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?; Q25. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?

[c] Reporting sub-scale: -Q8. Have all important adverse events that may be a consequence of the intervention been reported?; Internal validity sub-scale:—Q14. Was an attempt made to blind study subjects to the intervention they have received?; Q15. Was an attempt made to blind those measuring the main outcomes of the intervention?; Selection bias sub-scale:—Q22. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case–control studies) recruited over the same period of time?; Q23. Were study subjects randomised to intervention groups?; Q24: Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?

potentially underpowered. If corresponding confidence intervals were consistently reported, it would facilitate a clearer adjudication of these results.

Global estimates for LBP were extrapolated to create a rudimentary set of criteria to assess external validity (item 11) and uniformly applied to each study's sample. LBP is typically more common in females, but these differences appear to diminish once chronicity is accounted for [56] whilst age-related LBP prevalence is generally negatively skewed and reported to be highest between 40 to 69 years [4] whilst global LBP prevalence reportedly peaks around 80 years old [57]. Accordingly, nine studies [36, 38, 41, 44, 46, 47, 50, 52, 54] scored '1' for satisfying both conditions: (i) the proportion of females is higher but less than 60% overall; and (ii) the mean/median age falls within the range of 40.00 to 63.5 years (but 10 and 17 studies satisfied one condition respectively – see Additional file 1: Item 11 scoring grid Results S1). Since comorbid and/or confounding conditions (e.g., age restrictions, pregnancy, neurological, rheumatological, cancer, fractures, recent surgery) were generally excluded, these samples are fairly homogenous since their inclusion–exclusion criteria were comparable, but older patients were typically excluded.

Similarly, item 13, pertains to the representativeness of the staff, facilities, intervention and setting the majority of patients would typically have access to or receive. Studies scoring '1' should demonstrate that the intervention was representative of that in use in the source population. Given the geographic variability between studies, what is considered typical treatment for cLBP differs across settings and regions. Although not universally applicable, the NICE guideline [23] for non-invasive LBP treatments guided the assessment. Studies receiving a zero rating involved the following: three employed experimental techniques (namely classical conditioning, and sham versus *verum* interferential current therapy (IFC)) [37, 45, 46]; two offered a single educational pain biology session (not specifically encouraging self-management behaviours) [42, 51]; and four used cognitive behavioural approaches but were not combined with exercise and/or manual therapies [38, 44, 48, 54].

Study characteristics

Twenty-one studies ($N=3075$ participants) with a wide range of research designs were included in the review; specifically, 12 randomised clinical trials (RCTs; $n=1064$ [35–40, 42–46]; $n=255$ cluster-randomised [41]), three non-randomised, controlled clinical trials (CCTs; $n=460$) [47–49], four observational cohort studies ($n=1220$) [52–55], one case series ($n=50$) [51], and one interrupted time series ($n=26$) [50]. RCT sample sizes ranged from 38 (pilot [42]) to 222 (3-armed trial [44]) patients. Across the remaining studies, sample sizes ranged from 26 (interrupted time series [50]) to 688 participants (prospective cohort; [52]). All samples consisted of adult patients with cLBP; mean ages ranged from 30 to 66.8 years, whilst the mean duration of LBP varied considerably (ranging from 3–12 months up to 18.5 years). There were higher ratios of female patients in all studies except one [49], whilst the cumulative gender proportions were skewed towards females (59.1% female; $n=1761$; 40.9% male; $n=1219$; (95 missing cases)). The studies were predominantly clustered in the Northern hemisphere but geographically diverse, originating from twelve countries. Fourteen settings involved single-centre treatment/rehabilitation clinics, whilst seven involved multiple-centres. Only one study explicitly indicated that the intervention took place in a private healthcare setting [36], and another involved a combination of both in-patient and out-patient orthopaedic rehabilitation centres [52].

A variety of outcome measures were reported; pain intensity was most commonly measured using a Numeric Rating Scale ((NRS);16 studies) whilst four studies utilised a Visual Analogue Scale (VAS), and one did not include pain severity as an outcome [54]. Eight studies employed the Roland-Morris Disability Questionnaire (RMDQ), eight the Oswestry Disability Index (ODI), and one did not measure physical functioning [37]. The remaining studies utilised the following measures:

Patient Specific Functional Scale (PSFS) [39, 44, 54], the Hannover Activities of Daily Living Questionnaire (ADL) accompanied by the specified activities [45, 46], a lumbar flexion test operationalised as the change in distance between the fingertips to the floor [51], and a Timed-Up-and-Go (TUG, measured in seconds) [43]. Three studies used more than one measure of physical functioning, namely, the ODI and PSFS [39, 44] and the RMDQ and TUG [43]. Refer to Additional file 1: Table S1 for a summary of the key characteristics of the included studies.

Overall influence of contextual factors

Across the 21 studies, patient's beliefs were the most commonly manipulated (16 studies) [35, 36, 38–48, 50, 51, 54] or measured CF (1 study) [55] followed by the patient-practitioner relationship (nine studies) [35, 37, 41, 42, 44, 47, 49, 52, 53], and the treatment characteristics (seven studies) [35, 37, 39, 40, 43, 45, 46] whilst only one modified the treatment context [49]. Nine modified (or measured) one CF only [36, 38, 48, 50–55] while 12 modified two or more CFs [35, 37, 39–47, 49]. None of the included studies examined the influence of practitioner beliefs and characteristics. Assessing both between-group differences and within-group differences delineates the overall impact of CFs on patient outcomes.

Within-group differences: pain intensity and physical functioning

Considering only the CF-intervention arm(s) across the 21 included studies, nine demonstrated statistically significant differences in pain intensity within-groups [35, 36, 45, 46, 48–52], whilst one did not measure it [54]. The overall trend was a reduction in pain intensity over time, as another nine studies [37–42, 44, 47] also demonstrated improvements, although relevant test-statistics and/or corresponding *p-values* were not reported. Both quasi-experimental studies reported 54% and 42% of patients achieved a minimal clinically important difference (MCID) in pain intensity after receiving treatment modifying CFs [50, 51]. Two studies reported clinically meaningful improvements [37, 38]. In the RCT using either active or sham inferential current therapy (IFC), the two enhanced therapeutic alliance groups both reported 77.4% and 54.5% improvements in pain intensity respectively [37]. Similarly, in the Pain Reprocessing Therapy (PRT) trial [38], 78% of patients experienced more than a 30% reduction in pain intensity at post-treatment and 70% at 1-year follow-up. In the Portuguese open-label placebo (OLP) trial [40], the CF-manipulation arm experienced a 28% reduction in pain intensity which falls shy of a clinically meaningful improvement (30% reduction). Two observational cohorts reported significant relationships between therapeutic alliance and pain [53] and patient's competence perceptions and pain [55] respectively. However, the Japanese OLP trial reported no statistically significant improvements from baseline, but 45.8% of patients experienced $\geq$ 2-unit change in pain intensity at 12-weeks follow-up [43].

Correspondingly, 20 studies reported within-group differences in respect of physical functioning outcomes; of these, ten demonstrated statistically significant improvements from baseline [35, 36, 43, 45, 46, 48–52] whilst one did not include disability as an outcome [37]. Seven studies reported the mean differences but did not include relevant test-statistics nor *p-values* [38–42, 44, 47], but the general trend was an overall improvement in physical functioning from baseline. For example, both quasi-experimental studies reported 62.5% and 36% of patients achieved a MCID after treatment modifying CFs [50, 51], and a larger improvement was reported in the CF-manipulation arm compared to the control arm in a non-randomised CCT [47]. The Portuguese OLP group experienced a 29% improvement in physical functioning compared to 0% (no change) in the treatment as usual arm [40], whilst the Japanese OLP trial reported significant changes in RMDQ scores but not TUG times from baseline [43]. Additionally, three observational cohorts reported significant relationships between therapeutic alliance and physical functioning [53], patient's rational problem-solving skills and physical functioning [54] as well as patient's competence perceptions and physical functioning [55]. Overall, these within-group improvements suggest that interventions involving CFs are influencing pain intensity and physical functioning outcomes in patients with cLBP over time. Refer to Additional file 1: Table S2 for a summary of within-group changes in outcomes from baseline clustered by research design.

Between-group differences: pain and physical functioning

Fifteen studies involved two or more treatment arms; of these, eight (of 12) RCTs demonstrated statistically significant differences in pain intensity between groups in favour of the CF-manipulation [36–40, 42, 45, 46] as illustrated in Table 4. One three-armed trial only demonstrated significant differences at 12-months follow-up [44] between each arm receiving an educational intervention compared to the group receiving no education, but there were no differences between the two groups receiving the educational intervention (one with an emphasis on developing the therapeutic alliance). Of these eight RCTs, six modified more than one CF, and four [37–39, 45] were adequately powered (80%; $\alpha = 0.05$) to detect changes in pain intensity. The remaining six failed to demonstrate statistically significant differences between groups regarding pain intensity [35, 41, 43, 47–49]. Of these, three were RCTs [35, 41, 43], three were

non-randomised CCTs [47–49] and three of these studies were adequately powered [43, 47, 49]. However, at 12-months follow-up, one CCT reported the CF-manipulation arm had significantly lower '*worst pain*' ratings, but not significantly lower '*average pain*' ratings compared to conventional physical therapy [47]. In one RCT, a significant increase in pain intensity (potential nocebo effect) was reported in one of the four treatment conditions – *open-label placebo instruction without conditioning arm* [45].Regarding physical functioning outcomes, seven of the fourteen studies demonstrated statistically significant differences between groups in favour of the CF-intervention [36, 38–40, 44–46], all of which were RCTs, and five modified more than one CF. Of these, four studies were adequately powered [38, 39, 44, 45]. At 12-months follow-up, one CCT reported the CF-manipulation arm had significantly improved physical functioning compared to conventional physical therapy but there was no between-group difference at post-treatment [47]. The remaining six studies failed to demonstrate between-group differences in physical functioning [35, 41–43, 48, 49], but only two were adequately powered [43, 49]. Notably, one RCT observed that sex moderated the intervention's effect, where women in the CF-intervention arm improved 4.94 RMDQ points compared to the usual care physiotherapy group [41].

Impact of contextual factors by type

Table 5 provides an overview of types of CF interventions and their impact on patient outcomes.

Patient's beliefs and characteristics

Sixteen studies involved direct manipulation of patient's beliefs and can be categorised according to their theoretical underpinnings which range from purely cognitive (i.e., both implicit and explicit), a combined cognitive-behavioural strategy, to those involving cognitive-behavioural and affective components. Eleven studies primarily aimed to address LBP-related fear-avoidance beliefs and associated behaviours, and/or maladaptive cognitions related to persistent LBP illness perceptions, pain mechanisms, and treatment [35, 36, 38, 41, 42, 44, 47, 48, 50, 51, 54] whilst five involved implicit learning/pre-cognitive associations [39, 40, 43, 45, 46] such as verbal suggestions. Overall, across the CF-intervention arms targeting patient's beliefs, there is consistent evidence to suggest that altering cLBP illness or treatment perceptions positively influenced pain intensity (i.e., 7 RCTs [35, 36, 38, 40, 42, 45, 46], 1 CCT [48], 2 quasi-experimental studies [50, 51]; $n=837$) and physical functioning (6 RCTs [35, 36, 40, 43, 45, 46], 1 CCT [48], 2 quasi-experimental studies [50, 51]; $n=751$) outcomes. Six of the 16 studies modified patient's beliefs alone [36, 38, 48, 50, 51, 54]; of these, both pain intensity and physical functioning substantially improved in five [36, 38, 48, 50, 51]. A cohort study ($n=135$) which targeted unhelpful patient beliefs during treatment demonstrated an increase in patient's rational problem-solving abilities predicted decreased disability (pain intensity was not an outcome) [54]. Another observational cohort ($n=64$) measured the relationship between patient's competence perceptions (beliefs regarding their ability to meet physical therapy demands) and found higher levels were associated with lower pain intensity and disability following rehabilitation [55]. Below is an overview of the different strategies used to modify patients' beliefs and the corresponding results are summarised in Table 5.

Implicit cognitive strategies are designed to tacitly or subtly influence patient's expectations of an imminent symptom change either positively (e.g., anticipate less pain), negatively (e.g., anticipate more pain) or neutrally (e.g., anticipate no change). Five RCTs overtly targeted patients' beliefs using verbal suggestions to influence patient's expectations of symptom change (e.g., *"the placebo effect is powerful, and the body can automatically respond to placebo pills"* [40]). Three involved the administration of OLPs [39, 40, 43], and two combined this with a social learning approach [39, 40] using a video of a news report of other patient's positive experiences of OLP to infer it is a legitimate treatment. One OLP trial reinforced the message midway through the trial [40] and reported both interactions were conducted in a warm and supportive manner. The other two RCTs used a sham opioid [45, 46] suggesting it would reduce pain and improve physical functioning (in the hidden/deception condition [45]).

Explicit cognitive strategies aim to actively educate or alter patient's LBP beliefs by targeting illness or treatment misconceptions/fallacies and/or provide accurate knowledge regarding pain modulation mechanisms. Two studies involved pain neuro-biology education interventions [42, 51]. Both targeted misconceptions about the mechanisms of pain experiences and used educational strategies to alter patient's understanding of LBP. Whilst another two studies utilised Leventhal's Common-Sense Model (CSM)/Self-regulation model as a theoretical basis to facilitate a change in patient's illness and treatment perceptions [48, 54]. The CSM is a framework linking patients' illness perceptions to behaviour and health outcomes. Lastly, although the primary focus of CONNECT trial [41] was augmenting the patient-practitioner relationship via enhanced communication skills, a subcomponent involved addressing fear-avoidance beliefs via reshaping patient's understanding of the relationship between pain and physical activity.

Table 4 Between-group comparisons in outcomes clustered by research design

Ref no. (Year) Design [Grading]	CF-intervention	Comparison condition(s)	Between-group difference Mean (*SD*) Pain Intensity	Intervention's influence: pain intensity	Between-group difference Mean (*SD*) Physical functioning	Intervention's influence: Physical functioning
[35] (2011) RCT [Excellent]	Motivational Enhancement Treatment (**MET**) + PT: ($n=38$) included proxy efficacy, treatment expectancy, therapeutic alliance, and empathy, combined with physical therapy	**PT** ($n=38$): 30-min physical therapy (PT) sessions for 8 weeks, including 15 min of interferential therapy and a tailored back exercise programme. Dummy MET included general communication (non-counselling) skills	**MET + PT** Post: $M=3.3$ (± 2.1) 1-month: $M=3.1$ (± 2.1) **PT only:** Post: $M=3.6$ (± 2.4) 1-month: $M=3.9$ (± 2.5)	**MET + PT ~ PT** ($p=.50$) 95% C.I. [− 1.09 to 0.54] MET + PT larger reduction in pain intensity than PT-alone but *non-significant*	**MET + PT** *Post:* $M=6.3$ (± 4.8) 1-month: $M=5.6$ (± 4.5) **PT only** $M=7.2$ (± 5.6) 1-month: $M=7.6$ (± 6.4)	**MET + PT ~ PT** ($p=.424$) 95% C.I. [− 2.83 to 1.44] MET + PT larger reduction in physical disability than PT-alone but *non-significant*
[36] (2013) RCT [Excellent]	Cognitive Functional Therapy **(CFT)** ($n=51$): focuses on reframing back pain in a person-centred manner along with altering maladaptive/unhelpful behaviours to normalise movement	**MT-EX** ($n=43$): consisted of manual therapy and exercise which included joint mobilisation or manipulation applied to the spine or pelvis; most patients (82.5%) were given exercises or a home exercise programme	**CFT** Post: $M=1.7$ (± 1.7) 1-year: $M=2.3$ (± 2.0) **MT-EX** Post: $M=3.8$ (± 1.9) 1-year: $M=3.8$ (± 2.1)	**CFT > MT-EX** Post: **($p<.001$)** $M_{Diff}=-2.1$ 95% C.I. [− 2.7 to − 1.4] 1-year**: ($p<.001$)** $M_{Diff}=-1.3$ 95% C.I. [− 2.1 to − 0.5] *Effect size unreported*	**CFT** Post: $M=7.6$ (± 6.7) 1-year: $M=9.9$ (± 9.8) **MT-EX** Post: $M=18.5$ (± 8.1) 1-year:$M=19.7$ (± 11.7)	**CFT > MT-EX** Post: **($p<.001$)** $M_{Diff}=-9.7$ 95% C.I. [− 12.7 to − 6.7] 1-year: **($p<.001$)** $M_{Diff}=-8.2$ 95% C.I. [− 12.6 to − 3.8] *Effect size unreported*
[37] (2014) RCT (2 × 2) [Excellent]	Enhanced versus limited therapeutic alliance (**TA**) following active or sham interferential current therapy (**IFC**)	Variation of CFs: Enhanced TA (**E**): **AE**: Active IFC ($n=29$) **SE**: Sham IFC ($n=29$) Limited TA (**L**): **AL**: Active IFC ($n=30$) **SL**: Sham IFC ($n=29$)	Significant differences between the SL and the AL, AE & SE groups Compared to **SL** (Sham IFC/ Limited TA) mean differences were: **AE**: $M\Delta=2.3$ **SE**: $M\Delta=1.19$ **AL**: $M\Delta=0.8$	**($p<.01$)** Dose response AE > SL: $d=2.51$ **Enhanced > Limited TA** SE > SL: $d=1.73$ AE > AL: $d=1.36$ **Active > Sham IFC** AE > SE: $d=1.0$ AL > SL: $d=0.89$	*Not applicable*	*Not applicable*
[38] (2022) RCT [Excellent]	**PRT** ($n=50$): Pain Reprocessing Therapy (PRT) aims to shift patients' beliefs about the causes and threat value of pain	**TAU** ($n=50$): Treatment as usual; Participants were given no additional treatment and agreed to continue their ongoing care as usual and not start new treatments before the post-treatment assessment	**PRT** Post: $M=1.18$ (± 1.24) 1-year: $M=1.51$ (± 1.59) **TAU** Post: $M=3.13$ (± 1.45) 1-year: $M=3.0$ (± 1.77)	**PRT > TAU** Post: **($p<.001$)** g (SE) = − 1.75 (0.24) 1-year: **($p<.001$)** g (SE) = − 1.05 (0.24)	**PRT** Post: $M=10.14$ (± 10.6) 1-year: $M=11.16$ (± 13.1) **TAU** Post: $M=20.68$ (± 10.7) 1-year: $M=18.78$ (± 12.6)	**PRT > TAU** Post: **($p<.001$)** g (SE) = − 1.70 (0.26) 1-year: **($p<.001$)** g (SE) = − 0.83 (0.24)
[39] (2019) RCT [Excellent]	**OLP** ($n=63$): Open-label placebo pills, social learning with **TAU**	**TAU** ($n=59$): Treatment as usual (TAU) patients received no intervention (*no further description provided*)	**OLP + TAU**: Post: $M\Delta=-0.62$ ($\pm$ SE = 0.23) **TAU**: Post: $M\Delta=0.11$ ($\pm$ SE = 0.17)	**OLP + TAU > TAU** Post: **($p=.001$)** $d=-0.44$	**OLP + TAU**: Post: $M\Delta=23.21$ (SE $\pm$ 1.59) **TAU**: Post: $M\Delta=0.65$ ($\pm$ SE = 1.15)	**OLP + TAU > TAU** Post: **($p=.02$)** $d=-0.45$

Table 4 (continued)

Ref no. (Year) Design [Grading]	CF-intervention	Comparison condition(s)	Between-group difference Mean (*SD*) Pain Intensity	Intervention's influence: pain intensity	Between-group difference Mean (*SD*) Physical functioning	Intervention's influence: Physical functioning
[40] (2016) RCT [Excellent]	**OLP** ($n=41$): Open-label placebo pills, verbal suggestions, social learning with **TAU**	**TAU** ($n=42$): Treatment as usual in an outpatient pain unit of a general public hospital (*no further description of treatment provided*)	**OLP + TAU**: $M\Delta=1.49$ (± 1.68) **TAU**: $M\Delta=0.24$ (± 1.61)	**OLP + TAU > TAU** Post: **($p<.001$)** $g=0.76$	**OLP + TAU**: $M\Delta=2.86$ (± 3.91) **TAU**: $M\Delta=0.02$ (± 3.73)	**OLP + TAU > TAU** Post: **($p<.001$)** $g=0.74$
[41] (2017) RCT (Cluster) [Excellent]	Communication Style and Exercise Compliance in Physiotherapy (**CONNECT**) ($n=108$): Enhancing physiotherapists' communication skills to alter unhelpful patient beliefs and improve motivation	**TAU** ($n=99$): Treatment as usual; publicly funded physiotherapy with no restrictions on the number of sessions or the type of treatment the physiotherapist administered	**CONNECT** Post: $M\Delta=-1.53$ (± 2.71) 24 weeks: $M\Delta=-1.53$ (± 2.78) **TAU** Post: $M\Delta=-1.31$ (± 2.36) 24 weeks: $M\Delta=-1.18$ (± 3.19)	**CONNECT ~ TAU** ($p=.75$) $M_{Diff}=-0.10$ 95% C.I. [−0.71 to 0.51] $d=-0.04$	**CONNECT** Post: $M\Delta=-3.48$ (± 5.72) 24 weeks: $M\Delta=-4.87$ (± 5.86) **TAU** Post: $M\Delta=-2.82$ (± 5.77) 24 weeks: $M\Delta=-4.09$ (± 5.95)	**CONNECT[3] ~ TAU** ($p=.60$) $M_{Diff}=-0.36$ 95% C.I. [−1.68–0.96] $d=-0.08$
[42] (2010) RCT [Good]	**ED** ($n=18$): Pain biology education for the management of cLBP	Variation of CFs: **ED-EX** ($n=20$): Pain biology education plus six weekly exercise sessions (in a group format)	**ED** Post: $M\Delta=-30.9$ **ED-EX** Post: $M\Delta=-4.2$	**ED > ED-EX** ($p=.025$)	**ED** Post: $M\Delta=-7.5$ **ED-EX** Post: $M\Delta=-3.8$	**ED ~ ED-EX** ($p=.127$)
[43] (2020) RCT [Good]	**OLP** ($n=26$): Open-label placebo pills, verbal suggestions, with TAU (advice, education, reassurance, self management)	**TAU** ($n=26$): Treatment as usual included advice to remain active, along with education and reassurance in addition to a psychological education self-management strategy to improve pain-related disabilities	**OLP + TAU**: Post: $M\Delta=-0.9$ (± 1.8) 12-weeks: $M\Delta=-1.1$ (± 1.9) **TAU**: Post: $M\Delta=-0.2$ (± 1.8) 12-weeks: $M\Delta=-0.8$ (± 1.9)	**OLP + TAU ~ TAU** Post: ($p=.19$) $d=0.38$ 12-weeks: ($p=.18$) $\eta_p^2=0.01$	**OLP + TAU**: RMDQ: $M\Delta=-2.2$ (± 2.9) TUG: $M\Delta=-0.7$ (± 1.0) 12-weeks: RMDQ: $M\Delta=-3.3$ (± 3.2) TUG: $M\Delta=-0.62$ (± 1.5) **TAU**: RMDQ: $M\Delta=-1.4$ (± 3.6) TUG: $M\Delta=-0.7$ (± 1.5) 12-weeks: RMDQ: $M\Delta=-2.3$ (± 3.2) TUG: $M\Delta=-1.1$ (± 1.1)	**OLP + TAU ~ TAU** **RMDQ:** ($p=.40$) $d=0.24$ **TUG:** ($p=.98$) $d=0.01$ 12-weeks **RMDQ**: ($p=.37$) $\eta_p^2=0.02$ **TUG:** ($p=.28$) $\eta_p^2=0.03$

Table 4 (continued)

Ref no. (Year) Design [Grading]	CF-intervention	Comparison condition(s)	Between-group difference Mean (*SD*) Pain Intensity	Intervention's influence: pain intensity	Between-group difference Mean (*SD*) Physical functioning	Intervention's influence: Physical functioning
[44] (2021) RCT [Good]	**ED + TA** ($n = 74$): Patient education (ED) relating to return to daily activities, advice on coping with pain, a clear explanation of signs and symptoms with an emphasis on increasing empathy and therapeutic alliance (TA)	Variation of CFs: **ED only** ($n = 74$): the same structured patient education sessions (ED) but with no emphasis on enhancing the patient-practitioner relationship **No ED** ($n = 74$): Patients received no-education and were advised not to seek treatment in the first month after randomisation	**ED + TA *vs* ED only** Post: $M_{Diff} = 0.09$ 6-mo: $M_{Diff} = 0.61$ 1-year: $M_{Diff} = -0.02$ **ED + TA *vs* No ED** Post: $M_{Diff} = 0.06$ 6-mo: $M_{Diff} = -0.05$ 1-year: $\boldsymbol{M_{Diff} = 1.40}$ **ED only *vs* No ED**: Post: $M_{Diff} = 0.15$ 6-mo: $M_{Diff} = 0.55$ 1-year: $\boldsymbol{M_{Diff} = 1.37}$	**ED + TA ~ ED only** *ns:* (*p*-values unreported) **ED + TA > No ED** 1-year: **(*p* < .05)** Post & 6-months: *ns* **ED only > No ED** 1-year: **(*p* < .05)** Post & 6-months: *ns* *Effect sizes unreported*	M_{Diff} **PSFS/ODI** **ED + TA *vs* ED only** Post: $M_{Diff} = 0.46/1.90$ 6-mo: $M_{Diff} = 0.52/1.27$ 1-yr: $M_{Diff} = 0.40/2.26$ **ED + TA *vs* NoED** Post: $\boldsymbol{M_{Diff} = -1.41}/4.39$ 6-mo: $\boldsymbol{M_{Diff} = -1.21/5.30}$ 1-yr: $\boldsymbol{M_{Diff} = -1.69/9.26}$ **ED only *vs* No ED** Post: $\boldsymbol{M_{Diff} = -0.95}/2.48$ 6-mo: $M_{Diff} = -0.68/4.02$ 1-yr: $\boldsymbol{M_{Diff} = -1.29/7.00}$	**ED + TA ~ ED only** *ns:* (*p*-values unreported) **ED + TA > No ED** **PSFS: (*p* < .05)** Post, 6-months, 1-year **ODI: (*p* < .05)** 6-months, 1-year **ED only > No ED** **PSFS: (*p* < .05)** Post, 1-year **ODI: (*p* < .05)** 1-year *Effect sizes unreported*
[45] (2017) RCT (2 × 2) [Good]	Manipulating patient's pain expectations using an inert solution/labelling, verbal instructions, and classical conditioning (CC)	Variation of CFs: Opioid Instruction (OI) (Deceptive/Hidden) **With CC**: ($n = 12$) **No CC**: ($n = 12$) Placebo Instruction (PI) (Truthful/Open-Label) **With CC**: ($n = 12$) **No CC**: ($n = 12$)	*Post: (Day 1)* Opioid Instruction **With CC:** $M = 1.92$ (± 1.73) **No CC**: $M = 3.00$ (± 2.73) Placebo Instruction: **With CC:** $M = 4.58$ (± 2.31) **No CC:** $M = 5.83$ (± 1.95)	**Deception > Truth (*p* = < .01)*** Dose–response: **Deception (OI)** With CC: $d = 1.83$* No CC: $d = 0.83$* **Truthful (PI)** With CC: $d = 0.32$; *ns* No CC: $d = -0.64$* (**nocebo effect**)	*Post: (Day 1)* Opioid Instruction **With CC:** $M = 77.22$ (± 15.43) **No CC:** $M = 67.78$ (± 29.24) Placebo Instruction: **With CC:** $M = 53.89$ (± 24.03) **No CC:** $M = 44.44$ (± 15.66)	**Deception > Truth (*p* = < .01)*** Dose–response: **Deceptive: (OI)** With CC: $d = -0.92$* No CC: $d = -0.59$* **Truthful: (PI)** With CC: $d = -0.17$ No CC: $d = 0.43$
[46] (2019) RCT (2 × 2) [Good]	Manipulating patient's pain expectations using an inert drain dressing infusion with mirrors/labelling, verbal instructions, and either placebo or nocebo conditioning (PC or NC)	Variation of CFs: Sham "Opioid" Infusion: Placebo Conditioning (**PC**): ($n = 17$) Sham only (**SO**): ($n = 21$) Nocebo Conditioning (**NC**): ($n = 21$) Natural History (**NH**): ($n = 14$) no sham infusion (waiting only) nor any classical conditioning	*Post infusion: (Day 1)* **PC**: $M = 3.24$ (± 2.48) **SO**: $M = 2.43$ (± 1.88) **NC**: $M = 3.57$ (± 2.27) **NH**: $M = 5.00$ (± 2.35) *Post infusion: (Day 8)* **PC**: $M = 3.41$ (± 2.52) **SO**: $M = 2.57$ (± 2.22) **NC**: $M = 3.48$ (± 2.18) **NH**: $M = 5.36$ (± 1.98)	**Sham Infusion > NH** **PC & SO (*p* = < .001)** **NC (*p* = < .01)** **PC**: $\eta^2 = 0.38$ **SO**: $\eta^2 = 0.56$ **NC**: $\eta^2 = 0.21$ **NH: (*p* = .92)** **NH**: $\eta^2 = 0.01$	*Post infusion: (Day 1)* **PC**: $M = 72.54$ (± 29.2) **SO**: $M = 77.46$ (± 21.4) **NC**: $M = 73.33$ (± 23.2) **NH**: $M = 54.76$ (± 23.7) *Post infusion: (Day 8)* **PC**: $M = 76.86$ (± 29.2) **SO**: $M = 78.73$ (± 22.5) **NC**: $M = 78.73$ (± 18.0) **NH**: $M = 53.86$ (± 23.0)	**Sham Infusion > NH** **SO (*p* = < .01)** **PC & NC (*p* = < .05)** **PC**: $\eta^2 = 0.15$ **SO**: $\eta^2 = 0.27$ **NC**: $\eta^2 = 0.20$ **NH: (*p* = .63)** **NH**: $\eta^2 = 0.03$

Table 4 (continued)

Ref no. (Year) Design [Grading]	CF-intervention	Comparison condition(s)	Between-group difference Mean (*SD*) Pain Intensity	Intervention's influence: pain intensity	Between-group difference Mean (*SD*) Physical functioning	Intervention's influence: Physical functioning
[47] (2017) CCT [Excellent]	Enhanced Transtheoretical Model Intervention **(ETMI)** ($n=94$): focusing on therapists' communication skills; improving TA using empathy, active listening; addressing low motivation, self-efficacy, and addressing maladaptive beliefs/ behaviours	Conventional physical therapy (**PT** ($n=95$)) treatments: mobilisation, manipulation, back exercises, postural training, back school, electrical stimulation, shortwave diathermy, cooling, and stretching	Average Pain Post: $M\Delta=0.6$ 95% C.I. [− 0.2 to 1.4] Follow-up: $M\Delta=0.9$ 95% C.I. [− 0.03 to 1.8] Worst Pain Post: $M\Delta=0.10$ 95% C.I. [− 0.8 to 1.2] Follow-up: $M\Delta=1.2$ 95% C.I. [0.05 to 2.3]	**ETMI ~ PT** Post: ($p=.10$) Follow-up: ($p=.06$) Worst pain **ETMI > PT** Post: ($p=.70$) Follow-up: **($p=.04$)** *Effect size unreported*	Post: $M\Delta=1.3$, 95% C.I. [− 0.3 to 3.0] Follow-up: $M\Delta=2.7$ 95% C.I. [0.9 to 4.5]	**ETMI ~ PT** Post: ($p=.10$) **ETMI > PT** Follow-up: **($p=.004$)** $d=0.54$
[48] (2012) CCT [Good]	Intervention ($n=93$) focused on patient's illness and treatment beliefs and their information needs	**TAU** ($n=95$): Treatment as usual; inpatient musculoskeletal rehabilitation which is typically multimodal and multidisciplinary	**Intervention** $M=42.91$ (± 21.50) **TAU** $M=42.26$ (± 20.77)	**Intervention ~ TAU** ($p=.319$)	**Intervention** $M=30.98$ (± 15.70) **Control** $M=31.46$ (± 16.19)	**Intervention ~ TAU** ($p=.412$)
[49] (2018) CCT [Fair]	Adding one weekly group-based physical therapy session in a rehabilitation setting compared to home treatment alone	Variation of CFs: **Rehab** ($n=13$): Weekly group-based physical therapy session involving exercises **Home** ($n=17$): No physical therapy supervision	*Post-treatment* $M_{Diff}=-0.9$ 95% C.I. [− 2.3 to 0.5]	**Rehab ~ Home** ($p=.655$)	*Post-treatment* $M_{Diff}=-0.2$ 95% C.I. [− 3.8 to 3.3]	**Rehab ~ Home** ($p>0.999$)

~ indicates equivalence between groups; ns: not statistically significant; 95% C.I.: 95% Confidence Interval; TUG: Timed-Up-and-Go (measured in seconds); RMDQ: Roland–Morris Disability Questionnaire – where higher scores represent higher levels of physical disability. PSFS: Patient-Specific Functional Scale – where higher scores represent higher levels of functioning; ODI: Oswestry Disability Index – where higher scores represent higher levels of physical disability

[a] This RCT involved three arms, including an open-label placebo (OLP) group. However, the OLP involved the administration of an injection rather than pills/capsules. These results were therefore excluded from the synthesis since it is an invasive procedure (exclusion criteria) and was not directly comparable to the other OLP trials

[b] Sex moderated the effect. Women in the CONNECT arm improved 4.94 RMDQ points compared to women in the control group

Table 5 Summary of Contextual Factor intervention types and their influence on patient outcomes

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
[36] (2013) RCT	1	Patient's beliefs (1)	**Cognitive Behavioural Approach** – reframing back pain, explaining biopsychosocial pain mechanisms, changing maladaptive (i.e., fear-avoidant) movement using, goal setting, graded activity, and reflective communication	**Significant** improvement (*pain intensity* & *physical functioning*)	**Superior**	*Unreported*
[37] (2014) RCT (2 × 2)	2	Patient-practitioner relationship (1)	**Therapeutic Alliance** – interactions enhanced through verbal behaviours, active listening, tone of voice, non-verbal behaviours (i.e., eye contact, touch), and empathy	**Clinically meaningful** improvement (*pain intensity*)	**Superior** to limited TA	Sham + TA > Sham ***d*** **= 1.73** Active + TA > Active ***d*** **= 1.36**
		Treatment characteristics (1)	**Sham vs Active Treatment** – both patients and practitioners could not visually discriminate between sham or active IFC		**Superior** to Sham IFC	Active + TA > Sham + TA ***d*** **= 1.0** Active > Sham ***d*** **= 0.89**
[38] (2022) RCT	1	Patient's beliefs (2)	**Cognitive-Behavioural and Affective Approach—** aims to shift patients' beliefs about the causes and threat value of pain, focuses on reframing pain sensations through a lens of safety, addressing emotional threats and enhancing positive feelings and sensations through exposure to feared movements and evidence to provide reassurance	**Clinically meaningful** improvement (*pain intensity*) Improvement (*physical functioning*)	**Superior**	Pain Intensity ***g*** **= − 1.75** Physical Functioning ***g*** **= − 1.70**

Table 5 (continued)

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
[39] (2019) RCT	2	Patient's beliefs (3)	**Implicit Cognitive Approach** – Verbal suggestions to positively influence patient's symptom change expectations introduced by principal investigator wearing a white coat. **Social learning** – News report video (German subtitles/dubbing) regarding patients' experiences of OLP to infer it is a legitimate/credible treatment approach	Improvement (*pain intensity & physical functioning*)	**Superior**	Pain Intensity ***d*** **= −0.44** Physical Functioning ***d*** **= −0.45**
		Treatment characteristics (2)	**Response Expectancy** – physical cues (i.e., typical, labelled medicine bottle and capsules) to connote pain-relieving treatment properties			
[40] (2016) RCT	2	Patient's beliefs (4)	**Implicit Cognitive Approach** – Verbal suggestion to positively influence patient's symptom change expectations using a warm and supportive communication style. **Social learning** – video of a news report regarding patients' experiences of OLP to infer it is a legitimate/credible treatment approach	**Much Improved** (*pain intensity & physical functioning*)	**Superior**	Pain Intensity ***g*** **= 0.76** Physical Functioning ***g*** **= 0.74**
		Treatment characteristics (3)	**Response Expectancy** – physical cues (i.e., typical, labelled medicine bottle and capsules) to connote pain-relieving treatment properties			
[42] (2010) RCT	2	Patient's beliefs (5)	**Explicit Cognitive Strategy** – Pain neuro-biology education (PNE) targeted misconceptions about the mechanisms of pain experiences (1 × 2.5 h)	**Significant** improvement (*pain intensity only*)	**PNE Superior** to PNE plus Exercise	*Unreported* **Note**: Patients attending group exercise classes interacted with non-trial staff/patients which may have undermined the PNE

Table 5 (continued)

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
		Patient-practitioner relationship (2)	**Additional Interactions** – group-based physical exercise classes open to the general community (via NHS)			
[45] (2017) RCT (2 × 2)	2	Patient's beliefs (6)	**Implicit Cognitive Approach** – *Truthful* [or Deceptive] verbal suggestions to influence patient's symptom change expectations: "*this solution is neutral, a placebo* [an opioid], *it has no effect* [reduces pain and improves physical capacity]")	**Significant** improvement (*pain intensity* & *physical functioning*)	**Superior** to truthful verbal suggestions	Pain Intensity With CC: $d = 1.83$ No CC: $d = 0.83$ Physical Functioning: With CC: $d = -0.92$ No CC: $d = -0.59$
		Treatment characteristics (4)	**Response Expectancy** – visual and physical cues to connote pain-relieving treatment properties (i.e., bottles labelled as "*Opioid Klinische Prüfung*" (i.e., Opioid Clinical Trial). **Classical Conditioning** (CC) – 6 × experimental pain stimuli			
[46] (2019) RCT (2 × 2)	2	Patient's beliefs (7)	**Implicit Cognitive Approach** – Deceptive verbal suggestions to influence patient's symptom change expectations: "*…a new and very powerful transdermal infusion which reduces clinical back pain and improves functional capacity.*")	**Significant** improvement (*pain intensity* & *physical functioning*)	**Superior** to Natural History group	Pain Intensity Sham Only: $\eta^2 = 0.56$ Placebo Cond: $\eta^2 = 0.38$ Nocebo Cond: $\eta^2 = 0.21$ Physical Functioning: Sham Only: $\eta^2 = 0.27$ Placebo Cond: $\eta^2 = 0.15$ Nocebo Cond: $\eta^2 = 0.20$

Table 5 (continued)

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
		Treatment characteristics (5)	**Response Expectancy** – visual and physical cues to connote pain-relieving treatment properties (patch was labelled as "*Taroxin – hydromorphone, 1 mL = 10 mg*, so patients believed it was a potent analgesic"), could see its application using mirrors and felt a damp sensation too. **Classical Conditioning** (CC) – use of experimental pain stimuli to positively (PC) or negatively (NC) influence pain perceptions			
[44] (2021) RCT	2	Patient's beliefs (8)	**Explicit Cognitive Strategy** – Patient education (ED) relating to return to daily activities, advice on coping with pain, a clear explanation of signs and symptoms as recommended by treatment guidelines (2 × 1-h)	Improvement (*pain intensity & physical functioning*)	Equivalent *(ED + TA ~ ED only)* **Superior to No ED group**	Pain Intensity (1-year) *Unreported* Physical Functioning (see Table 4) *Unreported*
		Patient-practitioner relationship (3)	**Therapeutic Alliance** – In one group (ED + TA) the therapist aimed to enhance TA and empathy by emphasising a warm and caring reception, showing interest in the patient, asking about the patient's condition in an interested manner, and demonstrating interest in the current complaint etc			
[35] (2011) RCT	3	Patient's beliefs (9)	**Cognitive-Behavioural and Affective Approach** – including motivation enhancing factors such as proxy efficacy, treatment expectancy, and goal setting (MET)	**Significant** improvement (*pain intensity & physical functioning*)	Equivalent	*Not Applicable*

Table 5 (continued)

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
		Patient-practitioner relationship (4)	**Therapeutic Alliance** – use of motivational interviewing to develop working alliance			
		Treatment characteristics (6)	**Dummy MET** (Motivational Enhancement Treatment) – general communication skills, but deliberately avoided adopting MET-based counselling skills			
[43] (2020) RCT	2	Patient's beliefs (10)	**Implicit Cognitive Approach** – Verbal suggestion to positively influence patient's symptom change expectations (1-h session)	**Significant** improvement (*physical functioning* (RMDQ) *only*)	Equivalent	*Not Applicable*
		Treatment characteristics (7)	**Response Expectancy** – physical cues (i.e., typical, medicine bottle and capsules) to connote pain-relieving treatment properties			
[41] (2017) RCT (Cluster)	2	Patient's beliefs (11)	**Explicit Cognitive Approach** – ensure patients understand their LBP and the relationship to physical activity; addressing fear-avoidance beliefs	Improvement (*pain intensity* & *physical functioning*)	Equivalent	**Note**: Sex moderated the effect. Women in the intervention arm improved (i.e., 4.94 RMDQ points lower) compared to women in the control arm
		Patient-practitioner relationship (5)	**Improved Communication** – enhance physiotherapists' communication skills using the '5A' framework (i.e., ask, advise, agree, assist, arrange)			
[47] (2017) CCT	2	Patient's beliefs (12)	**Cognitive-Behavioural and Affective Approach** – address low motivation/self-efficacy for physical activity using behaviour change principles, graded activity to target fear-avoidance beliefs/behaviour, and educational messages informed by effective reassurance	Improvement (*pain intensity* & *physical functioning*)	Equivalent at post-treatment **Superior at follow-up***	*Physical Functioning ***d* = 0.54**

Table 5 (continued)

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
		Patient-practitioner relationship (6)	**Therapeutic Alliance** – building the relationship with an emphasis on communicating empathy and active listening			
[48] (2012) CCT	1	Patient's beliefs (13)	**Explicit Cognitive Strategy** – Educational intervention covering beliefs about medicines, rehabilitation, and individualised information to address unhelpful illness perceptions	**Significant** improvement (*pain intensity* & *physical functioning*)	Equivalent	**Note**: Control-arm involved in-patient multidisciplinary rehabilitation
[49] (2018) CCT	2	Patient-practitioner relationship (7)	**Additional Interactions** – one weekly group-based physical therapy session (i.e., extra time/attention)	**Significant** improvement (*pain intensity* & *physical functioning*)	Equivalent	*Not Applicable*
		Treatment Setting (1)	**Environment** – one group participated in physical therapy at home only whilst the other also attended weekly classes at a rehabilitation facility			
[50] (2015) Quasi-exp	1	Patient's beliefs (14)	**Cognitive Behavioural Approach** – reframing back pain, explaining biopsychosocial pain mechanisms, changing maladaptive (i.e., fear-avoidant) movement using goal setting, graded activity, and reflective communication	**Significant** improvement (*pain intensity & physical functioning*)	*Not Applicable*	Pain Intensity ***d*** **= 0.65** Physical Functioning ***d*** **= 0.85**
[51] (2017) Quasi-exp	1	Patient's beliefs (15)	**Explicit Cognitive Strategy** – Pain neuro-biology aimed at re-educating older patients on the relationship between LBP and normal aging processes	**Significant** improvement (*pain intensity* & *physical functioning*)	*Not Applicable*	Pain Intensity ***r*** **= 0.45** Physical Functioning partial ***η2*** **= 0.54**

Table 5 (continued)

Ref no. (year) & Design	No. of CFs	Which CFs? (frequency)	How CFs manipulated during the intervention?	Influence on cLBP outcome(s)	Compared to active treatment	Effect size(s)
[54] (2011) Obs. Cohort	1	Patient's beliefs (16)	**Explicit Cognitive Strategy** – Using the Socratic dialogue technique to investigate and restructure patient's maladaptive or unhelpful illness perceptions	**Significant** improvement (*physical functioning*)	*Not Applicable*	r^2 **= 3.9%** An increase in patient's rational problem-solving skills was associated with improved physical functioning outcomes
No direct manipulation of CFs						
[52] (2013) Obs. Cohort	1	Patient-practitioner relationship (8)	***Measuring* Communication Skills** – patient information, perceived involvement in care, trust, satisfaction, and aspects of their communication behaviour during multimodal orthopaedic pain rehabilitation involving educational, psychotherapeutic, social, and occupation-related therapy	**Significant** improvement (*pain intensity & physical functioning*)	*Not Applicable*	Pain Intensity Post: ***d*** **= 0.60** Follow-up: ***d*** **= 0.48** Physical Functioning Post: ***d*** **= 0.53** Follow-up: ***d*** **= 0.48**
[53] (2013) Obs. Cohort	1	Patient-practitioner relationship (9)	***Measuring* Therapeutic Alliance –** sense of collaboration, warmth, and support between the patient and therapist. Includes agreement on (a) goals, (b) treatment, and (c) the affective or emotional bond	**Significant** improvement (*pain intensity & physical functioning*)	*Not Applicable*	One unit increase in TA reduced pain intensity by 0.044 units One unit increase in TA reduced disability by 0.113 units
[55] (2019) Obs. Cohort	1	Patient's beliefs (17)	***Measuring relationships* between patients' Competence Perceptions and Motivation** for undertaking physical therapy and whether patient motivations mediate the relationship between Competence Perceptions (CP) and pain and disability. *Competence Perceptions refers to the patient's beliefs regarding their ability, efficacy, and proficiency to meet rehabilitation demands. Along a continuum, amotivation represents the least self-determined type whereas autonomous motivation is the most self-determined*	**Significant** associations (*pain intensity & physical functioning*)	*Not Applicable*	**Note**: Higher CP levels were associated with lower pain and disability at post-treatment Amotivation was the only significant mediator CP negatively predicted amotivation, which in turn positively predicted greater pain and disability

Cognitive-behavioural strategies included interventions exclusively designed and tailored for persistent LBP combined with cognitive-behavioural principles (e.g., cognitive reframing, graded activity, goal setting). Two studies [36, 50] used Cognitive Functional Therapy (CFT) which is a bespoke intervention specifically designed for disabling LBP. CFT aims to normalise provocative movements while discouraging pain behaviours via cognitive reconceptualization, graded activity, and goal setting [58]. CFT appears to be the most arduous of the interventions for practitioners, considering 106 h of training was undertaken prior to its implementation [36].

Cognitive-behavioural and affective strategies Contain elements of behaviour change techniques but also considers the patient's emotional or affective state during rehabilitation. Two studies [35, 47] considered each patient's initial state of motivation, as classified via the transtheoretical model (TTM; 'stages-of-change'), and then used motivational interviewing (MI) to address patient's beliefs, feelings, and behaviour [35, 47]. Whereas the PRT [38] trial aimed to shift patients' beliefs about the causes and threat value of their pain experiences, by reframing pain sensations through a lens of safety, addressing emotional threats, along with gradual exposure to feared movements. PRT also incorporated pain neuro-biology education and aimed to consistently reinforce the same message throughout treatment [38].

Patient-Practitioner Relationship

Seven studies involved the direct modulation of the patient-practitioner relationship [35, 37, 41, 42, 44, 47, 49], whilst two observational cohorts [52, 53] measured aspects of the pre-existing dyadic relationship rather than purposefully altering it. These interventions are sub-categorised as follows: (2.1.) therapeutic alliance (TA:- creating asense of collaboration, warmth, and support viatechnical skill, communicative competence, and reflective capacity) [35, 37, 44, 47, 53]; (2.2.) improved communication skills [41, 52]; and (2.3.) additional therapeutic interactions (i.e., extra attention/time) [42, 49]. There is some preliminary evidence (2 RCTs [35, 37], 1 CCT [47]; $n=413$) that enhancing TA resulted in improved clinical outcomes from baseline, but there is an inconsistency since one study found no between-group differences after attempting to emphasise TA during two educational sessions [44]. The authors noted it was possible their attempts to improve TA failed, or perhaps a high level of TA was present after first contact with the patient regardless of group allocation [44]. Notably, these interventions all involved multiple components of care: physical (active treatments), cognitive (patient's beliefs), and interpersonal (TA)—consequently, the impact of TA alone remains unclear. Only two of eight studies examined the role of the patient-practitioner relationship alone—both observational cohorts ($n=928$). These indicated positive communication/relationship predicted improved pain intensity and physical functioning in patients with cLBP [52, 53]. Below is an overview of the different strategies used to influence the patient-practitioner relationship and the corresponding results are summarised in Table 5.

Therapeutic Alliance (TA) Two interventions using Motivational Interviewing (MI) [35, 47] supported the development of TA by cultivating a sense of mutual collaboration between patients and practitioners using empathy and active listening. Although MI aims to facilitate a change in patient's beliefs, the technique also involves fostering TA between the patient and practitioner by: (i) expressing accurate empathy, (ii) developing discrepancy, (iii) avoiding argumentation, and (iv) supporting patient's self-efficacy. In a three-armed RCT [44], one group received an educational intervention with an emphasis on improving empathy and TA by providing a warm and caring reception, showing interest in the patient, and demonstrating interest in their complaint. In another RCT comparing enhanced versus limited TA [37], patients received enhanced TA through extra time to convey empathy, warmth, encouragement, and support. Irrespective of electrotherapy condition (active or sham), the enhanced TA patients had significantly larger improvements in pain intensity after a single session. Likewise, in an observational cohort, higher TA ratings at the end of the second treatment session were associated with significant decreases in both pain and disability outcomes [53].

Improved Communication Skills The focus of the CONNECT trial was improving the patient-practitioner relationship via enhanced communication skills based on self-determination theory [41]. The intention was to facilitate the development of patient's autonomy (i.e., feeling free to engage in activity), competence/self-efficacy (i.e., feeling effective or capable), and relatedness (i.e., feeling connected to and cared for by others) using the 5A framework. Eight hours of training positively influenced these physiotherapists' communication skills, but independent observers rated their support below ideal (i.e., $M=4.57$ using a 7-point rating scale) [41]. In an observational cohort study measuring various aspects the patient-practitioner relationship (i.e., trust, communication skills, and satisfaction with information received and expression of empathy), higher ratings on patient-practitioner variables were associated with improved pain and disability

outcomes but inter-individual differences[1] were apparent [52].

Additional Therapeutic Interactions (Attention/Time) Two studies involved variations in time spent with the practitioner [42, 49]. In both studies the exercise classes were group-based, so it is unclear how much extra attention each patient received and whether there was continuity of care (i.e., same practitioner every class).

Treatment Characteristics

Seven RCTs involved a variation in the treatment characteristics either in terms of the absence or presence of the stimulus/cue/treatment condition [35, 37, 39, 40, 43, 45, 46]. Of these, five reported significant improvements in pain intensity following treatment ($n=409$) [35, 37, 39, 40, 45, 46], whilst five of six reported significant improvements in physical functioning ($n=344$) [35, 40, 43, 45, 46]. These studies involved administering sham/dummy treatments [35, 37], classical conditioning to manipulate pain perceptions [45, 46], or the presence/absence of visual or physical cues to denote pain-relieving treatment properties [39, 40, 43, 45, 46]. For example, during the application of a sham "opioid" infusion, the patch was labelled as "*Taroxin – hydromorphone, 1 mL = 10 mg*" so patients believed it was a potent analgesic, they could see its application using mirrors, and also felt a damp sensation where applied [46]. Active treatments (namely IFC: interferential current therapy and MET: *Motivational Enhancement Treatment*), the presence of a medicalised symbolic cue (specifically an inert solution/infusion/capsules) or classical conditioning had a positive impact on both pain and physical functioning in patients with cLBP, suggesting there is consistent evidence relating to varying the treatment characteristics. However, none of these studies manipulated the treatment characteristics alone, since all these interventions involved more than one CF.

Therapeutic setting/environment

Only one study involved the manipulation of the therapeutic setting [49]. The principal difference between the two non-randomised groups were: one received weekly supervision from a physical therapist at the rehabilitation site, the other used an exercise booklet at home. All patients experienced improved clinical outcomes following the intervention but there were no significant between-group differences. This study had the lowest quality assessment grade ('Fair') across the studies but was adequately powered despite its small sample size ($n=30$).

Practitioner's beliefs and characteristics

None of the included studies modified practitioner beliefs or characteristics as a means of eliciting placebo analgesia in patients with cLBP.

Discussion

Summary of findings

Therapeutic encounters consist of multiple elements, the most obvious of which is an assumed specific treatment. These elements during clinical encounters, perceived as non-specific or implicit in nature—and referred to as CFs—may have important impacts on the modulation of pain and disability [11, 12]. The findings from this review suggest preliminary evidence for CFs adjunctive role and adds three unique contributions to the complex phenomenon of cLBP treatment.

Firstly, most patients with cLBP experienced improved clinical outcomes regardless of treatment arm. Overall, patients in the CF-manipulation arm(s) tended to demonstrate larger symptom improvements from baseline, even if the between-group differences were non-significant. There is initial evidence indicating CF-interventions appear, to some extent, comparable or equivalent to usual care/active treatments. CFs appear to be influencing both pain intensity and physical functioning outcomes over time in patients with cLBP. Since nearly all the included studies involved active treatments/comparison groups, and only two employed a no treatment/natural history group [44, 46], it is difficult to discern the precise level of impact of CFs on these outcomes compared to other confounders such as regression towards the mean. Pragmatic research designs were used as studies occurred in everyday rehabilitation settings, but findings may have differed if more of the studies included a waiting-list control. Of the two studies which included a no treatment condition, one was brief (8-days) [46], whilst the other only reported significant post-treatment between-group differences for one of the two disability measures (PSFS but not the ODI) [44]. In a series of neuroimaging studies, preliminary evidence suggested inactive pills successfully induced placebo analgesia that could not be explained by regression towards the mean, natural history, or mere exposure to the study [59]. To better disentangle effects underpinned by CFs, specific treatments, and natural history or regression to the mean, future studies might consider at least three comparison groups, including a waiting-list control (with the option of treatment at a later date), or factorial designs with a no treatment condition as this will

[1] For instance, some patients had lower improvements if the practitioner was perceived to have communicated in a patient-centred manner and involved them in treatment decisions. These patients also tended to rate their satisfaction and trust in their practitioner lower too, suggesting patient-centred communication ought to consider patient's particular preferences (e.g., collaborative versus authoritative) or possibly their characteristics.

enable a direct comparative view of the magnitude of any observed effects [60, 61].

Secondly, there is consistent evidence to indicate CF-manipulations may augment usual care treatment in rehabilitation settings in patients with cLBP. In studies with at least two comparison groups [35–49], half reported significant improvements in pain intensity, in favour of the CF-interventions [36–40, 42, 45, 46]. Notable CFs influencing pain intensity outcomes included (a) patient-centred education to address misinformed, unhelpful, or maladaptive cLBP or pain-related beliefs (i.e., *illness representations*); (b) verbal suggestions to influence patient's symptom change beliefs (i.e., *treatment expectations*); (c) visual or physical cues (i.e., *treatment characteristics*) to connote pain-relieving treatment properties (i.e., *treatment expectations*); and (d) positive or patient-centred communication to promote the therapeutic alliance (i.e., *patient-practitioner relationship*).

Similarly, half the studies demonstrated significant improvements in favour of the CF-manipulation arm(s) for physical functioning outcomes [36, 38–40, 44–46]. The same CFs were apparent, with a few variations regarding the patient-practitioner relationship. For instance, facilitating TA via reassurance was only significant at 12-months' follow-up, not post-treatment [47], and female patients were more responsive to an intervention enhancing communication and TA than males [41]. This review found the strongest evidence relates to patient's expectations/beliefs. When reported, the magnitude of effects was generally medium to large, suggesting these CFs had a meaningful impact on clinical outcomes despite their heterogeneity. The findings were less consistent for the patient-practitioner relationship; although enhancing TA appears to be influential, the best approach for achieving an improved working relationship may require further training, such as motivational interviewing.

Treatment expectation shapes the patient's pain experience [62–64] which is a recognised prognostic factor in MSK pain [65–67]. A patient's prior treatment experiences and preferences can also affect the outcome [68] and alter the magnitude of the response in MSK rehabilitation [69]. General expectations for pain relief influence pain and physical functioning in patients with LBP [70, 71] and neck pain [72] as well as practitioner-rated outcome expectancies [73, 74]. Ignoring patients' preferences, expectations, or prior experiences can negatively influence outcomes [75]. A meta-analysis involving interventions which aimed to induce expectation, using verbal suggestion, conditioning, or mental imagery on patient's pain indicated the effects on chronic pain were small [64]. It suggested that combining different forms of expectations and more extensive interventions that addressed the patient's expectations might enhance these effects which is consistent with the findings from this review.

The patient-practitioner relationship also positively influences outcomes like pain, physical functioning [73, 74], patient satisfaction, and strengthens the therapeutic alliance [76]. Empathy and expectation are notable features for reducing pain [77]. Both therapeutic alliance and practitioner-rated expectations of how each patient will respond to treatment were the strongest predictors of back-related disability in a prospective cohort study in a rehabilitation setting [74]. These effects were however mediated by improved patient self-efficacy in pain coping, perceiving back pain as less threatening, along with a reduction in psychosocial distress [74]. Similarly, a systematic review examining patient-practitioner communication found that increasing practitioner empathy and encouraging positive patient expectations had small but significant effects on acute pain [78]. Although heterogeneity between interventions made it difficult to pinpoint the effective elements. A variety of communication skills such as active listening, paraphrasing, language reciprocity, verbal encouragement, humour, and empathy have been shown to influence treatment outcomes [69, 75, 79, 80]. In this review, intensive training (e.g., CFT) seems to have had a stronger influence on patient outcomes compared to shorter training. The reason being that specialised psychosocial competences are not typically incorporated into undergraduate training programmes. It is suggested that the influence of the early acquisition of these skills is investigated in future.

Lastly, it is possible that modifying more than one CF may be more impactful on patients' clinical outcomes. This review found consistent evidence relating to the treatment characteristics; but all seven RCTs involved more than one CF. It is therefore challenging to ascertain which CFs may have influenced overall clinical improvements and may be complicated by any synergistic action between CFs. The quality assessment highlighted that these innovative approaches may not have direct clinical utility, and there is considerable debate concerning the ethical application of 'placebos' which is intrinsically linked to definitional ambiguities [81] and their perceived illegitimacy historically [82]. For instance, the three OLP trials included in this review reported differing outcomes. The administration approaches were similar, but not identical, suggesting future studies might investigate patients' experiences to understand how these cues are perceived and which are essential elements for reliably inducing placebo analgesia using OLP. In a study using an inert cream, placebo analgesia clearly increased in a "dose"-dependent manner, mediated by the anticipated level of pain-relief (i.e., corresponding to the degree of

conditioned expectation) [83]. The authors [83] explained placebo analgesia as:

> *a dynamic product of interactions among expectations, physiological arousal, and somatic perception. Over time, the individual in pain inevitably evaluates how well his expectation of relief comports with reality, and this comparison can influence future expectation. Past success in decreasing pain increases the expectation that future relief is possible, while past failure suppresses the expectation of future success.*

This illustrates the complex interplay between all five CFs; none are static states, rather dynamic, fluid synergies. Patients are continually interpreting and being influenced by co-occurring internal and external contexts and cues, including interpersonal interactions during health encounters, through the lens of their prior experiences, to anticipate if symptom change can be expected [11, 12]. It seems explicitly inducing placebo analgesia is informed by the cogency and consistency between the CFs (i.e., creating a credible and coherent 'story') to evoke this innate biological response. Modifying more than one CF may be more impactful on patients' outcomes, namely: attempting to create coherence between illness representations and treatment expectations whilst ensuring consistency between treatment characteristics and treatment expectations; along with cultivating the patient-practitioner relationship.

In this sense, practitioners could be viewed as the "sugar pill". What appears to be an important therapeutic process is the manner in which a practitioner interacts with their patient, such as expressing empathy and warmth, to facilitate the development of TA or a working relationship which might then enable practitioners to address misinformed or unhelpful cLBP illness beliefs negatively influencing patient's cognitions and behaviour (e.g., vicious cycle of pain, fear-avoidance, catastrophising). Furthermore, practitioners might simultaneously aim to influence patient's treatment expectations regarding symptom improvements through feedback (e.g., visual, or physical cues and/or verbal suggestions) to explain how or why the features of the conservative treatment are suitable or effective for the patient's cLBP (i.e., to develop treatment credibility). These two processes may be clinically useful approaches which help explain the role of important CFs positively influencing pain intensity and physical functioning outcomes in those with cLBP.

Strengths and limitations

This review used a robust search strategy evaluated by two experienced librarians. The array of search terms arising from the plethora of interchangeable terminology illustrates the need for an integrated theoretical framework [24]. Although Howick's paper [26] helps to refine and clarify definitional issues, the chosen CF framework offered a utilitarian approach. It is plausible the inclusion–exclusion criteria precluded studies where practitioner's beliefs/expectations or characteristics were overtly manipulated. An ineligible RCT, identified via the search strategy, involving 128 patients with acute, non-specific LBP patients found that formal or casual attire had no effect on treatment credibility [84]. Accordingly, the search strategy was sensitive and specific enough to identify studies which may have modified this CF, but none were eligible for inclusion. However, future research should examine the crucial role of practitioner's beliefs/expectations and characteristics (see [85]). Most of the included studies were not specifically designed as CF-interventions but focusing on everyday treatment settings may enable the findings to be adapted for clinical use. The included studies utilised complex interventions, with multiple components, and modified one or more CFs making it difficult to separate out the precise influence of a specific CF (see [86] for a discussion).

This review may not be all-encompassing; grey literature, retrospective cohorts, and secondary analyses were excluded. There is potential bias as a single reviewer conducted the screening, data extraction, and quality assessment but a sample of the of potentially eligible full-text articles were independently cross-checked by the entire review team. Since the included studies were fairly heterogeneous, it may have been worthwhile using several quality assessment tools rather than modifying the scoring criteria. Overall, only one study was graded as 'Fair' but since eligible studies were published between 2009 and 2022, current reporting standards in conjunction with research checklists/guidelines may have influenced the quality of studies included. Key issues affecting quality related to statistical power and generalizability. Cumulative low scoring on item 11 (external validity) implies that these findings are not necessarily generalisable since both men and older patients are likely underrepresented. These studies were also generally clustered in the Northern hemisphere and may overrepresent patients from developed or higher income countries. Similarly, studies scoring '0' regarding the representativeness of the staff, facilities, intervention, and setting (item 13) used novel, bespoke, or innovative approaches to care. Although this is not necessarily problematical, it suggests that specific interventions may not have immediate practical utility, nor be directly transferable to other rehabilitation settings without appropriate modification. Consequently, these findings are promising, but require judicious interpretation.

Conclusion

In conclusion, this systematic review has demonstrated preliminary evidence to indicate explicitly leveraging CFs augments conservative cLBP treatment. It identified CFs reducing pain intensity and improving physical functioning outcomes and extracted specific strategies with prospective clinical utility. The heterogeneity of interventions suggests modifying more than one CF may be more impactful. In essence, the practitioner's therapeutic potency lies in their capacity to simultaneously provide physical, cognitive, and emotional care to influence the patient's mindset and consequently their physiology.

Abbreviations

MSK: Musculoskeletal; LBP: Low back pain; cLBP: Chronic low back pain; NSAID: Non-steroidal anti-inflammatory drug; CFs: Contextual factors; NICE: National Institute for Health and Care Excellence; TIDieR: Template of Intervention Description and Replication; EPOC: Cochrane Effective Practice and Organisation of Care Review Group; ESRC: Economic and Social Research Council; RCT : Randomised Controlled Trial; CCT: Controlled Clinical Trial; IFC: Interferential current therapy; NRS: Numeric Rating Scale; VAS: Visual Analogue Scale; ODI: Oswestry Disability Index; PSFS: Patient Specific Functional Scale; ADL: Hannover Activities of Daily Living Questionnaire; OLP: Open-label placebo; MCID: Minimal clinically important difference; CSM: Leventhal's Common-Sense Model; CONNECT: Communication Style and Exercise Compliance in Physiotherapy; CFT: Cognitive Functional Therapy; TTM: Transtheoretical model ('stages of change'); MI: Motivational interviewing; MET: Motivational Enhancement Treatment; PT: Physical therapy; MT-EX: Manual therapy and exercise; TAU: Treatment as usual; ED-EX: Education and exercise; ETMI: Enhanced Transtheoretical Model Intervention; TA: Therapeutic alliance; PNE: Pain neurobiology education; CC: Classical conditioning; PRT: Pain Reprocessing Therapy; ED: Patient education; ED + TA: Patient education and therapeutic alliance.

Supplementary Information

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Additional file 1. The search strategies per database (**Methods S1-S4**), a scoring grid for item 11 of the quality assessment (**Results S1**), a summary of the study characteristics (**Table S1**), and a summary of the within group changes from baseline (**Table S2**).

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Author contributions

BS: review inception, designed protocol, searched databases, identified eligible studies, extracted relevant data, conducted quality assessments, synthesised results, wrote the original draft. DN, CC, CK: review inception, protocol development, screened sample of full-text articles, discussed and interpreted the results. All authors discussed the results, critically reviewed, and commented on earlier drafts of the manuscript, and significantly contributed to and approved the final version. All authors read and approved the final manuscript.

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Availability of data and materials

The dataset generated during and/or analysed during the current study are not publicly available yet since it will be published in Bournemouth University's online research data repository (BORDaR) following the completion of the dissertation. It is available from the corresponding author on reasonable request and with the permission of Bournemouth University via a data sharing agreement.

Declarations

Ethics approval and consent to participate

Not applicable. This is a systematic review; no individual nor identifiable data has been extracted, rather it is derived from published studies.

Consent for publication

Not applicable.

Competing interests

No potential conflict of interest was reported by the authors.

Author details

[1]Department of Rehabilitation and Sport Sciences, Faculty of Health and Social Sciences, Bournemouth University, Bournemouth, England. [2]AECC University College, Bournemouth, England. [3]Department of Sport, Health and Exercise Sciences, Faculty of Health Sciences, University of Hull, Hull, England.

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The following supplementary materials are included in **Appendix I**:

(i) Search strategies per database (Methods S1-S4);
(ii) Scoring grid for item 11 of the quality assessment (refer to Results S1);
(iii) Summary of the study characteristics (refer to Table S1);
(iv) Summary of the within-group changes from baseline for the contextual factor intervention group(s) (refer to Table S2); and
(v) Quality assessment results (refer to Tables S3.1 and S3.2).

These materials aim to promote transparency in the process and outcomes of the review.

3.3. Quality appraisal tool

The modified Downs and Black (1998) scale, comprising 27 items, was selected to assess the methodological quality of studies included in the systematic review (Sherriff et al., 2022), based on its versatility in evaluating both randomised and non-randomised studies and its prior use in similar systematic reviews (Collins et al., 2018; Morton et al., 2014; Richmond et al., 2013). The inclusion of sub-scales covering several methodological components, such as quality of reporting, external validity, internal validity, and statistical power, highlights its suitability (Deeks et al., 2003). Higher scores denoted better methodological quality, enabling a quantitative evaluation of studies. The reported psychometric properties, including internal consistency, test-retest reliability, inter-rater reliability, and criterion validity, confirm the tool's reliability and validity (Deeks et al., 2003; Downs & Black, 1998). It has previously been ranked among the top six quality assessment tools suitable for systematic reviews of non-randomised studies (Deeks et al., 2003). A standardised framework for interpreting the quality assessment scores, based on cut-off points proposed by O'Connor and colleagues (2015), facilitated the classification of studies into different quality categories (excellent, good, fair, and poor). Total scores were then converted into percentages ((study score / total possible score) × 100) to allow for comparisons across study designs. Tables S3.1 and S3.2 present the quality assessment results of the studies included in the systematic review (see Appendix I).

Despite its suitability and robust psychometric properties, it is important to acknowledge potential limitations associated with its application. Modifying the scoring criteria, in line with previous research (Morton et al., 2014; O'Connor et al., 2015), involved adjusting the relevance of criteria for non-randomised designs, such as blinding and random assignment, to accommodate the heterogeneity of included studies. This may have introduced bias into the quality assessment process (Sherriff et al., 2022). Eliminating irrelevant items and adjusting subsequent scoring highlights the complexities of adapting a single tool to accommodate different study designs. Modifying the scale may have affected the validity and reliability of the quality assessment through the risk of introducing bias. The subjective interpretation of these criteria may have introduced variability or inconsistency, potentially resulting in an overestimation of assessment scores or an underestimation of bias. For example, percentage scores for uncontrolled and observational studies were rated out of 22, whereas RCTs were scored out of 28, possibly inflating the corresponding assessment scores.

While efforts were made to ensure consistency, the quality assessment was performed by a single reviewer, potentially introducing subjectivity and bias. This highlights the importance of robust quality assurance measures to mitigate the risk of errors or discrepancies in the assessment process. It is worth noting that the assessment may not fully capture the nuances and complexities inherent in the varying research methodologies. Moreover, the systematic review identified key issues affecting methodological quality, such as the under-representation of certain demographics, geographical clustering of studies, and the use of novel care approaches (Sherriff et al., 2022). These findings imply potential limitations in the generalisability and practical utility of the reviewed studies. However, it is unlikely that the aforementioned limitations meaningfully impacted the interpretation of results, main findings, or overall conclusions drawn.

To address these concerns, future research should consider involving multiple reviewers in the quality assessment process where feasible, aiming to enhance the reliability and validity of findings. Incorporating diverse perspectives and expertise may help minimise bias and ensure a more comprehensive evaluation of study quality. Furthermore, exploring alternative quality appraisal tools tailored to specific study designs or developing standardised guidelines for adapting existing tools could enhance their applicability and validity across heterogenous research methodologies.

3.4. Link to Delphi study

The preliminary Delphi statements were derived from recommendations made by various researchers and relevant reviews, which discussed the potential use of placebo effects in clinical practice (Bishop et al., 2017; Dijkstra et al., 2006; Drahota et al., 2013; Hasenbring & Pincus, 2015; Iyendo et al., 2016; Klinger et al., 2017; Klinger et al., 2018; Klinger & Flor, 2014; Rossettini et al., 2018a; Stewart & Loftus, 2018; Testa & Rossettini, 2016). In addition, the initial findings of the systematic review influenced the design of the Delphi survey and aided in identifying potentially appropriate CF care approaches for patients with cLBP. The link between the systematic review and the Delphi study serves the purposes of development and complementarity in mixed-methods research.

Development aims to utilise the findings from one method to inform and develop the other method (Greene et al., 1989 as cited in Johnson & Onwuegbuzie, 2004). The initial systematic review findings (Sherriff et al., 2022) guided decisions regarding the content and structure of the Delphi survey, exemplifying the purpose of development. For instance, statements like "*Explaining the multi-dimensional nature of pain via suitable educational*

materials," "*Reframing patient's prior misconceptions about low back pain*," "*Using verbal expressions of empathy*," and "*Promoting the patient's sense of relatedness and partnership with you*" illustrate how the review provided initial evidence for their inclusion in the Delphi survey. Moreover, the Delphi study addressed a knowledge gap by including statements that explored the practitioner's beliefs and characteristics, as no previous studies were identified that investigated this CF domain in the systematic review.

Complementarity seeks to elaborate, enhance, illustrate, and clarify results by incorporating different methodological approaches (Greene et al., 1989 as cited in Johnson & Onwuegbuzie, 2004). In this research, the Delphi study captured MSK practitioners' opinions and recommendations, while the systematic review provided a comprehensive analysis of the literature. By combining these approaches, this research aimed to gain a more nuanced understanding of the role of CFs during conservative cLBP treatment. This integrated approach demonstrates the complementary nature of the two research phases.

Chapter 4. Delphi study

4.1. Chapter overview

This chapter presents a published manuscript of a modified Delphi-consensus survey, which constitutes the second study of the multiphase research design. This study aimed to gather insights from eligible MSK practitioners in the UK to establish which CF care approaches were perceived as clinically relevant and influential during conservative cLBP treatment. The manuscript provides a concise background and rationale for the Delphi study, followed by a description of the materials, methods, participant recruitment, data collection procedures, and analysis. The main results of each Delphi round are presented sequentially for each of the five main CF domains. The first-round results include the panel's self-reported use of the 64 statements under consideration and their opinions on the clinical validity of these CF care approaches for patients with cLBP. Between rounds, various amendments were made, including incorporating practitioners' suggestions, refining, and deleting redundant statements to improve the overall clarity. The second-round results indicated the extent of panel consensus regarding the perceived influence of each of the 74 statements during cLBP rehabilitation. The findings are then discussed in relation to the existing literature, accompanied by a consideration of the study's strengths and limitations. Lastly, the chapter concludes with an explanation of how the Delphi study influenced specific research design decisions in the subsequent qualitative study.

4.2. Published manuscript

The undernoted section presents the manuscript published in Chiropractic and Manual Therapies as part of the journal's thematic series titled: *A new paradigm for musculoskeletal pain care: moving beyond structural impairments* as part of the integrated thesis format submission.

See: Sherriff, B., Clark, C., Killingback, C., and Newell, D., 2023. Musculoskeletal practitioners' perceptions of contextual factors that may influence chronic low back pain outcomes: a modified Delphi study. *Chiropractic & Manual Therapies, 31*(1), 1-28.

The following Springer Nature link provides access to the full-text PDF: https://rdcu.be/c9gzO

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Musculoskeletal practitioners' perceptions of contextual factors that may influence chronic low back pain outcomes: a modified Delphi study

Bronwyn Sherriff[1,2*], Carol Clark[1†], Clare Killingback[3†] and Dave Newell[2†]

Abstract

Background Optimal shaping of contextual factors (CFs) during clinical encounters may be associated with analgesic responses in treatments for musculoskeletal pain. These CFs (i.e., the patient-practitioner relationship, patient's and practitioner's beliefs/characteristics, treatment characteristics, and environment) have not been widely evaluated by musculoskeletal practitioners. Understanding their views has the potential to improve treatment quality and effectiveness. Drawing on a panel of United Kingdom practitioners' expertise, this study aimed to investigate their perceptions of CFs during the management of patients presenting with chronic low back pain (LBP).

Methods A modified two-round online Delphi-consensus survey was conducted to measure the extent of panel agreement regarding the perceived acceptability and influence of five main types of CFs during clinical management of patients with chronic LBP. Qualified musculoskeletal practitioners in the United Kingdom providing regular treatment for patients with chronic LBP were invited to take part.

Results The successive Delphi rounds included 39 and 23 panellists with an average of 19.9 and 21.3 years of clinical experience respectively. The panel demonstrated a high degree of consensus regarding approaches to enhance the patient-practitioner relationship (18/19 statements); leverage their own characteristics/beliefs (10/11 statements); modify the patient's beliefs and consider patient's characteristics (21/25 statements) to influence patient outcomes during chronic LBP rehabilitation. There was a lower degree of consensus regarding the influence and use of approaches related to the treatment characteristics (6/12 statements) and treatment environment (3/7 statements), and these CFs were viewed as the least important. The patient-practitioner relationship was rated as the most important CF, although the panel were not entirely confident in managing a range of patients' cognitive and emotional needs.

Conclusion This Delphi study provides initial insights regarding a panel of musculoskeletal practitioners' attitudes towards CFs during chronic LBP rehabilitation in the United Kingdom. All five CF domains were perceived as capable of influencing patient outcomes, with the patient-practitioner relationship being perceived as the most important CF during routine clinical practice. Musculoskeletal practitioners may require further training to enhance their proficiency and confidence in applying essential psychosocial skills to address the complex needs of patients with chronic LBP.

†Carol Clark, Clare Killingback and Dave Newell contributed equally.

*Correspondence:
Bronwyn Sherriff
bsherriff@bournemouth.ac.uk; beesherriff@gmail.com
Full list of author information is available at the end of the article

Keywords Chronic low back pain, Musculoskeletal pain, Contextual factors, Delphi study, Placebo effect, Physician-patient relations, Health professional-patient relations, Physiotherapy, Chiropractic, Osteopathy

Background

Healthcare practitioners' views regarding the recognition and modulation of contextual factors (CFs) during routine clinical practice is important and has the potential to improve the quality and effectiveness of patient care [1, 2]. CFs are integral to both placebo and nocebo effects, capable of triggering positive or negative clinical outcomes, particularly in their capacity to modulate patients' pain [1, 3]. One categorisation of CFs encompasses five broad domains: (i) the patient-practitioner relationship; (ii) patient's characteristics/beliefs; (iii) practitioner's characteristics/beliefs; (iv) the treatment characteristics; and (v) the treatment environment/setting [4]. These CFs are conceptualised to include the patient's perception of both the external context such as the healthcare environment, treatment, and associated social cues, (e.g., verbal suggestions, practitioner features) together with their internal context such as their prior experiences, emotional states, and expectations which then mutually informs their appraisal of future health and wellbeing [1, 3].

CF mediated pain modulation involves defined endogenous neural pathways evoked by psychological processes such as a patient's mindset, expectations, or social and observational learning [5–7]. Both the social and environmental features of the treatment context inform these psychological processes, which are conscious and non-conscious. The mindset of a patient regarding their health, specific illness, and treatment is also influenced by the patient-practitioner relationship which affects both the quality and effectiveness of care received [5, 7, 8]. Accordingly, healthcare practitioners are capable of shaping patients' thoughts and feelings during therapeutic encounters via (a) cognitive care—influencing patients' expectations regarding their treatment or illness beliefs; and (b) emotional care—influencing unhelpful emotional states (e.g., fear, anxiety) through empathy, warmth, and reassurance [4]. In the context of health and illness, dyadic interactions between patients and practitioners serve as a conduit for exchanging sociobiological information [5]. Developing a positive therapeutic alliance or a person-centred approach creates a foundation for interpersonal healing which can either catalyse or inhibit placebo and nocebo effects respectively. How practitioners establish the recovery context can positively shape patients' expectations and influence their clinical outcomes [5, 6]. Optimal shaping of CFs during clinical encounters may be associated with substantive placebo effects such as pain reduction; conversely, a negative treatment environment may be associated with nocebo effects, potentially increasing pain [9]. The patient-practitioner relationship, environmental and social cues, and even the observation of others can add to or stimulate placebo/nocebo effects [3, 5, 6]. The experience and magnitude of such effects is modulated by an individual's psychosocial perceptions, whether positive or negative, which arises from the context in which they occur [3, 5, 10, 11].

A proposed range of clinical applications to potentially harness placebo effects for non-malignant pain was categorised using the five main CF domains [12]. The authors examined 169 studies derived from seven systematic reviews relating to placebo literature across a range of settings. The initial list was evaluated and validated by leading placebo researchers using a survey, resulting in a taxonomy of possible clinical applications to deliberately harness placebo effects during routine practice [12]. Similarly, other clinicians and researchers have also recommended approaches to avoid nocebo effects [13] and enhance placebo effects for pain and musculoskeletal (MSK) disorders [14, 15]. This raises the possibility of ethically harnessing placebo analgesia and integrating such effects into clinical rehabilitation, particularly for MSK pain.

It is important to note that the aforementioned applications originate from a range of studies that may include healthy controls, experimental designs, or have been extrapolated from qualitative research [1, 14, 15]. Accordingly, it is yet to be explicitly uncovered how CFs may be optimally or consistently harnessed to induce placebo analgesia during clinical practice for specific MSK conditions. Moreover, during MSK rehabilitation, predictions in clinical practice may be challenging since disentangling effects underpinned by CFs, effects of complex interventions with interacting components, and confounding factors (e.g., natural history, symptom regression to the mean) is complicated [15, 16]. There is growing recognition that translational placebo research is required [1, 17] to explore and understand patients', practitioners', and other stakeholders' views regarding the ethical and appropriate use of CFs for different MSK disorders, as well as for acute and chronic conditions [1, 12, 15, 17].

Recently, a national Italian survey examining manual therapists' (MTs) perspectives regarding the use of CFs during clinical practice [2] and a subsequent investigation of Italian physiotherapists' views [18] suggest these practitioners believe CFs contribute to therapeutic effects. However, neither focused on the relevance of CFs in relation to a specific MSK condition. Since there are numerous placebo/nocebo effects with distinctive mechanisms across a range of illnesses and interventions [19, 20], it is important to investigate practitioners' attitudes towards the use of CFs for particular health complaints.

MSK conditions account for a considerable proportion of persistent pain globally [21, 22] with low back pain (LBP) being a leading cause of disability [23–26] particularly in regions with higher life expectancies [27]. The prevalence of chronic LBP (i.e., persistent symptoms for 12 or more weeks) is approximately 19.6% between the economically active ages of 20 and 59 years [28]. Persistent LBP negatively impacts patients' quality of life, activity levels, ability to work, and earning potential [27] creating deleterious personal, social, and economic consequences [29–31]. Existing chronic LBP (cLBP) treatments are inadequate [32], and those focusing on symptom management typically provide modest relief [31, 33, 34]. Consequently, multimodal cLBP management strategies incorporating the biopsychosocial perspective are required [32].

There is an opportunity to harness placebo effects and clinical practices which involve social and cognitive pain modulation [35] to improve treatment effectiveness for patients with cLBP [32]. Understanding MSK practitioners' beliefs regarding the deliberate use of CFs during cLBP management may identify areas for further training and skills development. Consequently, there is a need for studies on CFs to support clinicians in implementing contemporary research knowledge in everyday practice [1, 17, 36, 37]. It is unclear whether MSK practitioners believe they have sufficient skills or knowledge to incorporate them into clinical practice which may present a barrier for implementation. Accordingly, it is important to understand practitioners' views to determine whether there is collective agreement on which of these CF care approaches are perceived as clinically valid or appropriate for the management of cLBP. Drawing on United Kingdom (UK) MSK practitioners' collective opinions and knowledge, may help understand the present appetite for the modulation of CFs which are perceived to augment usual care for patients with cLBP and the identification of further potentially effective CFs for further study.

Materials and methods

Aims

The primary aim of this study was to explore a panel of UK MSK practitioners' perceptions regarding the acceptability and influence of five main types of CFs during clinical management of patients with cLBP using an iterative process to determine whether group-level consensus was reached. Accordingly, the primary research questions are: (a) To what extent do a panel of UK MSK practitioners perceive CFs as clinically acceptable care approaches capable of influencing patients cLBP outcomes? And (b) To what extent do the panellists agree with each other regarding the use of CF care approaches to influence clinical outcomes for patients with cLBP? Secondary research questions explore the extent to which the UK panel use and regard CFs as clinically valid and important, and how confident they are in applying CFs during the routine care of patients with cLBP. To clarify, the objective of this Delphi study is not to provide recommendations regarding which CFs are important, nor to prescribe their use by other healthcare practitioners.

Research design

This study involved a modified two-round online Delphi-consensus survey to achieve panel consensus following recommendations for conducting and reporting Delphi studies (CREDES) in palliative medicine where appropriate [38]. Similar methods were used to achieve consensus amongst prominent interdisciplinary placebo researchers regarding the ethical use of placebo/nocebo effects during clinical practice [36], to ascertain what should be disclosed to patients, and how practitioners should be trained [37].

The Delphi-method is a structured group-approach, involving anonymous experts, with the objective of iteratively reducing the range of responses to measure consensus [39]. Compared to the nominal group technique, structured group meetings using an experienced moderator are not necessary enabling broader geographical inclusion [40], encouraging honest and open expression of opinions, and reducing the likelihood of dominant ideas, group pressure or social conformity which can potentially confound the results [41, 42]. The number of rounds was decided a priori since attrition may increase following successive iterations [40, 43]. Consequently, the ideas generation and evaluation phases [39] were combined rather than conducting three rounds. The between-round aims were to refine, clarify and reduce redundant statements whilst including panel suggestions [44]. Incorporating pre-determined content derived

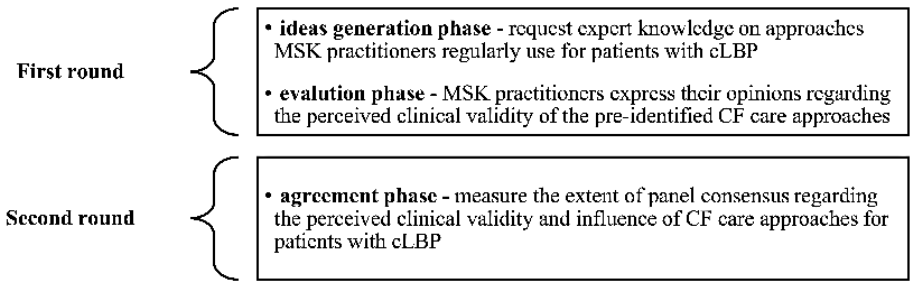


Fig. 1 Purpose of each Delphi round

from literature reviews, guidelines or preparatory work is another accepted Delphi study modification [44]. The purpose of each iteration is presented in Fig. 1 below.

Participants

This study aimed to recruit between 20 and 40 qualified UK MSK practitioners assuming a 25% drop-out rate between rounds (i.e., 15–30 panellists in the last round). This is consistent with a systematic review indicating 64% of Delphi studies had between 11 and 50 participants in the final round [45]. The aim was to recruit a heterogenous group of MSK practitioners with an interest in the study as the purpose, resources, and complexity determine an appropriate panel size [46, 47]. Although there are no clear rules regarding panel selection and size [42], convenience or purposive samples are frequently used [44].

This Delphi study used convenience sampling as potential participants were identified and recruited using direct emails through publicly listed websites (e.g., Chartered Society of Physiotherapy, British Chiropractic Association, General Chiropractic Council, BackCare charity) and social media advertisements (e.g., Musculoskeletal Association of Chartered Physiotherapists Twitter page; Understanding Placebo Effects in Manual Therapy Facebook group). Email invitations were also sent via professional networks and word-of-mouth recommendations (i.e., snowballing). Although National Health Service (NHS) practitioners were not directly targeted, five panellists provided personal email addresses during the first-round.

Participants required at least three years of clinical experience which appears to be a common admission requirement for UK master's training. Since CFs represent psychosocial aspects of care, it was important to include recently qualified MSK practitioners who may have exposure to biopsychosocial training. Panellists therefore self-identified as MSK 'experts', proficient in the rehabilitation of patients with cLBP, based on inclusion–exclusion criteria presented in Table 1 below.

Materials: survey development and piloting

Preliminary Delphi statements were extracted from various researchers' recommendations for potentially harnessing placebo effects during clinical practice and relevant reviews [1, 12–15, 48–54]. The first-round survey was initially developed and piloted with two independent/non-participating Physiotherapists and a Chiropractor providing input concerning: time taken to complete; overall clarity, language, terminology/phrasing; ease of completion (e.g., layout, instructions); general comments and functionality. Following ethics approval, participants were invited to complete the first-round survey. Thereafter, the second-round Delphi survey was modified and piloted ($n = 5$). Two

Table 1 Fligibility criteria

Inclusion criteria	Exclusion criteria
Qualified Physiotherapists, Chiropractors, Osteopaths, or Sports Therapists	Non-qualified/student manual and physical therapists
Three or more years' clinical experience in providing regular care for patients with cLBP	Fewer than three years' clinical experience in providing regular care for patients with cLBP
Currently practising in the United Kingdom	Practising outside the United Kingdom or healthcare practitioners who do not primarily provide manual and physical therapy (e.g., General Practitioners, Psychologists, Orthopaedic surgeons)
Able and willing to respond to an online survey in English	

non-participating Physiotherapists, a Chiropractor, a professor familiar with Delphi studies and survey design, along with an academic who has previously published research relating to CFs critically evaluated the survey to ensure face and content validity. To review the modifications to the survey between rounds, please refer to Additional file 1: Tables S1 and S2 respectively.

Data collection procedure

Bournemouth University's (England) Research Ethics Panel provided ethics approval prior to data collection (**IDs: 28052** and **32406**, approved on 30/10/2019 and 18/06/2020 for each version of the questionnaire respectively). Data were collected over encrypted SSL (TLS) connections via the JISC online survey platform (https://www.jisc.ac.uk/online-surveys) following informed consent, from 13 January until 11 March 2020 and from 23 June until 23 July 2020 for each round respectively.

In total, 64 statements were included in the first round, accompanied by open-ended questions so panellists could provide ideas for each of the five main CF domains. A brief introduction was included, to ensure there was a general understanding of the topic, with verbatim text presented in Fig. 2 below.

Panellists were asked to *"select/tick all applicable column(s)"* if they believed the corresponding statement: (a) reflected a potentially valid care approach; (b) is an approach they currently use as part of their everyday practice; and (c) is an approach they feel confident to use without further training/experience; or alternatively, they believed the corresponding care approach might contribute to or enhance overall treatment effects. An example of the question format was included to ensure the instructions were clear and easy to follow, as depicted in Fig. 3 below.

During the first round, panellists did not rate their agreement levels nor indicate the strength of their preference, they simply selected the applicable response option(s) as depicted in Fig. 3 above. The final section of the survey included basic demographic information (i.e., age, gender, practitioner type, practice setting, and region), and an option to provide their email address for second-round participation. Panellists expressing interest during the first round were subsequently invited to participate in the second-round ($n=31$).

During the second round, demographic data were collected first. Thereafter, panellists rated 74 statements using a five-point Likert scale ranging from strongly disagree (1) to strongly agree (5) to indicate whether they

Introduction:

- Manual and physical therapists use a variety of tools to achieve shared therapeutic goals such as improving patient's pain, physical functioning, and self-perceived health.

- Modifying contextual factors, including psychosocial aspects of care, are a promising supplementary approach to usual care for pain, which can potentially induce pain modulation and influence clinical outcomes via the following domains:

1. **patient's characteristics and beliefs** (e.g., preferences, previous experiences, gender, age);
2. **practitioner's characteristics and beliefs** (e.g., reputation, appearance, beliefs, and behaviours);
3. **the patient-practitioner relationship** (e.g., communication, trust, patient-centred approach);
4. **the treatment features or characteristics** (e.g., clear diagnosis, overt therapy, therapeutic touch);
5. **the physical environment / setting** (e.g., environment, interior design).

- Contextual factors are therapeutic cues which may be essential for the perception and interpretation of care, which can be interpreted positively or negatively, but may dually affect symptom perception, experience, and meaning.

Fig. 2 Copy of the introductory text preceding the first-round survey questions

Example Question

For each statement, you will be able to ***select / tick all applicable column(s)*** if:

a) You believe the statement reflects a potentially valid care approach;
b) It is an approach/technique you currently use as part of your everyday practice;
c) It is an approach/technique you feel confident to use without further training / experience;

For Example:

What is your opinion of the following statements?

	Please tick applicable box(es)			
	a) I think it is a valid approach	b) I use this approach in practice	c) I am confident to use without training	Not applicable
e.g., Switching treatment approaches if a patient expresses prior negative experiences	✓	✓	✓	
e.g., Ensuring treatment areas and equipment are clean		✓	✓	
e.g., Showing signs of being in a hurry (e.g., talking quickly)				✓
e.g., Matching the practitioner and patient according to characteristics (e.g., gender, culture, home language)			✓	

Fig. 3 Example question and response options included in the first-round survey

had intentionally used each CF approach believing it could influence cLBP outcomes. Two additional response options (i.e., *Not Valid*, and *Do Not Recall/Use*—coded as 0 and missing respectively) were provided which is appropriate where participants have varied knowledge or qualifications [43]. The following instructions preceded each set of statements:

- Below is a list of care approaches for patients with chronic or persistent low back pain (LBP).
- Please indicate whether you **have intentionally used** each approach **believing it could influence patient's LBP outcome(s)**.

Panellists were then asked to indicate the extent to which they agreed or disagreed with the influence of each CF approach on patients' cLBP outcome(s) as depicted in Fig. 4 below.

To review original copies of each round of the Delphi survey, refer to Additional file 1: DS-R1 and DS-R2 respectively.

Data analysis

The main analysis involved generating descriptive statistics and frequency tables using SPSS version 28.0. Mean scores were used to rank statements for each of the five main CF domains. Consensus was defined a priori as percentage agreement $\geq$ 75% (i.e., panellists rating 4 or 5) except if a panellist disagreed (i.e., ratings of 1 or 2) or rated the statement as '*Not Valid*' (0) during the second round. Cumulative percentages were calculated to measure overall panel agreement (i.e., ratings $\geq$ 4) for each statement.

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select 'Not **Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s).

	1 – Strongly Disagree	2 – Disagree	3 – Neither Agree nor Disagree	4 – Agree	5 – Strongly Agree	Not Valid	Do Not Recall / Use
1. Remaining attentive and fully focused on the patient throughout the appointment.							
2. Being genuine and honest to instil a sense of trustworthiness and authenticity.							

Fig. 4 Example of the question format and response options during the second-round survey

Results

Response rates

The first-round panel consisted of 39 qualified MSK practitioners in the UK. Thirty-one practitioners expressed interest in the second round, whilst eight did not. Thus, the attrition rate was 25.8% (i.e., 8/31) between the two iterations. Of the 31 invitations sent, another eight were lost to follow-up as depicted in Fig. 5 below. The second-round response rate was 74.2% (i.e., 23/31) with an overall attrition rate from the original sample of 41.0% (i.e., 16/39).

Panel characteristics

During the first round ($n=39$), more than half the panel were male MSK practitioners (56.4%; $n=22$). Overall, the average age was 46.5 years ($S.D.\pm11.7$; range: 28–75 years), with an average of 19.9 years of clinical experience ($S.D.\pm10.3$; range: 3–40 years). During the second round ($n=23$), the majority of the panel were also male MSK practitioners (60.9%; $n=14$). The average age was 47.9 years ($S.D.\pm11.9$; range: 32–75 years) with an average of 21.3 years of clinical experience ($S.D.\pm11.5$; range: 3–41 years). Table 2 below presents a summary of the panel's characteristics for each round.

Self-reported use and perceived influence of CFs

Tables 3, 5, 7, 9 and 11 below describe the panel's ($n=39$) self-reported use of the 64 statements under consideration during the first round, and their perceptions regarding the clinical validity or appropriateness of these CF care approaches for patients presenting with cLBP. Furthermore, Tables 4, 6, 8, 10 and 12 present the panel's ($n=23$) agreement levels with each of the 74 statements under consideration during the second round along with indicating the panel's consensus (i.e., their agreement with each other) regarding the perceived influence of each statement during the treatment of patients with cLBP. Across each of the five main CF domains, statements have been ranked using the Likert-score mean. Consensus was considered to be achieved if at least 75% of the panel ($n=23$) agreed they had deliberately employed the CF care approach believing it was capable of influencing outcomes in patients with cLBP and none

Table 2 Summary of panel's characteristics

Demographic information	Round 1 ($n=39$)		Round 2 ($n=23$)		Total dropouts (%)
	Frequency	%	Frequency	%	
Gender					
Male	22	56.4	14	60.9	8 (20.5)
Female	17	43.6	9	39.1	8 (20.5)
Practitioner type					
Chiropractor	23	59.0	16	69.6	7 (17.9)
Physiotherapist	10	25.6	4	17.4	6 (15.4)
Osteopath	4	10.3	3	13.0	1 (2.6)
Other[a]	2	5.1	0	0	2 (5.1)
Practice setting					
Private practice	28	71.8	18	78.3	10 (25.6)
Public (NHS)	5	12.8	4	17.4	1 (2.6)
Combination	3	7.7	0	0	3 (7.7)
Other[b]	3	7.7	1	4.3	2 (5.1)
Practice region					
South West	10	25.6	7	30.4	3 (7.7)
London	6	15.4	2	8.7	4 (10.3)
South East	6	15.4	4	17.4	2 (5.1)
Wales	5	12.8	4	17.4	1 (2.6)
Scotland	3	7.7	1	4.3	2 (5.1)
East Midlands	3	7.7	1	4.3	2 (5.1)
Yorkshire and the Humber	2	5.1	2	8.7	0 (0)
Northern Ireland	1	2.6	0	0	1 (2.6)
North East and Cumbria	1	2.6	0	0	1 (2.6)
North West	1	2.6	1	4.3	0 (0)
West Midlands	1	2.6	1	4.3	0 (0)

[a] Other practitioners: Chiropractor and Physiotherapist; Clinical Functional Neurologist registered as a Chiropractor

[b] Other settings: Round 1: Private practice and education; education and charity sector; combination of private practice and corporate/manufacturing sectors; Round 2: Educational organisation

of the panel members rated the statement as '*Not Valid*' or disagreed.

Patient-practitioner relationship

Self-reported use, perceived as clinically valid, and self-confidence

During the first round ($n=39$) the self-reported use of CF care approaches to develop the patient-practitioner relationship ranged from 76.9 to 100%. Similarly, CF care approaches which were perceived as potentially valid during the treatment of patients with cLBP ranged from 76.9 to 92.3%. Although 76.9% of the panel thought *applying different forms of touch* was perceived as a clinically valid care approach during the first round, there was insufficient consensus (73.9%) during the second round. The least frequently used diagnostic approach related to exploring the *meaning of the patient's symptoms* (see Table 3, rank 16) with only 53.8% expressing self-confidence.

The self-reported use and perceptions regarding the acceptability of CF care approaches to improve the patient-practitioner relationship were generally higher than the panel's self-confidence to apply them without undertaking further training. Less than 70% of the panel reported being confident about their non-verbal communication skills such as not interrupting the patient or using open body language. More importantly, less than 70% of the panellists were confident about using particular person-centred care approaches such as developing the therapeutic alliance, expressing genuine empathy, engaging in collaborative decision-making, or requesting the patient's opinion. Table 3 below presents a summary of the first-round results.

Table 3 Panel's self-reported use, perceived clinical validity, and confidence concerning the patient-practitioner relationship (Round 1; $n=39$)

Rank	Sub-set	Statement	Self-reported use (%)	Valid (%)	Confidence (%)
Patient-practitioner relationship (k = 17 statements)					
2	Non-verbal behaviour	Being warm, confident, friendly, relaxed, and open during the appointment	100 ($n=39$)	87.2 ($n=34$)	79.5 ($n=31$)
2	Non-verbal behaviour	Using eye contact, smiling, caring expressions of support and interest to convey empathy and compassion	100 ($n=39$)	87.2 ($n=34$)	76.9 ($n=30$)
2*	Using specific diagnostic approach	Providing effective reassurance via clear and understandable explanations	100 ($n=39$)	87.2 ($n=34$)	71.8 ($n=28$)
4.5	Using specific diagnostic approach	Examining the patient fully using appropriate therapeutic 'hands on' touch during the clinical examination	97.4 ($n=38$)	87.2 ($n=34$)	76.9 ($n=30$)
4.5	Person-centred care approach	Ensuring the patient feels listened to and heard (e.g., active listening or noting their responses)	97.4 ($n=38$)	87.2 ($n=34$)	71.8 ($n=28$)
6.5	Non-verbal behaviour	Not rushing or interrupting the patient; giving them time to tell their story	94.9 ($n=37$)	89.7 ($n=35$)	66.7 ($n=26$)
6.5	Person-centred care approach	Engaging in collaborative decision-making with patients (e.g., mutually agreed and flexible goals)	94.9 ($n=37$)	82.1 ($n=32$)	66.7 ($n=26$)
8*	Person-centred care approach	Providing treatment choices and encouraging patients to choose option(s) if they so wish	92.3 ($n=36$)	87.2 ($n=34$)	69.2 ($n=27$)
9.5	Non-verbal behaviour	Using affirmative head nodding, forward leaning, open body postures/orientations	89.7 ($n=35$)	84.6 ($n=33$)	69.2 ($n=27$)
9.5	Person-centred care approach	Promoting the patient's sense of relatedness and partnership with you (i.e., therapeutic alliance)	89.7 ($n=35$)	82.1 ($n=32$)	64.1 ($n=25$)
12	Person-centred care approach	Using verbal expressions of empathy, support, and language reciprocity (e.g., using the patient's words/phrasing)	84.6 ($n=33$)	92.3 ($n=36$)	69.2 ($n=27$)
12*	Person-centred care approach	Requesting the patient's opinions and demonstrating you trust and respect them	84.6 ($n=33$)	84.6 ($n=33$)	64.1 ($n=25$)
12	Person-centred care approach	Individualising the interaction style according to a patient's preference (e.g., collaborative or authoritative)	84.6 ($n=33$)	87.2 ($n=34$)	59.0 ($n=23$)
14*	Using specific diagnostic approach	Providing a detailed, definitive, and confident diagnosis	79.5 ($n=31$)	79.5 ($n=31$)	56.4 ($n=22$)
16	Person-centred care approach	Adopting psychosocial talk or partnership statements (e.g., we, us, together)	76.9 ($n=30$)	82.1 ($n=32$)	66.7 ($n=26$)
16	Non-verbal behaviour	Applying different forms of touch (e.g., assistive touch, touch to prepare the patient, touch to provide information, touch to reassure the patient)	76.9 ($n=30$)	76.9 ($n=30$)	66.7 ($n=26$)
16	Using specific diagnostic approach	Asking questions about the meaning of the patient's symptoms (i.e., what symptoms indicate to them)	76.9 ($n=30$)	82.1 ($n=32$)	53.8 ($n=21$)

If two or more statements had equal percentages of self-reported use, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, three statements ranked combined "second" (i.e., $(1+2+3)/3=2$) and a rank of 4.5 indicates joint "fourth/fifth" (i.e., $(4+5)/2=4.5$) and so forth

*This statement was revised between the two Delphi rounds

Perceived influence: panel consensus

With regards to the patient-practitioner relationship, there was group-consensus for 18 of 19 statements included in the second round. Of these 18 statements, overall levels of agreement were high, ranging from 86.9 to 100%. For six statements, 100% of the panel agreed they had intentionally used non-verbal behaviours, person-centred care approaches, and cognitive reassurance believing it would influence clinical outcomes. Table 4 below presents a summary of these results. Notably, the

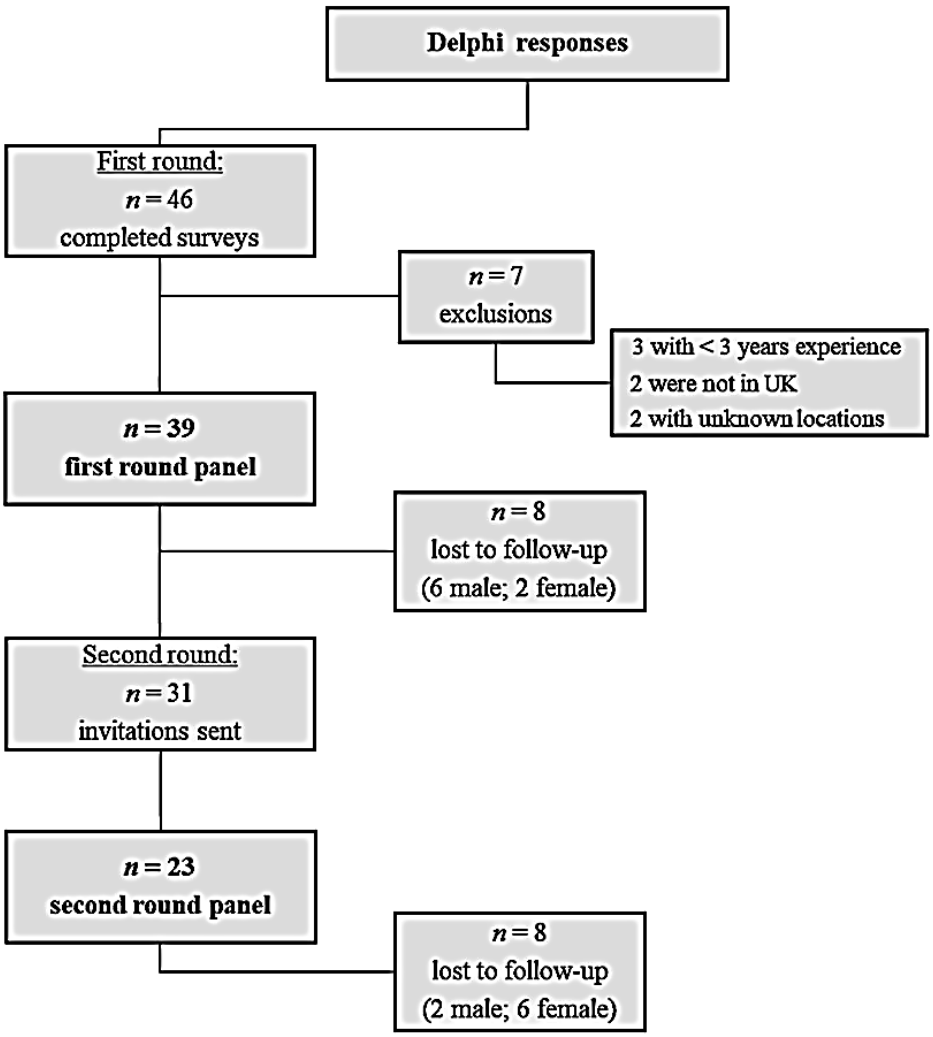


Fig. 5 Flowchart of Delphi responses

only statement where panel consensus was below the 75% threshold (i.e., 73.9% agreement) involved *applying different forms of touch* (see Table 4, rank 19).

Patient's beliefs and characteristics

Self-reported use, perceived as clinically valid, and self-confidence

The self-reported use of CF care approaches aiming to modify patient's beliefs ranged from 51.3 to 100% and perceptions relating to the potential clinical validity during cLBP treatment ranged from 61.5 to 92.3%. The most commonly used CF care approaches which were also perceived as clinically acceptable included actively investigating the patient's needs, feelings, preferences, and previous experiences, and supporting the patient in reframing negative memories (e.g., reinterpret an X-ray, explain radiological reports or GP letters). Notably, the panel's self-reported use of approaches to modify patient's individual beliefs was typically higher than their self-reported confidence.

The two most commonly used cognitive behavioural approaches involved reframing the patient's prior LBP misconceptions and addressing inaccurate treatment beliefs whilst the least commonly used included helping a patient plan and monitor treatment success and empowering each patient to self-care. Less than 40% of the panel were confident to use these CF care approaches despite perceiving them as clinically acceptable. Contrastingly,

Table 4 Summary of panel's agreement levels concerning the patient-practitioner relationship (Round 2; $n = 23$)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
Patient-practitioner relationship (k = 19 statements)							
1.5	Non-verbal behaviour	Using eye contact, smiling, caring expressions of support to convey empathy or compassion	4.74 (± 0.45)	[4.54, 4.93]	73.9% strongly agree 26.1% agree	Yes (100%)	0%
1.5	Using specific diagnostic approach	Providing a meaningful explanation of the patient's LBP (i.e., cognitive reassurance) which is clear, understandable, and can be referred to after treatment	4.74 (± 0.45)	[4.54, 4.93]	73.9% strongly agree. 26.1% agree	Yes (100%)	0%
3.5	Person-centred care approach	Ensuring the patient feels listened to and heard (e.g., active listening or noting their responses)	4.70 (± 0.56)	[4.45, 4.94]	73.9% strongly agree 21.7% agree	Yes (95.7%)	4.3% (unsure)
3.5	Person-centred care approach	Individualising the interaction style according to a patient's preference (e.g., collaborative, or authoritative)	4.70 (± 0.56)	[4.45, 4.94]	73.9% strongly agree 21.7% agree	Yes (95.7%)	4.3% (unsure)
5	Non-verbal behaviour	Being warm, friendly, and relaxed during the appointment	4.65 (± 0.49)	[4.44, 4.86]	65.2% strongly agree 34.8% agree	Yes (100%)	0%
6.5*	Person-centred care approach	Compassionately expressing your understanding of how LBP affects them (e.g., *'I understand how frustrating it is not to be able to walk your dog/go dancing/garden'* etc.)	4.61 (± 0.50)	[4.39, 4.82]	60.9% strongly agree 39.1% agree	Yes (100%)	0%
6.5	Person-centred care approach	Promoting the patient's sense of relatedness and partnership with you (i.e., therapeutic alliance)	4.61 (± 0.58)	[4.36, 4.86]	65.2% strongly agree 30.4% agree	Yes (95.7%)	4.3% (unsure)
9*	Person-centred care approach	Confirming the patient not only heard but also understood the content of your communication	4.57 (± 0.51)	[4.35, 4.78]	56.5% strongly agree 43.5% Agree	Yes (100%)	0%
9	Non-verbal behaviour	Not rushing or interrupting the patient; giving them time to tell their story	4.57 (± 0.59)	[4.31, 4.82]	60.9% strongly agree 34.8% agree	Yes (95.7%)	4.3% (unsure)
9	Person-centred care approach	Engaging in collaborative decision-making together (e.g., mutually agreed, and flexible goals)	4.57 (± 0.66)	[4.28, 4.85]	65.2% strongly agree 26.1% agree	Yes (91.3%)	8.7% (unsure)
12.5	Person-centred care approach	Using verbal expressions of empathy, support, and language reciprocity (e.g., using the patient's words)	4.52 (± 0.51)	[4.30, 4.74]	52.2% strongly agree 47.8% agree	Yes (100%)	0%
12.5	Using specific diagnostic approach	Examining the patient fully using appropriate therapeutic 'hands on' touch during the clinical examination	4.52 (± 0.59)	[4.27, 4.78]	56.5% strongly agree 39.1% agree	Yes (95.6%)	4.3% (unsure)
12.5	Non-verbal behaviour	Using affirmative head nodding, forward leaning, open body postures/orientations	4.52 (± 0.67)	[4.23, 4.81]	60.9% strongly agree 30.4% agree	Yes (91.3%)	8.7% (unsure)
12.5*	Person-centred care approach	Demonstrating you trust or respect the patient and their opinions	4.52 (± 0.67)	[4.23, 4.81]	60.9% strongly agree 30.4% agree	Yes (91.3%)	8.7% (unsure)

Table 4 (continued)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
15	Using specific diagnostic approach	Asking questions about the meaning of the patient's symptoms (i.e., what symptoms indicate to them). ($n=22$)[a]	4.50 (±0.60)	[4.24, 4.76]	54.5% strongly agree 40.9% agree	Yes (95.4%)	4.5% (unsure)
16	Using specific diagnostic approach	Providing a confident diagnosis (e.g., providing a diagram with simple explanations and/or notes)	4.43 (±0.73)	[4.12, 4.75]	56.5% strongly agree 30.4% agree	Yes (86.9%)	13.0% (unsure)
17*	Using specific diagnostic approach	Explaining improvement(s) can be dynamic, and their condition/symptoms may change throughout treatment	4.39 (±0.72)	[4.08, 4.70]	52.2% strongly agree 34.8% agree	Yes (87.0%)	13.0% (unsure)
18	Person-centred care approach	Adopting psychosocial talk or partnership statements (e.g., we, us, together)	4.22 (±0.67)	[3.93, 4.51]	34.8% strongly agree 52.2% agree	Yes (87.0%)	13.0% (unsure)
19	Non-verbal behaviour	Applying different forms of touch (e.g., assistive touch, touch to prepare the patient, touch to provide information, touch to reassure the patient)	3.96 (±0.83)	[3.60, 4.31]	26.1% strongly agree 47.8% agree	**No (73.9%)**	21.7% (unsure) 4.3% disagree

If two or more statements had equal means, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, rank 1.5 indicates joint "first/second" (i.e., $(1+2)/2=1.5$) and a rank of 3.5 indicates joint "third/fourth" (i.e., $(3-4)/2=3.5$) and so forth

*A new item suggested by a panel member during the first round

[a] Where n is < 23, the corresponding responses were excluded from the analysis if the response option '*Do not recall/use*' was selected

Table 5 Panel's self-reported use, perceived clinical validity, and confidence addressing patient's beliefs/characteristics (Round 1; $n=39$)

Rank	Sub-set	Statement	Self-reported use (%)	Valid (%)	Confidence (%)
Patient's beliefs and characteristics (k = 23 statements)					
1.5	Patient's treatment history	Actively investigating patient's needs, feelings, preferences, and previous experiences	100 ($n=39$)	89.7 ($n=35$)	74.4 ($n=29$)
1.5	Patient's treatment history	Supporting the patient in reframing negative memories (e.g., reinterpret an X-ray/scan or explain radiological reports/GP letters)	100 ($n=39$)	89.7 ($n=35$)	64.1 ($n=25$)
3.5*	Cognitive behavioural approach	Reframing patient's prior misconceptions about low back pain (e.g., *'pain is not always a sign of physical tissue damage,' 'your spine is flexible not fragile'*)	97.4 ($n=38$)	87.2 ($n=34$)	71.8 ($n=28$)
3.5*	Patient's treatment history	Taking note of inaccurate knowledge from previous treatment experiences (e.g., *'my spine is crumbling'* or *'my back is worn out'*)	97.4 ($n=38$)	89.7 ($n=35$)	69.2 ($n=27$)
6.5	Cognitive behavioural approach	Reframing patient's prior misconceptions about treatment (e.g., *'bed rest does not usually help patients recover faster but modified activity can'*)	94.9 ($n=37$)	84.6 ($n=33$)	71.8 ($n=28$)
6.5	Reducing negative outcomes	Reinforcing a shift in patient's negative thoughts to positive ones (e.g., outcomes to highlight progress)	94.9 ($n=37$)	87.2 ($n=34$)	59.0 ($n=23$)
6.5	Cognitive behavioural approach	Clarifying maladaptive perceptions (e.g., catastrophising: *'My vertebrae are out of line. I stopped gardening, so I won't end up in wheelchair'*)	94.9 ($n=37$)	84.6 ($n=33$)	59.0 ($n=23$)
6.5*	Cognitive behavioural approach	Assisting in decreasing fear-avoidance and harm beliefs along with avoidant behaviours	94.9 ($n=37$)	87.2 ($n=34$)	59.0 ($n=23$)
9	Creating positive outcomes	Communicating to patients an intervention is likely to be effective (e.g., *'this treatment usually works for most people with low back pain'*)	92.3 ($n=36$)	89.7 ($n=35$)	74.4 ($n=29$)
11.5	Creating positive outcomes	Being optimistic during the consultation and regarding their dysfunction (e.g., *'I believe you will get back to your usual level of functioning again'*)	89.7 ($n=35$)	89.7 ($n=35$)	76.9 ($n=30$)
11.5	Reducing negative outcomes	Allocating time for patients to ask about negative aspects of treatment	89.7 ($n=35$)	89.7 ($n=35$)	66.7 ($n=26$)
11.5	Cognitive behavioural approach	Explaining the multi dimensional nature (biopsychosocial aspects) of pain (i.e., beliefs, emotions, and behaviours (movement and lifestyle)) via suitable educational materials	89.7($n=35$)	87.2 ($n=34$)	61.5 ($n=24$)
11.5	Cognitive behavioural approach	Developing patient's self-confidence in performing and persisting with a new behaviour to pursue a goal	89.7 ($n=35$)	89.7 ($n=35$)	51.3 ($n=20$)
14	Reducing negative outcomes	Anticipating and helping reduce patient's anxiety about the treatment/procedure	87.2 ($n=34$)	92.3 ($n=36$)	56.4 ($n=22$)
15.5	Creating positive outcomes	Emphasising positive outcomes such as overall pain-reducing effects (e.g., *'manual or physical therapies are often as effective as painkillers'*)	82.1 ($n=32$)	79.5 ($n=31$)	66.7 ($n=26$)
15.5*	Sociocultural context[a]	Displaying a balanced attitude to patient's alternative or cultural beliefs if not harmful (e.g., acupuncture)	82.1 ($n=32$)	82.1 ($n=32$)	53.8 ($n=21$)
17	Reducing negative outcomes	Avoiding negative phrases (e.g., 'wear and tear,' 'damage,' 'degeneration,' 'ongoing' instead of 'chronic' pain, 'plan activities' instead of 'do exercise')	79.5 ($n=31$)	87.2 ($n=34$)	56.4 ($n=22$)
18	Reducing negative outcomes	Rephrasing negative information (e.g., during leg flexion test: *'this procedure may lead to a slight increase in pain' rather say instead: 'this procedure might be a bit uncomfortable but only temporarily'*)	76.9 ($n=30$)	89.7 ($n=35$)	59.0 ($n=23$)
19.5*	Cognitive behavioural approach	Helping patients plan and monitor treatment success (e.g., SMART goals, motivational interviewing)	71.8 ($n=28$)	87.2 ($n=34$)	35.9 ($n=14$)

Table 5 (continued)

Rank	Sub-set	Statement	Self-reported use (%)	Valid (%)	Confidence (%)
19.5*	Cognitive behavioural approach	Empowering patients to self-care and anticipate barriers (e.g., reminders, implementation intentions, journal/logbook, NHS online self-care resources)	71.8 ($n=28$)	89.7 ($n=35$)	33.3 ($n=13$)
21*	Sociocultural context[a]	Involving significant others and/or primary carers in treatment	69.2 ($n=27$)	79.5 ($n=31$)	46.2 ($n=18$)
22.5*	Creating positive outcomes	Helping patients associate hands on techniques with positive outcomes using positive verbal instructions (e.g., *'I expect your pain will improve after this manipulation'*)	51.3 ($n=20$)	61.5 ($n=24$)	51.3 ($n=20$)
22.5*	Reducing negative outcomes	Describing how (un)common side effects are numerically (e.g., 1 in 100 people)	51.3 ($n=20$)	76.9 ($n=30$)	38.5 ($n=15$)

If two or more statements had equal percentages of self-reported use, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, rank 1.5 indicates joint "first/second" (i.e., $(1+2)/2=1.5$) and a rank of 3.5 indicates joint "third/fourth" (i.e., $(3+4)/2=3.5$) and so forth

*This statement was revised between the two Delphi rounds

[a] Statements relating to the socio-cultural context were not included in the second round

more than 90% of the panel reported addressing unhelpful illness perceptions and fear-avoidance behaviours, although less than 60% expressed self-confidence. Table 5 below presents a summary of these results.

Perceived influence: panel consensus

There was group-consensus for 21 of 25 statements relating to patient's beliefs and characteristics. For 21 statements, levels of agreement ranged from 82.6 to 100% indicating practitioners were actively using these CF care approaches to influence clinical outcomes. Of the five statements with 100% agreement, four related to the patient's treatment history. Mean rankings suggest examining the patient's treatment history by understanding their prior experiences and addressing misinformed beliefs were perceived as important CFs. Table 6 below presents a summary of these results.

Three statements where consensus was not achieved were new additions from the first round, even though agreement levels exceeded the 75% threshold (see Table 6), specifically, instilling hope (rank 16); explaining self-care involves managing stress (rank 18); and explaining why imaging is unnecessary (rank 23.5). Another statement was below the consensus threshold (73.9% agreement), namely, *emphasising positive outcomes such as overall pain-reducing effects* (see Table 6, rank 25), as 26.1% of the panellists were unsure whether this might influence patient outcomes.

Practitioner's beliefs and characteristics

Self-reported use, perceived as clinically valid, and perceived treatment effects

Self-reported use of CF care approaches relating to the practitioner's own beliefs or characteristics ranged from 56.4 to 100%, whilst their perceptions regarding the potential clinical validity ranged from 53.8 to 89.7%. During the first round, the panel indicated whether they believed each CF care approach might enhance overall treatment effects instead of reporting their self-confidence. Table 7 below presents a summary of these results.

Notably, 100% of the panel reported adapting their mindset or attitude during treatment by remaining attentive and fully focused on patients and being genuine and honest to promote trustworthiness. More than 80% of the panel perceived these CF care approaches as clinically valid and thought they might enhance treatment effects (see Table 7, ranks 1.5). However, 59.0% of the panel reported wearing uniforms or formal clothing whilst only 53.8% perceived it as a clinically valid care approach (see Table 7, rank 6). Similarly, only 56.4% of the panel reported using indicators to tacitly display their expertise, although 66.7% thought these cues (e.g., qualifications) may enhance treatment effects (see Table 7, rank 7).

Perceived influence: panel consensus

There was group-consensus for 10 of 11 statements related to the practitioner's beliefs and characteristics during the second round, with overall levels of agreement ranging from 91.3 to 100% suggesting practitioners were actively adapting their mindset or attitude and demonstrating their expertise believing it could influence clinical outcomes. There were three statements where 100% of the panel agreed that their mindset or attitude could enhance cLBP treatment (see Table 8, ranks 1–3).

However, panel consensus was not met regarding the use of indicators (e.g., qualifications, professional

Table 6 Summary of panel's agreement levels concerning the patient's beliefs/characteristics (Round 2; $n = 23$)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
Patient's beliefs and characteristics (k = 25 statements)							
1	Patient's treatment history	Reframing misinformed beliefs from previous healthcare experiences (e.g., *'my spine is crumbling,' 'my spinal curve is abnormal,' 'my back is worn out'*)	4.91 (±0.29)	[4.79, 5.04]	91.3% Strongly Agree 8.7% Agree	Yes (100%)	0%
2	Patient's treatment history	Actively investigating patient's needs, feelings, preferences, and previous experiences	4.83 (±0.39)	[4.66, 4.99]	82.6% Strongly Agree 17.4% Agree	Yes (100%)	0%
3	Patient's treatment history	Supporting the patient in reframing negative memories (e.g., reinterpret an X-ray/scan or explain radiology reports/GP letters)	4.78 (±0.42)	[4.60, 4.96]	78.3% Strongly Agree 21.7% Agree	Yes (100%)	0%
4.5	Reducing negative outcomes	Allocating time for patients to ask about negative aspects of treatment to address their concerns openly and honestly	4.70 (±0.47)	[4.49, 4.90]	69.6% Strongly Agree 30.4% Agree	Yes (100%)	0%
4.5	Reducing negative outcomes	Anticipating and helping reduce patient's anxiety about the treatment/procedure	4.70 (±0.64)	[4.42, 4.97]	78.3% Strongly Agree 13.0% Agree	Yes (91.3%)	8.7% (unsure)
7*	Cognitive behavioural approach	Explaining routine activities, movement, or exercise can help 'rewire' perceived pain pathways (e.g., *some pain or discomfort is normal but is not a sign their LBP is "worsening"*)	4.65 (±0.57)	[4.40, 4.90]	69.6% Strongly Agree 26.1% Agree	Yes (95.7%)	4.3% (unsure)
7	Cognitive behavioural approach	Clarifying maladaptive perceptions (e.g., catastrophising: *'My vertebrae are out of line. I stopped gardening, so I won't end up in a wheelchair'*)	4.65 (±0.57)	[4.40, 4.90]	69.6% Strongly Agree 26.1% Agree	Yes (95.7%)	4.3% (unsure)
7	Cognitive behavioural approach	Developing patient's self-confidence in performing or persisting with a new behaviour or goal	4.65 (±0.65)	[4.37, 4.93]	73.9% Strongly Agree 17.4% Agree	Yes (91.3%)	8.7% (unsure)
10*	Patient's treatment history	Exploring the patient's current or pre-existing beliefs about the cause(s) of their LBP	4.61 (±0.50)	[4.39, 4.82]	60.9% Strongly Agree 39.1% Agree	Yes (100%)	0%
10	Cognitive behavioural approach	Reframing patient's prior misconceptions about treatment (e.g., *'bed rest does not usually help patients recover faster but modified activity can'*)	4.61 (±0.58)	[4.36, 4.86]	65.2% Strongly Agree 30.4% Agree	Yes (95.7%)	4.3% (unsure)
10	Cognitive behavioural approach	Assisting in decreasing fear-avoidance and harm beliefs by recognising, confronting, and correcting them	4.61 (±0.58)	[4.36, 4.86]	65.2% Strongly Agree 30.4% Agree	Yes (95.7%)	4.3% (unsure)
12.5	Cognitive behavioural approach	Helping patients plan and monitor treatment success (e.g., explain outcome measures; co-create short-term and long-term goals or target-driven stages of improvement)	4.57 (±0.59)	[4.31, 4.82]	60.9% Strongly Agree 34.8% Agree	Yes (95.7%)	4.3% (unsure)
12.5	Creating positive outcomes	Communicating an intervention is likely to be effective using positive verbal instructions (e.g., *'I expect your pain will improve after treatment'*)	4.57 (±0.59)	[4.31, 4.82]	60.9% Strongly Agree 34.8% Agree	Yes (95.7%)	4.3% (unsure)
14	Cognitive behavioural approach	Reframing patient's prior misconceptions about their anatomy/physiology (e.g., *'your spine is flexible not fragile'*)	4.52 (±0.67)	[4.23, 4.81]	60.9% Strongly Agree 30.4% Agree	Yes (91.3%)	8.7% (unsure)

Table 6 (continued)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
16	Reducing negative outcomes	Reinforcing a shift in patient's negative thoughts to positive ones (e.g., monitor outcomes to highlight progress)	4.48 (±0.59)	[4.22, 4.73]	52.2% Strongly Agree 43.5% Agree	Yes (95.7%)	4.3% (unsure)
16	Creating positive outcomes	Being optimistic during treatment by providing a prognosis (e.g., *'I believe you will recover and get back to your usual level of functioning'*)	4.48 (±0.67)	[4.19, 4.77]	56.5% Strongly Agree 34.8% Agree	Yes (91.3%)	8.7% (unsure)
16*	Creating positive outcomes	Instilling genuine hope in patients regarding how their life can change for the better	4.48 (±1.08)	[4.01,4.95]	65.2% Strongly Agree 30.4% Agree	**No (95.6%)**	**4.3% Not Valid**
18*	Reducing negative outcomes	Explaining that calming their stress response is a part of everyday self-care for physical pain and healing. (n = 22)[a]	4.45 (±0.91)	[4.05, 4.86]	59.1% Strongly Agree 36.4% Agree	**No (95.5%)**	**4.5% Strongly Disagree**
20*	Cognitive behavioural approach	Explaining basic pain science (i.e., *perceived pain is not necessarily actual physical pain from nerve or tissue damage, but whilst very real, is more of a 'learned' response to prior experiences*)	4.43 (±0.59)	[4.18, 4.69]	47.8% Strongly Agree 47.8% Agree	Yes (95.7%)	4.3% (unsure)
20	Cognitive behavioural approach	Explaining the multi-dimensional nature (biopsychosocial aspects) of pain (i.e., beliefs, emotions, and behaviours (movement and lifestyle)) via suitable educational materials	4.43 (±0.79)	[4.09, 4.78]	60.9% Strongly Agree 21.7% Agree	Yes (82.6%)	17.4% (unsure)
20*	Reducing negative outcomes	Using simple, everyday analogies to alter patient's negative illness perceptions (e.g., *'rusty hinges often work well despite their appearance'*)	4.43 (±0.79)	[4.09, 4.78]	60.9% Strongly Agree 21.7% Agree	Yes (82.6%)	17.4% (unsure)
22	Reducing negative outcomes	Avoiding negative phrases (e.g., 'wear and tear', 'damage','degeneration', 'abnormal')	4.35 (±0.71)	[4.04, 4.66]	47.8% Strongly Agree 39.1% Agree	Yes (87.0%)	13.0% (unsure)
23.5	Reducing negative outcomes	Rephrasing negative information (e.g., leg flexion test:*'this procedure might be a bit uncomfortable but only temporarily'*)	4.26 (±0.69)	[3.96, 4.56]	39.1% Strongly Agree 47.8% Agree	Yes (87.0%)	13.0% (unsure)
23.5*	Reducing negative outcomes	Explaining imaging is usually unnecessary because scans may not explain the extent of their pain and/or dysfunction	4.26 (±0.96)	[3.84, 4.68]	47.8% Strongly Agree 39.1% Agree	**No (87.0%)**	8.7% (unsure) **4.3% Strongly Disagree**
25	Creating positive outcomes	Emphasising positive outcomes such as overall pain-reducing effects (e.g., *'manual or physical therapies are often as effective as painkillers'*)	4.22 (±0.85)	[3.85, 4.59]	47.8% Strongly Agree 26.1% Agree	**No (73.9%)**	26.1% (unsure)

If two or more statements had equal means, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, a rank of 4.5 indicates joint "fourth/fifth" (i.e., (4 + 5)/2 = 4.5) and three statements ranked combined "seventh" (i.e., (6 + 7 + 8)/3 = 7) and so forth

*A new item suggested by a panel member during the first round

[a] Where *n* is < 23, the corresponding responses were excluded from the analysis if the response option '*Do not recall/use*' was selected

Table 7 Panel's self-reported use, perceived clinical validity and effects of the practitioner's beliefs/characteristics (Round 1; $n=39$)

Rank	Sub-set	Statement	Self-reported use (%)	Valid (%)	Enhance Treatment (%)
Practitioner's beliefs and characteristics (k = 7 statements)					
1.5	Mindset/attitude	Remaining attentive and fully focused on the patient throughout the appointment	100 ($n=39$)	89.7 ($n=35$)	84.6 ($n=33$)
1.5	Mindset/attitude	Being genuine and honest to instil a sense of trustworthiness and authenticity	100 ($n=39$)	87.2 ($n=34$)	82.1 ($n=32$)
3*	Mindset/attitude	Displaying self-confidence without appearing arrogant or dismissive	97.4 ($n=38$)	84.6 ($n=33$)	79.5 ($n=31$)
4	Expertise/credibility	Clearly communicating your expectations (i.e., what you anticipate will occur) whilst administering care	94.9 ($n=37$)	84.6 ($n=33$)	74.4 ($n=29$)
5*	Expertise/credibility	Prescribing or administering treatments you believe and expect to be effective	92.3 ($n=36$)	82.1 ($n=32$)	76.9 ($n=30$)
6*	Expertise/credibility	Wearing a laboratory coat/medical apparel or tailored/formal clothing to symbolise professionalism	59.0 ($n=23$)	53.8 ($n=21$)	59.0 ($n=23$)
7*	Expertise/credibility	Using indicators of expertise/high status (e.g., health qualifications, professional memberships) in offices or correspondence	56.4 ($n=22$)	59.0 ($n=23$)	66.7 ($n=26$)

If two or more statements had equal percentages of self-reported use, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, rank 1.5 indicates joint "first/second" (i.e., $(1+2)/2=1.5$)

*This statement was revised between the two Delphi rounds

memberships) in clinics, online, or via correspondence (71.4% agreement). Practitioners preferred to demonstrate their expertise by clearly communicating their expectations, only administering treatments they expected to be effective, and demonstrating professionalism through their general appearance (e.g., being clean, tidy, and presentable) rather than wearing a medical uniform. A summary of these results is presented in Table 8 below.

Treatment characteristics

Self-reported use, perceived as clinically valid, and perceived treatment effects

Using treatment characteristics ranged from 30.8 to 89.7% whilst perceptions regarding the potential clinical validity ranged from 53.8 to 89.7%. More than 80% of panellists reported encouraging patients to try activity reinforcement strategies and engaging in treatment/exercise with an optimistic mindset. Although continuity of care was commonly used and considered to be a clinically valid care approach during the first round (87.2%), two panellists disagreed during the second round, despite 87.0% believing it might influence patient outcomes.

Only 53.8% of the panel thought increasing the frequency/duration of appointments to provide extra time or attention was a clinically valid care approach, but 64.1% thought it might enhance treatment effects. Providing alternative feedback or encouraging engagement with other patients (see Table 9, ranks 7 and 8 respectively) experiencing positive results were not commonly used nor viewed as clinically valid care approaches. Table 9 below presents a summary of these results.

Perceived influence: panel consensus

There was group-consensus for six of 12 statements relating to treatment characteristics during the second round with agreement levels ranging between 82.6 and 100%. CF care approaches which were perceived to be influential included using reinforcement strategies to increase daily activity, explaining treatment advice in line with patient's expectations, encouraging an optimistic mindset during therapy/exercise, providing self-management materials, demonstrating functional changes following treatment, and providing a patient with clear milestones to demonstrate progress. A summary of these results is presented in Table 10 below.

There was insufficient panel consensus for the remaining six statements; four were below the 75% threshold, whilst another two exceeded it, but panellists rated the statement as *'Not Valid'* and/or expressed disagreement. Two involved modifying appointment features such as ensuring continuity of care and increasing the frequency or duration of appointments. Using verbal or visual feedback (e.g., sharing positive patient stories, or mirrors during exercises) were also not considered to be beneficial nor was explaining the difference between a clinical examination and treatment.

Table 8 Summary of panel's agreement levels concerning the practitioner's beliefs/characteristics (Round 2; $n = 23$)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
3) Practitioner's beliefs and characteristics (k = 11 statements)							
1	Mindset/attitude	Remaining attentive and fully focused on the patient throughout the appointment	4.87 (± 0.34)	[4.72, 5.02]	87.0% Strongly Agree 13.0% Agree	Yes (100%)	0%
2	Mindset/attitude	Being genuine and honest to instil a sense of trustworthiness and authenticity	4.83 (± 0.39)	[4.66, 4.99]	82.6% Strongly Agree 17.4% Agree	Yes (100%)	0%
3*	Mindset/attitude	Displaying a professional and caring (not only "curing") attitude	4.78 (± 0.42)	[4.60, 4.96]	78.3% Strongly Agree 21.7% Agree	Yes (100%)	0%
4.5*	Mindset/attitude	Being calm and compassionate throughout the appointment	4.70 (± 0.56)	[4.45, 4.94]	73.9% Strongly Agree 21.7% Agree	Yes (95.7%)	4.3% (unsure)
4.5	Expertise/credibility	Clearly communicating your expectations (i.e., what you anticipate will occur) whilst administering care	4.70 (± 0.64)	[4.42, 4.97]	78.3% Strongly Agree 13.0% Agree	Yes (91.3%)	8.7% (unsure)
6.5	Expertise/credibility	Administering treatments you expect to be effective	4.61 (± 0.58)	[4.36, 4.86]	65.2% Strongly Agree 30.4% Agree	Yes (95.7%)	4.3% (unsure)
6.5	Mindset/attitude	Displaying self-confidence without appearing dismissive	4.61 (± 0.58)	[4.36, 4.86]	65.2% Strongly Agree 30.4% Agree	Yes (95.7%)	4.3% (unsure)
8*	Mindset/attitude	Creating a caring atmosphere (e.g., appear to have all the time in the world; ensure each patient feels like a priority)	4.52 (± 0.59)	[4.27, 4.78]	56.5% Strongly Agree 39.1% Agree	Yes (95.7%)	4.3% (unsure)
9.5	Expertise/credibility	Demonstrating professionalism through your general appearance (i.e., being clean, tidy, smart, and presentable)	4.48 (± 0.59)	[4.22, 4.73]	52.2% Strongly Agree 43.5% Agree	Yes (95.7%)	4.3% (unsure)
9.5*	Mindset/attitude	Actively build rapport with each patient (e.g., discuss common interests/hobbies; enquire about their lives)	4.48 (± 0.67)	[4.19, 4.77]	56.5% Strongly Agree 34.8% Agree	Yes (91.3%)	8.7% (unsure)
11	Expertise/credibility	Using indicators to display your expertise or credibility (e.g., qualifications, insurance, professional memberships) in reception/office, website, or correspondence. ($n = 21$)[a]	4.00 (± 0.89)	[3.59, 4.41]	33.3% Strongly Agree 38.1% Agree	**No (71.4%)**	23.8% (unsure) **4.8% Disagree**

If two or more statements had equal means, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, a rank of 4.5 indicates joint "fourth/fifth" (i.e., (4 + 5)/2 = 4.5) and so forth

*A new item suggested by a panel member during the first round

[a] Where *n* is < 23, the corresponding responses were excluded from the analysis if the response option '*Do not recall/use*' was selected

Table 9 Panel's self-reported use, perceived clinical validity, and effects of treatment characteristics (Round 1; $n=39$)

Rank	Sub-set	Statement	Self-reported use (%)	Valid (%)	Enhance Treatment (%)
Treatment characteristics (k = 8 statements)					
1	Appointment features	Ensuring the patient is cared for by the same practitioner/therapist (i.e., continuity of care)	89.7 ($n=35$)	87.2 ($n=34$)	79.5 ($n=31$)
2.5	Treatment advice or options	Overtly encouraging patients to engage in therapy/exercise with an optimistic mindset to try establish positive associations with pain relief	84.6 ($n=33$)	87.2 ($n=34$)	76.9 ($n=30$)
2.5	Treatment advice or options	Encouraging patients to find suitable incentives/reinforcement strategies to increase daily activity (e.g., personalised activities, exercise partners)	84.6 ($n=33$)	89.7 ($n=35$)	69.2 ($n=27$)
4*	Treatment advice or options	To show and tell the patient that as a therapy is applied it helps (e.g., *'I am applying pressure here because it helps…'*)	66.7 ($n=26$)	61.5 ($n=24$)	66.7 ($n=26$)
5*	Appointment features	Verbalising future treatment plans by stating the number of appointments and/or follow-ups (e.g., *'I will treat you every second week for 30 min'*)	61.5 ($n=24$)	66.7 ($n=26$)	64.1 ($n=25$)
6	Appointment features	Increasing the frequency and/or duration of appointments (i.e., provide extra time/attention)	59.0 ($n=23$)	53.8 ($n=21$)	64.1 ($n=25$)
7	Alternative feedback	Administering treatments along with visual feedback (e.g., using mirrors during exercises)	41.0 ($n=16$)	71.8 ($n=28$)	61.5 ($n=24$)
8*	Alternative feedback	Enabling patients to engage with other patients undergoing treatment with positive results (e.g., group exercise classes, sharing success stories/testimonials, informally in the waiting area)	30.8 ($n=12$)	59.0 ($n=23$)	51.3 ($n=20$)

If two or more statements had equal percentages of self-reported use, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, rank 2.5 indicates joint "second/third" (i.e., $(2-3)/2=2.5$)

*This statement was revised between the two Delphi rounds

Treatment environment/setting

Self-reported use, perceived as clinically valid, and perceived treatment effects

Using CF care approaches to enhance the treatment environment ranged from 46.2 to 92.3% whilst the perceptions of their potential clinical validity ranged from 56.4 to 82.1%. Ensuring adequate privacy for patients was most commonly used, whereas positive distractors (e.g., soothing music, nice aromas) were used less frequently. Overall, less than 60% of the panellists thought altering the décor or layout was likely to enhance the overall treatment effects except for providing privacy, natural lighting, and ensuring a comfortable temperature. Table 11 below presents a summary of these results.

Perceived influence: panel consensus

There was only group-consensus for three of seven statements relating to the treatment environment. Of these, agreement levels ranged from 87.0 to 91.3%. All three related to the interior design including providing adequate privacy, ample natural lighting, a comfortable temperature, and ensuring clinic facilities are tidy. Contrastingly, there was insufficient consensus regarding the clinic's décor (36.4–69.6%). Despite exceeding the 75% threshold, one panellist disagreed that rearranging furniture or seating in treatment rooms influenced patient outcomes. These results are summarised in Table 12 below.

Perceived importance of CFs

The panel rated the patient-practitioner relationship as the most important CF whilst the treatment environment/setting was perceived as the least important CF during the treatment of patients with cLBP. Summary statistics for each of the main CF domains are presented in Table 13 below.

Additionally, the panel were asked to select one of the main CF domains which they perceived as being the most and least important during the treatment of patients with cLBP. Similar to the results presented in Table 13, Fig. 6 below indicates that nearly half the panel selected the patient-practitioner relationship

Table 10 Summary of panel's agreement levels concerning the treatment characteristics (Round 2; $n = 23$)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
Treatment characteristics ($k = 12$ statements)							
1	Treatment advice or options	Encouraging patients to find suitable incentives/reinforcement strategies to increase daily activity (e.g., personalised activities, exercise partners)	4.52 (± 0.51)	[4.30, 4.74]	52.2% Strongly Agree 47.8% Agree	Yes (100%)	0%
2*	Treatment advice or options	Explaining your treatment advice in line with the patient's treatment expectations	4.48 (± 0.67)	[4.19, 4.77]	56.5% Strongly Agree 34.8% Agree	Yes (91.3%)	8.7% (unsure)
3	Treatment advice or options	Overtly encouraging patients to engage in therapy/exercise with an optimistic mindset to try establish positive associations with pain relief. ($n = 22$)[a]	4.45 (± 0.74)	[4.13, 4.78]	59.1% Strongly Agree 27.3% Agree	Yes (86.4%)	13.6% (unsure)
4*	Treatment advice or options	Demonstrating whether functional change has occurred immediately after treatment (e.g., pain, range of motion, or strength)	4.39 (± 0.67)	[4.11, 4.68]	47.8% Strongly Agree 43.5% Agree	Yes (91.3%)	8.7% (unsure)
5*	Treatment advice or options	Providing self-management materials (e.g., videos, rehabilitation booklets) or email/telephone support to promote a patient's engagement in physical activities. ($n = 22$)[a]	4.32 (± 0.65)	[4.03, 4.60]	40.9% Strongly Agree 50.0% Agree	Yes (90.9%)	9.1% (unsure)
6.5	Alternative feedback	Providing patients with clear milestones or signposting to indicate their progression through the treatment programme	4.22 (± 0.74)	[3.90, 4.54]	39.1% Strongly Agree 43.5% Agree	Yes (82.6%)	17.4% (unsure)
6.5	Appointment features	Ensuring the patient is cared for by the same practitioner/therapist (i.e., continuity of care)	4.22 (± 1.20)	[3.70, 4.74]	52.2% Strongly Agree 34.8% Agree	**No (87.0%)**	4.3% (unsure) **4.3% Disagree** **4.3% Not Valid**
8	Alternative feedback	Displaying feedback from other patients to provide reassurance (i.e., testimonials displayed on TV in waiting area, or online via website). ($n = 17$)[a]	3.88 (± 0.99)	[3.37, 4.39]	29.4% Strongly Agree 41.2% Agree	**No (70.6%)**	17.6% (unsure) **11.8% Disagree**
9*	Alternative feedback	Sharing positive stories of other (anonymous) patients with similar problems or goals. ($n = 22$)[a]	3.86 (± 1.08)	[3.38, 4.34]	22.7% Strongly Agree 54.5% Agree	**No (77.3%)**	18.2% (unsure) **4.5% Not Valid**
10	Alternative feedback	Administering treatments along with visual feedback (e.g., using mirrors during exercises). ($n = 20$)[a]	3.80 (± 1.06)	[3.31, 4.29]	30.0% Strongly Agree 35.0% Agree	**No (65.0%)**	20.0% (unsure) **15.0% Disagree**
11	Appointment features	Increasing the frequency and/or duration of appointments (i.e., provide extra time/attention). ($n = 22$)[a]	3.64 (± 1.43)	[3.00, 4.27]	36.4% Strongly Agree 22.7% Agree	**No (59.1%)**	22.7% (unsure) **9.1% Disagree** **4.5% Strongly Disagree** **4.5% Not Valid**
12*	Treatment advice or options	Clearly explaining the difference between a clinical examination and treatment. ($n = 21$)[a]	3.62 (± 0.97)	[3.18, 4.06]	23.8% Strongly Agree 23.8% Agree	**No (47.6%)**	42.9% (unsure) **9.5% Disagree**

*A new item suggested by a panel member during the first round

[a] Where n is < 23, the corresponding responses were excluded from the analysis if the response option '*Do not recall/use*' was selected

Table 11 Panel's self-reported use, perceived clinical validity and effects of the treatment environment (Round 1; $n=39$)

Rank	Sub-set	Statement	Self-reported use (%)	Valid (%)	Enhance Treatment (%)
Treatment environment/setting (k = 9 statements)					
1	Interior design/layout	Ensuring treatment facilities have privacy provisions (e.g., private changing area and treatment room, curtains/blinds on windows)	92.3 ($n=36$)	82.1 ($n=32$)	61.5 ($n=24$)
2*	Interior design/layout	Considering seating provisions in treatment office (e.g., relative position to desk, additional chairs for carer)	87.2 ($n=34$)	79.5 ($n=31$)	59.0 ($n=23$)
3.5	Setting's décor	Waiting areas and treatment facilities are uncluttered and tidy	84.6 ($n=33$)	71.8 ($n=28$)	59.0 ($n=23$)
3.5*	Setting's décor	Decorating the waiting area with cheerful ornamentation (e.g., healthy indoor plants, leisure reading materials, comfortable cushions)	84.6 ($n=33$)	71.8 ($n=28$)	59.0 ($n=23$)
5	Interior design/layout	Ensuring facilities have ample natural light or windows, and are suitably heated/ventilated (i.e., comfortable temperature)	79.5 ($n=31$)	79.5 ($n=31$)	69.2 ($n=27$)
6	Setting's décor	Providing visual indicators or cues to signify it is a medical setting (e.g., model of spine, patient information brochures, medicalised décor)	71.8 ($n=28$)	64.1 ($n=25$)	53.8 ($n=21$)
7*	Interior design/layout	Considering seating provisions in the waiting areas (e.g., quantity, varying chair sizes, general arrangement)	64.1 ($n=25$)	74.4 ($n=29$)	59.0 ($n=23$)
8*	Setting's décor	Using nature artworks that include green vegetation, flowers, or water may help to reduce anxiety	48.7 ($n=19$)	59.0 ($n=23$)	59.0 ($n=23$)
9*	Setting's décor	Combining positive distractors such as soft or soothing music, nice aromas, hot or cold beverages	46.2 ($n=18$)	56.4 ($n=22$)	59.0 ($n=23$)

If two or more statements had equal percentages of self-reported use, then fractional ranks were computed by averaging the ordinal ranks to reflect ties. For example, rank 3.5 indicates joint "third/fourth" (i.e., $(3+4)/2=3.5$)

*This statement was revised between the two Delphi rounds

(47.8%; $n=11$) as the most important CF, followed by the patient's beliefs and characteristics (30.4%; $n=7$). Contrastingly, Fig. 7 below demonstrates the majority of the panel rated the treatment environment/setting (73.9%; $n=17$) as the least important CF during cLBP treatment.

Discussion

Recently, a range of CFs within therapeutic encounters have been highlighted as potentially influencing placebo analgesia in clinical practice for patients with MSK conditions and non-malignant pain [12–15]. These CF care approaches have not been widely evaluated amongst MSK practitioners to determine whether they are perceived as clinically acceptable and/or whether they are being deliberately harnessed during everyday clinical practice. Clinicians' views and use of CFs is limited [2, 18], particularly in relation to specific MSK conditions. Accordingly, this Delphi study aimed to examine the extent to which a UK panel of MSK practitioners perceived CFs as acceptable modulators of outcomes for patients with cLBP and their use in clinical practice to determine if there was group consensus.

This Delphi study found three useful insights. Firstly, the UK panel of MSK practitioners perceived that all five CF domains (i.e., the patient-practitioner relationship, the patient's and the practitioner's beliefs/characteristics, the treatment characteristics, and environment [4]) were capable of influencing cLBP outcomes. Secondly, practitioners reported a lack of confidence in applying some of these CF care approaches, and these findings suggest potential training opportunities which could assist MSK practitioners in better adopting CFs aimed at supporting a positive therapeutic encounter. Lastly, the panel's collective views indicated that the patient-practitioner relationship was perceived as the most important CF during cLBP treatment.

Agreement with the five main CF domains

The UK panel demonstrated a high degree of consensus regarding the perceived influence, perceived clinical validity or acceptability and intentional use of person-centred communication, non-verbal behaviours, and diagnostic practices such as effective reassurance to enhance the *patient-practitioner relationship.* This is

Table 12 Summary of panel's agreement levels concerning the treatment environment or setting (Round 2; $n = 23$)

Rank	Sub-set	Statement	Mean (S.D.)	[95% CIs]	Agreement levels	Panel consensus	Percentage Disagree
Treatment environment/setting (k = 7 statements)							
1	Interior design/layout	Ensuring treatment facilities have privacy provisions (e.g., private changing area and treatment room, curtains/blinds on windows)	4.52 (± 0.67)	[4.23, 4.81]	60.9% Strongly Agree 30.4% Agree	Yes (91.3%)	8.7% (unsure)
2	Interior design/layout	Rearranging the furniture or seating provisions in the treatment office (e.g., relative position to desk, additional chairs for carer)	4.35 (± 0.89)	[3.97, 4.73]	56.5% Strongly Agree 26.1% Agree	**No (82.6%)**	13.0% (unsure) **4.3% Disagree**
3	Setting's décor	Ensuring waiting areas and treatment facilities are uncluttered and tidy	4.22 (± 0.67)	[3.93, 4.51]	34.8% Strongly Agree 52.2% Agree	Yes (87.0%)	13.0% (unsure)
4	Interior design/layout	Ensuring treatment facilities have ample natural light or windows, and are suitably heated/ventilated (i.e., comfortable temperature)	4.13 (± 0.55)	[3.89, 4.37]	21.7% Strongly Agree 69.6% Agree	Yes (91.3%)	8.7% (unsure)
5	Setting's décor	Creating a positive ambience or atmosphere (e.g., flowers, plants, interesting magazines, friendly staff, relaxing background music, warm lighting)	3.87 (± 1.22)	[3.34, 4.40]	34.8% Strongly Agree 34.8% Agree	**No (69.6%)**	21.7% (unsure) **4.3% Disagree** **4.3% Not Valid**
6	Setting's décor	Providing visual indicators or cues to signify it is a medical setting (e.g., model of spine, patient information brochures, medicalised décor)	3.61 (± 1.27)	[3.06, 4.16]	30.4% Strongly Agree 21.7% Agree	**No (52.1%)**	34.8% (unsure) **8.7% Disagree** **4.3% Not Valid**
7	Setting's décor	Using nature artworks that include green vegetation, flowers, or water features. ($n = 22$)[a]	3.36 (± 1.14)	[2.86, 3.87]	18.2% Strongly Agree 18.2% Agree	**No (36.4%)**	54.5% (unsure) **4.5% Disagree** **4.5% Not Valid**

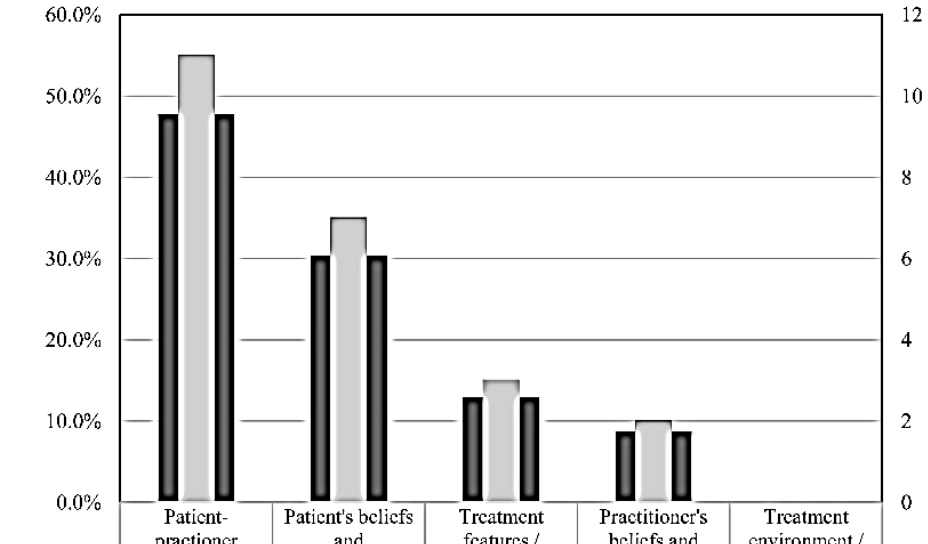
[a] Where n is < 23, the corresponding responses were excluded from the analysis if the response option '*Do not recall/use*' was selected

Table 13 Summary statistics rating the perceived importance of main CF domains (Round 2; $n = 23$)

Rank	Main CF domain	Mean (S.D.)	95% Confidence Interval	Median; Interquartile Range (Min–Max)
1	Patient-practitioner relationship	6.17 (± 0.65)	5.89–6.46	6.00; 1 (5–7)
2	Patient's beliefs and characteristics	6.09 (± 0.73)	5.77–6.40	6.00; 1 (5–7)
3	Practitioner's beliefs and characteristics	5.78 (± 0.74)	5.46–6.10	6.00; 1 (4–7)
4	Treatment characteristics	5.48 (± 1.08)	5.01–5.95	6.00; 1 (2–7)
5	Treatment environment/setting	4.91 (± 1.00)	4.48–5.34	5.00; 2 (3–7)

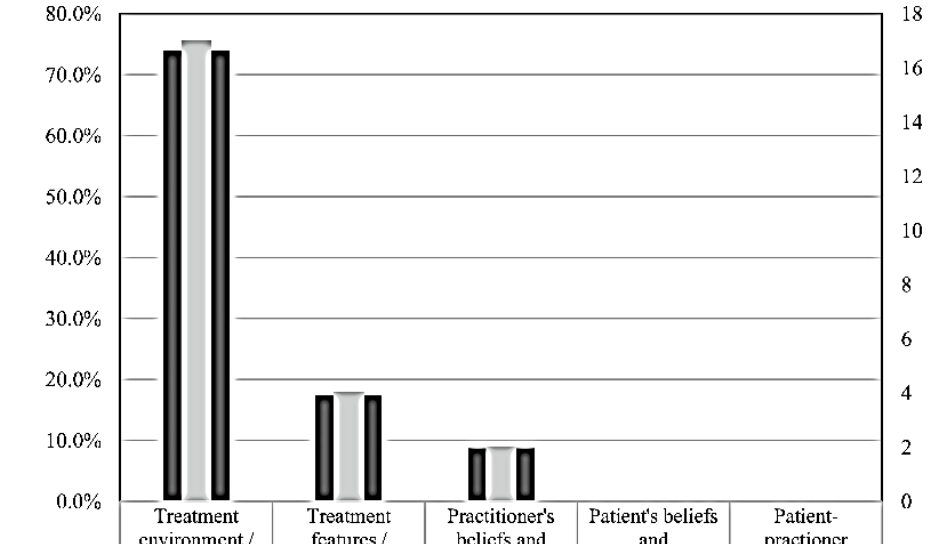
Question: *On a scale ranging from 1 (not at all important) to 7 (extremely important), based on your experience and beliefs, please rate the importance of each contextual factor to the patient's treatment during the healthcare encounter*

Response options: 1 – Not at all important; 2 – Low importance; 3 – Slightly important; 4 – Neutral; 5 – Moderately important; 6 – Very important; 7 – Extremely important



	Patient-practioner relationship	Patient's beliefs and characteristics	Treatment features / characteristics	Practitioner's beliefs and characteristics	Treatment environment / setting
Percentage	47.8%	30.4%	13.00%	8.70%	0%
Frequency	11	7	3	2	0

Fig. 6 Panel's perception regarding the most important CF domain during cLBP treatment



	Treatment environment / setting	Treatment features / characteristics	Practitioner's beliefs and characteristics	Patient's beliefs and characteristics	Patient-practioner relationship
Percentage	73.9%	17.4%	8.7%	0.0%	0.0%
Frequency	17	4	2	0	0

Fig. 7 Panel's perception regarding the least important CF domain during cLBP treatment

consistent with findings from a national survey of Italian MTs ($n=558$) as the most beneficial CFs included developing an empathic therapeutic alliance and using a person-centred approach [2]. Similarly, the therapeutic relationship was rated as the most important CF in a national survey of Italian physiotherapists ($n=699$) where key practices included adopting a person-centred approach, active listening, paraphrasing, and metaphors to facilitate improved patient understanding [18]. Essential CF care approaches for developing the patient-practitioner relationship include expressing empathy, warmth, friendliness, and authentic interest or involvement [5]. Purposeful body language to demonstrate active listening, genuine concern, and responsiveness to the patient can also strengthen the relationship [5].

Three beneficial inter-related care approaches in acute care settings included therapeutic listening, person-centredness, and responding to the patient's emotions and unmet needs [55]. These approaches were associated with improvements in quality of life, anxiety and depression, treatment adherence, and patient satisfaction. Contrastingly negative interactions were linked to psychological distress as patients felt invalidated or dehumanised [55]. Likewise, key factors influencing the patient-practitioner relationship during MSK treatment include the practitioner's interpersonal and communication skills; practical training and expertise; ability to provide patient education; person-centred and individualised care; along with time and flexible appointments [56]. Notably, there was a lack of consensus by the UK panel regarding the influence of different forms of touch (e.g., to assist, reassure or provide information) which differs from the Italian MTs [2] and may indicate cultural differences concerning the perceived effects of touch during MSK treatment.

The UK panel also exhibited a high degree of consensus regarding *patient's beliefs and characteristics*, perceiving these CFs as acceptable modulators of clinical outcomes during cLBP management. The patient's history and prior experiences were consistently viewed as influential CFs, along with attempting to reduce a patient's anxiety about their treatment and discussing any concerns. Anticipatory anxiety activates cholecystokinin which facilitates pain transmission and is implicated in the nocebo response [19]. Accordingly, the UK panel may be helping to reduce anticipatory anxiety and potentially preventing negative outcomes by understanding each patient's prior experiences along with actively managing their anxiety and addressing their specific concerns. Likewise, the Italian MTs thought the patient's expectations, preferences, and previous experiences had potentially beneficial effects and often used these approaches on a weekly or daily basis [2]. The Italian physiotherapists rated the patient's characteristics and beliefs as the second most important CF whilst noting the most useful approaches related to stimulating positive expectations and taking the patient's expectations into account [18]. In our Delphi study there was insufficient panel consensus regarding the role of imaging, stress-management, instilling hope in recovery, or emphasising the pain-reducing effects of manual/physical therapies. Explaining severe injury or illness has been ruled out combined with a thorough physical examination may help reassure patients scans are unnecessary [57]. Furthermore, person-centred education to address misinformed pain-related beliefs and verbal suggestions to influence symptom change expectations may augment conservative treatment in patients with cLBP [54].

The UK panel displayed a high degree of consensus regarding *practitioner's beliefs and characteristics* as CFs capable of influencing clinical outcomes. In our Delphi study, being attentive, kind, calm, compassionate, genuine, honest, creating a caring atmosphere, and ensuring every patient feels prioritised were consistently used and perceived as influential approaches to build trust. However, there was insufficient panel consensus regarding the use of indicators to display their expertise. Preferred ways to demonstrate professionalism included clearly communicating their expectations, and wearing clean, smart clothing rather than a uniform. Uniforms were also not viewed as important by the Italian MTs and physiotherapists [2, 18] but were often worn by MTs in the private sector or hospitals [2]. The Italian MTs believed their professional reputation might have some beneficial effects but did not frequently use it [2], whilst the Italian physiotherapists rated communication strategies as the most important way to demonstrate their professionalism, followed by their reputation, and hygiene/cleanliness [18]. In a recent systematic review, higher levels of clinician/experimenter confidence, competence, professionalism, as well as positive body language (e.g., smiling, tone of voice, eye-contact) modulated pain [58]. This highlights the importance of MSK practitioners being mindful of how patients might perceive their body language and professional attitudes, as subtle cues can influence pain [1, 15, 58].

The UK panel reached consensus for half the statements concerning the *treatment characteristics* including using reinforcement strategies to increase daily activity, providing self-management materials, encouraging an optimistic mindset during therapy, explaining treatment advice in line with a patient's expectations, and demonstrating functional changes following treatment. Important needs of patients include a clear understanding of their LBP [59], consistent, comprehensible, and

individualised information relating to their prognosis, treatment options, and self-management tools, which consider their work and healthcare concerns [60]. Notably, there was insufficient panel consensus regarding the use of visual feedback (e.g., mirrors), altering appointment features, ensuring continuity of care, or sharing positive stories of other (anonymous) patients to provide reassurance. It is possible that MSK practitioners are unaware of the role of social or observational learning mechanisms associated with placebo analgesia [1, 3, 15]. Italian MTs reported using mirrors and physical contact to inform, assist, prepare, and take care of the patient on a daily basis [2] which differs from the UK panel and might indicate another cultural difference. The treatment characteristics were rated the third most important CF by the Italian physiotherapists [18], although comparable statements (e.g., one-to-one versus group sessions, and price) were not included in our Delphi study.

The *treatment environment* was perceived as the least important CF overall, and group-consensus was only achieved for three statements relating to the interior design, namely, adequate privacy, uncluttered treatment facilities, and a comfortable environment. The UK panel's views are comparable to the Italian MTs and physiotherapists as both focused on a comfortable environment [2, 18]. A comfortable setting was viewed as more beneficial for patients than the architecture (windows, skylights) or the use of decorations, ornaments, and colours amongst Italian MTs [2]. Using relaxing music, soft lighting and creating a comfortable treatment setting may provide an opportunity to manage negative emotions such as fear or anxiety, which are common in patients with MSK pain [15, 50–52]. Rehn and Schuster [61] emphasise how appropriate design elements evoke expectations which can promote healing and support treatment by influencing patients' experiences and health behaviour. Consequently, there may be a missed opportunity to improve patient outcomes by leveraging additional features of the treatment environment.

Lack of confidence in applying CFs

Despite recognising the patient-practitioner relationship as the most important CF, the UK panel were not entirely confident in applying a range of person-centred care approaches. Furthermore, these MSK practitioners were not altogether confident handling patients' negative emotional states, explaining the multi-dimensional nature of pain, using cognitive-behavioural approaches to challenge unhelpful beliefs/behaviours, cultivating self-efficacy, or promoting self-management strategies. This is important because it helps identify skills gaps which may support the optimal use of CFs during cLBP rehabilitation.

A growing body of evidence suggests emotional and cognitive factors influence pain processing, pain-related distress, and coping responses in patients with cLBP [57, 62]. Accordingly, a key recommendation of this Delphi study is MSK practitioners require further training to enhance their proficiency and confidence in applying essential psychosocial skills to address the complex needs of patients with cLBP. For instance, educational interventions to assist MSK practitioners in changing patients' unhelpful illness beliefs may serve to augment the treatment of pain-related disability [54, 63]. Another example may include targeted interventions to address MSK practitioners misinformed or erroneous beliefs (e.g., use of imaging scans for LBP management/diagnosis) [63]. Similarly, adopting a framework to promote person-centredness in MSK practice may help to cultivate and enhance the therapeutic relationship (see [64] for applied clinical principles). Moreover, different training formats (e.g., face-to-face, and online) should be used to inform clinicians about placebo/nocebo effects [37]. Supporting practitioners' skills development and confidence through bespoke short courses, workshops/seminars, which include practical exercises and activities, may be beneficial. Additionally, co-creating such interventions with both patients and practitioners may help ensure common challenges encountered during LBP rehabilitation are incorporated.

Perceived importance of CFs

The UK panel's collective ratings may indicate some of the main CF domains were perceived as more important during the treatment of patients with cLBP. The *patient-practitioner relationship* was generally perceived as the most important CF, followed by the *patient's beliefs and characteristics,* with higher levels of panel consensus for these respective CF domains. The *practitioner's beliefs and characteristics* were rated as the third most important, followed by the *treatment characteristics,* whereas the Italian physiotherapists rated them vice versa [18]. Both the UK panel and the Italian physiotherapists [18] perceived the *treatment environment* as the least important CF overall. However, these questionnaires were not identical, which may explain these differences to some extent. Notably, in our Delphi study, there was limited variability between these main CF domains. It may therefore be useful for future studies to consider using a larger sample of MSK practitioners to determine if there is sufficient evidence to indicate a hierarchy of importance regarding the use of CFs during clinical practice. Additionally, whether there is a hierarchy of importance that is reflected by clinical outcomes remains to be studied.

Future research might consider developing a standardised and validated questionnaire to investigate

practitioners' awareness, attitudes towards, and use of CFs during clinical practice. Greco and colleagues [65] have developed the Healing Encounters and Attitudes Lists (HEAL) for patients, but an equivalent version is not available for practitioners. It is therefore challenging to make direct comparisons across regions and professions because there is a lack of uniformity on how these broad CF domains have been operationalised and measured.

Strengths and limitations

Strengths of the current study was the use of piloting to refine the statements included in the Delphi to ensure reasonable face and content validity. Additionally, statements were extracted from a range of sources which may have reduced researcher bias, but also provides an extensive array of CF care approaches which may be beneficial in clinical practice. The self-reported use of CFs during the management of patients with cLBP was relatively high. It is possible the UK panellists may have (inadvertently) responded in a socially desirable manner and it is unclear how frequently or consistently these approaches were applied. Furthermore, panel members self-selected to participate in this Delphi study based on their interest in the topic of CFs and their expertise as MSK practitioners. Accordingly, it is likely that self-selection/recruitment bias occurred, which may mean the panel's perceptions may not represent the views of other MSK practitioners who are less familiar with, or less interested in the topic of CFs, or those working within public healthcare settings (NHS). For this reason, it would be worthwhile to test these findings using a larger sample size along with aiming to reduce selection bias in future. Further limitations include: the response options differing between rounds, as this may have affected the overall methodological rigour; the time lag between iterations, arising from the impact of Covid-19 during data collection, which may have affected the overall response rates; and that a study protocol was not pre-registered, which is recommended for future research.

Lastly, since a conservative approach was used to define panel consensus, the authors acknowledge this may have skewed some of the results (i.e., where agreement levels exceeded 75% but panel consensus was not achieved as a result of dissenting opinion(s)). The authors recognise percentage cut-off points are somewhat arbitrary and may impact the overall interpretation of the data. However, including cases of minority dissenting views does not appear to have substantively altered the conclusions. A conservative approach was taken since those expressing dissent might give further information regarding other MSK practitioners' views which may provide an indication of skills/knowledge gaps or identify potential barriers for the future implementation of CFs during routine clinical practice.

Conclusion

This Delphi study provides initial insights regarding a panel of UK MSK practitioners' attitudes towards the influence, use, and relative importance of CFs during cLBP treatment. All five CF domains were perceived as capable of influencing patient outcomes, with the *patient-practitioner relationship* being perceived as the most important CF during routine clinical practice. Various skills gaps were highlighted where supplementary training may support MSK practitioners' capacity to address their patients' complex cognitive and emotional needs. Increasing practitioners' knowledge of CFs may help them to optimally harness these therapeutic effects and potentially improve patients' outcomes during cLBP rehabilitation.

Abbreviations

CFs	Contextual factors
CI	Confidence Interval
MSK	Musculoskeletal
MTs	Manual therapists
LBP	Low back pain
cLBP	Chronic low back pain
UK	United Kingdom
CREDES	Conducting and REporting DElphi studies
NHS	National Health Service
HEAL	Healing Encounters and Attitudes Lists

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12998-023-00487-4.

Additional file 1: **Table S1**. Synopsis of new statements included in second round survey. **Table S2**. Summary of amendments to statements between rounds. Copy of Delphi Survey – Round 1 (DS–R1). Copy of Delphi Survey – Round 2 (DS–R2).

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Author contributions

BS: study design or conception, drafting and piloting surveys, participant recruitment, data collection, data analysis, and drafting the initial manuscript. DN, CC, CK: study design or conception, commented on provisional survey drafts, participant recruitment, discussed and interpreted the results. All authors discussed the results, critically reviewed, and commented on earlier manuscript drafts, and significantly contributed to, read, and approved the final manuscript.

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Availability of data and materials
The dataset generated and/or analysed during the current study are not publicly available yet since it will be published in Bournemouth University's online research data repository (3ORDaR) following the completion of the dissertation. It is available from the corresponding author on reasonable request and with the permission of Bournemouth University via a data sharing agreement.

Declarations

Ethics approval and consent to participate
Ethics approval was obtained from Bournemouth University's (England) Research Ethics Panel prior to data collection (IDs: 28052 and 32406 for each version of the questionnaire respectively). Participation was entirely voluntary, and participants were able to withdraw without penalty. No coercion, nor deception was used. Participants who wished to be informed of the study's findings were debriefed. All results have been presented in the aggregate only.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Department of Rehabilitation and Sport Sciences, Faculty of Health and Social Sciences, Bournemouth University, 504 Bournemouth Gateway Building, 10 St Paul's Lane, Bournemouth, Dorset BH8 8AJ, England. [2]AECC University College, Bournemouth, England. [3]Department of Sport, Health and Exercise Sciences, Faculty of Health Sciences, University of Hull, Hull, England.

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Publisher's Note

The following supplementary materials are included in **Appendix II**:

(i) A synopsis of the new statements included in the second round (refer to Table S1);
(ii) A summary of the amendments to the statements between rounds (refer to Table S2);
(iii) A copy of the first round Delphi survey (refer to DS-R1);
(iv) A copy of the second round Delphi survey (refer to DS-R2); and
(v) Discussion of the mean 95% Confidence Intervals.

These materials aim to promote transparency in the Delphi study's process and outcomes by providing access to the amended statements and instruments used in the research.

4.3. Link to qualitative study

The findings from the Delphi study influenced the design of the subsequent qualitative study. To address potential response bias stemming from the relatively high self-reported use of CF care approaches by Delphi panellists (Sherriff et al., 2023), an inclusive approach was adopted in the qualitative study. It incorporated both patients' and MSK practitioners' perspectives to triangulate data and explore their experiences of LBP consultations aiming to assess the involvement of CFs. This approach aligns with the purpose of triangulation, which seeks convergence and corroboration of results across different methods investigating the same phenomenon (Greene et al.,. 1989 as cited in Johnson & Onwuegbuzie, 2004).

Furthermore, the Delphi findings indicated that the majority of panellists expressing interest in CFs were MSK practitioners in private practice (Sherriff et al., 2023). Considering the ongoing strain on NHS services during the pandemic and the limited integration of Chiropractors, Osteopaths, and Sports Therapists within the NHS, involving NHS practitioners in the qualitative study was not feasible. Accordingly, the study concentrated on recruiting eligible participants from private practice settings to gain more detailed insights into MSK practitioners' experiences with CFs and their relevance in clinical practice. This is consistent with the purpose of expansion, which involves broadening the scope and range of research by using different methods for different inquiry components (Greene et al.,. 1989 as cited in Johnson & Onwuegbuzie, 2004). By incorporating multiple perspectives and employing different methods, this research aimed to enhance the overall interpretation of the data and gain a more comprehensive understanding of the topic.

To ensure effective engagement with eligible participants, adjustments were necessary because of lockdown restrictions. Initially, recruitment targeted participants who had recently experienced virtual consultations for LBP, reflecting the use of remote consultations

during that period. However, as the research context rapidly evolved, several ethics amendments were made based on feedback from MSK practitioners during the data collection phase. These allowed for adjustments to the recruitment approach and inclusion-exclusion criteria to ensure the qualitative study remained relevant and responsive to the changing circumstances of the research context.

Chapter 5

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5. Qualitative study

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See: https://eprints.bournemouth.ac.uk/40101/

Chapter 6. Discussion

6.1. Chapter overview

This chapter presents an integrated discussion of the findings derived from three consecutive studies that were conducted to investigate the role of CFs in the conservative management of cLBP. The chapter begins by briefly introducing the research problem, the respective research questions, and an overview of each study. Subsequently, a synopsis of the key findings is presented. The focus then shifts to each of the five main CF domains (i.e., patient's beliefs/characteristics, practitioner's beliefs/characteristics, patient-practitioner relationship, treatment characteristics, and treatment environment) and their role and influence during cLBP management. Thereafter, a conceptual map is presented to illustrate the interconnectedness of CFs in clinical practice together with a proposed process of clinical change suggesting potential modifications during LBP consultations. This chapter then delves into the role of illness representations, as explained by the Common-sense model, and the practitioner's role in influencing illness and treatment representations. The unique contribution of this research are highlighted, and potential practical, educational, and theoretical implications are explained. The chapter briefly evaluates the strengths and limitations of the studies and suggests directions for future research aiming to advance the understanding of CFs in the context of conservative cLBP rehabilitation.

6.2. Introduction

The aim of this study was to investigate the role and influence of CFs during conservative cLBP management. This is important because cLBP is a significant public health concern that leads to considerable disability worldwide, and profoundly impacts affected individuals' quality of life (Briggs et al., 2018; James et al., 2018). While clinical guidelines recommend conservative treatments, specifically biopsychosocial approaches (Foster et al., 2018; Traeger et al., 2017), there is a need to better understand the role of CFs during conservative care. Di Blasi and colleagues (2001) introduced a framework that captured key elements of clinical encounters and categorising CFs into five broad domains. These CF domains include the beliefs and characteristics of both the patient and the practitioner, the patient-practitioner relationship, the treatment characteristics, and the environment (Di Blasi et al., 2001). Acknowledging and targeting implicit or 'non-specific' elements within clinical encounters – referred to as CFs – may have important impacts on the modulation of pain and disability which could enhance the quality and effectiveness of care (Rossettini et al., 2020; Testa & Rossettini, 2016). Translational research is needed to explore ethical ways of harnessing CFs

(Colloca & Miller 2011b), given patients' and practitioners' underexplored perspectives (Bishop et al. 2017; Hardman et al., 2019). Examining the role and influence of CFs during usual care rehabilitation may assist in identifying which CFs have the potential to be clinically useful. The following overarching research question supported the aim of this study:

> Which CFs have an impact on patients' outcomes during conservative cLBP management and are perceived as relevant from a clinical perspective?

Additional research questions aiming to address identified knowledge gaps included:

1) What is the impact of interventions modifying CFs during conservative cLBP care on patients' pain and physical functioning outcomes?
2) What is the extent of panel consensus amongst MSK practitioners regarding the perceived acceptability and influence of CFs during cLBP rehabilitation?
3) What are the views of patients and practitioners on their experiences of LBP consultations and to what extent are CFs involved?

These research questions were operationalised using three consecutive studies: (1) a systematic literature review, (2) a modified Delphi-consensus survey, and (3) semi-structured interviews with patient-practitioner dyads.

6.3. Overview of each study

6.3.1. Study 1: Systematic literature review

The first study involved a systematic review of the current literature which aimed to examine the impact of interventions modifying CFs during conservative care on patient's pain and physical functioning outcomes (Sherriff et al., 2022; reported in Chapter 3). Four electronic databases (Medline, CINAHL, PsycINFO and AMED) were searched resulting in 3,476 unique citations. After initial screening, 170 full-text records were potentially eligible and assessed against the inclusion–exclusion criteria. Thereafter, methodological quality was assessed, data were extracted, and then synthesised using a narrative approach (Sherriff et al., 2022).

Twenty-one primary studies ($N = 3{,}075$ participants) were included in the review. Eight studies reported significant improvements in pain intensity, and seven in physical functioning, in favour of CF-modification(s) (Sherriff et al., 2022). Notable CFs included: addressing unhelpful illness beliefs; verbal suggestions to influence expectations of

symptom change; visual or physical cues to suggest pain-relieving treatment properties; and positive communication, such as empathy, to enhance the therapeutic alliance (Sherriff et al., 2022). Among the included studies, the majority focused on the patient's beliefs, followed by the patient-practitioner relationship. Notably, there was only one small study with a 'Fair' rating that examined the treatment setting, and no studies that specifically investigated the practitioner's beliefs or characteristics (Sherriff et al., 2022). This suggest that there is a paucity of research regarding these two CF domains during cLBP rehabilitation.

These findings provide useful insights into the role of CFs during cLBP treatment and suggest CFs may have an adjunctive role in augmenting usual care treatments and improving patients' pain intensity and physical functioning outcomes. The initial review findings influenced the design of the subsequent Delphi survey, by identifying potentially suitable CF care approaches for patients with cLBP. The Delphi study also included statements about the perceived influence of practitioner's beliefs and characteristics on patient outcomes to help address the knowledge gap identified in the systematic review.

6.3.2. Study 2: Delphi study

The second consecutive study involved a modified two-round online Delphi-consensus survey to measure the extent of panel consensus regarding the perceived acceptability and influence of CFs during LBP rehabilitation (Sherriff et al., 2023; reported in Chapter 4). Qualified MSK practitioners in the UK providing regular treatment for patients with cLBP were invited to take part. The successive Delphi rounds included 39 and 23 panellists with an average of 19.9 and 21.3 years of clinical experience respectively (Sherriff et al., 2023). The panel indicated a high degree of consensus regarding the influence of CFs during cLBP rehabilitation. Specifically, enhancing the patient-practitioner relationship (18/19 statements); leveraging their own characteristics/beliefs (10/11 statements); modifying the patient's beliefs and considering the patient's characteristics (21/25 statements) with the intention of influencing patient outcomes (Sherriff et al., 2023). However, there was a lower degree of consensus regarding the influence and use of approaches related to the treatment characteristics (6/12 statements) and treatment environment (3/7 statements), and these CFs were viewed as comparatively less important (Sherriff et al., 2023).

In general, all five CF domains were perceived as influential in shaping patient outcomes, with the patient-practitioner relationship being considered the most important CF during clinical practice (Sherriff et al., 2023). The panel also highlighted the importance of the patient's beliefs/characteristics and their own beliefs/characteristics during cLBP

management. However, the panel were not entirely confident in managing a range of patients' cognitive and emotional needs (Sherriff et al., 2023). MSK practitioners may require further training to enhance their proficiency and confidence in applying essential psychosocial skills to address the complex needs of patients with cLBP (Sherriff et al., 2023). These findings provide a deeper understanding of the perceived importance of CFs during cLBP rehabilitation, particularly from the perspective of MSK practitioners in the UK, in addition to highlighting areas for future research and training.

The Delphi study findings influenced the design of the subsequent qualitative study. To address potential response bias resulting from the relatively high self-reported use of CF care approaches by Delphi panellists (Sherriff et al., 2023), the qualitative study adopted an inclusive approach. It incorporated the perspectives of both patients and MSK practitioners to triangulate data and gain insights into their experiences of LBP consultations, with the aim of assessing the involvement of CFs.

6.3.3. Study 3: Qualitative study

The third and final study (reported in Chapter 5) involved separate semi-structured interviews with three patient-practitioner dyads (n = 6) to gain deeper insights into the perceived importance and perceived influence of CFs during LBP consultations. The three dyads involved patients with cLBP and their respective MSK practitioners following private care appointments for persistent LBP. These dyads were recruited from three separate MSK clinics in England. Through interviews with patient-practitioner dyads, four main themes emerged: the journey with LBP, quality of the relationship, shared recovery journey, and quality of the treatment space. Notable features of these LBP consultations involving the use of CFs were identified.

Firstly, the values, beliefs, and characteristics of MSK practitioners were pivotal in shaping their approach during LBP consultations, which is a novel finding considering the limited evidence in the systematic review. Practitioners' overall philosophy of practice[2] allowed them to gather crucial information, explore important aspects of each patient's experience, establish an initial rapport, and identify any unaddressed patient needs. Secondly, to establish trusting therapeutic relationships, practitioners' person-centredness and

[2] The concept of philosophy of practice encapsulates the fundamental values, guiding principles, and beliefs that inform practitioners' clinical approach and interactions with patients (Trede & Higgs, 2009). This philosophy is shaped by various factors, including their professional experiences, personal background, education, practice setting, and learning from reflective practice (Trede & Higgs, 2009). It encompasses their mindset, treatment strategies, and their approach to delivering care. Essentially, it is rooted in and reflects their core beliefs, values, and perspectives, which in turn shapes their patient care approach and overall ethos (Trede & Higgs, 2009).

interpersonal communication skills were essential, ensuring that patients felt supported, empowered, and engaged in their journey towards recovery. Thirdly, practitioners acknowledged the significance of tailoring treatments to address each patient's complex needs, which helped set realistic expectations for their recovery. The beliefs and characteristics of practitioners played a significant role in shaping each interaction, allowing for authentic connections to be formed with patients. Lastly, the treatment environment also played a necessary role in creating a safe, clean, and welcoming space for patients, which served as a supportive foundation for effective communication. Accordingly, CFs were intertwined throughout LBP consultations and were instrumental in ensuring that patients care experiences were positive.

6.4. Integrated findings

6.4.1. Summary of findings across studies

A synopsis of the key findings from the three studies is presented in Table 4 below. Subsequently, these findings are discussed in relation to each CF domain, exploring their potential implications and providing additional insights.

Table 4. Synopsis of key findings per study across each CF Domain

CF Domains (Di Blasi et al., 2001)	**Systematic Review** (Sherriff et al., 2022)	**Delphi Study** (Sherriff et al., 2023)	**Qualitative Study**
Patient's beliefs and characteristics	Strongest evidence relates to patients' expectations and beliefs (medium to large effect sizes)	Perceived as important CF domain (Consensus: 21/25 statements)	Shaped by the practitioner's attitudes, beliefs, and behaviours
Practitioner's beliefs and characteristics	No studies met the inclusion-exclusion criteria	Perceived as important CF domain (Consensus: 10/11 statements)	Shapes the quality of interactions during LBP consultations
Patient-practitioner relationship	Person-centred communication to promote the therapeutic alliance (TA); impact of TA alone unclear; interventions involved multiple CFs	Perceived as most important CF domain (Consensus: 18/19 statements)	Shaped by person-centred care approach and the practitioner's attitudes, beliefs, and behaviours
Treatment characteristics	Included studies did not manipulate the treatment characteristics alone; interventions involved multiple CFs	Perceived as fairly important CF domain (Consensus: 6/12 statements)	Practitioners shaped the credibility of treatments and informed both patients' treatment and recovery expectations
Treatment environment	Single study identified; lowest quality assessment grade	Perceived as least important CF domain (Consensus: 3/7 statements)	Patients valued clean, safe, and welcoming treatment environments

Table 4 highlights that each study provided useful insights into the role of CFs during cLBP management. Firstly, the systematic review yielded compelling evidence suggesting that *patients' expectations and beliefs* have a considerable impact on clinical outcomes, with medium to large effect sizes observed (Sherriff et al., 2022). This implies that what patients expect and believe about their LBP and their treatment can impact the effectiveness of these interventions. Likewise, patient beliefs and characteristics emerged as an important CF in the Delphi study, with a consensus being reached for 21 of 25 statements (Sherriff et al., 2023). This agreement reinforces the notion that patient beliefs are a key CF that must be considered during cLBP management given their influence on treatment outcomes. The qualitative study further solidified the prominence of the patient's beliefs and characteristics, particularly in relation to the role of MSK practitioners influencing patients' beliefs, expectations, and mindsets. Additionally, the qualitative study sheds light on the dynamic relationship between practitioners and patients, highlighting the potential for practitioners to influence patient beliefs and recovery expectations. This interplay may have implications for the decision-making process and patient recovery.

Despite the lack of eligible studies meeting the inclusion-exclusion criteria in the systematic review, the two subsequent studies shed light on the importance of the *practitioner's beliefs and characteristics* in managing cLBP. The Delphi study highlighted that MSK practitioners perceived the practitioner's beliefs and characteristics as an important CF domain, with 10 out of 11 statements reaching consensus (Sherriff et al., 2023). This consensus emphasises the potential impact of practitioners' individual traits and beliefs on patient outcomes in cLBP management. The qualitative study provided further insights, revealing that MSK practitioners' characteristics and beliefs shaped the quality of patient-practitioner interactions and the development of a strong patient-practitioner relationship, indicating it is an influential CF. Patients felt heard and understood when practitioners took the time to listen to their experiences, which increased their confidence in their practitioner's ability to help. Patients valued attributes such as kindness, calmness, welcoming demeanour, friendliness, professionalism, and knowledgeable practitioners, indicating the significance of these traits in shaping positive patient experiences.

Similarly, a person-centred communication style emerged as a key factor in promoting the *therapeutic relationship* in the systematic review (Sherriff et al., 2022). Although the impact of the relationship alone was unclear, effective interventions involving multiple CFs were shown to influence patient outcomes (Sherriff et al., 2022). Likewise, the patient-practitioner relationship was perceived as the most important CF in the Delphi study, with strong consensus on 18 of 19 statements (Sherriff et al., 2023). This highlights the significance of

establishing a positive and collaborative relationship in cLBP management. The qualitative study further emphasised the patient-practitioner relationship, revealing that it was shaped by person-centred practices and the attitudes and behaviours of the practitioner. The individual traits and actions of the practitioner can positively impact the dynamics of the therapeutic relationship. By adopting a person-centred communication style and being mindful of their own attitudes and behaviours, practitioners can enhance the patient's experience and influence treatment outcomes.

In the systematic review, *treatment characteristics* were not manipulated alone, and interventions involved multiple CFs, making it challenging to isolate their specific impact on clinical outcomes (Sherriff et al., 2022). This exemplifies the complexity of real-world interventions, where various factors interact to influence treatment effectiveness. The Delphi study revealed that treatment characteristics were perceived as fairly important, with consensus being reached on 6 of 12 statements (Sherriff et al., 2023). Although not the most salient CF, treatment characteristics may still shape patients' experiences and beliefs about their treatment. The qualitative study accentuated the role of practitioners in shaping the credibility of treatments and informing patients' treatment and recovery expectations. How treatments were presented and discussed can influence patients' perceptions of their effectiveness. Meaningful treatment characteristics that may positively influence patients' expectations include articulating an optimistic prognosis, demonstrating functional progress, collaborative goal setting, and establishing treatment credibility.

The systematic review only identified one study involving the *treatment environment*, which received a 'Fair' quality assessment grade (Sherriff et al., 2022). This limited evidence calls for further research to better understand its influence on patient outcomes. It also underlines the scarcity of high-quality studies specifically focusing on this CF domain. The treatment environment/setting was perceived as the least important CF in the Delphi study, with consensus being reached for only 3 of 7 statements (Sherriff et al., 2023). From the perspective of MSK practitioners, the Delphi study's lower level of consensus suggests that while the treatment environment was considered relevant and capable of influencing outcomes, it was considered less influential compared to other CFs (Sherriff et al., 2023). Accordingly, there was limited evidence, and a relatively low perceived importance of the treatment environment by practitioners. However, the qualitative study offered useful insights from the patient's perspective, revealing that patients valued a clean, safe, and welcoming treatment environment. It was perceived to have a positive impact on patients' emotions and perceptions, fostering open communication to support their recovery, and shaping their overall perceptions of care.

The studies collectively demonstrate the adjunctive role of CFs in enhancing usual care treatment for cLBP and the complexity and interconnectedness of the five CF domains (Sherriff et al., 2022; 2023). The patient's beliefs/characteristics, the practitioner's beliefs/characteristics, the patient-practitioner relationship, treatment characteristics, and the treatment environment all play integral roles in shaping patient experiences and treatment outcomes. This research has suggested that modifying multiple CFs may have a more meaningful impact on clinical outcomes (Sherriff et al., 2022). In both the Delphi study and the qualitative study, MSK practitioners described actively leveraging CFs during LBP consultations with the intention of positively influencing patients' emotions and perceptions to support their recovery (Sherriff et al., 2023). These MSK practitioners recognised the potential influence of all five main CF domains on patient outcomes (Sherriff et al., 2023).

However, the Delphi study highlighted the need for training opportunities to improve practitioners' knowledge of CFs, which may help them harness CFs more effectively to support positive therapeutic encounters (Sherriff et al., 2023). This is important because Delphi panellist expressed a lack of confidence in specific areas where they were less assured in their skills, indicating the complexity and fluidity of these interactions (Sherriff et al., 2023). These areas included handling patients' negative emotional states, explaining the multi-dimensional nature of pain, using cognitive-behavioural approaches to challenge unhelpful beliefs/behaviours, cultivating self-efficacy, and promoting self-management strategies (Sherriff et al., 2023). To address these skill gaps and support the optimal use of CFs during cLBP rehabilitation, improving MSK practitioners' training and education is necessary. Supplementary training in effective communication skills (e.g., motivational interviewing) and practical implementation of person-centred practices, along with using cognitive-behavioural approaches and self-management strategies may be beneficial (Sherriff et al., 2023). These insights may help inform the development of more effective and person-centred interventions for cLBP and guide the development of training initiatives for MSK practitioners to better adopt CFs in their practice. Further research is required to validate these findings and explore the impact of CFs on clinical outcomes in different settings and populations, as well as examine the complex interplay between all five CFs during MSK treatment.

Overall, these studies suggest that a more holistic approach to cLBP management is needed, one that considers the various CFs that influence patient outcomes. This may involve a shift towards focusing on person-centred care, with an emphasis on building strong patient-practitioner relationships, addressing patients' beliefs and expectations, and tailoring treatment to individual patient needs. It may also involve a more collaborative and multi-

disciplinary approach to care, concentrating on addressing the psychosocial factors contributing to cLBP. Bespoke interventions for disabling LBP such as Cognitive Functional Therapy (CFT; see O'Sullivan et al., 2018) provide a useful approach which may help MSK practitioners implement these ideas in clinical practice. Altogether the three studies suggest that the integration of CFs into the management of cLBP is important and can positively influence patient outcomes. Accordingly, MSK practitioners should consider the influence of both the patient's beliefs and characteristics, their own characteristics and beliefs, and the patient-practitioner relationship when designing and implementing care plans for patients with cLBP. By doing so, practitioners can help address the complex and multifaceted nature of cLBP to improve patient outcomes.

In clinical practice, the concept of mind-body dualism may not be particularly useful as it could undermine a person-centred and holistic approach to care. However, placebo analgesia exemplifies the intentional targeting of CFs (specifically physical, psychological, and interpersonal elements of care) that can influence clinical outcomes. Although there are different ways to modulate pain, purposefully harnessing CFs represents a potentially low-risk and cost-effective strategy, which could be broadly implemented across different treatment modalities. Explicitly inducing placebo analgesia may be influenced by the practitioner's ability to create a credible, consistent, and coherent "story" by modulating CFs during clinical interactions (Sherriff et al., 2022). Patients continuously process internal and external factors, including past experiences and interpersonal cues during healthcare appointments (Wager & Atlas, 2015). These factors shape patients' perceptions and cognitive processes, thereby impacting their expectations regarding symptom improvement or change.

6.4.2. The role of cognitive representations

Mental models are cognitive representations that aid understanding, reasoning, prediction, and decision-making (Getner, 2001). These models draw on past experiences, serving as dynamic frameworks for making predictions and inferences. However, they can be prone to inaccuracies because of idiosyncratic internal and external cues and the influence of socio-cultural knowledge (Getner, 2001). Mental models include common-sense rules of cause and effect, guiding perception, interpretation, and integration of new information (Reisberg, 2001). Individuals continuously adapt and modify their responses based on prior knowledge and experiences, along with employing problem-solving strategies when predictions are incongruent with reality (Reisberg, 2001). Mental models encompass various internal representations, including cognitive schema (Getner, 2001).

Conceptual processes integrate information from multiple brain systems to form an overall schema or conceptualisation of the situation, helping individuals make sense of their experiences (Wager & Atlas, 2015). In healthcare contexts, cognitive representations guide individuals' interpretation and understanding of events and their implications for survival and well-being (Wager & Atlas, 2015). These schemata are shaped by a combination of sensory cues, internal motivation, interoceptive information, and thoughts, extending beyond external cues to incorporate internal factors like motivation and bodily states (Wager & Atlas, 2015). Schema assist individuals in interpreting and responding to specific situations by activating associated scripts or behavioural responses that are context-specific and adaptive, allowing them to anticipate and meet the demands and expectations of different scenarios effectively (Wager & Atlas, 2015). Moreover, verbal suggestions, pre-existing beliefs, and the overall treatment context can activate various schemata, including outcome expectations, assessments regarding the importance of symptoms and treatment, and past memories or experiences, potentially contributing to placebo effects (Wager & Atlas, 2015). Understanding patients' schemata may have important implications for healthcare interactions, as it offers the possibility of modifying their cognitive representations.

6.4.3. Proposed process of clinical change

Based on the findings of this research, there appears to be a common sequence or set of clinical processes which may augment conservative treatments for cLBP as illustrated in Figure 17 below. The diagram provides a conceptual map of how CFs may be interconnected during healthcare consultations. The proposed process of clinical change involves several key steps. First and foremost, establishing a strong therapeutic relationship with the patient is essential. This entails building trust, actively listening, showing empathy, exploring, and understanding the patient’s prior experiences, preferences, and beliefs about pain/anatomy, along with any unhelpful behaviours or unmet needs they may have. It is also important to identify and address any misinformation or concerns stemming from previous healthcare experiences. Accordingly, the practitioner's characteristics, attitude toward the patient, interpersonal skills, and beliefs underpin their approach to care and plays a key role in cultivating a trusting therapeutic relationship. Physical features of the treatment environment can also support and enhance the development of a strong therapeutic relationship by promoting effective communication and demonstrating professional credibility.

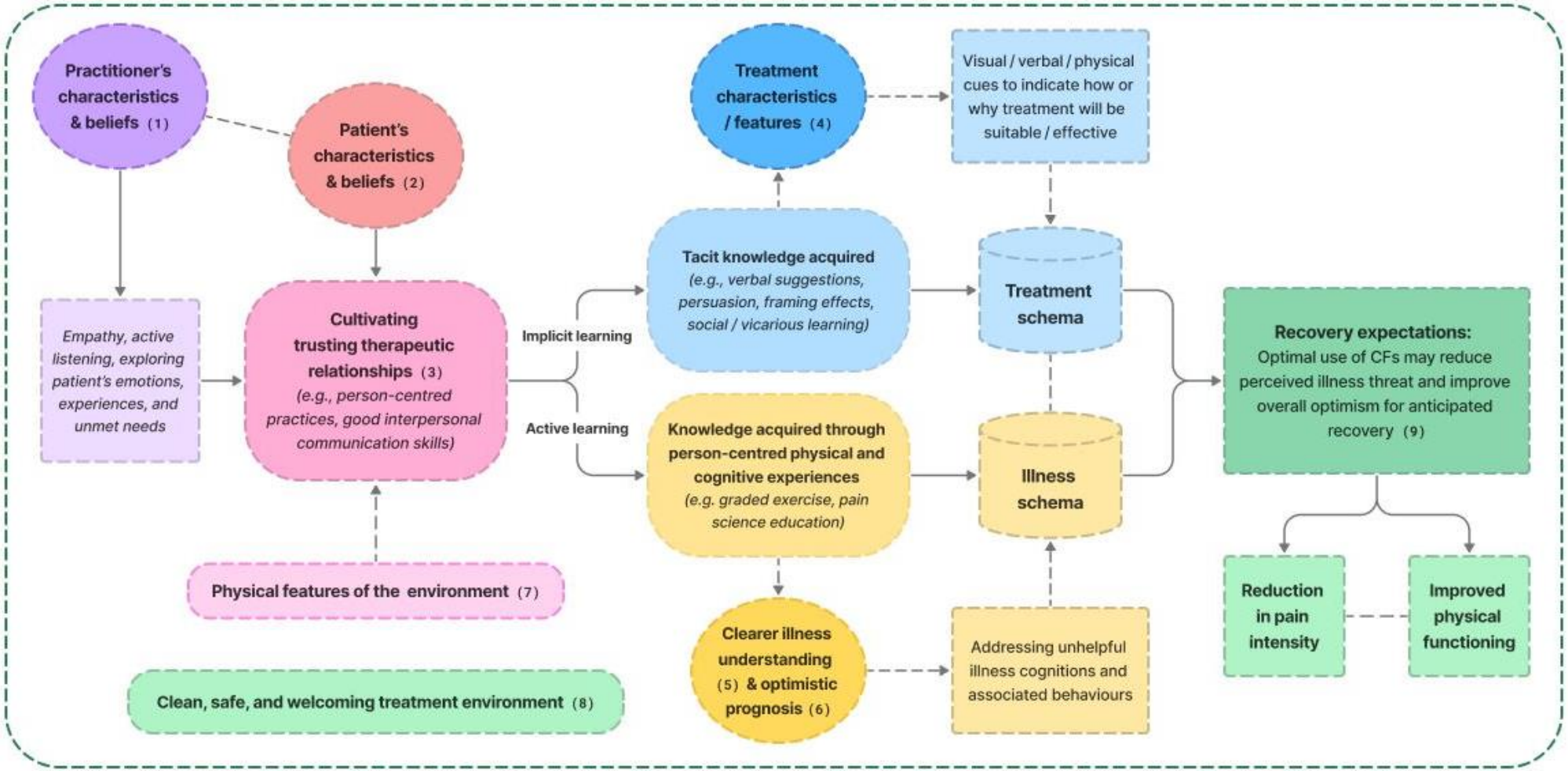

Figure 17. Proposed conceptual map of CFs and their interconnections during clinical practice

Examples of patients' experiences:

(1): "...he was very professional, very calm, very kind... it's good to feel safe with the person who is dealing with your back."

(2): "...going through what my main goals are, which was really important to me. ...Why do I want to get this sorted? Where do I want to be? What am I trying to achieve?"

(3): "...he was fully, fully listening to me, but more importantly understanding me... I was feeling that trust for him. ...building trust is on my terms. It's a partnership, it's a two-way thing."

(4): "...he makes you thoroughly understand what he's doing and why he's doing it." ~~ "...I was really clear on what those [treatments] would do for me, which is good."

(5): "...because I've been very wary of it, a lot of it has become psychological, which I totally understand... I think it's a good thing that I've understood that now."

(6): "...it meant that I was recovering... it meant that my back was progressing, and he was happy with the progress" ~~ "...I just feel open and optimistic, because I trust him."

(7): "...these are the people who work there, and what their qualifications were, their history of the job... because then you know who you're dealing with."; "Everything just felt safe."

(8): "...the lady at the desk is always smiling... that helps to have someone who is approachable and friendly." ~~ "...before I got there, he cleaned from the last person, so I didn't have to worry."

(9): "It's definitely not as frequent, it's definitely not as bad, and there's less symptoms than what I used to have... Now I do [feel there is hope]."

Figure 17 continued. Proposed conceptual map of CFs and their interconnections during clinical practice

Second, once a strong relationship is established, the practitioner can play a role in modifying and updating the patient's understanding of their LBP (i.e., *illness schema*) to influence their mindset. This may be achieved through articulating an optimistic prognosis, using reputable pain science education resources, and through experiential learning (e.g., graded exercise). Considering the patient's goals, preferences, characteristics, and beliefs can fortify the relationship and support the patient's receptiveness to new knowledge, experiences, or treatment approaches. Part of the process may also involve shifting the focus from solely alleviating symptoms to adopting a broader perspective that acknowledges the potential for recovery. Tailored activities and interventions can be incorporated to actively involve the patient in their own recovery journey. By offering an optimistic prognosis, updating the patient's beliefs about pain and their anatomy, and encouraging the adoption of adaptive behaviours, practitioners can help cultivate a more accurate understanding of their LBP and a more positive outlook towards recovery. These steps aim to provide patients with a balanced perspective, combining realism with hope, and empowering them throughout their rehabilitation journey.

Third, practitioners can engage in discussions regarding recommended treatment options, clarifying how the treatment may help address specific aspects of the patient's LBP. By providing a clear, coherent, and credible explanation regarding the suitability and effectiveness of the treatment's characteristics, this may influence the patient's treatment perceptions (i.e., *treatment schema*) and their recovery expectations. Validating the credibility of new information during these discussions may help establish a logical coherence between illness and treatment representations, which may enhance the perceived effectiveness and suitability of the treatment approach.

Fourth, aligning treatment features with the patient's expectations is also important. This involves ensuring consistency in how the treatment is described and implemented to positively influence the patient's treatment expectations. Providing regular feedback about functional improvements or symptom changes further builds the patient's confidence in the treatment plan. Incorporating social learning approaches, such as patient testimonials or facilitating interactions with other patients who have experienced positive outcomes, can also influence treatment expectations. These real-life examples may inspire and motivate patients, while fostering hope and optimism in their own treatment outcomes. Lastly, creating a clean, safe, and welcoming atmosphere that helps the patient feel at ease and comfortable promotes a supportive environment that may improve patient engagement and satisfaction with the treatment process.

Throughout the treatment process, the therapeutic relationship remains pivotal in reinforcing the connection between the patient's updated understanding of their LBP and shaping their treatment beliefs. By focusing on addressing any inconsistencies and establishing a logical connection between the patient's illness and treatment schemata, practitioners can enhance the likelihood of inducing placebo analgesia over time. This ongoing reinforcement has the potential to positively influence patients' recovery expectations, which can contribute to improved clinical outcomes. Positive recovery expectations may then trigger positive physiological responses (placebo effects), whilst negative expectations may induce negative responses (nocebo effects). Consequently, the combined factors of a strong therapeutic relationship, updated illness representations, establishing the relevance and credibility of treatment features, and reinforcing coherence between the patient's illness and treatment representations may result in enhanced recovery expectations and improved outcomes during conservative cLBP rehabilitation. However, it is important to note that the application of the proposed clinical processes may vary depending on each patient's characteristics, the clinical context, and evidence-based guidelines. Exercising clinical judgment and adapting to the patient's unique needs are important for providing optimal care.

6.4.4. Illness representations

Di Blasi and colleagues (2001) noted the relevance of the Common-sense Model (CSM) of self-regulation (Leventhal et al., 1992) in explaining how practitioners can potentially influence healing processes during clinical encounters. The CSM, also known as the Illness Representations Model, Illness Perceptions Model, Self-Regulatory Model, or Parallel Process Model, is a self-regulatory and social-cognition model that focuses on cognitive factors influencing health-related behaviours, which individuals actively manage (Leventhal & Mora, 2005; Sutton, 2010). The model offers useful insights into how individuals perceive and make sense of their illness, and how these perceptions influence self-regulatory processes and health-related behaviours (Leventhal & Mora, 2005).

The CSM proposes that individuals' health behaviours are primarily influenced by their illness representations, which are subjective beliefs and perceptions about the nature, cause(s), and significance of physical symptoms or health conditions (Hagger & Orbell, 2003). These representations are based on an individual's common-sense understanding and knowledge of their health, incorporating objective and subjective information into a cognitive schema of the perceived illness threat (Hagger & Orbell, 2003). Individuals actively develop illness representations based on a pool of health-related knowledge (which may be culturally specific and/or medically (in)accurate) in conjunction with social

communication with healthcare practitioners, family, friends, and past illness experiences (Hagger & Orbell, 2003).

The model suggests that external and internal health threats are processed through two distinct systems, represented in Figure 18 (Leventhal et al., 1992, p.147). These systems function independently but interact through two parallel pathways (Hagger & Orbell, 2003). The first pathway involves creating a cognitive illness representation and developing a coping plan, while the second focuses on the emotional representation and coping with the emotional response (Hagger & Orbell, 2003). These parallel pathways interact through feedback loops, allowing adjustments in coping strategies (Hagger & Orbell, 2003). Notably, the CSM places equal emphasis on both emotional and cognitive factors in health-related decision-making. Individuals form multi-attribute illness representations influencing emotional and objective coping strategies, leading to heuristic evaluations of appropriate behavioural responses to perceived health threats (Leventhal & Mora, 2005).

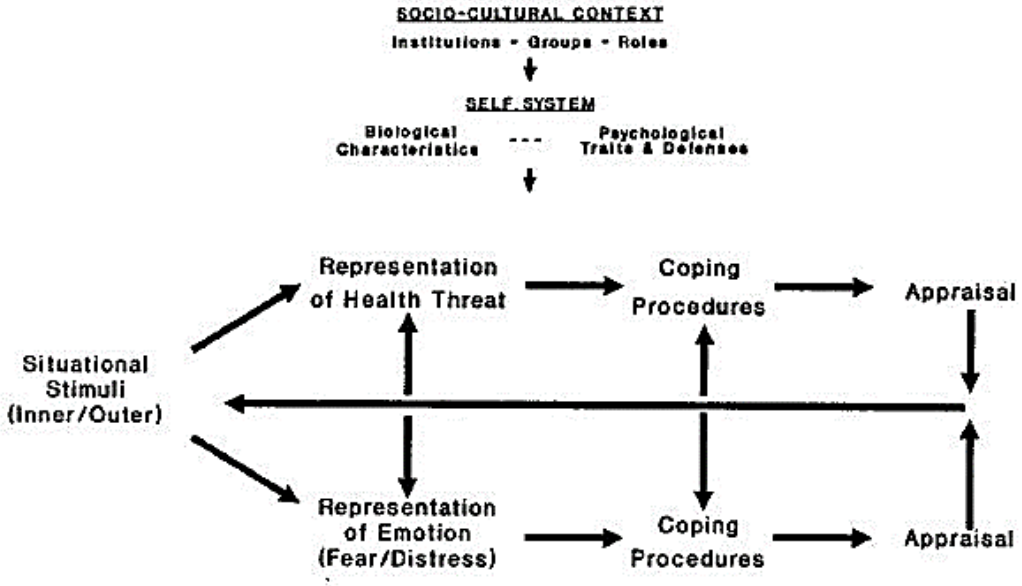

Figure 18. Common-sense model of self-regulation of health behaviour (Leventhal et al., 1992, p.147. Reproduced with permission from SNCSC.)

The CSM proposes a three-step problem-solving process in addressing health threats. Firstly, there is the interpretation of information, which is influenced by general socio-cultural knowledge, specific knowledge obtained from reliable sources, and experiential knowledge derived from past or present situations (Hagger & Orbell, 2003). Secondly, individuals generate potential coping responses based on their interpretations. Lastly, they evaluate various strategies before selecting a specific response (Hagger & Orbell, 2003). Figure 18 depicts that these interpretations take place within a particular socio-cultural context and are

also influenced by psychobiological factors, such as the individual's personality and behavioural traits (Leventhal et al., 1992).

The model argues that individuals construct illness representations with five main attributes: identity, timeline, consequences, cause, and cure/control (Leventhal et al., 1992). The attribute of *identity* refers to the disease label assigned to the perceived condition or symptoms (Leventhal et al., 1992). The *timeline* attribute involves the individual's predictive belief regarding the expected duration of the illness, which can be brief, cyclical, or persistent, and may change as new information is processed (Leventhal et al., 1992). *Consequences* relate to the individual's perceptions of the physical, social, and economic impacts arising from the illness, which can be realistic or unrealistic (Leventhal et al., 1992).

The attribute of antecedent *cause* involves the individual's beliefs about the origin of the illness or symptoms, such as injury, infection, genetics, and so forth (Leventhal et al., 1992). These beliefs may be shaped by accurate biomedical information or biased by personal experiences and external influences such as media exposure or persuasive messages from significant others. Lastly, the attribute of potential *cure/control* relates to the individual's beliefs about the severity of the illness (curable or incurable) and their perceived ability to influence the eventual outcome (Leventhal et al., 1992). This belief can change over time as individuals gain a better understanding of the illness and evaluate the effectiveness of their attempts to modify the outcome, regardless of the actual causal effect of their behaviours (Hale et al., 2007).

Researchers commonly operationalise these five attributes using the revised Illness Perception Questionnaire (IPQ-R) (Moss-Morris et al., 2002). A meta-analysis provided evidence for the construct and discriminant validity of the five attributes within the CSM (Hagger & Orbell, 2003). The analysis found strong positive correlations between illness identity and coping strategies, as well as between perceived controllability, cognitive re-appraisal, expressing emotions, and problem-focused coping (Hagger & Orbell, 2003). These results support the validity of the CSM, as the observed relationships align with the theory's predictions regarding the connections between illness cognitions, coping strategies, and outcomes (Hagger & Orbell, 2003).

When individuals experience changes in somatic activity (e.g., symptoms), a self-regulatory process is triggered, involving the integration of pre-existing ideas about the illness with their current physical experiences, which subsequently influences coping behaviours (Hagger & Orbell, 2003). Illness representations are cumulative and subject to ongoing

formulation and reformulation based on experiences and emotions, leading individuals to adopt, discard, or adapt information as necessary, linking it to different coping strategies, action plans, and outcomes (Hale et al., 2007). The CSM proposes a temporal unfolding of the self-regulatory system, recognising that illness episodes are dynamic and change, with illness representations fluctuating as new information is integrated and through the process of re-appraisals. Consequently, coping mechanisms are also altered in response to evolving illness representations to address the changing implications of the illness experience (Leventhal et al., 1992).

Coping procedures involve cognitive and behavioural actions individuals undertake to improve their health, prevent illness, as well as treat or manage existing illnesses (Leventhal et al., 1998). These actions are guided by specific "IF-THEN" rules based on the attributes of the health threat (Leventhal et al., 1998).The "IF" part of the rule informs the individual about the nature of the health threat, while the "THEN" part represents the specific actions or coping strategies undertaken based on the individual's understanding of the problem (Leventhal et al., 1998). The effectiveness of coping responses is evaluated by individuals, leading to revised perceptions of the health threat. When faced with ambiguous symptoms (e.g., increased fatigue, mild headache), individuals may choose to wait and see how symptoms evolve or take specific actions to address the symptoms (Leventhal et al., 1998).

The overlap between illness attributes and coping procedures influences the formation of domain-specific "IF-THEN" rules. For instance, individuals experiencing MSK pain may believe that exercise contributes to movement-induced "wear and tear," resulting in pain or an exacerbation of their condition (Leventhal et al., 1998). Consequently, they may consider exercise as a potentially harmful or unsuitable therapy because of their belief about its potential negative consequences resulting in a cautious or avoidant response (Leventhal et al., 1998). This illustrates how subjective perceptions and cognitive factors shape coping responses and subsequent appraisals, leading to revised perceptions of health threats that influence future actions (Leventhal et al., 1998).

Previous research provides support for the relevance of the CSM, indicating that pain-related disability is linked to individual patients' understanding of pain (Bunzli et al., 2017; de Raaij et al., 2018; O'Sullivan et al., 2018). However, a notable gap in the CSM is its lack of specific focus on the individual's treatment representations, although it is indirectly implied in the coping response to the perceived illness threat. An important CF identified in the systematic review suggested that actively leveraging treatment characteristics positively influenced patients' expectations of symptom change which affected their clinical outcomes

(Sherriff et al., 2022). Additionally, the qualitative interviews indicated that providing a coherent explanation of how the treatment attributes could help address specific LBP symptoms contributed to the treatment's perceived credibility. This suggests that a patient's treatment representation may also contribute to their understanding and acceptance of the recommended treatment, potentially influencing their expectations related to symptom management and recovery.

6.4.5. Influencing illness and treatment representations

At the heart of clinical encounters are the practitioners themselves, whose beliefs, attitudes, values, and behaviours shape the nature of each interaction and important clinical processes. The practitioner could be conceptualised as a catalyst, as their ability to provide physical, cognitive, and emotional care can affect the patient's mindset and may even provoke or trigger a physiological response. In essence, the practitioner's therapeutic effectiveness is not solely based on the specific treatments or medications they administer, but also on their ability to care for the patient as a whole. In addition, their healing status is a powerful cue arising from tacit socio-cultural knowledge of clinical interactions.

Practitioners are instrumental in shaping the quality of the patient-practitioner relationships, influencing patients' illness and treatment beliefs, as well as their recovery expectations. The manner in which a practitioner interacts with their patient to facilitate the development of the therapeutic alliance, may be an important therapeutic process (Sherriff et al., 2022). Moreover, practitioners can simultaneously influence patients' treatment expectations regarding symptom improvements by providing feedback and explanations about the suitability and effectiveness of conservative treatments for their cLBP (Sherriff et al., 2022). These two processes, when modified together, may be more impactful on patients' outcomes.

CF care approaches appear to influence patients' cognitive representations of cLBP and their treatment beliefs and expectations. These two cognitive schemata may be interdependent, since a strong patient-practitioner relationship may enhance the perceived credibility of the treatment, while an effective treatment may also strengthen the patient-practitioner relationship. Notably, there appears to be a synergistic relationship among CFs, suggesting that modifying multiple CFs concurrently can foster positive expectations for symptom improvement and potentially lead to the modulation of pain and physical functioning (Sherriff et al., 2022). This implies that instead of optimising treatments, it may be more beneficial to rather focus on optimising the clinical encounter and actively harness CFs to improve clinical outcomes.

During LBP consultations, MSK practitioners may aim to strategically target two cognitive representations: (i) the patient's *illness schema* and (ii) the patient's *treatment schema*. The treatment schema may vary depending on the treatment modality. For example, in pharmacological approaches, features such as colour, brand, labelling, mode of administration (e.g., oral, injection, topical), and price may influence patient perceptions. In contrast, during chiropractic treatment, patients' preferences and past experiences may influence the perceived effectiveness with specific elements like thrust techniques and audible popping sounds. The choice of manual therapy technique depends on the MSK condition, patient comfort level, preferences, treatment goals, and the practitioner's clinical judgment. Thus, identifying common or generic attributes across different LBP treatments, such as price, consultation duration, personalised attention, continuity of care, clear and credible diagnosis, overt therapy procedures, therapeutic touch, or person-centred practices could enhance treatment delivery and patient perceptions of treatment credibility, suitability, and effectiveness. Notably, the intention is not to advocate that practitioners mislead patients, use deception, nor unethical practices.

Benedetti (2019) has previously raised concerns regarding the ethical implications of exploiting scientific advancements related to placebo effects, such as intentionally enhancing patients' expectations. There is a risk that non-medical organisations and individuals may exploit scientific knowledge to support unorthodox and pseudoscientific practices, which can be harmful (Benedetti, 2019). The paradox lies in the fact that scientific knowledge can convince the public that placebos work through specific biological mechanisms. However, this understanding can be misused by unscrupulous individuals or organisations for unethical purposes, leading to a regression in medical practices (Benedetti, 2019). To address these ethical implications, Benedetti (2019) emphasises the importance of education and effective communication. Both patients and practitioners should be educated about placebo phenomenon and its associated issues. For example, while placebo-interventions may have a neuropsychological impact on certain conditions, they cannot cure diseases like cancer nor eradicate bacterial infections (Benedetti, 2019). Clear communication is therefore essential to dispel confusion and prevent misconceptions that placebos can cure all illnesses. It is also important to recognise that placebo-interventions have limitations and should not replace evidence-based medical treatments. (Benedetti, 2019).

Consequently, it is imperative to prioritise open and honest communication, respect for patient autonomy, and adherence to ethical principles to protect patients' rights and provide ethical, high-quality care. The implementation of the suggested clinical processes should incorporate ethical considerations and establish patient safeguards. This may involve

obtaining informed consent, involving patients in shared decision-making, regularly evaluating, and monitoring their progress, and making appropriate referrals to specialist or psychosocial support services where necessary. Furthermore, it is important to ensure that the proposed clinical processes are aligned with the principles and practices of evidence-based medicine (EBM).

EBM aims to provide a comprehensive approach to healthcare decision-making that is evidence-informed, clinically sound, and person-centred (Peterson et al., 2016). EBM encourages practitioners to consider three equally essential aspects to inform clinical decision-making namely, the best available evidence, the practitioner's clinical expertise, as well as each patient's unique needs and preferences to provide the most appropriate and effective care (Peterson et al., 2016). Practitioners should therefore consider current, relevant, reliable, and person-centred evidence from high-quality systematic research and guidelines which provides a foundation to inform clinical decisions (Sackett et al., 1996; Sackett, 1997). Practitioners should be able to critically appraise and interpret the evidence while considering its relevance and applicability to the patient's unique circumstances, clinical presentation, and preferences (Guyatt et al., 1992). A practitioner's clinical expertise encompasses the skills acquired through clinical experience and practice, enabling them to make well-informed medical judgements (Sackett et al., 1996). Effective practitioners should be able to combine their clinical expertise with up-to-date external evidence, because relying on either aspect alone is insufficient (Sackett, 1997). Solely relying on external evidence may overlook the individual patient's needs, potentially leading to inappropriate care. Conversely, disregarding relevant external evidence can result in the perpetuation of outdated practices that may harm patients (Sackett, 1997). Accordingly, these key aspects of clinical decision-making are closely intertwined and interdependent.

The third aspect of EBM includes actively involving patients in decision-making processes (Sackett et al., 1996). EBM recognises the importance of incorporating the patient's circumstances, characteristics, values, preferences, and goals into decision-making processes (Sackett et al., 1996). This suggests that EBM is compatible with person-centred care since both approaches emphasise understanding and respecting the patient's individual needs, preferences, cultural background, social context, and personal circumstances. The aim is to collaboratively arrive at treatment decisions that align with the patient's values and desired outcomes. Regarding the clinical processes outlined above, it is important for practitioners to strike a balance with EBM practices to ensure they are implemented in an ethical manner. By combining the outlined clinical processes with EBM practices, practitioners can provide

care that is grounded in evidence, respects patient preferences, and accounts for the individual needs and circumstances of each patient.

6.5. Unique contribution

Each study provided unique insights into the role of CFs during the management of cLBP. Collectively, these three studies add novel contributions to the existing literature by providing a deeper understanding of the important role of CFs in the management of cLBP.

The systematic literature review synthesised existing evidence and findings from previous studies to identify common themes and key CFs. The review highlighted the importance of CFs in the management of cLBP, supporting the need for interventions that target CFs alongside traditional biomedical treatments. The Delphi study builds on this by identifying the specific CF domains that are most important in cLBP management according to a panel of MSK practitioners in the UK. It also identified gaps in practitioner confidence in applying specific CF approaches, highlighting the need for further training and support. The Delphi study established areas of consensus and disagreement among MSK practitioners, which could help inform the development of interventions to improve the use of CFs. The qualitative study provided a detailed exploration of the experiences of patient-practitioner dyads in the UK and highlighted the role of practitioners' characteristics and beliefs as beneficial CFs in shaping the quality of patient-practitioner interactions. It also delineated specific treatment characteristics and qualities of the treatment environment that positively influenced patients' treatment and recovery expectations.

Together, these studies contribute to building a more nuanced understanding of the role of CFs in managing cLBP from diverse perspectives. The findings highlight areas for further investigation, aiming to address existing knowledge gaps. These findings have the potential to inform the development of interventions targeting CFs to improve outcomes for patients with cLBP. By incorporating the experiences and opinions of influential stakeholders, the studies provide useful insights into how CFs are perceived and used in real-world contexts. This can help to bridge the divide between research and clinical practice by elucidating key CFs that are important to patients and practitioners and may be effective in improving patient outcomes. The use of different research methods strengthens the reliability/dependability and validity/credibility of the findings by providing a better understanding of the complex factors influencing treatment success.

One additional point to note is the interdisciplinary nature of this study. By involving researchers and practitioners from multiple disciplines, it may offer a more comprehensive view of the complex factors that influence cLBP management. This may also have implications for clinical practice, as it adds weight to the importance of a collaborative and integrated approach to care that considers the physical, psychological, and social dimensions of cLBP. Moreover, it highlights the significance of ongoing interdisciplinary research to advance knowledge and identify innovative approaches for improving cLBP care.

6.5.1. Practical implications

Based on the findings of this research, some clinical recommendations for the conservative management of cLBP include:

Improving the patient-practitioner relationship: – this study adds weight to the importance of developing a strong therapeutic alliance with patients experiencing cLBP. Building a strong patient-practitioner relationship is an ongoing process that requires continuous effort and adaptability to meet the patient's individual needs during MSK rehabilitation. Strategies practitioners may consider using to cultivate the therapeutic relationship involve building trust, actively listening, reflecting, or paraphrasing, enhancing communication, and engaging in collaborative goal-setting. One approach to build trust more effectively is by demonstrating empathy and understanding towards the patient's pain experiences and their individual concerns. Active listening is also necessary for effective communication.

MSK practitioners can improve their active listening skills by:

- ✓ Maintaining eye contact and using non-verbal cues to show attentiveness.
- ✓ Asking open-ended questions and avoiding interrupting the patient to help encourage them to fully express their thoughts and feelings.
- ✓ Paraphrasing, summarising, or reflecting on the patient's concerns helps to ensure a more accurate understanding which can help patients feel heard, understood, and respected.
- ✓ Expressing accurate empathy (e.g., verbal, and non-verbal expressions to convey authentic compassion, dignity, and respect).

Effective communication is important for cultivating a strong therapeutic relationship. MSK practitioners can improve their communication skills by:

- ✓ Using clear and jargon-free language to ensure the patient understands the information provided.
- ✓ Creating a safe and non-judgmental environment that encourages open and honest communication.
- ✓ Checking the patient's comprehension along with encouraging questions.
- ✓ Being responsive to the patient's queries or concerns, whether in person, over the phone, or through electronic correspondence.

Collaborative goal setting is another useful approach. Engaging patients in collaborative goal setting promotes a sense of ownership and empowerment which may enhance their engagement in the treatment process. MSK practitioners should involve patients in setting achievable goals aligned with their valued activities and priorities. Regularly reviewing and modifying goals together ensures a person-centred approach whilst reinforcing treatment expectations. MSK Practitioners can cultivate a stronger relationship by respecting their patient's autonomy and involving them in decision-making processes. MSK practitioners can incorporate collaborative goal setting by:

- ✓ Discussing the patient's expectations and desired outcomes.
- ✓ By setting realistic and measurable goals together with the patient, both the practitioner and the patient can track progress and adjust these goals along the way.
- ✓ Breaking down long-term goals into smaller milestones to monitor progress.
- ✓ Regularly reviewing and modifying goals based on the patient's feedback and progress.

Incorporating person-centred care approaches: – this study adds weight to the benefits of adopting a person-centred approach, which can promote patient engagement and adherence to treatment to improve clinical outcomes during cLBP rehabilitation. Creating a supportive and trusting environment that encourages open communication underpins effective treatment. Building a collaborative and positive relationship, considering the patient's preferences, and promoting self-management strategies can influence patient outcomes. Empowering patients to actively participate in their own care is essential for long-term cLBP management. MSK practitioners can facilitate the adoption of self-management strategies by explaining the benefits of physical activity and exercise and teaching self-care techniques or pain-related coping behaviours to promote a patient’s self-efficacy.

Addressing patient beliefs and characteristics is important for effective cLBP management. MSK practitioners should consider patient's beliefs, attitudes, and expectations, and tailor

treatment plans to address their specific needs. By recognising and addressing these factors, practitioners can provide more personalised and effective care. Engaging in discussions with patients is essential to understand their perspectives on pain, their previous experiences, and their treatment preferences. Given the multi-dimensional nature of cLBP, it may be useful to explore physical, psychological, and social factors to better understand their experiences. This information can then be used to individualise the rehabilitation process to the patient's unique needs and concerns.

One important aspect of addressing the patient's beliefs and characteristics is providing education about cLBP and its treatment options. By offering clear and accurate information, practitioners can empower patients to make informed decisions about their care. MSK practitioners can provide patient education during LBP consultations, along with offering supplementary educational resources. MSK practitioners can provide patient education by:

- ✓ Addressing any misconceptions, concerns, and unhelpful or negative beliefs the patient may have about the nature of LBP through person-centred pain science education, if appropriate.
- ✓ Offering appropriate educational resources, such as brochures, videos, or websites, to enable patients to acquire new knowledge.
- ✓ Using visual aids, diagrams, or models to help patients better understand their diagnosis, illness, or pain experience.
- ✓ Explaining the underlying factors (i.e., physical, psychological, and social) contributing to their LBP experiences and its management.
- ✓ Sharing evidence-based information regarding different treatment approaches, including potential benefits and risks.

MSK practitioners should ensure that patients receive clear information regarding their condition and treatment options. Using plain language whilst avoiding jargon helps patients to better understand their care and feel actively involved in decision-making. By challenging negative or unhelpful beliefs about the nature of LBP, practitioners can help patients develop a more optimistic mindset, and a clearer understanding of their symptoms. By providing education tailored to each patient's needs, MSK practitioners can foster trust. This may serve to strengthen the therapeutic relationship and contribute to more effective and person-centred care.

Focusing on meaningful treatment characteristics: – MSK practitioners should consider using strategies that positively influence patients' treatment and recovery expectations.

Several key approaches can be implemented including articulating an optimistic prognosis, regular symptom change feedback, and establishing the credibility of recommended treatments. Communicating an optimistic prognosis can instil hope. MSK practitioners can take several steps to establish patient confidence and trust:

- ✓ Overtly rule out signs of serious illness, injury, or pathology, if appropriate.
- ✓ Avoid vague or ambiguous words or phrases that can be interpreted to imply signs of a permanent, irreparable, untreatable, abnormal, or serious illness (see Stewart & Loftus, 2018 for alternative phrasing suggestions).
- ✓ Emphasise the potential for improvement and recovery to instil hope.
- ✓ Demonstrate functional progress and provide regular symptom-change feedback.
- ✓ Assess and track patients' functional improvements, along with highlighting milestones achieved.

Demonstrating functional progress and providing regular symptom change feedback can be reassuring and encouraging to patients. Providing consistent feedback is a tangible sign of progress, which may help patients recognise improvements and enhance positive recovery expectations. It is also important to develop the credibility of treatments to build patients' confidence and trust. When discussing treatment options, MSK practitioners might consider:

- ✓ Providing a clear rationale for treatment(s) that aligns with the patient's needs and goals.
- ✓ Linking treatment characteristics to the patient's LBP symptoms to demonstrate relevance.
- ✓ Outlining the expected potential benefits of the recommended treatment(s) on patient's daily lives and activities.
- ✓ Discussing the effectiveness of similar interventions by sharing essential information about relevant clinical guidelines or studies supporting the approach.
- ✓ Sharing successful clinical experiences and patient testimonials to shape recovery expectations and further strengthen the treatment's credibility.

By linking the treatment features to the patient's symptoms, practitioners can help patients understand why the chosen treatment is relevant and potentially beneficial for their cLBP. It is also helpful for MSK practitioners to outline the expected potential benefits of the recommended treatment(s) to develop positive treatment expectations. By illustrating real-life examples, such as success stories, MSK practitioners may inspire hope. These strategies

may promote positive treatment expectations and further establish patients' trust and confidence in the treatment plan.

Additionally, tailored advice, and providing personalised graded activities may also be beneficial. Tailoring advice to the patient's individual circumstances may enhance treatment relevance and improve treatment expectations. MSK practitioners should consider the unique characteristics and needs of each patient such as their beliefs, lifestyle, work environment, and preferences. Patients may also value personalised activities that are gradually introduced and progressed based on their capabilities. MSK practitioners can implement activity plans that gradually challenge and build the patient's self-efficacy and functional capacity. This may help patients recognise tangible progress and potentially promote positive treatment expectations.

Considering the treatment environment: – The treatment environment can also play a role in shaping patients' experiences and perceptions of care. MSK practitioners should consider creating a safe and welcoming treatment space with friendly and approachable support staff, maintaining high hygiene standards, and safeguarding privacy and confidentiality, which may contribute to building patient trust, satisfaction, and engagement during cLBP rehabilitation.

Patients should feel safe and comfortable in the treatment environment. MSK practitioners can create a welcoming atmosphere by providing a well-maintained and organised treatment space, including comfortable seating, natural lighting, suitable temperatures, creating a calming ambiance, or reducing noise levels to establish a positive treatment environment. Additionally, support staff's attitudes and behaviours may influence patients' overall satisfaction and comfort. Encouraging a culture of kindness and respect by being friendly, approachable, and empathetic may support positive patient experiences.

MSK practitioners should follow infection control protocols so patients feel reassured that their well-being is a priority, which may help establish a sense of safety and trust. Respecting patients' privacy and confidentiality is also paramount. MSK practitioners should create a space where patients feel comfortable openly discussing their personal information, concerns, and treatment details. Implementing measures to safeguard privacy, such as private consultation rooms and secure handling of medical records, reinforces patient trust and confidentiality. It is also important to ensure the treatment area is easily accessible for patients with mobility challenges. Features of the MSK clinic which support effective

communication can positively influence the patient-practitioner relationship and potentially amplify the impact of other CFs.

6.5.2. Educational Implications

The findings of these studies have important educational implications for MSK practitioners, educators, and training providers. The Delphi study's results suggest that MSK practitioners require additional training and support to improve their confidence and competency in applying person-centred care approaches and addressing patients' negative emotional states. The panel also identified training needs in providing self-management strategies and explaining the multidimensional nature of pain to patients. The systematic review and qualitative study's findings suggest that MSK practitioners could benefit from training in effective communication skills, such as active listening, empathy, and explaining treatment options to patients. Therefore, educators and training providers could develop training programmes to enhance MSK practitioners' skills in these areas.

Providing training and support in person-centred care can enhance practitioners' skills in building strong patient-practitioner relationships. This training should emphasise active listening, empathy, and shared decision-making to ensure that patients' values, preferences, and goals are considered during cLBP management. MSK practitioners can benefit from training that helps them more effectively address patients' negative emotional states, such as LBP-related fear, anxiety, or depression. Training should focus on strategies to empathetically acknowledge and validate patients' emotions, while also providing appropriate support and guidance to manage these challenging emotions. Training in pain science education can enhance MSK practitioners' ability to explain the multi-dimensional nature of pain. This involves educating patients about the complex interactions between biological, psychological, and social factors contributing to their LBP experiences. By improving their own understanding of pain mechanisms, MSK practitioners can better communicate with patients and address any misconceptions or unhelpful beliefs related to pain.

Moreover, training MSK practitioners in cognitive-behavioural approaches may better equip practitioners with tools to identify and challenge unhelpful illness beliefs and behaviours, promote positive coping strategies, and facilitate behavioural changes to support patients experiencing cLBP. Such training could also focus on fostering self-efficacy to help patients develop confidence in their ability to manage their cLBP. This may involve providing positive reinforcement, setting realistic goals, and guiding patients in gradually increasing

their self-management skills. It could also include providing personalised guidance on exercise and physical activity, teaching self-care techniques, and offering patient-friendly education, resources, and tools.

Overall, the educational implications of these studies suggest that MSK practitioner training programmes could be enhanced by incorporating person-centred care approaches, communication skills, and strategies for leveraging beneficial CFs. By doing so, MSK practitioners could be better equipped to provide high-quality care to patients with cLBP and other MSK conditions.

6.5.3. Theoretical Implications

The findings from this research have some theoretical implications. Firstly, they highlight the importance of a neuro-biopsychosocial approach to understanding and treating cLBP. This approach recognises that persistent pain is not just a physical symptom but also involves psychological and social factors that influence the experience of pain and the effectiveness of treatments. The CFs identified in these studies are consistent with this approach and highlight the importance of addressing the patient's beliefs, emotions, and expectations, as well as the quality of the patient-practitioner relationship.

Secondly, the findings suggest that the use of CFs is consistent with person-centred care, which prioritises the patient's needs, preferences, and values. Person-centred care has been shown to improve patient satisfaction, treatment adherence, and health outcomes across a range of health conditions. Meaningful treatment features such as collaborative goal setting, tailored advice, and personalised treatment are consistent with person-centred care and may contribute to its effectiveness.

Finally, this research has acknowledged that CFs are intricately linked during clinical interactions. It has proposed a conceptual map of how these CFs may interact and contribute to improved clinical outcomes. Notably, it has suggested that practitioners' values, skills, beliefs, and characteristics are the foundation of positive clinical interactions, tying together important components of care. This finding is novel, as the patient-practitioner relationship and the patient's beliefs are commonly acknowledged as fundamental CFs. However, both are informed by and rely on practitioners' overt behaviours, including consistently demonstrating empathy, person-centeredness, and good interpersonal communication skills. These elements contribute to developing a strong therapeutic relationship and allow for

consideration of patients' unique characteristics and needs, enabling the modification of patients' recovery expectations and illness beliefs.

Essentially, the practitioner plays a critical role in shaping the cognitive, emotional, and physical space through which the patient journeys. They offer support and guidance and collaboratively explore potential solutions for perceived obstacles and challenges. By identifying pathways and bridges where patients see barriers, the journey becomes more manageable and less daunting. This shift in perspective influences how patients perceive their LBP and their recovery journey. As patients' mindsets change and they adopt more positive expectations and beliefs, their neurobiology aligns with these new outlooks. This alignment can lead to positive changes in their physical responses and behaviours, ultimately resulting in improved outcomes. By targeting and leveraging these factors, practitioners can potentially enhance treatment outcomes and patient experiences during the rehabilitation process. This study's findings provide a promising foundation for understanding the complex dynamics of CFs and their impact on clinical outcomes in the context of cLBP management. However, it is important to note that further research is required to validate and substantiate this proposal.

6.6. Strengths and Limitations

In Chapters 3, 4, and 5, each study's strengths and limitations were previously discussed, but there are additional factors to consider across the three studies. The systematic review included studies with various research designs and sample sizes, which may have influenced the consistency of the results. A single reviewer conducted the initial screening, assessed the methodological quality, and extracted the data, which could potentially introduce researcher bias. Only studies published in English were included, potentially excluding relevant studies in other languages. The review specifically focused on cLBP, so the findings may not be generalisable to other types of pain or health conditions.

Moreover, both the Delphi study and the qualitative research had relatively small sample sizes and were limited to those who were willing to participate, potentially introducing bias. The Delphi technique relies on expert opinions and may not necessarily reflect the views of patients or other MSK practitioners. Since the Delphi study and the qualitative research were both conducted in the UK, this may also limit the transferability of the findings to other contexts, particularly different healthcare settings (e.g., the NHS) and other countries with different cultural backgrounds. Additionally, both studies involved self-reported data and may be subject to recall bias or social desirability bias.

A key strength of this research is the use of a multiphase research approach, which allowed for a comprehensive and in-depth exploration of the topic. The combination of quantitative and qualitative data provided a more complete understanding of the role of CFs in the treatment of cLBP. The strengths of these studies include their use of established research methods to gather and analyse data and the inclusion of both patients' and practitioners' perspectives. Using multiple data sources adds to the credibility and validity of the findings. The systematic review included a wide range of studies that examined CFs in the context of LBP, which allowed for a comprehensive review of the literature. Furthermore, the subsequent studies provided a richer understanding of the topic.

Collectively, these studies have practical implications and may help guide the development and delivery of evidence-based interventions for patients with persistent MSK pain. By identifying CFs that are most important for treatment outcomes, MSK practitioners can tailor their interventions to better meet the needs of individual patients. This has the potential to improve treatment effectiveness, patient satisfaction, and the overall quality of care. Furthermore, these studies provide important insights into the complex and multifaceted nature of cLBP and the CFs that can influence treatment outcomes. The findings may have clinical, theoretical, educational, and/or policy implications which may help improve the management of LBP. However, the findings should be interpreted in light of their limitations.

6.7. Directions for future research

This study identifies several areas that merit further research. One such area is the investigation of specific CF domains, namely the practitioner's characteristics and beliefs, the healthcare environment, and treatment characteristics during the management of cLBP, given the limited available evidence. Exploring how CFs are utilised and vary across healthcare settings (e.g., public/private or inpatient/outpatient), populations, and different geographical or cultural contexts can provide a more comprehensive understanding of their influence on clinical outcomes. Moreover, expanding the exploration of CFs to encompass other chronic pain conditions can contribute to a broader understanding and application of CF-interventions.

Building upon the insights from the qualitative study, future research could enhance its breadth by undertaking a larger dyad investigation involving a diverse range of allied healthcare professionals across therapeutic modalities. While the qualitative study offered useful insights, broadening the scope may reveal subtle nuances that play a role in achieving

effective patient care. For example, further exploration could delve into how MSK therapists navigate disruptions in the patient-practitioner relationship or sustain this relationship over time. By examining these dynamics, it may help inform strategies for optimising patient care and may offer practical recommendations for clinical settings.

In addition to the aforementioned areas, future research should also investigate how CFs interact with other variables, such as demographic, psychological, or social factors. For instance, exploring how patients' and practitioners' characteristics like age, gender, or socio-economic status may interact can illuminate disparities in treatment responses. By investigating potential interactions, researchers can better understand the heterogeneity of treatment responses among patients with LBP and inform more targeted interventions.

Another important direction is to explore the feasibility and acceptability of interventions that specifically target CFs. By focusing on CFs, interventions can be tailored to address the unique and complex needs of patients with LBP to improve their overall effectiveness. Such research can provide important insights into the interactions between different CFs and their impact on patient outcomes, which may shed light on the complexities of LBP treatment. However, ethical considerations regarding the utilisation of CF-interventions in clinical practice should also be carefully assessed. To investigate the effectiveness of CF-interventions, it may be necessary to include multiple comparison groups, such as usual care and waiting-list controls. Establishing reliable and valid measures for determining how CFs influence clinical outcomes is important for advancing research and clinical practice. This includes developing tools and instruments that accurately assess the impact of CFs on patient outcomes, allowing for more precise evaluation.

Further investigation is needed to understand the optimal implementation and integration of CF care approaches into clinical practice, with the aim of supporting person-centred care and improving clinical outcomes. More specifically, there is a need for research on the most effective methods to train MSK practitioners to use CF care approaches. By identifying the most efficient training strategies, practitioners can further develop the necessary skills and knowledge to effectively incorporate CFs into clinical practice. In addition, it is important to explore the optimal ways to integrate CF care approaches into existing rehabilitation protocols. Such research can offer insights into seamlessly integrating CFs into current treatment frameworks. Future research should also focus on developing robust evaluation methods, which may inform the development of evidence-based guidelines for incorporating CFs into clinical practice.

Research is needed to further uncover the underlying mechanisms through which CFs influence clinical outcomes. By unravelling these mechanisms or pathways, researchers can identify new targets for future interventions. Further validation of the proposed framework is necessary to confirm its validity and applicability. This framework serves as a conceptual foundation for investigating potential pathways that may elucidate how CFs can be intentionally leveraged to evoke placebo effects. By exploring these proposed pathways, researchers can gain insights into how CFs can optimise clinical encounters, particularly in the management of cLBP. This understanding of how CFs may interact, and trigger placebo effects can inform the design and implementation of interventions that capitalise on these factors. Strategic targeting of CFs may empower MSK practitioners to enhance existing treatments and improve patient outcomes.

The need to explore interactions among different CFs has emerged as a research priority (Griswold et al., 2024). This aligns with clinical practice, where patients often experience multiple CFs concurrently. This may also address limitations in the current literature, which typically focus on individual CFs in isolation. Investigating idiographic responses (i.e., single-subject, or single-case designs) through N-of-1 studies could advance patient-centred, individualised, and holistic care approaches (Alemayehu et al., 2018). Utilising N-of-1 studies may allow for the systematic exploration of CFs within the context of an individual patient's experience.

N-of-1 methods are beneficial for testing theories and interventions along with directly addressing individual variability since each patient serves as their own control, leading to more precise and reliable conclusions (McDonald et al., 2017). By focusing on individual responses rather than group averages, N-of-1 studies may help uncover unique factors influencing treatment effectiveness for each patient, leading to tailored interventions (McDonald et al., 2017). Exploring the influence of CFs through an N-of-1 study could offer important insights into how CFs interact and change clinical outcomes within individuals over time. For example, employing alternating treatment designs, such as ABABA or ABACA, may provide a robust framework. This design allows for the detection of latency patterns and trends, particularly in terms of how rapidly or gradually outcomes change upon altering or removing the treatment (McDonald et al., 2017). An alternating treatment design is useful for pinpointing specific components of an intervention that are driving changes in outcomes. By systematically alternating between different interventions or conditions, the effects of individual components can be isolated (McDonald et al., 2017). This approach may be useful to identify which CFs are most effective or influential in producing positive outcomes for the patient. While traditional RCTs can be expensive and time-consuming, N-

of-1 studies are more resource-efficient since they involve a single patient or a small number of patients (Alemayehu et al., 2018). This makes them a viable option for investigating the influence of CFs on clinical outcomes in a more cost-effective manner.

Understanding placebo effects and the role of CFs during LBP treatment stresses the importance of rigorous study designs. In pain therapy research, acknowledging the complexities and methodological challenges highlighted in recent literature is important for critically evaluating the utility of sham control designs. Hohenschurz-Schmidt and colleagues (2023a; 2023b) shed light on the significance of sham controls and blinding techniques in trials of physical, psychological, and self-management interventions (PPS) for pain. Waiting-list controls or comparative therapeutic modalities are often chosen for clinical trials involving rehabilitation/exercise, physical or manual therapies, and psychological therapies, citing the challenges of blinding participants (Hohenschurz-Schmidt et al., 2023a). Blinding, which conceals group allocation to prevent expectation effects and manipulation of trial procedures, is essential for maintaining internal validity (Hohenschurz-Schmidt et al., 2023a). However, no-treatment arms can exaggerate effect sizes, and comparative effectiveness designs may address different research questions compared to efficacy and mechanistic trials (Hohenschurz-Schmidt et al., 2023a).

Sham interventions are considered essential in PPS trials to distinguish treatment effects and minimise bias (Hohenschurz-Schmidt et al., 2023a). Sham interventions in non-pharmacological RCTs often do not closely resemble the experimental treatment, increasing the risk of unblinding. Achieving blinding in non-pharmacological trials poses unique challenges considering the participatory nature of such interventions (Hohenschurz-Schmidt et al., 2023a). Moreover, the absence of unified criteria for control interventions in PPS trials leads to diverse approaches and inadequate reporting on blinding effectiveness (Hohenschurz-Schmidt et al., 2023a).

Following an analysis of 198 sham control interventions, common designs emerged, but significant gaps in reporting were also evident (Hohenschurz-Schmidt et al., 2023a). While assessments of the similarity between control and experimental interventions prioritise certain features, variability persists, reflecting the difficulties in designing control interventions given the complexity of treatments and mechanistic considerations (Hohenschurz-Schmidt et al., 2023a). Insufficient reporting of blinding methods and control intervention development hampers the assessment of the credibility and effectiveness of control interventions. There were also deficiencies in reporting provider characteristics and the theoretical background of control interventions (Hohenschurz-Schmidt et al., 2023a).

Future recommendations should focus on trial objectives, theory-driven development, feasibility testing, and enhanced reporting standards to ensure successful blinding with complex control interventions in large-scale trials of PPS therapies (Hohenschurz-Schmidt et al., 2023a).

Despite these challenges, high-similarity control interventions are feasible and capable of offering insights into treatment efficacy and mechanisms (Hohenschurz-Schmidt et al., 2023a). A recent meta-analysis delved into the significance of blinding and sham control methods in PPS trials for pain (Hohenschurz-Schmidt et al., 2023b). Blinding is necessary to prevent participants from establishing their treatment allocation and to avoid bias from treatment expectations. While placebo controls are standard in drug trials, designing appropriate sham controls for non-pharmacological interventions is more challenging given the complexity of these treatments and their reliance on patient-practitioner interactions (Hohenschurz-Schmidt et al., 2023b). In non-pharmacological studies, control interventions, often termed "sham" or "attention controls," aim to mimic the experimental treatment without its active components (Hohenschurz-Schmidt et al., 2023b).

Complications arise in matching control interventions, particularly touch and attention focus, as seen in manual/physical therapy trials where control interventions targeting non-affected body parts may not align with experimental treatments (Hohenschurz-Schmidt et al., 2023a). Concerns regarding the perceived benefits of human touch prompt consideration of non-touch control interventions. For instance, massage-based or mobilisation-based treatments may be compared with detuned ultrasound or other devices (Hohenschurz-Schmidt et al., 2023a). Similarly, psychological interventions often lack sham controls, relying instead on comparisons with treatment-as-usual, complicating efforts to isolate specific treatment mechanisms. Achieving similarity between control and experimental interventions is essential to accurately assess treatment efficacy (Hohenschurz-Schmidt et al., 2023a).

A recent meta-analysis revealed moderate placebo responses across PPS therapies for pain, with patients in sham control groups showing improvements (Hohenschurz-Schmidt et al., 2023b). However, differences in outcomes were partly explained by variations in the similarity between experimental and control interventions, particularly the number of treatment sessions, mode of application, intervention individualisation, fidelity monitoring, and treatment environment (Hohenschurz-Schmidt et al., 2023b). This highlights the importance of well-matched control interventions to enhance participant blinding, prevent biased trial results, and minimise differential attrition (Hohenschurz-Schmidt et al., 2023b).

These studies emphasise the need for rigorous study designs to accurately assess treatment efficacy while minimising bias (Hohenschurz-Schmidt et al., 2023a; 2023b). Accordingly, routine assessments of blinding effectiveness, and improved reporting standards for control interventions are required. Ensuring equivalence between experimental and control groups is indispensable for the validity and reliability of PPS trial outcomes in pain management research (Hohenschurz-Schmidt et al., 2023b). Enhanced reporting standards may provide a more comprehensive understanding of trial environments, patient demographics, and treatment characteristics, which are necessary for assessing the generalisability of trial findings (Hohenschurz-Schmidt et al., 2023a). Clearer standards for interpreting trial results and adhering to reporting guidelines are needed (Hohenschurz-Schmidt et al., 2023a).

To address these challenges, recent guidelines were established using a three-round Delphi study relating to the design, implementation, and documentation of control interventions in PPS trials (Hohenschurz-Schmidt et al., 2023c). Key recommendations for clinical PPS trials assessing treatment efficacy or mechanisms included developing control interventions that closely resemble the tested intervention, with the exception of the specific components under investigation (Hohenschurz-Schmidt et al., 2023c). The modified TIDieR-Placebo/CoPPS reporting checklist was proposed as a useful tool to promote adequate reporting and facilitate evidence-based recommendations for designing and conducting PPS trials (Hohenschurz-Schmidt et al., 2023c). Additionally, engaging stakeholders early, conducting feasibility studies, and piloting interventions can enhance the quality and acceptability of control interventions. If it is a trial objective, then regular assessment and reporting of blinding effectiveness are also recommended. Detailed and transparent reporting practices are important to enhance the interpretation and reproducibility of trial findings (Hohenschurz-Schmidt et al., 2023c).

The critical examination of clinical trials in pain therapy highlights the limitations of traditional RCTs and the need for more pragmatic approaches to bridge the gap between research and clinical practice (Hohenschurz-Schmidt et al., 2022). Pragmatic trials offer a unique opportunity to assess treatment effectiveness in real-world settings, addressing the limitations associated with stringent exclusion criteria and narrow outcome measures in traditional RCTs (Hohenschurz-Schmidt et al., 2022). By involving large participant cohorts, multiple trial sites, and longer follow-up periods, pragmatic trials aim to replicate the complexities of clinical practice. However, they face challenges such as complex recruitment strategies, difficulty in standardising treatment protocols, and limitations in implementing blinding procedures, all of which can impact internal and external validity (Hohenschurz-Schmidt et al., 2022).

Despite these problems, pragmatic trials provide useful insights into intervention effectiveness, particularly in assessing non-pharmacological approaches, which are often overlooked in traditional RCTs (Hohenschurz-Schmidt et al., 2022). A comprehensive overview of important considerations for the design of pragmatic trials for pain treatment is provided by Hohenschurz-Schmidt and colleagues (2023d). It focuses on providing recommendations for enhancing the internal validity of pragmatic trials and facilitating the translation of research findings into clinical practice (Hohenschurz-Schmidt et al., 2023d). Accordingly, future research involving CFs in pain management should carefully consider and review these methodological issues and associated recommendations to ensure the reliability and validity of the findings.

Chapter 7. Conclusion

The purpose of this study was to examine the role of CFs during conservative treatment for cLBP. This is important because of the high prevalence and debilitating nature of LBP, which is a leading cause of disability both in the UK (IMHE, 2020) and globally (James et al., 2018). Despite the widespread occurrence of LBP, current treatments often provide modest symptom relief (Bradbury et al., 2016). CFs can be broadly categorised into five key domains, which encompass various aspects of the clinical encounter. These domains include the beliefs and characteristics of both the patient and the practitioner, the patient-practitioner relationship, treatment characteristics, and the treatment environment or setting (Di Blasi et al., 2001). Optimally modulating CFs during clinical interactions has the potential to enhance the quality and effectiveness of MSK care (Rossettini et al., 2020; Testa & Rossettini, 2016). A gap in the literature was identified concerning the limited knowledge regarding the specific role of CFs during the management of patients experiencing cLBP. Translational research is needed to bridge the gap between theory and clinical practice (Bishop et al., 2017; Colloca & Miller, 2011b). Additionally, it is important to explore underrepresented stakeholders' perspectives, who may have influential insights, to better understand how CFs can be explicitly targeted and harnessed (Bishop et al., 2017).

Accordingly, this study adopted a multiphase research design consisting of three consecutive studies to examine how CFs influenced conservative cLBP management and outcomes from three different perspectives. Firstly, a systematic literature review was conducted to evaluate the existing evidence regarding the impact of CFs on pain intensity and physical functioning outcomes following conservative LBP treatment (Sherriff et al., 2022). This approach allowed for a comprehensive analysis of the literature, enabling the identification of relevant studies and the synthesis of their findings. Secondly, a Delphi-consensus survey was administered to a panel of UK MSK practitioners to gauge their perceptions of CFs during cLBP management (Sherriff et al., 2023). The Delphi study sought to gather expert opinions and establish consensus amongst MSK practitioners regarding the perceived applicability and influence of CFs in clinical practice. The third study involved semi-structured interviews with UK patient-practitioner dyads to explore their experiences of CFs during private LBP consultations. This qualitative approach provided in-depth insights into the experiences and perspectives of individuals directly involved in the treatment process. By integrating these three approaches, the study aimed to provide deeper insights into the role and influence of CFs during conservative cLBP treatment.

This research yielded several notable findings that have the potential to improve current treatment approaches for patients experiencing cLBP. These findings may offer beneficial insights for MSK practitioners, which may inform their understanding and awareness of CFs. This knowledge may facilitate improved pain management and physical functioning outcomes for patients undergoing conservative cLBP treatment. Consequently, these findings have several plausible clinical, educational, and theoretical implications that are subsequently delineated.

From a clinical perspective, this study provides valuable insights by highlighting important CFs and how they may be optimally harnessed during clinical practice. The systematic review identified prominent CFs that play an important role during conservative cLBP management which have a positive impact on patient outcomes. These CFs include: (a) addressing misinformed, unhelpful, or maladaptive beliefs about cLBP or pain (i.e., illness representations) through education tailored to the patient's needs; (b) shaping the patient's beliefs about symptom improvements (i.e., treatment expectations) through positive verbal suggestions; (c) using visual or physical cues that signify pain-relieving properties of treatments (i.e., treatment characteristics), thus shaping the patient's treatment expectations; as well as (d) fostering a positive and person-centred communication approach, including empathy, to strengthen the therapeutic relationship (Sherriff et al., 2022). The strongest evidence was found in relation to the patients' expectations and beliefs, with medium to large effects observed, indicating a meaningful influence on clinical outcomes despite variations among studies. Enhancing the therapeutic alliance was also found to be impactful, but additional training, such as motivational interviewing, may be necessary to strengthen the patient-practitioner relationship (Sherriff et al., 2022). Further research is required to determine the most effective approach for developing and maintaining effective therapeutic relationships during MSK care. Notably, no studies investigating the practitioner’s beliefs or characteristics were identified, and only one small study with a 'Fair' rating examined the treatment setting, suggesting limited available research regarding the role of these two CF domains during cLBP rehabilitation (Sherriff et al., 2022).

The Delphi study revealed that a panel of UK MSK practitioners expressed positive attitudes towards CFs during cLBP rehabilitation and reported actively leveraging CFs, both explicitly and implicitly (Sherriff et al., 2023). Although all five CF domains were acknowledged as capable of influencing patient outcomes, the patient-practitioner relationship, the patient's beliefs/characteristics, and the practitioners' own beliefs/characteristics were perceived as comparatively more important than the treatment characteristics and the environment (Sherriff et al., 2023). However, the study also

highlighted that MSK practitioners may be underestimating the role of their attitudes and behaviour as key CFs underpinning the quality of patient-practitioner relationships and the subsequent impact on patients' beliefs and expectations.

The qualitative study emphasised the pivotal role that MSK practitioners' beliefs and characteristics played in shaping the quality of LBP consultations. This is important because the systematic review did not identify studies examining this particular CF domain. The qualitative research indicated that actively leveraging CFs during LBP consultations enabled MSK practitioners to augment conservative treatments and assist patients in adopting a more hopeful and optimistic mindset, which is a novel finding. By demonstrating empathy and active listening, practitioners established trusting and cooperative partnerships, enabling them to gather important information about each patient's LBP journey, including their emotional state and psychosocial factors contributing to their pain experiences. The qualitative study also emphasised that a personalised approach, tailored to meet patients' unique cognitive and emotional needs, positively influenced patients' treatment expectations, and helped address patients' unhelpful or misinformed illness beliefs. This corresponds with previous research and clinical guidelines, which emphasise providing a holistic approach to cLBP care. The study sheds light on how CFs were purposefully harnessed during LBP consultations to influence patient outcomes, emphasising the importance of MSK practitioners' attitudes and how these informed their approach to patient care.

This research also identified several treatment characteristics that held significance for patients experiencing cLBP. Beneficial treatment features included clear and credible LBP explanations coupled with an optimistic prognosis, regular symptom change feedback, establishing treatment credibility, collaborative goal setting, as well as tailoring treatment and advice. These findings may provide useful clinical insights into effective approaches during the management of cLBP. Conveying clear and credible explanations of the patient's LBP together with an optimistic outlook for recovery by ruling out serious injury, illness, or pathology were found to be important. This aligns with previous research and emphasises the significance of providing patients with person-centred explanations to help them make sense of their LBP experiences but stresses the need to instil an optimistic outlook for recovery too. Additionally, providing regular feedback to patients regarding changes in their symptoms, including demonstrating functional improvements, appeared to positively impact patients' expectations. This feedback appeared to help patients monitor their progress and inform their recovery expectations, which may shed new light on the importance of ongoing feedback during cLBP treatment.

This research also suggested that it was important to establish the credibility of recommended treatments to positively influence patients' expectations. Practitioners who focused on cultivating trusting therapeutic relationships appeared to positively shape patients' treatment expectations by explaining how relevant treatment characteristics could aid in alleviating LBP symptoms. Effective communication regarding these potential benefits, tailored to the patient's needs, can contribute to increased patient confidence. When patients are provided with a clear understanding of the rationale or prospective benefits of a treatment plan, it may increase their trust and belief in the approach. This may improve treatment adherence and motivate patients to actively engage in self-management strategies, which can influence clinical outcomes.

Other meaningful treatment features included involving patients in the process of collaboratively setting goals. This may help ensure the treatment plan aligns with each patient's needs and preferences. Patients also valued tailored advice and individualised treatment, which are consistent with the principles of person-centred care. By empowering patients with knowledge and fostering a collaborative approach, MSK practitioners can help patients feel more confident in their treatment journey, leading to better clinical outcomes. These findings corroborate previous research and reinforce the value of adopting person-centred practices during cLBP rehabilitation. The identified treatment characteristics played a meaningful role in managing cLBP. By incorporating these CFs into clinical practice, practitioners can potentially enhance clinical outcomes and improve the quality of care.

The qualitative research findings highlighted the significance of treatment environments in shaping patient experiences during cLBP care. This is important given the limited number of high-quality studies identified in the systematic review. Treatment environments, which were perceived as clean, safe, and inviting, contributed to positive patient experiences. This implies that it is important to create both physically and psychologically safe treatment spaces. Recognising the impact of the treatment environment adds weight to the existing body of knowledge. Maintaining high standards of hygiene may promote confidence and trust by meeting patients' expectations and fostering a positive treatment context. Although data collection occurred during the Covid-19 pandemic, the importance of safety and hygiene may extend beyond this context and could be especially relevant for inpatient settings. Ensuring clean and safe treatment spaces is essential for high-quality healthcare environments, as it demonstrates professionalism and a commitment to patient well-being. Patients are more likely to feel comfortable, at ease, and confident in the care they are receiving, which is important for promoting positive experiences and facilitating favourable outcomes.

Furthermore, features of the clinical environment that facilitate effective communication can also strengthen trust-based relationships, especially where patients consistently receive respectful, dignified, and compassionate treatment from all clinical staff. Ensuring patient privacy and confidentiality appears to enhance a sense of security, which may improve communication and strengthen patient-practitioner relationships. Displaying MSK practitioners' credentials and certificates may also contribute to a sense of professionalism and trustworthiness, reinforcing patients' confidence. These findings may not only be applicable during unique circumstances, like the Covid-19 pandemic, but as an ongoing commitment to providing optimal patient care.

By acknowledging the role of treatment environments, practitioners can take proactive measures to create positive and supportive environments during MSK care. This may involve implementing strategies to ensure cleanliness, enhance privacy measures, and promote a welcoming and professional atmosphere. Such initiatives may contribute to improved patient experiences and influence treatment outcomes. However, since the environment of care may be influenced by other CFs, adopting an integrated approach could potentially amplify these effects. Future studies could delve deeper into understanding specific elements of treatment settings that may have the largest impact on patient experiences. This may help inform the development of guidelines and recommendations for creating person-centred and conducive MSK care environments. Collectively, these findings provide useful clinical insights into the role and influence of CFs during cLBP management.

The study's educational relevance highlights the importance of training MSK practitioners to effectively utilise CFs when managing patients experiencing cLBP. The Delphi study further identified unique areas where MSK practitioners may benefit from additional support to explicitly implement CFs during clinical practice (Sherriff et al., 2023). While MSK practitioners demonstrated awareness of CF care approaches, they expressed a lack of confidence in implementing various person-centred practices and addressing patients' complex cognitive and emotional needs. It suggested that to ensure the optimal modulation of CFs during cLBP rehabilitation, it is necessary to address gaps in MSK practitioners' skills and knowledge, which may help bridge the divide between theory and clinical practice (Sherriff et al., 2023). Supplementary training could focus on enhancing practitioners' communication skills, implementing person-centred practices, and utilising behaviour change techniques and self-management strategies to develop patients' self-efficacy. Supporting practitioners' emotional intelligence is also important to enable them to better identify and address patients' negative feelings or thoughts, erroneous beliefs, and unhelpful behaviours (Sherriff et al., 2023).

This research recommends more comprehensive training that goes beyond acquiring biomedical expertise to enhance MSK practitioners' confidence and competence. Integrating contemporary knowledge of CFs into educational curricula and professional development programmes can better prepare MSK practitioners and improve their skills in managing cLBP. Cultivating MSK practitioners' proficiency in applying essential psychosocial skills during LBP management and increasing their awareness of CFs has the potential to enhance conservative therapeutic approaches. By incorporating psychosocial aspects into practice and considering the complex interplay between CFs, MSK practitioners can provide more comprehensive and effective care. However, further research is needed to determine the most effective training methods for MSK practitioners to explicitly implement CF care approaches. Such research should explore the integration of CFs into existing rehabilitation protocols and how to better assess their impact on outcomes.

Lastly, a notable contribution of the current study is its comprehensive examination of all five CF domains, which goes beyond previous research that has often focused on individual CFs within clinical encounters. This broad approach, encompassing multiple perspectives, offers a more holistic understanding of CFs during cLBP rehabilitation. By exploring the interconnections among these CF domains, the study enhances the theoretical understanding of their collective influence on patient outcomes. Furthermore, it emphasises the intricate interplay between the main CF domains and delineated important CFs relevant to clinical practice. The findings suggest that deliberately and cohesively modifying multiple CFs in a coordinated manner may yield greater clinical benefits (Sherriff et al., 2022). This knowledge contributes to the existing understanding of CFs while also highlighting their role in cLBP care, which is valuable considering the challenges associated with managing non-specific LBP given its significance as a public health concern (Maher et al., 2017).

This study provides unique insights by proposing a conceptual framework that illustrates the interconnected nature of CFs in clinical practice. This framework provides a deeper conceptual understanding of how CFs can positively shape patients' recovery expectations and, consequently, their clinical outcomes. It may serve as a practical tool for MSK practitioners to consider when planning treatment interventions and patient management strategies. Purposefully leveraging CFs presents a potentially parsimonious, cost-effective, and low-risk strategy that could be widely implemented across various treatment modalities. The study suggests a shift in focus from solely identifying new or improving existing treatments for cLBP. Instead, it may be more advantageous to prioritise the optimisation of clinical encounters by intentionally leveraging CFs. The recognition of the importance of

integrating CFs into clinical practice and modulating multiple CFs in the management of cLBP underscores their potential to enhance patient outcomes.

In summary, the implications of this research are not limited to clinical practice and may extend to education and theory too. The key findings offer insights into how MSK practitioners can better manage cLBP and enhance patient outcomes using CFs. By identifying the role of key CFs, this research has the potential to inform the development of future evidence-based interventions that incorporate CFs into cLBP care. By focusing on psychosocial factors during LBP consultations, practitioners can provide more comprehensive and individualised care that addresses patients' specific needs and concerns. It may guide the training and education of MSK practitioners so they are better equipped to incorporate CFs into clinical practice in the future, which may improve patient outcomes and satisfaction. This study highlights the value of person-centred care and considers the dynamic connections between CFs, adding weight to the importance of adopting a comprehensive and integrated approach to managing patients with cLBP. Creating safe treatment environments where patients feel respected, valued, and supported is also important. Providing high-quality care that meets patients' needs and expectations improves their overall treatment experience. Furthermore, this study proposes a novel conceptual understanding of CFs by exploring their intricate connections and impact on patients with cLBP, which may be applicable in other clinical settings. In conclusion, this research demonstrates the clinical utility of CFs in managing cLBP. It highlights the prospective benefits of supplementary education and bespoke training to facilitate the effective modulation of CFs. Finally, it may also contribute to the advancement of theoretical models for conservatively managing cLBP.

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Appendices

Appendix I – Supplementary Material (Systematic Review)

The following supplementary materials are included in this Appendix:

(i) **Methods S1.** Search Strategy for Medline (Sherriff et al., 2022);

(ii) **Methods S2.** Search Strategy for CINAHL (Sherriff et al., 2022);

(iii) **Methods S3.** Search Strategy for PsycINFO (Sherriff et al., 2022);

(iv) **Methods S4.** Search Strategy for AMED (Sherriff et al., 2022);

(v) **Results S1.** External validity sub-scale (Item 11): Quality assessment scoring grid (Sherriff et al., 2022);

(vi) **Table S1.** Summary of study characteristics clustered by research design (Sherriff et al., 2022);

(vii) **Table S2.** Contextual Factor intervention group(s) within-group change in outcomes from baseline clustered by research design (Sherriff et al., 2022); and

(viii) **Tables S3.1** and **S3.2.** Quality assessment results of included studies

(i) Methods S1: Search strategy for Medline

Line Number	Search Terms
1	(placebo ADJ (effect* OR response* OR analgesi*)).ti,ab
2	(nocebo ADJ (effect* OR response* OR hyperalgesia)).ti,ab
3	(context* ADJ (factor* OR effect* OR response*)).ti,ab
4	(common ADJ (factor* OR effect*)).ti,ab
5	(non?specific ADJ (effect* OR factor*)).ti,ab
6	(alliance*).ti,ab
7	(patient ADJ (relation* OR interact*)).ti,ab
8	(patient* ADJ (expect* OR belief* OR attitude*)).ti,ab
9	(practitioner* ADJ (belief* OR attitude* OR effect*)).ti,ab
10	(positive ADJ (expect* OR suggest*)).ti,ab
11	(negative ADJ (expect* OR suggest*)).ti,ab
12	(empath* OR warm* OR kind* OR compassion* OR friendl*).ti,ab
13	(rapport).ti,ab
14	(“open label placebo”).ti,ab
15	(expect* ADJ (effect* OR response*)).ti,ab
16	(patient* ADJ (experience* OR perspective*)).ti,ab
17	(illness ADJ (perception* OR belief*)).ti,ab
18	(“initial consultation”).ti,ab
19	(“white coat” OR “white?coat effect”).ti,ab
20	exp “NOCEBO EFFECT”/
21	exp “PLACEBO EFFECT”/
22	exp “THERAPEUTIC ALLIANCE”/
23	exp “PROFESSIONAL-PATIENT RELATIONS”/
24	exp “PHYSICIAN-PATIENT RELATIONS”/
25	exp HOPE/
26	exp “FACIAL EXPRESSION”/
27	exp “NONVERBAL COMMUNICATION”/
28	exp “VERBAL BEHAVIOR”/
29	exp “PERSUASIVE COMMUNICATION”/
30	exp “HEALTH COMMUNICATION”/
31	exp “FACIAL EXPRESSION”/
32	exp “ATTITUDE OF HEALTH PERSONNEL”/
33	exp TRUST/
34	(“back pain”).ti,ab
35	(“low back pain”).ti,ab
36	(“LBP”).ti,ab
37	(“chronic low back pain”).ti,ab
38	(“cLBP”).ti,ab
39	(“persistent low back pain”).ti,ab
40	(“non?specific low back pain”).ti,ab
41	(“non?specific back pain”).ti,ab
42	(“lumbar pain”).ti,ab
43	(lumbago).ti,ab
44	(radiculitis).ti,ab
45	(sciatica).ti,ab
46	(“discogenic low back pain”).ti,ab
47	(“facet joint pain”).ti,ab
48	(“sacroiliac joint pain”).ti,ab
49	exp SCIATICA/
50	exp “LUMBOSACRAL REGION”/
51	exp “LOW BACK PAIN”/
52	exp “BACK PAIN”/
53	(1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33)
54	(34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50 OR 51 OR 52)
59	(53 AND 54) *[DT 2009-2022]*

(ii) Methods S2. Search Strategy for CINAHL

Line Number	Search Terms
1	(placebo ADJ (effect* OR response* OR analgesi*)).ti,ab
2	(nocebo ADJ (effect* OR response* OR hyperalgesia)).ti,ab
3	(context* ADJ (factor* OR effect* OR response*)).ti,ab
4	(common ADJ (factor* OR effect*)).ti,ab
5	(non?specific ADJ (effect* OR factor*)).ti,ab
6	(alliance*).ti,ab
7	(patient ADJ (relation* OR interact*)).ti,ab
8	(patient* ADJ (expect* OR belief* OR attitude*)).ti,ab
9	(practitioner* ADJ (belief* OR attitude* OR effect*)).ti,ab
10	(positive ADJ (expect* OR suggest*)).ti,ab
11	(negative ADJ (expect* OR suggest*)).ti,ab
12	(empath* OR warm* OR kind* OR compassion* OR friendl*).ti,ab
13	(rapport).ti,ab
14	(“open label placebo”).ti,ab
15	(expect* ADJ (effect* OR response*)).ti,ab
16	(patient* ADJ (experience* OR perspective*)).ti,ab
17	(illness ADJ (perception* OR belief*)).ti,ab
18	(“initial consultation”).ti,ab
19	(“white coat” OR “white?coat effect”).ti,ab
20	exp "PLACEBO EFFECT"/
21	exp PLACEBOS/
22	exp "PROFESSIONAL-CLIENT RELATIONS"/
23	exp "PHYSICIAN-PATIENT RELATIONS"/
24	exp "NURSE-PATIENT RELATIONS"/
25	exp "PROFESSIONAL-PATIENT RELATIONS"/
26	exp "INTERPERSONAL RELATIONS"/
27	exp "VERBAL BEHAVIOR"/
28	exp "NONVERBAL COMMUNICATION"/
29	exp "COMMUNICATION SKILLS"/
30	exp COMMUNICATION/
31	exp TRUST/
32	exp CHARACTER/
33	exp CARING/
34	exp EMPATHY/
35	exp "THERAPEUTIC ALLIANCE"/
36	exp COMPASSION/
37	exp HOPE/
38	exp "ATTITUDE OF HEALTH PERSONNEL"/
39	(“back pain”).ti,ab
40	(“low back pain”).ti,ab
41	(“LBP”).ti,ab
42	(“chronic low back pain”).ti,ab
43	(“cLBP”).ti,ab
44	(“persistent low back pain”).ti,ab
45	(“non?specific low back pain”).ti,ab
46	(“lumbar pain”).ti,ab
47	(sciatica).ti,ab
48	(“discogenic low back pain”).ti,ab
49	exp "LOW BACK PAIN"/
50	exp "BACK PAIN"/
51	(1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19)
52	(20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38)
53	(51 OR 52)
54	(39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50)
55	(53 AND 54) *[DT 2009-2022]*

(iii) Methods S3. Search Strategy for PsycINFO

Line Number	Search Terms
1	(placebo ADJ (effect* OR response* OR analgesi*)).ti,ab
2	(nocebo ADJ (effect* OR response* OR hyperalgesia)).ti,ab
3	(context* ADJ (factor* OR effect* OR response*)).ti,ab
4	(common ADJ (factor* OR effect*)).ti,ab
5	(non?specific ADJ (effect* OR factor*)).ti,ab
6	(alliance*).ti,ab
7	(patient ADJ (relation* OR interact*)).ti,ab
8	(patient* ADJ (expect* OR belief* OR attitude*)).ti,ab
9	(practitioner* ADJ (belief* OR attitude* OR effect*)).ti,ab
10	(positive ADJ (expect* OR suggest*)).ti,ab
11	(negative ADJ (expect* OR suggest*)).ti,ab
12	(empath* OR warm* OR kind* OR compassion* OR friendl*).ti,ab
13	(rapport).ti,ab
14	(“open label placebo”).ti,ab
15	(expect* ADJ (effect* OR response*)).ti,ab
16	(patient* ADJ (experience* OR perspective*)).ti,ab
17	(illness ADJ (perception* OR belief*)).ti,ab
18	(“initial consultation”).ti,ab
19	(“white coat” OR “white?coat effect”).ti,ab
20	exp PLACEBO/
21	exp "THERAPEUTIC ALLIANCE"/
22	exp "COMMON FACTORS"/
23	exp "INTERPERSONAL RELATIONSHIPS"/
24	exp "THERAPEUTIC ENVIRONMENT"/
25	exp "CARING BEHAVIORS"/
26	exp "INTERPERSONAL INTERACTION"/
27	exp EXPECTATIONS/
28	exp HOPE/
29	exp "TRUST (SOCIAL BEHAVIOR)"/
30	exp "LISTENING (INTERPERSONAL)"/
31	exp "EYE CONTACT"/
32	exp "BODY LANGUAGE"/
33	exp "ACTIVE LISTENING"/
34	exp "INTERPERSONAL COMMUNICATION"/
35	exp "CLIENT ATTITUDES"/
36	exp GESTURES/
37	exp "FACIAL EXPRESSIONS"/
38	exp "VERBAL LEARNING"/
39	(“back pain”).ti,ab
40	(“low back pain”).ti,ab
41	(“LBP”).ti,ab
42	(“chronic low back pain”).ti,ab
43	(“cLBP”).ti,ab
44	(sciatica).ti,ab
45	exp "BACK PAIN"/
46	(1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19)
47	(20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38)
48	(46 OR 47)
49	(39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45)
50	(48 AND 49) *[DT 2009-2022]*

(iv) Methods S4. Search Strategy for AMED

Line Number	Search Terms
1	(placebo ADJ (effect* OR response* OR analgesi*)).ti,ab
2	(nocebo ADJ (effect* OR response* OR hyperalgesia)).ti,ab
3	(context* ADJ (factor* OR effect* OR response*)).ti,ab
4	(common ADJ (factor* OR effect*)).ti,ab
5	(non?specific ADJ (effect* OR factor*)).ti,ab
6	(alliance*).ti,ab
7	(patient ADJ (relation* OR interact*)).ti,ab
8	(patient* ADJ (expect* OR belief* OR attitude*)).ti,ab
9	(practitioner* ADJ (belief* OR attitude* OR effect*)).ti,ab
10	(positive ADJ (expect* OR suggest*)).ti,ab
11	(negative ADJ (expect* OR suggest*)).ti,ab
12	(empath* OR warm* OR kind* OR compassion* OR friendl*).ti,ab
13	(rapport).ti,ab
14	(“open label placebo”).ti,ab
15	(expect* ADJ (effect* OR response*)).ti,ab
16	(patient* ADJ (experience* OR perspective*)).ti,ab
17	(illness ADJ (perception* OR belief*)).ti,ab
18	(“initial consultation”).ti,ab
19	(“white coat” OR “white?coat effect”).ti,ab
20	exp PLACEBOS/
21	exp "NURSE PATIENT RELATIONS"/
22	exp "PHYSICIAN PATIENT RELATIONS"/
23	exp "PROFESSIONAL PATIENT RELATIONS"/
24	exp "VERBAL BEHAVIOR"/
25	exp "TRUTH DISCLOSURE"/
26	exp "NONVERBAL COMMUNICATION"/
27	exp COMMUNICATION/
28	exp "INTERPERSONAL RELATIONS"/
29	exp EMPATHY/
30	exp "ATTITUDE OF HEALTH PERSONNEL"/
31	(“back pain”).ti,ab
32	(“low back pain”).ti,ab
33	(“LBP”).ti,ab
34	(“chronic low back pain”).ti,ab
35	(“cLBP”).ti,ab
36	(“non?specific low back pain”).ti,ab
37	(sciatica).ti,ab
38	(“sacroiliac joint pain”).ti,ab
39	exp "LOW BACK PAIN"/
40	exp BACKACHE/
41	(1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19)
42	(20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30)
43	(41 OR 42)
44	(31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40)
45	(43 AND 44) *[DT 2009-2022]*

(v) Results S1

Results S1. External validity sub-scale (Item 11): Quality assessment scoring grid

Reference	**Gender** Ratio of females < 60.0%	**Age** Mean Sample Age: ≥ 40.00 and ≤ 63.5 years	**Q11 Decision** (Score)
RCT			
[35]	No	Yes	No (0)
[36]	Yes	Yes	Yes (1)
[37]	No	No	No (0)
[38]	Yes	Yes	Yes (1)
[39]	No	Yes	No (0)
[40]	No	Yes	No (0)
[41]	Yes	Yes	Yes (1)
[42]	No	Yes	No (0)
[43]	No	No	No (0)
[44]	Yes	Yes	Yes (1)
[45]	No	Yes	No (0)
[46]	Yes	Yes	Yes (1)
CCT			
[47]	Yes	Yes	Yes (1)
[48]	No (unclear 5% missing)	Yes	No (0)
[49]	No	Not Specified	No (0)
Quasi-Experimental			
[50]	Yes	Yes	Yes (1)
[51]	Yes	No	No (0)
Observational cohort			
[52]	Yes	Yes	Yes (1)
[53]	No	Yes	No (0)
[54]	Yes	Yes	Yes (1)
[55]	No	Yes	No (0)
Total	**10 (47.62%)**	**17 (80.95%)**	**9 (42.86%)**

(vi) Table S1

Table S1. Summary of study characteristics clustered by research design

Reference	**Country of Origin**	**Study Setting**	**Total Sample size (*n*)**	**Mean age Years** (*SD*)	**Gender Proportions** (F : M %)	**Contextual Factor(s)**	**Frequency / Duration of Contextual Factor Treatment**
Randomised Controlled Trials (RCTs)							
[35]	Not specified *(possibly Hong Kong)*	Local outpatient physical therapy department	Allocated (88) Baseline (76) Midpoint (63) Post-Tx (60) Follow-up (55)	Control: 45.1 (±10.7); Intervention: 44.6 (±11.2)	63% : 37%	1) Patient's beliefs; 3) Patient-practitioner relationship; 5) Treatment characteristics	– 10 individual / one-on-one sessions (± 30 minutes each) – Duration: 8 weeks
[36]	Norway	Three different private clinics	Allocated (121) Baseline (121) Post-Tx (94) Follow-up (88)	Control: 42.9 (±12.5); Intervention: 41.0 (±10.3)	52% : 48%	1) Patient's beliefs	– Weekly: first 2 to 3 sessions; – Then one session every 2–3 weeks (12 weeks duration); – One-on-one sessions
[37]	Canada	University affiliated sports physical therapy/ rehabilitation centre	Allocated (117) Baseline (117) Post-Tx (117)	Combined: 30.0 (±6.8)	60% : 40%	3) Patient-practitioner relationship; 5) Treatment characteristics	– One individual / one-on-one session (± 30 to 45 minutes)
[38]	United States of America (Colorado)	A University setting	Allocated (100) Baseline (100) Post-Tx (91) 1-month (79) 2-month (75) 3-month (74) 6-months (79) 12-months (81)	Control: 41.3 (±15.9); Intervention: 42.6 (±16.2)	56% : 44%	1) Patient's beliefs	– 8 individual / one-on-one sessions (± 60 minutes each) – Twice weekly for 4 weeks
[39]	Germany	Back Pain Centre, University Hospital	Allocated (127) Baseline (122) Post-Tx (122)	Control: 58.4 (±14.0); Intervention: 60.3 (±15.2)	62% : 38%	1) Patient's beliefs; 5) Treatment characteristics	– 21 days (capsules taken twice a day); – Video providing standardised information regarding the placebo effect before randomisation.
[40]	Portugal	Outpatient pain unit in a general public hospital	Allocated (97) Baseline (83) Post-Tx (76)	Control: 44.1 (±13.7); Intervention: 44.4 (±13.2)	71% : 29%	1) Patient's beliefs; 5) Treatment characteristics	– 21 days (2 pills twice a day) plus treatment as usual; – 2 x individual / one-on-one interactions with Principal investigator (10-15 minutes each)

Table S1 continued. Summary of study characteristics clustered by research design

Reference	Country of Origin	Study Setting	Total Sample size (*n*)	Mean age Years (*SD*)	Gender Proportions (F : M %)	Contextual Factor(s)	Frequency / Duration of Contextual Factor Treatment
Randomised Controlled Trials (RCTs)							
[41]	Ireland (Dublin)	12 publicly funded outpatient physiotherapy clinics	Baseline (255) Week 1 (196) Week 4 (171) Week 12 (173) Week 24 (207)	Control: 46.71 (±13.48); CONNECT: 44.11 (±12.96)	54% : 46%	1) Patient's beliefs; 3) Patient-practitioner relationship	– CONNECT: *M* = 3.08 individual / one-on-one sessions with physical therapist (S.D. = ± 1.88) – Duration: *M* = 7.46 weeks
[42]	Scotland (Glasgow)	"Back to Fitness exercise classes" in the Greater Glasgow National Health Service (NHS)	Allocated (38) Baseline (38) Post-Tx (34) Follow-up (27)	ED-EX: 45.5 (±9.5) ED: 45.2 (±11.9)	66% : 34%	1) Patient's beliefs; 3) Patient-practitioner relationship	– ED-EX: One 2.5-hour PNE session and 6 weekly exercise sessions (± 1 hour each) – ED: One 2.5-hour pain (neuro) biology education (PNE) session (unspecified if ED was group-based or one-on-one)
[43]	Japan	Single tertiary medical centre	Allocated (52) Baseline (52) Post-Tx (52) Follow-up (48)	Combined: 66.8 (±13.4)	61.5%: 38.5%	1) Patient's beliefs; 5) Treatment characteristics	– 12 weeks (2 capsules taken twice a day (a.m. and p.m.); – At baseline, standardised information about placebo effects (covering 5 main points) lasting (± 60 minutes.
[44]	Brazil	An outpatient clinic with patients from the waiting list of two University physical therapy services	Allocated (222) Baseline (222) Post-Tx (205) 6-months (194) 12-months (191)	ED+TA: 46.0 (± 14.7) ED only: 47.2 (± 14.8) No ED: 50.8 (± 13.2)	57% : 43%	1) Patient's beliefs; 3) Patient-practitioner relationship	– Two individual / one-on-one sessions (± 60 minutes each) – 1-week interval between sessions
[45]	Germany	Department of Orthopaedics (University Hospital)	Allocated (Unclear) Baseline (48) Post-Tx $_{T1}$ (48) Post-Tx $_{T2}$ (48)	Combined: 49.97 (±13.64)	75% : 25%	1) Patient's beliefs; 5) Treatment characteristics	– One individual / one-on-one session (± 2 hours)
[46]	Germany	Treatment room in the Pain Therapy Section of the Department of Anaesthesiology	Allocated (96) Baseline (85) Post-Tx (73)	Combined: 50.04 (±11.07)	56% : 44%	1) Patient's beliefs; 5) Treatment characteristics	– Two individual / one-on-one sessions (± 2 hours each). – 8-day interval between sessions

Table S1 continued. Summary of study characteristics clustered by research design

Reference	**Country of Origin**	**Study Setting**	**Total Sample size (*n*)**	**Mean age Years** (*SD*)	**Gender Proportions** (F : M %)	**Contextual Factor(s)**	**Frequency / Duration of Contextual Factor Treatment**
Controlled Clinical Trials (CCT; non-randomised)							
[47]	Israel	8 participating physical therapy clinics (Public Health Services)	Baseline (220) Post-Tx (198) Follow-up (189)	Control: 42.0 (±7.0) ETMI: 42.0 (±8.0)	54% : 46%	1) Patient's beliefs; 3) Patient-practitioner relationship	– At least two individual / one-on-one treatment sessions (±20-30 minutes) and no upper limit. – ETMI: *M* = 3.5 sessions (S.D. = ± 1.9)
[48]	Germany	4 inpatient MSK rehabilitation centres	Baseline (210) Post-Tx (201)	Control: 54.01 (±10.99) Intervention: 54.17 (±11.82)	64% : 36% (11 missing)	1) Patient's beliefs	– Three individual / one-on-one sessions (20 minutes each)
[49]	Brazil	University affiliated Spine Clinic of Sports Injury Centre	Baseline (30) Midpoint (30) Post-Tx (30)	Not reported	40% : 60%	3) Patient-practitioner relationship; 4) Therapeutic setting / environment	– Rehab: *M* = 13.6 sessions (of 16; in 8 weeks) in a group-format – Home: *M* = 13.9 sessions (of 24; in 8 weeks)
Quasi-experimental (uncontrolled)							
[50]	Ireland (Limerick)	Outpatient University affiliated treatment setting	$Baseline_{1\ to\ 3}$ (26) Post-Tx (24) $Follow\text{-}up_1$ (23) $Follow\text{-}up_2$ (22) $Follow\text{-}up_3$ (21)	Combined: 44.3 (±9.73)	54% : 46%	1) Patient's beliefs	– *M* = 7.7 individual / one-on-one sessions (S.D. = ± 2.5) – ± 60.0 minutes each – Duration: *M* = 12.0 weeks (S.D. = ± 3.5)
[51]	United States of America	4 physiotherapy clinics (in 2 different States)	Baseline (50) Post-Tx (50)	Combined: 64.3 (±10.73)	56% : 44%	1) Patient's beliefs	– One individual / one-on-one session (± 5 minutes) – Followed by Question-and-Answer session

Table S1 continued. Summary of study characteristics clustered by research design

Reference	Country of Origin	Study Setting	Total Sample size (*n*)	Mean age Years (*SD*)	Gender Proportions (F : M %)	Contextual Factor(s)	Frequency / Duration of Contextual Factor Treatment
Observational Cohort (uncontrolled)							
[52]	Germany	4 inpatient and 7 outpatient orthopaedic rehabilitation centres	Baseline (688) Post-Tx (611) Follow-up (468)	Combined: 51.0 (±11.2)	57% : 43%	3) Patient-practitioner relationship	– 4–5 therapy sessions per day (on weekdays). – *M* = 20.6 days (S.D. = ± 4.5) – Unclear whether individual or group-based treatment.
[53]	Australia	3 outpatient public hospital physiotherapy departments	Baseline (240) Post-Tx (182)	Group A: 54.2 (±15.4) Group B: 52.0 (±15.7); Group C: 53.6 (±14.3)	69% : 31%	3) Patient-practitioner relationship	– Up to 12 treatment sessions – Physical therapists chose the dose and techniques based on participant's clinical features. – Duration: 8 weeks – Exercises involved a group-format whilst those receiving spinal manipulative therapy involved individual sessions.
[54]	Netherlands	Outpatient rehabilitation centre	Baseline (156) Post-Tx (135)	Combined: 46.12 (±12.30)	56% : 44%	1) Patient's beliefs	– 10-14 individual / one-on-one sessions (± 60 minutes each)
[55]	Not specified *(possibly Australia)*	University outpatient physical therapy clinic	Baseline (136) Post-Tx (64)	Combined: 41.5 (±16.3)	69% : 31%	1) Patient's beliefs	– Physical Therapy (no additional information provided)
Notes: Post-Tx: post-treatment							

(vii) Table S2

Table S2. Contextual Factor intervention group(s) within-group change in outcomes from baseline clustered by research design

Ref No. (Year) & Study Design	**Quality Assessment Grading**	**Type of Contextual Factor(s)**	**Main CF-intervention Elements**	**Mean Change (Δ) from Baseline:** **Pain Intensity**	**Mean Change (Δ) from Baseline:** **Physical Functioning**
[35] (2011) RCT	Excellent (92.9%)	1) Patient's beliefs; 3) Patient-practitioner relationship; 5) Treatment characteristics	**MET**: Motivational Enhancement Treatment – proxy efficacy, treatment expectancy, therapeutic alliance, and empathy, combined with conventional physical therapy.	**Significant ($p < .001$)** VAS (0-10) *Post-treatment (1 month)* ***MΔ* = 2.2**; *n* = 38	**Significant (< .001)** RMDQ (0-24) *Post-treatment (1 month)* ***MΔ* = 4.4**; *n* = 38
[36] (2013) RCT	Excellent (89.3%)	1) Patient's beliefs	**CFT**: Cognitive Functional Therapy – strong focus on reframing back pain in a person-centred manner along with altering maladaptive / unhelpful behaviours to normalise movement.	**Significant ($p < .001$)** NRS (0-10) *Post-treatment (3 months)* ***MΔ* = 3.2**; *n* = 51; 95% C.I. [2.5 – 3.9]	**Significant ($p < .001$)** ODI (0-100) *Post-treatment (3 months)* ***MΔ* = 13.7**; *n* = 51 95% C.I. [11.4 – 16.1]
[37] (2014) RCT (2x2)	Excellent (89.3%)	3) Patient-practitioner relationship; 5) Treatment characteristics	Enhanced Therapeutic Alliance (**TA**) versus limited TA in patients receiving either active or sham interferential current therapy (IFC).	**Clinically important** NRS (0-10) *Post-treatment (1 session)* **Enhanced Therapeutic Alliance** Active IFC: ***MΔ* = 3.13**; *n* = 29 77.4% ↓ in pain intensity Sham IFC: ***MΔ* = 2.22**; *n* = 29 54.5% ↓ in pain intensity	*Not applicable*
[38] (2022) RCT	Excellent (89.3%)	1) Patient's beliefs	**PRT**: Pain Reprocessing Therapy – aims to shift patients' beliefs about the causes and threat value of pain via five main components: 1) education about the brain origins and reversibility of pain; 2) reinforcing personalised evidence for (1) above, 3) attending to and appraising pain sensations through a safety lens; 4) addressing other emotional threats; and 5) gravitating to positive feelings and sensations.	**Clinically important** NRS (0-10) *Post-treatment (4 weeks)* ***MΔ* = 3.04**; *n* = 44 78% of patients: 30% pain reduction 70% of patients: 50% pain reduction 66% of patients: nearly pain-free *Follow-up (1-year)* ***MΔ* = 2.71**; *n* = 45 70% of patients: 30% pain reduction 60% of patients: 50% pain reduction 52% of patients: nearly pain-free	**Improvement** *p-value unknown* ODI (0-100) *Post-treatment (4 weeks)* ***MΔ* = 13.56**; *n* = 44 *Follow-up (1-year)* ***MΔ* = 12.54**; *n* = 45

Table S2 continued. Contextual Factor intervention group(s) within-group change in from baseline by study design

Ref No. (Year) & Study Design	**Quality Assessment Grading**	**Type of Contextual Factor(s)**	**Main CF-intervention Elements**	**Mean Change (Δ) from Baseline:** **Pain Intensity**	**Mean Change (Δ) from Baseline:** **Physical Functioning**
[39] (2019) RCT	Excellent (89.3%)	1) Patient's beliefs; 5) Treatment characteristics	Adding open-label placebo (**OLP**) pills (i.e., response expectancy & labelling) using social learning (video) and verbal suggestions to treatment as usual (TAU).	**Improvement** *p-value unknown* NRS (0-10) *Post-treatment (3 weeks)* ***MΔ* = -0.62**; *n* = 63	**Improvement** *p-value unknown* ODI (0-100) / PSFS (0-10) *Post-treatment (3 weeks)* **ODI: *MΔ* = -3.21**; *n* = 63 **PSFS: *MΔ* = 0.94**; *n* = 63
[40] (2016) RCT	Excellent (85.7%)	1) Patient's beliefs; 5) Treatment characteristics	Adding open-label placebo (**OLP**) pills (i.e., response expectancy & labelling) to treatment as usual (TAU), along with verbal suggestions (scripted dialogue) & social learning (video).	**28% Improvement** *p-value unknown* NRS (0-10) *Post-treatment (3 weeks)* ***MΔ* = 1.49**; *n* = 41	**29% Improvement** *p-value unknown* RMDQ (0-24) *Post-treatment (3 weeks)* ***MΔ* = 2.86**; *n* = 41
[41] (2017) RCT (Cluster)	Excellent (85.7%)	1) Patient's beliefs; 3) Patient-practitioner relationship	**CONNECT**: Enhancing physiotherapists' need-supportive communication skills to address maladaptive / unhelpful patient beliefs and improve motivation.	**Improvement** *p-value unknown* NRS (0-10) *Post: (12 weeks) / Follow-up (24 weeks)* ***MΔ* = -1.53 / *MΔ* = -1.53**; *n* = 108	**Improvement** *p-value unknown* RMDQ (0-24) *Post: (12 weeks) / Follow-up (24 weeks)* ***MΔ* = -3.48 / *MΔ* = -4.87**; *n* = 108
[42] (2010) RCT	Good (82.1%)	1) Patient's beliefs; 3) Patient-practitioner relationship	Pain (neuro) biology education for the management of cLBP with and without group-exercise classes.	**Improvement** *p-value unknown* NRS (0-100) *Post / Follow-up (12 weeks)* ***MΔ* = 30.9 / *MΔ* = -16.7**; *n* = 16	**Improvement** *p-value unknown* RMDQ (0-24) *Post / Follow-up (12 weeks)* ***MΔ* = -7.5 / *MΔ* = -6.5**; *n* = 16
[43] (2020) RCT	Good (82.1%)	1) Patient's beliefs; 5) Treatment characteristics	Adding open-label placebo (**OLP**) pills (i.e., response expectancy) using verbal suggestions (scripted dialogue) to treatment as usual (TAU).	**Not Significant** (p = .17) NRS (0-10) *Post-treatment (3 weeks)* ***MΔ* = -0.9**; *n* = 26 5 patients (19.2%) met or surpassed the MCID (≥ 2-unit change from baseline). *Follow-up (12 weeks)* ***MΔ* = -1.1**; *n* = 24 11 patients (45.8%) met or surpassed the MCID (≥ 2-unit change from baseline).	**RMDQ Significant (< .01)*** RMDQ (0-24) **TUG Not Significant** (p = .10) TUG (seconds) *Post-treatment (3 weeks)* ***RMDQ**: ***MΔ* = -2.2**; *n* = 26 **TUG**: ***MΔ* = -0.7**; *n* = 26 *Follow-up (12 weeks)* ***RMDQ: *MΔ* = -3.3**; *n* = 24 **TUG**: ***MΔ* = -0.6**; *n* = 24

Notes: PSFS: Patient-Specific Functional Scale – higher scores represent higher levels of functioning; MCID: minimal clinically important difference; TUG: Timed-Up-and-Go (measured in seconds)

Table S2 continued. Contextual Factor intervention group(s) within-group change in from baseline by study design

Ref No. (Year) & Study Design	**Quality Assessment Grading**	**Type of Contextual Factor(s)**	**Main CF-intervention Elements**	**Mean Change (Δ) from Baseline:** **Pain Intensity**	**Mean Change (Δ) from Baseline:** **Physical Functioning**
[44] (2021) RCT	Good (82.1%)	1) Patient's beliefs; 3) Patient-practitioner relationship	Patient education (ED) relating to return to daily activities, advice on coping with pain, a clear explanation of signs and symptoms with an emphasis on increasing empathy and therapeutic alliance (TA) in one treatment group (ED+TA).	**Improvement** *p-value unknown* NRS (0-10) *Post-treatment (1-month)* **ED+TA: *M*Δ = 2.1**; *n* = 68 **ED only: *M*Δ = 2.2**; *n* = 69 *Follow-up (6-months)* **ED+TA: *M*Δ = 1.62**; *n* = 65 **ED only: *M*Δ = 2.33**; *n* = 65 *Follow-up (1-year)* **ED+TA: *M*Δ = 2.53**; *n* = 64 **ED only: *M*Δ = 2.62**; *n* = 65	**Improvement** *p-value unknown* ODI (0-100) / PSFS (0-10) *Post-treatment (1-month)* **ED+TA: *M*Δ ODI = 6.26 / PSFS** = **1.9** **ED only: *M*Δ ODI = 5.12 / PSFS = 1.49** *Follow-up (6-months)* **ED+TA: *M*Δ ODI = 7.78 / PSFS** = **1.66** **ED only: *M*Δ ODI = 7.17** / **PSFS** = **1.31** *Follow-up (1-year)* **ED+TA: *M*Δ ODI = 11.54 / PSFS** = **2.13** **ED only: *M*Δ ODI = 9.92 / PSFS = 1.88**
[45] (2017) RCT (2x2)	Good (78.6%)	1) Patient's beliefs; 5) Treatment characteristics	Manipulating patient's expectations using an inert solution / labelling, verbal instructions, with or without classical conditioning (CC).	**Significant (*p* < .001)*** NRS (0-10) *Post-treatment (same day)* Opioid Instruction (*n* = 24) *With CC: ***M*Δ = 3.16** *No CC: ***M*Δ = 2.00** Placebo Instruction (*n* = 24) With CC: ***M*Δ = 0.67; (*p* < 0.26)** *No CC: ***M*Δ = -1.16*** *(increased pain)*	**Significant (*p* < .001)*** ADL (0-100%) *Post-treatment (same day)* Opioid Instruction (*n* = 24) *With CC: ***M*Δ = -16.66** *No CC: ***M*Δ = -15.26** Placebo Instruction (*n* = 24) With CC: ***M*Δ = -3.89**; *p* =.22 No CC: ***M*Δ = 6.67**; *p* = .06
[46] (2019) RCT (2x2)	Good (71.4%)	1) Patient's beliefs; 5) Treatment characteristics	Manipulating patient's expectations using a sham "opioid" infusion with mirrors / labelling, verbal instructions, and either placebo or nocebo conditioning (PC or NC). Sham "Opioid" Infusion: Placebo (**PC**): (*n* = 17) Sham only (**SO**): (*n* = 21) Nocebo (**NC**): (*n*= 21) Natural History (**NH**): (*n* = 14)	**Significant (*p* < .001)*** NRS (0-10) *Post-treatment (Day 1 / Day 8)* Sham "Opioid" Infusion: ***PC: *M*Δ = 2.23** / Day 8 ***M*Δ = 2.06*** ***SO: *M*Δ = 3.14** / Day 8 ***M*Δ = 3.00*** ***NC: *M*Δ = 1.48** / Day 8 ***M*Δ = 1.57*** Natural History (*p* = 0.92) NH: ***M*Δ = 0.29** / Day 8 ***M*Δ = -0.07***	**Significant (*p* < .001)*** ADL (0-100%) *Post-treatment (Day 1 / Day 8)* Sham "Opioid" Infusion: ***PC: *M*Δ = 5.09** / Day 8 ***M*Δ = 9.41*** ***SO: *M*Δ = 12.7** / Day 8 ***M*Δ = 13.97*** ***NC: *M*Δ = 12.07** / Day 8 ***M*Δ = 17.47*** Natural History (*p* = 0.63) NH: ***M*Δ = 1.43** / Day 8 ***M*Δ = 0.53***
Notes: ADL: Patient-Specific Functional Scale – higher scores represent higher levels of functioning; ADL: Hannover Activities of Daily Living Questionnaire.					

Table S2 continued. Contextual Factor intervention group(s) within-group change in from baseline by study design

Ref No. (Year) & Study Design	Quality Assessment Grading	Type of Contextual Factor(s)	Main CF-intervention Elements	Mean Change (Δ) from Baseline: Pain Intensity	Mean Change (Δ) from Baseline: Physical Functioning
[47] (2017) CCT	Excellent (88.5%)	1) Patient's beliefs; 3) Patient-practitioner relationship	**ETMI (**Enhanced Transtheoretical Model Intervention) targeted cLBP intervention focusing on therapists' communication skills, therapeutic alliance, low motivation, patient's self-efficacy, and maladaptive or unhelpful beliefs/behaviour.	**Improvement** *p-value unknown* NRS (0-10) Average Pain (*n* = 94) *3-months:* ***MΔ* = 2.1** 95% C.I. [1.5-2.7] *1 year:* ***MΔ* = 2.6** 95% C.I. [1.9-3.3] Worst Pain (*n* = 94) *3-months:* ***MΔ* = 1.9** 95% C.I. [1.2-2.7] *1 year:* ***MΔ* = 2.9** 95% C.I. [2.0-3.7]	**Improvement** *p-value unknown* RMDQ (0-23) *3-months:* ***MΔ* = 4.9** 95% C.I. [3.7-6.1] *1 year:* ***MΔ* = 6.7** 95% C.I. [5.4-8.0] 84% achieved ≥ 30% reduction in physical disability (*n* = 94).
[48] (2012) CCT	Good (73.1%)	1) Patient's beliefs	Targeted cLBP intervention focusing on patient's illness and treatment beliefs along with their individual information needs.	**Significant (*p* < .001)** VAS (0–100) *Post-treatment* ***MΔ* = -14.91**; *n* = 93; Standardised Effect Size = -0.66	**Significant (*p* = .002)** ODI (0–100) *Post-treatment* ***MΔ* = -3.26**; *n* = 92 Standardised Effect Size = -0.16
[49] (2018) CCT	Fair (65.4%)	3) Patient-practitioner relationship; 4) Therapeutic setting / environment	Adding one weekly group-based physical therapy session in a rehabilitation setting compared to home treatment alone.	**Significant (*p* < .001)** NRS (0-10) *Post-treatment (8 weeks)* Rehab: ***MΔ* = 2.0**, *n* = 13	**Significant (*p* < .001)** RMDQ (0-24) *Post-treatment (8 weeks)* Rehab: ***MΔ* = 2.8**, *n* = 13
[50] (2015) Quasi-exp. (*Interrupted Time Series*)	Excellent (86.4%)	1) Patient's beliefs	**CFT**: Cognitive Functional Therapy – strong focus on reframing back pain in a person-centred manner along with altering maladaptive / unhelpful behaviours to normalise movement.	**Significant (*p* < .001)** NRS (0–10) *Post:* ***MΔ* = 1.6**; *n* = 24 *1-year:* ***MΔ* = 1.7**; *n* = 21 13 patients (54.2%) met or surpassed the MCID (i.e., ≥ 30% reduction at 12-months)	**Significant (*p* < .001)** ODI (0–100) *Post:* ***Median* Δ = 22**; *n* = 24 *1-year:* ***Median* Δ = 24**; *n* = 21 15 patients (62.5%) met or surpassed the MCID (i.e., ≥ 30% reduction at 12-months)
[51] (2017) Quasi-exp. (*Case Series*)	Good (81.8%)	1) Patient's beliefs	Pain (neuro)science education (PNE) focusing on altering beliefs regarding cLBP and aging.	**Significant (*p* = .002)** NRS (0–10) *Post-treatment (same day)* ***MΔ* = −0.5**; *n* = 50; *r* = 0.45 21 patients (42%) met or surpassed the MCID (≥ 1-unit change).	**Significant (*p* < .001)** Active trunk forward flexion (cm) *Post-treatment (same day)* ***MΔ* = −4.0cm**; *n* = 50 18 patients (36%) met or exceeded the MCID (≥ 4.5cm)

Notes: MCID: minimal clinically important difference; *post-tx*: post-treatment

Table S2 continued. Contextual Factor intervention group(s) within-group change in from baseline by study design

Ref No. (Year) & Study Design	Quality Assessment Grading	Type of Contextual Factor(s)	Main CF-intervention Elements	Mean Change (Δ) from Baseline: Pain Intensity	Mean Change (Δ) from Baseline: Physical Functioning
[52] (2013) Obs. Cohort	Excellent (95.5%)	3) Patient-practitioner relationship	*No manipulation* - measuring pre-existing relational aspects: -perceived involvement in care; trust; satisfaction; healthcare practitioner's communication behaviour.	**Significant (*p* < .001)** VAS (0–100) *Post-treatment* ***MΔ* = 11.54**; *n* = 611 *Follow-up (6-months)* ***MΔ* = 12.67** *n* = 468	**Significant (*p* < .001)** ODI (0–100) *Post-treatment* ***MΔ* = 4.96**; *n* = 599 *Follow-up: (6-months)* ***MΔ* = 7.21**; *n* = 468
[53] (2013) Obs. Cohort	Excellent (90.9%)	3) Patient-practitioner relationship	*No manipulation* - measuring pre-existing relational aspects: - therapeutic alliance (**TA**) between patients and their practitioner (scale range 16-112).	**Significant (*p* = .001)** VAS (0–10) **↑ TA ↓ pain** β = -0.044, *n* = 182 One unit increase in TA reduced pain by 0.044 units.	**Significant (*p* < .000)** RMDQ (0-24) **↑ TA ↓ physical disability** β = –0.113, *n* = 182 One unit increase in TA reduced disability by 0.113 units.
[54] (2011) Obs. Cohort	Excellent (86.4%)	1) Patient's beliefs	Targeted cLBP intervention focusing on addressing maladaptive illness perceptions (predictors: rational problem-solving, discussion skills, and verbal skills) via Socratic dialogue.	*Not applicable*	**Significant (*p* = .014)** PSFS (0–100) **↑ Rational Problem-Solving (RPS) ↓ physical disability** β = –0.49, *n* = 136; r^2 = 3.9% One unit increase in the RPS scale results in a decrease of 0.49 in the Patient-Specific Functioning Scale (PSFS).
[55] (2019) Obs. Cohort	Excellent (86.4%)	1) Patient's beliefs and characteristics	*No manipulation* – measuring patient's competence perceptions (CP) to perform required physical therapy tasks and their self-reported motivations for undertaking physical therapy where, *amotivation* represents the least self-determined type and *autonomous* motivation is the most self-determined along a continuum.	**Significant (*p* < .01)** NRS (0–10) **↑ CP ↓ pain** ***r* = –0.34** (negative, moderate correlation with CP) (*n* = 64) **↑ amotivation ↑ pain** ***r* = 0.48** (positive, moderate correlation with amotivation) The individual indirect effect of amotivation on pain was statistically significant ($p < .05$). Thus, lower perceptions of competence were predictive of stronger amotivation, which was in turn predictive of greater pain. The percent of the pain model mediated through amotivation was 44.7%.	**Significant (*p* < .01)** ODI (0–100) **↑ CP ↓ physical disability** ***r* = –0.35** (negative, moderate correlation with CP) (*n* = 64) **↑ amotivation ↑ physical disability** ***r* = 0.39** (positive, moderate correlation with amotivation) The individual indirect effect of amotivation on disability was statistically significant ($p < .05$). Thus, lower perceptions of competence were predictive of stronger amotivation, which was in turn predictive of greater disability levels. The percent of the disability model mediated through amotivation was 70.2%.

(viii) Tables S3.1 and S3.2 – Quality assessment results of included studies

Table S3.1 Quality Assessment of included studies clustered by research design (RCTs only)

Reference	**Q1**. Is the hypothesis /aim / objective of the study clearly described?	**Q2**. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	**Q3**. Are the characteris-tics of the patients included in the study clearly described? [a]	**Q4**. Are the interventions of interest clearly described? [b]	**Q5**. Are the distributions of principal confounders in each group of subjects to be compared clearly described? [c]	**Q6**. Are the main findings of the study clearly described? [d]	**Q7**. Does the study provide estimates of the random variability in the data for the main outcomes? [e]	**Q8**. Have all important adverse events that may be a consequence of the intervention been reported? [f]	**Q9**. Have the characteris-tics of patients lost to follow-up been described? [g]	**Q10**. Have actual probability values been reported? (e.g. 0.035 rather than < 0.05 for the main outcomes except where the probability value is less than 0.001)	**Quality of reporting Sub-total (0–11 points)**
Randomised Controlled Trials (RCTs)											
[35] Vong et al., 2011	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**11**
[36] Fersum at al., 2013	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	No = 0	**10**
[37] Fuentes et al., 2014	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**11**
[38] Ashar et al., 2022	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**11**
[39] Kleine-Borgmann et al., 2019	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**11**
[40] Carvalho et al., 2016	Yes = 1	Yes = 1	Yes = 1	No = 0	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**10**

Table S3.1 continued. Quality Assessment of included studies clustered by research design (RCTs only)

Reference	Q1.	Q2.	Q3.	Q4.	Q5.	Q6.	Q7.	Q8.	Q9.	Q10.	Sub-total (0–11 points)
[41] Lonsdale et al., 2017	Yes = 1	No = 0	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**10**
[42] Ryan et al., 2010	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**10**
[43] Ikemoto et al., 2020	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**10**
[44] Miyamoto et al., 2021	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	Yes = 1	Yes = 1	No = 0	**10**
[45] Klinger et al., 2017	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**10**
[46] Schmitz et al., 2019	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Partially = 1	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**9**

Table S3.1 continued. Quality Assessment of included studies clustered by research design (RCTs only)

Reference	**Q11**. Were the subjects asked to participate in the study representa-tive of the entire population from which they were recruited? [h]	**Q12**. Were those subjects who were prepared to participate representa-tive of the entire population from which they were recruited? [i]	**Q13**. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? [j]	**External Validity Sub-total** **(0–3 points)**	**Q14**. Was an attempt made to blind study subjects to the intervention they have received? [k]	**Q15**. Was an attempt made to blind those measuring the main outcomes of the intervention?	**Q16**. If any of the results of the study were based on "data dredging", was this made clear? [l]	**Q17**. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? [m]	**Q18**. Were the statistical tests used to assess the main outcomes appropriate? [n]	**Q19**. Was compliance with the intervention/s reliable? [o]	**Q20**. Were the main outcome measures used accurate (valid and reliable)? [p]
Randomised Controlled Trials (RCTs)											
[35] Vong et al., 2011	No = 0	Yes = 1	Yes = 1	**2**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[36] Fersum at al., 2013	Yes = 1	Yes = 1	Yes = 1	**3**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[37] Fuentes et al., 2014	No = 0	Unable to Determine = 0	No = 0	**0**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[38] Ashar et al., 2022	Yes = 1	Yes = 1	No = 0	**2**	Unable to Determine = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1

Table S3.1 continued. Quality Assessment of included studies clustered by research design (RCTs only)

Reference	Q11	Q12	Q13	Sub-total (0–3 points)	Q14	Q15	Q16	Q17	Q18	Q19	Q20
[39] Kleine-Borgmann et al., 2019	No = 0	Unable to Determine = 0	Yes = 1	**1**	No = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[40] Carvalho et al., 2016	No = 0	Yes = 1	Yes = 1	**2**	No = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[41] Lonsdale et al., 2017	Yes = 1	Yes = 1	Yes = 1	**3**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[42] Ryan et al., 2010	No = 0	Yes = 1	No = 0	**1**	No = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[43] Ikemoto et al., 2020	No = 0	Yes = 1	Yes = 1	**2**	Unable to Determine = 0	No = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[44] Miyamoto et al., 2021	Yes = 1	Yes = 1	No = 0	**2**	No = 0	No = 0	Yes = 1	Yes = 1	Yes = 1	Unable to Determine = 0	Yes = 1
[45] Klinger et al., 2017	No = 0	Unable to Determine = 0	No = 0	**0**	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[46] Schmitz et al., 2019	Yes = 1	Yes = 1	No = 0	**2**	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1

Table S3.1 continued. Quality Assessment of included studies clustered by research design (RCTs only)

Reference	Internal Validity Sub-total (0–7 points)	**Q21**. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? [q]	**Q22**. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? [r]	**Q23**. Were study subjects randomised to intervention groups? [s]	**Q24**. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? [t]	**Q25**. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? [u]	**Q26**. Were losses of patients to follow-up taken into account? [v]	Selection bias / cofounding Sub-total (0–6 points)	**Q27**. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Was there a power calculation? [w]	Total Score (*27 items*) Range: (0–28 points)	Overall Grading: Excellent (24–28) Good (19–23) Fair (14–18) Poor (< 14)
Randomised Controlled Trials (RCTs)											
[35] Vong et al., 2011	**7**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**6**	Unable to Determine = 0	**26**	**Excellent**
[36] Fersum at al., 2013	**7**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	No = 0	Yes = 1	**5**	No = 0	**25**	**Excellent**
[37] Fuentes et al., 2014	**7**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**6**	Yes = 1	**25**	**Excellent**
[38] Ashar et al., 2022	**6**	Yes = 1	Yes = 1	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	**5**	Yes = 1	**25**	**Excellent**

Table S3.1 continued. Quality Assessment of included studies clustered by research design (RCTs only)

Reference	Sub-total (0–7 points)	Q21	Q22	Q23	Q24	Q25	Q26	Sub-total (0–6 points)	Q27	Total Score (0–28 points)	Overall Grading
[39] Kleine-Borgmann et al., 2019	**6**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**6**	Yes = 1	**25**	**Excellent**
[40] Carvalho et al., 2016	**6**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**6**	No = 0	**24**	**Excellent**
[41] Lonsdale et al., 2017	**7**	Yes = 1	Unable to Determine = 0	Yes = 1	No = 0	Yes = 1	Yes = 1	**4**	Unable to Determine = 0	**24**	**Excellent**
[42] Ryan et al., 2010	**6**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**6**	No = 0	**23**	**Good**
[43] Ikemoto et al., 2020	**5**	Yes = 1	Yes = 1	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	**5**	Yes = 1	**23**	**Good**
[44] Miyamoto et al., 2021	**4**	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	**6**	Yes = 1	**23**	**Good**
[45] Klinger et al., 2017	**6**	Yes = 1	Yes = 1	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	**5**	Yes = 1	**22**	**Good**
[46] Schmitz et al., 2019	**6**	Yes = 1	Unable to Determine = 0	Yes = 1	Unable to Determine = 0	Yes = 1	Unable to Determine = 0	**3**	No = 0	**20**	**Good**

Notes:
[a] In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.
[b] Treatments and placebo (where relevant) that are to be compared should be clearly described.
[c] A list of principal confounders is provided (e.g. baseline characteristics such as: Age, Sex/Gender, Marital status/family, chronicity, pre-intervention score on outcome measure, Employment status, SES (income or class), Education)
[d] Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions.

(This question does not cover statistical tests which are considered below).

[e] In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

[f] This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

[g] This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no, where a study does not report the number of patients lost to follow-up.

[h] The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine. Is this sample similar to cLBP patients in general? Consider age (18 to 65), gender (generally higher in woman ± 45% vs 55%); chronicity and comorbid conditions.

[i] The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population. What has been stated regarding who was excluded /chose not to participate prior to baseline measurement/ randomisation? Consider gender, age and chronicity of LBP, pain intensity and functional disability (at baseline). Is there a cluster or pattern of persons who chose not to participate or alternatively, are the sample biased because of inclusion/exclusion criteria?

[j] For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend. NICE Guidelines recommend the following non-invasive treatments: self-management (information and encouragement to continue with normal activities); exercise programmes (biomechanical, aerobic, mind–body or a combination); manual therapy (SMT, mobilisation or soft tissue techniques such as massage) including exercise, with or without psychological therapy; cognitive behavioural therapies only as part of a treatment package including exercise, with or without manual therapy; combined physical and psychological programmes; Do not offer acupuncture, electrotherapies (PENS, TENS, inferential therapy).

[k] For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

[l] Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned sub-group analyses were reported, then answer yes.

[m] Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

[n] The statistical techniques used must be appropriate to the data. For example, non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

[o] Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

[p] For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

[q] For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

[r] For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

[s] Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example, alternate allocation would score no because it is predictable.

[t] All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

[u] This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

[v] If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small (< 5%) to affect the main findings, the question should be answered yes.

[w] If yes, what were the required treatment arm sizes and did this match up to the sample sizes for the stated interval? If no interval stated, assume it relates to post-treatment outcomes rather than final follow-up.

Table S3.2 Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

Reference	**Q1**. Is the hypothesis /aim / objective of the study clearly described?	**Q2**. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	**Q3**. Are the characteris-tics of the patients included in the study clearly described? [a]	**Q4**. Are the interventions of interest clearly described? [b]	**Q5**. Are the distributions of principal confounders in each group of subjects to be compared clearly described? [c]	**Q6**. Are the main findings of the study clearly described? [d]	**Q7**. Does the study provide estimates of the random variability in the data for the main outcomes? [e]	**Q8**. Have all important adverse events that may be a consequence of the intervention been reported? [f]	**Q9**. Have the characteris-tics of patients lost to follow-up been described? [g]	**Q10**. Have actual probability values been reported? (e.g. 0.035 rather than < 0.05 for the main outcomes except where the probability value is less than 0.001)	**Quality of reporting Sub-total** **(0–11 points)**
Controlled Clinical Trials (CCT; non-randomised)											
[47] Ben-Ami et al., 2017	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**10**
[48] Glattacker et al., 2012	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**10**
[49] Kanas et al., 2018	Yes = 1	Yes = 1	Yes = 1	Yes = 1	No = 0	Yes = 1	No = 0	No = 0	Yes = 1	Yes = 1	**7**
Reference	**Q1**	**Q2**	**Q3**	**Q4**	**Q5**	**Q6**	**Q7**	**Q8**	**Q9**	**Q10**	**(0–11 points)**
Quasi-experimental											
[50] O'Sullivan et al., 2015	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	No = 0	**9**
[51] Louw et al., 2017	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	No = 0	Yes = 1	Yes = 1	**10**

Table S3.2 continued. Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

Reference	**Q1**. Is the hypothesis /aim / objective of the study clearly described?	**Q2**. Are the main outcomes to be measured clearly described in the Introduction or Methods section?	**Q3**. Are the characteris-tics of the patients included in the study clearly described? [a]	**Q4**. Are the interventions of interest clearly described? [b]	**Q5**. Are the distributions of principal confounders in each group of subjects to be compared clearly described? [c]	**Q6**. Are the main findings of the study clearly described? [d]	**Q7**. Does the study provide estimates of the random variability in the data for the main outcomes? [e]	**Q8**. Have all important adverse events that may be a consequence of the intervention been reported? [f]	**Q9**. Have the characteris-tics of patients lost to follow-up been described? [g]	**Q10**. Have actual probability values been reported? (e.g. 0.035 rather than < 0.05 for the main outcomes except where the probability value is less than 0.001)	**Quality of reporting Sub-total (0–10 points)**
Observational Cohort											
[52] Farin et al., 2013	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	*Not Applicable*	Yes = 1	Yes = 1	**10**
[53] Ferreira et al., 2013	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	*Not Applicable*	Yes = 1	Yes = 1	**10**
[54] Siemonsma et al., 2011	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 2	Yes = 1	Yes = 1	*Not Applicable*	Yes = 1	Yes = 1	**10**
[55] Podlog et al., 2019	Yes = 1	Yes = 1	Yes = 1	No = 0	Yes = 2	Yes = 1	Yes = 1	*Not Applicable*	No = 0	Yes = 1	**8**

Table S3.2 continued. Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

Reference	**Q11**. Were the subjects asked to participate in the study representa-tive of the entire population from which they were recruited? [h]	**Q12**. Were those subjects who were prepared to participate representa-tive of the entire population from which they were recruited? [i]	**Q13**. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? [j]	**External Validity Sub-total** **(0–3 points)**	**Q14**. Was an attempt made to blind study subjects to the intervention they have received? [k]	**Q15**. Was an attempt made to blind those measuring the main outcomes of the intervention?	**Q16**. If any of the results of the study were based on "data dredging", was this made clear? [l]	**Q17**. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? [m]	**Q18**. Were the statistical tests used to assess the main outcomes appropriate? [n]	**Q19**. Was compliance with the intervention/s reliable? [o]	**Q20**. Were the main outcome measures used accurate (valid and reliable)? [p]
Controlled Clinical Trials (CCT; non-randomised)											
[47] Ben-Ami et al., 2017	Yes = 1	Yes = 1	No = 0	**2**	No = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[48] Glattacker et al., 2012	No = 0	No = 0	Yes = 1	**1**	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1
[49] Kanas et al., 2018	No = 0	No = 0	Yes = 1	**1**	No = 0	No = 0	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
Reference	**Q11**	**Q12**	**Q13**	**(0–3 points)**	**Q14**	**Q15**	**Q16**	**Q17**	**Q18**	**Q19**	**Q20**
Quasi-experimental											
[50] O'Sullivan et al., 2015	Yes = 1	Yes = 1	Yes = 1	**3**	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[51] Louw et al., 2017	No = 0	Yes = 1	No = 0	**1**	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1

Table S3.2 continued. Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

Reference	**Q11**. Were the subjects asked to participate in the study representa-tive of the entire population from which they were recruited? [h]	**Q12**. Were those subjects who were prepared to participate representa-tive of the entire population from which they were recruited? [i]	**Q13**. Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive? [j]	**External Validity Sub-total** **(0–3 points)**	**Q14**. Was an attempt made to blind study subjects to the intervention they have received? [k]	**Q15**. Was an attempt made to blind those measuring the main outcomes of the intervention?	**Q16**. If any of the results of the study were based on "data dredging", was this made clear? [l]	**Q17**. In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls? [m]	**Q18**. Were the statistical tests used to assess the main outcomes appropriate? [n]	**Q19**. Was compliance with the intervention/s reliable? [o]	**Q20**. Were the main outcome measures used accurate (valid and reliable)? [p]
Observational Cohort											
[52] Farin et al., 2013	Yes = 1	Yes = 1	Yes = 1	**3**	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[53] Ferreira et al., 2013	No = 0	Yes = 1	Yes = 1	**2**	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1
[54] Siemonsma et al., 2011	Yes = 1	Yes = 1	No = 0	**2**	*Not Applicable*	*Not Applicable*	Yes = 1	Unable to Determine = 0	Yes = 1	Yes = 1	Yes = 1
[55] Podlog et al., 2019	No = 0	Yes = 1	Yes = 1	**2**	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	Yes = 1	Yes = 1	Yes = 1

Table S3.2 continued. Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

Reference	**Internal Validity Sub-total** (0–7 points)	**Q21**. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? [q]	**Q22**. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? [r]	**Q23**. Were study subjects randomised to intervention groups? [s]	**Q24**. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? [t]	**Q25**. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? [u]	**Q26**. Were losses of patients to follow-up taken into account? [v]	**Selection bias / cofounding Sub-total** (0–4 points)	**Q27**. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Was there a power calculation? [w]	**Total Score** (*25 items*) Range: (0–26 points)	**Adjusted Overall Grading** Excellent (22–26) Good (18–21) Fair (13–17) Poor (< 13)
Controlled Clinical Trials (CCT; non-randomised)											
[47] Ben-Ami et al., 2017	**6**	Yes = 1	Yes = 1	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	**4**	Yes = 1	**23**	**Excellent**
[48] Glattacker et al., 2012	**5**	Yes = 1	No = 0	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	**3**	No = 0	**19**	**Good**
[49] Kanas et al., 2018	**5**	Yes = 1	Yes = 1	*Not Applicable*	*Not Applicable*	Unable to Determine = 0	Yes = 1	**3**	Yes = 1	**17**	**Fair**

Table S3.2 continued. Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

	Internal Validity Sub-total (0–5 points)	**Q21**. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? [q]	**Q22**. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? [r]	**Q23**. Were study subjects randomised to intervention groups? [s]	**Q24**. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? [t]	**Q25**. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? [u]	**Q26**. Were losses of patients to follow-up taken into account? [v]	**Selection bias / cofounding Sub-total** (0–2 points)	**Q27**. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Was there a power calculation? [w]	**Total Score** (*21 items*) Range: (0–22 points)	**Adjusted Overall Grading** Excellent (19–22) Good (16–18) Fair (11–15) Poor (< 11)
Quasi-experimental											
[50] O'Sullivan et al., 2015	**5**	Yes = 1	*Not Applicable*	*Not Applicable*	*Not Applicable*	*Not Applicable*	Yes = 1	**2**	No = 0	**19**	**Excellent**
[51] Louw et al., 2017	**5**	Yes = 1	*Not Applicable*	*Not Applicable*	*Not Applicable*	*Not Applicable*	Yes = 1	**2**	No = 0	**18**	**Good**

Table S3.2 continued. Quality Assessment of included studies clustered by research design (CCTs, quasi-experimental and observational cohorts)

	Internal Validity Sub-total (0–5 points)	**Q21**. Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population? [q]	**Q22**. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time? [r]	**Q23**. Were study subjects randomised to intervention groups? [s]	**Q24**. Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable? [t]	**Q25**. Was there adequate adjustment for confounding in the analyses from which the main findings were drawn? [u]	**Q26**. Were losses of patients to follow-up taken into account? [v]	**Selection bias / cofounding Sub-total (0–3 points)**	**Q27**. Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%? Was there a power calculation? [w]	**Total Score (*21 items*) Range: (0–22 points)**	**Adjusted Overall Grading Excellent (19–22) Good (16–18) Fair (11–15) Poor (< 11)**
Observational Cohort											
[52] Farin et al., 2013	**5**	Yes = 1	*Not Applicable*	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	**3**	Unable to Determine = 0	**21**	**Excellent**
[53] Ferreira et al., 2013	**5**	Yes = 1	*Not Applicable*	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	**3**	Unable to Determine = 0	**20**	**Excellent**
[54] Siemonsma et al., 2011	**4**	Yes = 1	*Not Applicable*	*Not Applicable*	*Not Applicable*	Unable to Determine = 0	Yes = 1	**2**	Yes = 1	**19**	**Excellent**
[55] Podlog et al., 2019	**5**	Yes = 1	*Not Applicable*	*Not Applicable*	*Not Applicable*	Yes = 1	Yes = 1	**3**	Yes = 1	**19**	**Excellent**

Notes:

[a] In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

[b] Treatments and placebo (where relevant) that are to be compared should be clearly described.

[c] A list of principal confounders is provided (e.g. baseline characteristics such as: Age, Sex/Gender, Marital status/family, chronicity, pre-intervention score on outcome measure, Employment status, SES (income or class), Education)

[d] Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions.
(This question does not cover statistical tests which are considered below).

[e] In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

[f] This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

[g] This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no, where a study does not report the number of patients lost to follow-up.

[h] The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine. Is this sample similar to cLBP patients in general? Consider age (18 to 65), gender (generally higher in woman ± 45% vs 55%); chronicity and comorbid conditions.

[i] The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population. What has been stated regarding who was excluded /chose not to participate prior to baseline measurement/ randomisation? Consider gender, age and chronicity of LBP, pain intensity and functional disability (at baseline). Is there a cluster or pattern of persons who chose not to participate or alternatively, are the sample biased because of inclusion/exclusion criteria?

[j] For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend. NICE Guidelines recommend the following non-invasive treatments: self-management (information and encouragement to continue with normal activities); exercise programmes (biomechanical, aerobic, mind–body or a combination); manual therapy (SMT, mobilisation or soft tissue techniques such as massage) including exercise, with or without psychological therapy; cognitive behavioural therapies only as part of a treatment package including exercise, with or without manual therapy; combined physical and psychological programmes; Do not offer acupuncture, electrotherapies (PENS, TENS, inferential therapy).

[k] For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

[l] Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned sub-group analyses were reported, then answer yes.

[m] Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

[n] The statistical techniques used must be appropriate to the data. For example, non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

[o] Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

[p] For studies where the outcome measures are clearly described, the question should be answered yes. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

[q] For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

[r] For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

[s] Studies which state that subjects were randomised should be answered yes except where method of randomisation would not ensure random allocation. For example, alternate allocation would score no because it is predictable.

[t] All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

[u] This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

[v] If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small (< 5%) to affect the main findings, the question should be answered yes.

[w] If yes, what were the required treatment arm sizes and did this match up to the sample sizes for the stated interval? If no interval stated, assume it relates to post-treatment outcomes rather than final follow-up.

Appendix II – Supplementary Material (Delphi Study)

The following supplementary materials are included in this Appendix:

(i) **Table S1**. Synopsis of new statements included in second round survey (Sherriff et al., 2023);
(ii) **Table S2**. Summary of amendments to statements between rounds (Sherriff et al., 2023);
(iii) Copy of Delphi Survey – Round 1 (**DS–R1**) (Sherriff et al., 2023);
(iv) Copy of Delphi Survey – Round 2 (**DS–R2**) (Sherriff et al., 2023); and
(v) Discussion of the mean 95% Confidence Intervals.

(i) Table S1

Table S1. Synopsis of new statements included in second round survey

Practitioner's Beliefs and Characteristics			
Sub-Category	**No.**	**Round-2: New Statement**	**Originated from Panel Suggestion(s)**
Mindset / attitude	Q8.4	Being calm and compassionate throughout the appointment.	*"Calm, compassionate, confidence - this comes with experience"*
Mindset / attitude	Q8.5	Displaying a professional and caring (not only "curing") attitude.	*"Displaying a "caring" (not only "curing") but professional attitude to patient's"*
Mindset / attitude	Q8.6	Creating a caring atmosphere (e.g., *appear to have all the time in the world; ensure each patient feels like a priority*).	– *"Attentive, kind, caring and appearing to have all the time in the world! It is important to make patients feel valued and cared for, and as if they are the only patient that you are seeing that day"* – *"Being kind and having empathy"*
Mindset / attitude	Q8.7	Actively build rapport with each patient (e.g., *discuss common interests / hobbies; enquire about their lives*).	– *"Having similar hobbies as a Pt - I see many pts who ride horses and I ride - they believe I understand their ssx better because it affects them while riding and they believe I have a better understanding of that than someone who doesn't ride horses."* – *"Remembering specifics of that pts life, e.g., did your daughter pass GCSE?"*
Patient's Beliefs and Characteristics			
Patient's treatment history	Q9.4	Exploring the patient's current or pre-existing beliefs about the cause(s) of their LBP.	– *"Exploring a patient's current beliefs about the cause of their problem"*
*Creating **positive** outcomes*	Q9.8	Instilling genuine hope in patients regarding how their life can change for the better.	*"Give patients genuine hope for how their life can change for the better - and what life improving activities they could return to"*
*Reducing **negative** outcomes*	Q10.3	Using simple, everyday analogies to alter patient's negative illness perceptions (e.g., *rusty hinges often work well despite their appearance*).	*"Using simple, everyday analogies to help explanations e.g., 'rusty' hinges working well, taking your car for a gentle drive every day to keep it moving, rather than driving it once a month by which time it'll have seized up - aids understanding"*
*Reducing **negative** outcomes*	Q10.7	Explaining that calming their stress response is a part of everyday self-care for physical pain and healing.	*"That calming the stress reaction is a part of their self-care for physical pain and healing."*
*Reducing **negative** outcomes*	Q10.8	Explaining imaging is usually unnecessary because scans may not explain the extent of their pain and/or dysfunction.	*"Explaining that imaging is not often necessary - and that what is seen on imaging doesn't necessarily equate to the amount of pain or 'damage' - a bit like a rusty hinge looks pretty rubbish, but actually functions pretty well"*
Cognitive behavioural approach	Q11.4	Explaining basic pain science (i.e., perceived pain is not necessarily actual physical pain from nerve or tissue damage, but whilst very real, is more of a 'learned' response to prior experiences).	*"Explaining basic 'pain science' i.e., explaining that perceived pain is not necessarily actual physical pain from e.g., tissue damage, but whilst very real, is more of a 'learned' behaviour/response to a relatively benign, non-noxious stimulus"*
Cognitive behavioural approach	Q11.5	Explaining routine activities, movement, or exercise can help 'rewire' perceived pain pathways (e.g., *some pain or discomfort is normal but is not a sign their LBP is "worsening*").	– *"Explaining that normal activities, movement, exercise etc can help 'rewire' perceived pain pathways and help 'normalise' pain"* – *"Explaining that (some) pain during attempts at activity and ADL does not indicate tissue "damage" or "worsening" of the complaint (LBP)".*

Table S1 continued. Synopsis of new statements included in second round survey

Patient-Practitioner Relationship			
Sub-Category	**No.**	**Round-2: New Statement**	**Originated from Panel Suggestion(s)**
Using specific diagnostic approach	Q12.7	Explaining improvement(s) can be dynamic, and their condition / symptoms may change throughout treatment.	*"We don't always get the diagnosis right first time. Also improvement can be dynamic, and the diagnosis change."*
Person-centred care approach	Q13.2	Compassionately expressing your understanding of how LBP affects them (e.g., *'I understand how frustrating it is not to be able to walk your dog / go dancing / garden' etc*).	– *"Displaying empathy and understanding for how its life is affected by their condition. Such as "I understand how frustrating it is to not be able to play with your grandkids/go dancing anymore/garden etc"* – *"Validation (normal for someone in their situation to feel the emotions they have)"*
Person-centred care approach	Q13.9	Confirming the patient not only heard but also understood the content of your communication.	"*Making sure that, after communicating with the patient, the patient has not only heard but understood the content of the communication"*
Treatment Characteristics			
Treatment advice or options	Q14.3	Clearly explaining the difference between a clinical examination and treatment.	– *"Explain clearly what is examination and what is treatment"* – *"Possibility to have a phone call with me (on demand) to answer questions prior to initial appointment"* – *"A lot of information about what to expect from the initial appointment on website and provided over the phone"*
Treatment advice or options	Q14.4	Demonstrating whether functional change has occurred immediately after treatment (e.g., *pain, range of motion, or strength*).	– *"Document changes in function by regular testing patient's ROM, pain and strength"* – *"Patients will believe results more than explanations, and we should have the humility to accept this."* – *"Show patients if functional change has occurred immediately after treatment such as pain, ROM, strength"* – *"Carrying out post treatment examination (as appropriate)"*
Treatment advice or options	Q14.5	Explaining your treatment advice in line with the patient's treatment expectations.	– *"Explaining the advice in line with the treatment expectations"* – *"Framing explanations based on their functional limitations and functional goals"*
Alternative feedback	Q14.8	Providing patients with clear milestones or signposting to indicate their progression through the treatment programme.	– *"Have a fully laid out plan with various stages of improvement driven by targets."* – *"Reminding Pt how far they have come and noting changes e.g., you got on the table MUCH better than last week"* – *"Providing patients with specific rehabilitation sessions to give them a sense of progressing during treatment programme and demonstrate exercises in secure environment"*
Treatment advice or options	Q14.10	Providing self-management materials (e.g., videos, rehabilitation booklets) or email / telephone support to promote a patient's engagement in physical activities	– *"Empowering patient by demonstrating self-treatment activities that reduce the need for practitioner intervention. Otherwise, the patient becomes dependent on the treatment approach"* – *"Patient education is important. In the long run they will be looking after themselves, and need to have the information to take responsibility for their health."* – *"Providing email by support to increase the likelihood they do exercises or engage in physical activities"* – *"Providing videos and other material by email"*
Alternative feedback	Q14.12	Sharing positive stories of other (anonymous) patients with similar problems or goals.	– Pilot participant – *"Using (anon) positive stories of people I have seen with similar problem/goal"*

(ii) Table S2

Table S2. Summary of amendments to statements between rounds

Practitioner's Beliefs and Characteristics		
Original Statement (R1)	**Rephrased Statement (R2)**	***Panel Input* / (Notes)**
Prescribing or administering treatments you believe and expect to be effective	Administering treatments you expect to be effective (Q8.8).	Pilot participant – *"ambiguous / double-barrelled"*
Displaying self-confidence without appearing arrogant or dismissive	Displaying self-confidence without appearing dismissive. (Q8.3)	"*Whilst patients need to be involved in their care, they also expect confidence from their care-giver"*
Using indicators of expertise / high status (e.g., *health qualifications, professional memberships*) in offices or correspondence	Using indicators to display your expertise or credibility (e.g., *qualifications, insurance, professional memberships*) in reception / office, website, or correspondence. (Q8.10)	"*Have certificates of qualification, insurance, registration on display in reception area, website etc, . It provides reassurance and credibility. Be subtle, not blatant bragging!"*
Wearing a laboratory coat / medical apparel or tailored / formal clothing to symbolise professionalism	Demonstrating professionalism through your general appearance (i.e., being clean, tidy, smart, and presentable). (Q8.11)	– *"No uniform"* – *"Professionalism - in manner, dress etc. Always need to be clean, tidy and presentable. I think a white coat is a barrier as it can be unapproachable, but smart, professional dress in important"*
Patient's Beliefs and Characteristics		
Taking note of inaccurate knowledge from previous treatment experiences (e.g., *'my spine is crumbling*' or '*my back is worn out'*)	Reframing misinformed beliefs from previous healthcare experiences (e.g., *'my spine is crumbling', 'my spinal curve is abnormal', 'my back is worn out'*). (Q9.3)	"*Reframing misinformation they may have been told by other practitioners without creating cognitive dissonance. i.e., many patients are told by other HCPs that they have an "abnormal spinal curve" without being given further info or reassurance*."
Helping patients plan and monitor treatment success (e.g., SMART goals, motivational interviewing)	Helping patients plan and monitor treatment success (e.g., *explain outcome measures; co-create short-term and long-term goals or target-driven stages of improvement*). (Q11.8)	Pilot participant – *"Using goal setting for short and longer term, i.e., what they want to do once things are a bit better and then a lot better - using these as benchmarks through course of treatment"*
Communicating to patients an intervention is likely to be effective (e.g., '*this treatment usually works for most people with low back pain'*)	Communicating an intervention is likely to be effective using positive verbal instructions (e.g., *'I expect your pain will improve after treatment'*). (Q9.5)	(Two original statements were combined to reduce repetition / redundant items)
Helping patients associate hands on techniques with positive outcomes using positive verbal instructions (e.g., *'I expect your pain will improve after this manipulation'*)		
Being optimistic during the consultation and regarding their dysfunction (e.g., '*I believe you will get back to your usual level of functioning again'*)	Being optimistic during treatment by providing a prognosis (e.g., *'I believe you will recover and get back to your usual level of functioning'*). (Q9.7)	*"Treatment must also include prognosis"*

Table S2 continued. Summary of amendments to statements between rounds

Patient's Beliefs and Characteristics continued		
Original Statement (R1)	**Rephrased Statement (R2)**	***Panel Input* / (Notes)**
Rephrasing negative information (e.g., during leg flexion test: *'this procedure may lead to a slight increase in pain'* rather say instead: *'this procedure might be a bit uncomfortable but only temporarily'*)	Rephrasing negative information (e.g., leg flexion test: '*this procedure might be a bit uncomfortable but only temporarily*'). (Q10.2)	(Statement simplified / refined)
Reframing patient's prior misconceptions about low back pain (e.g., *'pain is not always a sign of physical tissue damage', 'your spine is flexible not fragile'*)	Reframing patient's prior misconceptions about their anatomy / physiology (e.g., '*your spine is flexible not fragile*'). (Q11.1)	(Statement simplified / refined)
Assisting in decreasing fear-avoidance and harm beliefs along with avoidant behaviours	Assisting in decreasing fear-avoidance and harm beliefs by recognising, confronting, and correcting them. (Q11.7)	*"Recognising, and confronting and correcting pre-existing fear-avoidance beliefs and behaviours"*
Avoiding negative phrases (e.g., '*wear and tear'*, '*damage', 'degeneration',* 'ongoing' instead of *'chronic'* pain, 'plan activities' instead of '*do exercise'*)	Avoiding negative phrases (e.g., 'wear and tear', 'damage', 'degeneration', 'abnormal'). (Q10.6)	(Statement simplified / refined)
Requesting the patient's opinions and demonstrating you trust and respect them	Demonstrating you trust or respect the patient and their opinions. (Q13.5)	(Statement simplified / refined)
Allocating time for patients to ask about negative aspects of treatment	Allocating time for patients to ask about negative aspects of treatment to address their concerns openly and honestly. (Q10.5)	*"Honesty - if a patient asks if it is going to hurt, or cause side effects, you MUST be honest with them, allowing time for them to relay concerns and then allay them openly and honestly."*
Displaying a balanced attitude to patient's alternative or cultural beliefs if not harmful (e.g., acupuncture).	Deleted.	(Beyond original scope of CFs)
Involving significant others and/or primary carers in treatment.	Deleted.	(Beyond original scope of CFs)
Describing how (un)common side effects are numerically (e.g., 1 in 100 people).	Deleted.	(Reduce number of statements in this CF domain; relatively less important)
Patient-Practitioner Relationship		
Being warm, confident, friendly, relaxed, and open during the appointment	Being warm, friendly, and relaxed during the appointment. (Q12.1)	Pilot participant – *"ambiguous / double-barrelled*"
Using eye contact, smiling, caring expressions of support and interest to convey empathy and compassion	Using eye contact, smiling, caring expressions of support to convey empathy or compassion. (Q12.2)	(Statement simplified / refined)
Providing effective reassurance via clear and understandable explanations	Providing a meaningful explanation of the patient's LBP (i.e., cognitive reassurance) which is clear, understandable, and can be referred to after treatment. (12.8)	– "*Explanation of the patient's particular problem in such a way that they can understand their condition"* – *"Providing cognitive reassurance i.e., providing meaningful information that patients can use when they are outside the treatment room"*
Providing treatment choices and encouraging patients to choose option(s) if they so wish.	Deleted.	(Similar statement included regarding collaborative decision-making.)

Table S2 continued. Summary of amendments to statements between rounds

Patient-Practitioner Relationship continued		
Original Statement (R1)	**Rephrased Statement (R2)**	***Panel Input* / (Notes)**
Providing a detailed, definitive, and confident diagnosis	Providing a confident diagnosis (e.g., providing a diagram with simple explanations and/or notes). (Q12.6)	– *"I don't believe a specific diagnosis is possible in low back pain /orthopaedics"* – *"Providing the patient with a (pre-printed with a diagram) sheet where notes and explanations in relation to their particular complaint have been written (in basic language)"* *"I do offer what I the assessment has shown and what we might be able to conclude"*
Treatment Characteristics		
Enabling patients to engage with other patients undergoing treatment with positive results (e.g., *group exercise classes, sharing success stories / testimonials, informally in the waiting area*)	Displaying feedback from other patients to provide reassurance (i.e., *testimonials displayed on TV in waiting area, or online via website*). (Q14.11)	*"Displaying feedback from other patients to provide reassurance i.e., testimonials displayed on TV in waiting area."*
Empowering patients to self-care and anticipate barriers (e.g., *reminders, implementation intentions, journal / logbook, NHS online self-care resources*)	Deleted.	(Replaced with Q14.10) *Providing self-management materials (e.g., videos, rehabilitation booklets) or email / telephone support to promote a patient's engagement in physical activities (practitioner input)*
Verbalising future treatment plans by stating the number of appointments and/or follow-ups (e.g., *'I will treat you every second week for 30 minutes*')	Deleted.	(Replaced with Q14.8) *Providing patients with clear milestones or signposting to indicate their progression through the treatment programme.* (practitioner input)
To show and tell the patient that as a therapy is applied it helps (e.g., '*I am applying pressure here because it helps…*').	Deleted.	(Reduce number of statements in this CF domain; similar new item included)
Treatment Environment / Setting		
Decorating the waiting area with cheerful ornamentation (e.g., *healthy indoor plants, leisure reading materials, comfortable cushions*)	Creating a positive ambience or atmosphere (e.g., flowers, plants, interesting magazines, friendly staff, relaxing background music, warm lighting) (Q15.6)	*"Flowers, plants, interesting magazines, friendly staff, relaxing background music (classical works well), warm, bright light."* (Two original statements were combined to reduce repetition / redundant items)
Combining positive distractors such as soft or soothing music, nice aromas, hot or cold beverages		
Considering seating provisions in the waiting areas (e.g., quantity, varying chair sizes, general arrangement).	Deleted.	(Similar statement included regarding seating provisions in treatment office.)
Using nature artworks that include green vegetation, flowers, or water may help to reduce anxiety.	Using nature artworks that include green vegetation, flowers, or water features. (Q15.7)	Pilot participant – *" remove 'may help to reduce anxiety' it may be leading"* *"Flowers, plants, interesting magazines, friendly staff, relaxing background music (classical works well), warm, bright light."*

(iii) Copy of Delphi Survey – Round 1 (DS-R1)

Page 1: Welcome and Introduction

Welcome to this Delphi-study regarding the perceived influence of contextual factors during treatment of chronic low back pain patients.

Intended For:

This survey is designed for:

- Qualified **manual and physical practitioners** (i.e., physiotherapists, chiropractors, and osteopaths);
- With three **(3) or more years' experience** in providing care for patients with **chronic low back pain**;
- Currently practicing in the **United Kingdom** (England, Scotland, Wales, and Northern Ireland).

Introduction:

- Manual and physical therapists use a variety of tools to achieve shared therapeutic goals such as improving patient's pain, physical functioning, and self-perceived health.
- Modifying contextual factors, including psychosocial aspects of care, are a promising supplementary approach to usual care for pain, which can potentially induce pain modulation and influence clinical outcomes via the following domains:
    1. **patient's characteristics and beliefs** (e.g., preferences, previous experiences, gender, age);
    2. **practitioner's characteristics and beliefs** (e.g., reputation, appearance, beliefs and behaviours);
    3. **the patient-practitioner relationship** (e.g., communication, trust, patient-centred approach);
    4. **the treatment features or characteristics** (e.g., clear diagnosis, overt therapy, therapeutic touch);
    5. **the physical environment / setting** (e.g., environment, interior design).
- Contextual factors are therapeutic cues which may be essential for the perception and interpretation of care, which can be interpreted positively or negatively, but may dually affect symptom perception, experience, and meaning.

Next Steps:

- The next page contains a **Participant Information Sheet** to help you make an informed decision.
- If you are willing to participate in the first survey, please **select the Consent Statement checkbox** at the bottom of the next page and then **click 'next'** to begin the survey.
- The questionnaire is expected to take between **15 and 20 minutes** to complete.
- Survey **responses are collected over encrypted SSL (TLS) connections** to ensure information is transmitted securely.
- You will be able to provide your email address at the end of the survey if you are interested in future participation in the second panel-round.

Ethics ID: 28052 **Version 1.0** **30.10.2019**

Participant Information Sheet

The title of the research project
Perceived influence of contextual factors during chronic low back pain treatment: a Delphi-consensus survey

What is the purpose of the research / questionnaire?
This study aims to explore your perceptions of the influence of five main types of contextual factors (that include psychosocial aspects of care) during the management of chronic low back pain patients. Since this study is a Delphi-consensus survey, there will be two consecutive online survey rounds consisting of short questionnaires. You will be given the opportunity to take part in both surveys, but participation in either one is voluntary.
The purpose of the first round is: to request your expert knowledge on care approaches you regularly use for patients with chronic low back pain; and to provide your opinion of and evaluate care approaches extracted from the literature and incorporated into this questionnaire. This Delphi-study forms part of a broader research project which is being conducted in order to obtain a PhD qualification from Bournemouth University, in partnership with AECC University College.

Why have I been chosen?
You are being asked to participate as we would like to understand physiotherapists', chiropractors', and osteopaths' views of contextual factors. We are seeking qualified practitioners, working in the UK, with three (3) or more years' experience providing regular care for patients with chronic low back pain. Expert opinion is required because of the limited research evidence currently available.

Do I have to take part?
It is entirely up to you to decide whether or not to take part. If you do decide to participate, you will have access to this online information sheet to read. If you do choose to proceed, beginning the online survey will mean that you agree to take part. You can withdraw from participating during the online survey at any time and without giving a reason. If you decide to withdraw, you can simply close the browser page, and this will remove any data collected about you from the study. Please note that once you have completed and submitted your survey responses, we are unable to remove your anonymised responses from the study. However, if you choose to provide your email address for the follow-up survey (second round), then your responses will be identifiable, and can then be removed. As we are unable to remove anonymised responses this can only be done prior to your email address being confidentially destroyed.

How long will the questionnaire / online survey take to complete?
Taking part will involve completing an online survey at a time convenient to you. The questionnaire is expected to take between 15 and 20 minutes to complete. You may also opt to *'finish later'* and either email yourself a copy of the link or leave the browser window open and continue at a later time.

What are the advantages and possible disadvantages or risks of taking part?
Whilst there are no immediate benefits for those people participating in the project, it is hoped that findings from this study will help improve outcomes for patients with chronic low back pain. The information collected will provide valuable insights into practitioners' views of contextual factors for clinical application during conservative care. There are no anticipated disadvantages of taking part in the survey, other than a small amount of time required to complete the voluntary questionnaires.

What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?
The survey has five sections relating to each of the contextual factors. The main questions are closed-ended (i.e., checkbox response options) and relate to your beliefs about contextual factors and their role in clinical practice. There are also optional open-ended questions for you to provide suggestions based on your knowledge and expertise. The final section relates to basic demographic information (e.g. age, gender, practitioner type, years of clinical experience) which will be useful for categorisation and statistical analysis. This data will be used to develop the second round of the Delphi-consensus survey.

At the end of the survey, you will be given the option of providing your email address if you wish to express interest in participating in the follow-up survey. This is the only personally identifiable information requested and it will be kept confidential. An expression of interest simply indicates you might be willing to take part in the second round.

Use of my information
Participation in this study is on the basis of consent: you do not have to complete the survey, and you can change your mind at any point before submitting the survey responses. Once we receive your survey response, your personal information is processed in compliance with the data protection legislation. We will use your data on the basis that it is necessary for the conduct of research, which is an activity in the public interest.

Bournemouth University (BU) is a Data Controller of your information which means that we are responsible for looking after your information and using it appropriately. BU's Research Participant Privacy Notice sets out more information about how we fulfil our responsibilities as a data controller and about your rights as an individual under the data protection legislation. We ask you to read this Notice so that you can fully understand the basis on which we will process your information. Once you have submitted your survey response it may not be possible for us to remove it from the study analysis, as this might affect our ability to complete the research appropriately, or the accuracy and reliability of the research findings.

Security and access controls
BU will hold the information we collect about you on a secure password protected BU network. Except where it has been anonymised, your personal information will only be accessed and used by appropriate, authorised individuals and when this is necessary for the purposes of the research or another purpose identified in the Privacy Notice. This may include giving access to BU staff or others responsible for monitoring and/or audit of the study, who need to ensure that the research is complying with applicable regulations.

Sharing and further use of your personal information
The information collected about you may be used in an anonymous form to support other research projects in the future and access to it in this format will not be restricted. It will not be possible for you to be identified from this data. Anonymised data will be added to BU's Data Repository (a central location where data is stored) and will be publicly available. You will not be able to be identified in the PhD thesis nor any external reports / publications about the research.

Retention of your data
Once the second round of email invitations / follow-ups are sent out, your email address will be confidentially destroyed. All other personal data collected for the purposes of this study will be held for three (3) years after the award of the degree. Although published research outputs are anonymised, we need to retain underlying data collected for the study in a non-anonymised form for a

certain period to enable the research to be audited and/or to enable the research findings to be verified.

Contact for further information

If you would like to contact the main researcher (Bronwyn Sherriff) to raise any concerns or request further information, please direct your enquiries to: bsherriff@bournemouth.ac.uk
Alternatively, you are welcome to contact any one of my PhD supervisors:
Prof. Carol Clark: cclark@bournemouth.ac.uk
Prof. David Newell: dnewell@aecc.ac.uk
Dr Clare Killingback: c.killingback@hull.ac.uk

In case of complaints

Any concerns which have not been answered by the researchers should be directed to Professor Vanora Hundley, Faculty of Health and Social Sciences, Bournemouth University by emailing researchgovernance@bournemouth.ac.uk

This study has been approved by the University Research Ethics Committee (UREC) of Bournemouth University **(Ethics I.D. 28052)**

1. Consent to Participate *Required*

Page 3: Example Question

For each statement, you will be able to ***select / tick all applicable column(s)*** if:
a) You believe the statement reflects a potentially valid care approach;
b) It is an approach/technique you currently use as part of your everyday practice;
c) It is an approach/technique you feel confident to use without further training / experience.

Example Question

For each statement, you will be able to ***select / tick all applicable column(s)*** if:

a) You believe the statement reflects a potentially valid care approach;
b) It is an approach/technique you currently use as part of your everyday practice;
c) It is an approach/technique you feel confident to use without further training / experience;

For Example:

What is your opinion of the following statements?

	Please tick applicable box(es)			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not applicable**
e.g., Switching treatment approaches if a patient expresses prior negative experiences	✓	✓	✓	
e.g., Ensuring treatment areas and equipment are clean		✓	✓	
e.g., Showing signs of being in a hurry (e.g., talking quickly)				✓
e.g., Matching the practitioner and patient according to characteristics (e.g., gender, culture, home language)			✓	

Page 4: (1) Patient's Beliefs and Characteristics

Please ***select / tick all applicable column(s)*** if:
a) You believe the statement below reflects a potentially valid care approach;
b) It is an approach/technique you currently use as part of your everyday practice;
c) It is an approach/technique you feel confident to use without further training / experience.

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2. What is your opinion of the following aspects of the *patient's treatment history*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Actively investigating patient's needs, feelings, preferences, and previous experiences.	☐	☐	☐	☐
2. Supporting the patient in reframing negative memories (e.g., reinterpret an x-ray / scan or explain radiological reports / GP letters).	☐	☐	☐	☐
3. Taking note of inaccurate knowledge from previous treatment experiences (e.g., 'my spine is crumbling' or 'my back is worn out').	☐	☐	☐	☐

3. What is your opinion of attempting to create *positive outcomes* via the following approaches?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Communicating to patients an intervention is likely to be effective (e.g., 'this treatment usually works for most people with low back pain').	☐	☐	☐	☐
2. Emphasising positive outcomes such as overall pain-reducing effects (e.g., 'manual or physical therapies are often as effective as painkillers').	☐	☐	☐	☐
3. Being optimistic during the consultation and regarding their dysfunction (e.g., 'I believe you will get back to your usual level of functioning again').	☐	☐	☐	☐

4. Helping patients associate hands on techniques with positive outcomes using positive verbal instructions (e.g., 'I expect your pain will improve after this manipulation').	☐	☐	☐	☐

4. What is your opinion of attempting to reduce *negative outcomes* via the following approaches?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Reinforcing a shift in patient's negative thoughts to positive ones (e.g., outcomes to highlight progress).	☐	☐	☐	☐
2. Rephrasing negative information (e.g., during leg flexion test: 'this procedure may lead to a slight increase in pain' rather say instead: 'this procedure might be a bit uncomfortable but only temporarily').	☐	☐	☐	☐
3. Describing how (un)common side effects are numerically (e.g., 1 in 100 people).	☐	☐	☐	☐
4. Anticipating and helping reduce patient's anxiety about the treatment / procedure.	☐	☐	☐	☐
5. Allocating time for patients to ask about negative aspects of treatment.	☐	☐	☐	☐
6. Avoiding negative phrases (e.g., 'wear and tear', 'damage', 'degeneration', 'ongoing' instead of 'chronic' pain, 'plan activities' instead of 'do exercise').	☐	☐	☐	☐

Please ***select / tick all applicable column(s)*** if:
a) You believe the statement below reflects a potentially valid care approach;
b) It is an approach/technique you currently use as part of your everyday practice;
c) It is an approach/technique you feel confident to use without further training / experience.

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5. What is your opinion of the following *cognitive behavioural strategies*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Reframing patient's prior misconceptions about low back pain (e.g., 'pain is not always a sign of physical tissue damage', 'your spine is flexible not fragile').	☐	☐	☐	☐
2. Reframing patient's prior misconceptions about treatment (e.g., 'bed rest does not usually help patients recover faster but modified activity can').	☐	☐	☐	☐
3. Explaining the multi-dimensional nature (biopsychosocial aspects) of pain (i.e., beliefs, emotions, and behaviours (movement and lifestyle)) via suitable educational materials.	☐	☐	☐	☐
4. Clarifying maladaptive perceptions (e.g., catastrophising: 'My vertebrae are out of line. I stopped gardening, so I won't end up in wheelchair').	☐	☐	☐	☐
5. Assisting in decreasing fear-avoidance and harm beliefs along with avoidant behaviours.	☐	☐	☐	☐
6. Helping patients plan and monitor treatment success (e.g., SMART goals, motivational interviewing).	☐	☐	☐	☐
7. Empowering patients to self-care and anticipate barriers (e.g., reminders, implementation intentions, journal / logbook, NHS online self-care resources).	☐	☐	☐	☐
8. Developing patient's self-confidence in performing and persisting with a new behaviour to pursue a goal.	☐	☐	☐	☐

6. What is your opinion of considering *sociocultural contexts*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Displaying a balanced attitude to patient's alternative or cultural beliefs if not harmful (e.g., acupuncture).	☐	☐	☐	☐
2. Involving significant others and/or primary carers in treatment.	☐	☐	☐	☐

Optional:
Please provide any additional ideas / suggestions concerning **patient's characteristics and beliefs** you may have based on your expertise, and practice with chronic LBP patients **and select the relevant checkbox(es)**.

7. Please specify any further suggestions:

	Optional	**Please tick applicable box(es)**		
		a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**
a)				
b)				
c)				
d)				
e)				

Page 6: (2) Practitioner's Beliefs and Characteristics

Please ***select / tick all applicable column(s)*** if:
a) You believe the statement below reflects a potentially valid care strategy;
b) It is a care strategy you currently use as part of your everyday practice;
c) You believe this care strategy might contribute to or enhance overall treatment effects.

---

8. What is your opinion of demonstrating *your expertise* via the following approaches?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Prescribing or administering treatments you believe and expect to be effective.	☐	☐	☐	☐
2. Clearly communicating your expectations (i.e., what you anticipate will occur) whilst administering care.	☐	☐	☐	☐
3. Using indicators of expertise / high status (e.g., health qualifications, professional memberships) in offices or correspondence.	☐	☐	☐	☐
4. Wearing a laboratory coat / medical apparel or tailored / formal clothing to symbolise professionalism.	☐	☐	☐	☐

9. What is your opinion of adapting your *mindset* or *attitude* via the following approaches?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Remaining attentive and fully focused on the patient throughout the appointment.	☐	☐	☐	☐
2. Being genuine and honest to instil a sense of trustworthiness and authenticity.	☐	☐	☐	☐
3. Displaying self-confidence without appearing arrogant or dismissive.	☐	☐	☐	☐

Optional:

Please provide any additional ideas / suggestions concerning **practitioner's characteristics and beliefs** you may have based on your expertise, and practice with chronic LBP patients **and select the relevant checkbox(es)**.

10. Please specify any further suggestions:

	Optional	**Please tick applicable box(es)**		
		a) I think it is a valid approach	**b) I use this approach in practice**	**c) It might enhance treatment effects**
a)				
b)				
c)				
d)				
e)				

Page 7: (3) Patient–Practitioner Relationship

Please ***select / tick all applicable column(s)*** if:
a) You believe the statement below reflects a potentially valid care approach;
b) It is an approach/technique you currently use as part of your everyday practice;
c) It is an approach/technique you feel confident to use without further training / experience.

---

11. What is your opinion of displaying the following *non-verbal behaviours*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Being warm, confident, friendly, relaxed, and open during the appointment.	☐	☐	☐	☐
2. Using eye contact, smiling, caring expressions of support and interest to convey empathy and compassion.	☐	☐	☐	☐
3. Using affirmative head nodding, forward leaning, open body postures / orientations.	☐	☐	☐	☐
4. Not rushing or interrupting the patient; giving them time to tell their story.	☐	☐	☐	☐
5. Applying different forms of touch (e.g., assistive touch, touch to prepare the patient, touch to provide information, touch to reassure the patient).	☐	☐	☐	☐

12. What is your opinion of the following aspects of the *patient-centred approach*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Using verbal expressions of empathy, support, and language reciprocity (e.g., using the patient's words / phrasing).	☐	☐	☐	☐
2. Ensuring the patient feels listened to and heard (e.g., active listening or noting their responses).	☐	☐	☐	☐
3. Adopting psychosocial talk or partnership statements (e.g., we, us, together).	☐	☐	☐	☐
4. Requesting the patient's opinions and demonstrating you trust and respect them.	☐	☐	☐	☐
5. Individualising the interaction style according to a patient's preference (e.g., collaborative or authoritative).	☐	☐	☐	☐
6. Providing treatment choices and encouraging patients to choose option(s) if they so wish.	☐	☐	☐	☐
7. Engaging in collaborative decision-making with patients (e.g., mutually agreed and flexible goals).	☐	☐	☐	☐
8. Promoting the patient's sense of relatedness and partnership with you (i.e., therapeutic alliance).	☐	☐	☐	☐

13. What is your opinion of using the following *diagnostic practices*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**	**Not Applicable**
1. Providing a detailed, definitive, and confident diagnosis.	☐	☐	☐	☐
2. Providing effective reassurance via clear and understandable explanations.	☐	☐	☐	☐
3. Asking questions about the meaning of the patient's symptoms (i.e., what symptoms indicate to them).	☐	☐	☐	☐
4. Examining the patient fully using appropriate therapeutic 'hands on' touch during the clinical examination.	☐	☐	☐	☐

Optional:

Please provide any additional ideas / suggestions concerning **the patient-practitioner relationship** you may have based on your expertise, and practice with chronic LBP patients **and select the relevant checkbox(es)**.

14. Please specify any further suggestions:

	Optional	**Please tick applicable box(es)**		
		a) I think it is a valid approach	**b) I use this approach in practice**	**c) I am confident to use without training**
a)				
b)				
c)				
d)				
e)				

Page 8: (4) Treatment Characteristics

Please ***select / tick all applicable column(s)*** if:
a) You believe the statement below reflects a potentially valid care strategy;
b) It is a care strategy you currently use as part of your everyday practice;
c) You believe this care strategy might contribute to or enhance overall treatment effects.

---

15. What is your opinion when explaining the following *treatment options*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Overtly encouraging patients to engage in therapy / exercise with an optimistic mindset to try establish positive associations with pain relief.	☐	☐	☐	☐
2. Encouraging patients to find suitable incentives / reinforcement strategies to increase daily activity (e.g., personalised activities, exercise partners).	☐	☐	☐	☐
3. To show and tell the patient that as a therapy is applied it helps (e.g. 'I am applying pressure here because it helps…').	☐	☐	☐	☐

16. What is your opinion of the following *appointment features*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Ensuring the patient is cared for by the same practitioner / therapist (i.e., continuity of care).	☐	☐	☐	☐
2. Verbalising future treatment plans by stating the number of appointments and/or follow-ups (e.g., 'I will treat you every second week for 30 minutes').	☐	☐	☐	☐
3. Increasing the frequency and/or duration of appointments (i.e., provide extra time / attention).	☐	☐	☐	☐

17. What is your opinion of the following *alternative feedback* strategies?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Administering treatments along with visual feedback (e.g., using mirrors during exercises).	☐	☐	☐	☐
2. Enabling patients to engage with other patients undergoing treatment with positive results (e.g., group exercise classes, sharing success stories / testimonials, informally in the waiting area).	☐	☐	☐	☐

Optional:
Please provide any additional ideas / suggestions concerning **the treatment characteristics** you may have based on your expertise, and practice with chronic LBP patients **and select the relevant checkbox(es)**.

18. Please specify any further suggestions:

	Optional	**Please tick applicable box(es)**		
		a) I think it is a valid approach	**b) I use this approach in practice**	**c) It might enhance treatment effects**
a)				
b)				
c)				
d)				
e)				

Page 9: (5) Healthcare Setting / Environment

Please ***select / tick all applicable column(s)*** if:
a) You believe the statement below reflects a potentially valid care strategy;
b) It is a care strategy you currently use as part of your everyday practice;
c) You believe this care strategy might contribute to or enhance overall treatment effects.

---

19. What is your opinion of the following *interior design and layout* strategies?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Ensuring facilities have ample natural light or windows, and are suitably heated / ventilated (i.e., comfortable temperature).	☐	☐	☐	☐
2. Ensuring treatment facilities have privacy provisions (e.g., private changing area and treatment room, curtains / blinds on windows).	☐	☐	☐	☐
3. Considering seating provisions in the waiting areas (e.g., quantity, varying chair sizes, general arrangement).	☐	☐	☐	☐
4. Considering seating provisions in treatment office (e.g., relative position to desk, additional chairs for carer).	☐	☐	☐	☐

20. What is your opinion of the *setting's decor*?

	Please tick applicable box(es) *Required*			
	a) I think it is a valid care strategy	**b) I use this care strategy in practice**	**c) It might enhance treatment effects**	**Not Applicable**
1. Waiting areas and treatment facilities are uncluttered and tidy.	☐	☐	☐	☐
2. Providing visual indicators or cues to signify it is a medical setting (e.g., model of spine, patient information brochures, medicalised décor).	☐	☐	☐	☐
3. Decorating the waiting area with cheerful ornamentation (e.g., healthy indoor plants, leisure reading materials, comfortable cushions).	☐	☐	☐	☐
4. Combining positive distractors such as soft or soothing music, nice aromas, hot or cold beverages.	☐	☐	☐	☐
5. Using nature artworks that include green vegetation, flowers, or water may help to reduce anxiety.	☐	☐	☐	☐

Optional:
Please provide any additional ideas / suggestions concerning **the healthcare environment** you may have based on your expertise, and practice with chronic LBP patients **and select the relevant checkbox(es)**.

21.Please specify any further suggestions:

		Please tick applicable box(es)		
	Optional	**a) I think it is a valid approach**	**b) I use this approach in practice**	**c) It might enhance treatment effects**
a)				
b)				
c)				
d)				
e)				

Page 10: Demographics

22. Age: (years)

Please enter a number.

23. Gender: *(please select option from drop-down menu)*

(drop-down menu)
Male
Female
Non-binary gender
Prefer not to disclose
Other

a. If you selected Other, please specify:

24. Practitioner Type: *(please select one option) Required*

- Chiropractor
- Osteopath
- Physiotherapist
- Sports Therapist
- Prefer not to disclose
- Other

a. If you selected Other, please specify:

25. Years of Clinical Experience (Post-Qualifying)**:** (years)

Please enter a number.

26. Current Practice Setting: *(please select one option)*

- Private practice
- Public (NHS setting)
- Combination of both
- Prefer not to disclose
- Other

a. If you selected Other, please specify:

27. Current Practice Region: *(please select option from drop-down menu) Required*

(*drop-down menu)*
Northern Ireland
Scotland
Wales
North East and Cumbria
North West
Yorkshire and the Humber
West Midlands
East Midlands
London
East of England
South East
South West
Prefer not to disclose
Other

a. If you selected Other, please specify:

Page 11: Expression of Interest

Second Panel-Round
If you might be **interested in participating in the second round** of this Delphi-study, please **include your email address** in the textbox below:

28. ***Please DO NOT provide your NHS email address:*** *Optional*
Please enter a valid email address.

Note:

- An invitation will be sent to you within the next six to eight months (i.e., between June and August 2020), providing information on the second panel-round, and inviting you to take part.
- In the interim, your email address will be securely stored on this password protected online survey platform (**hosted by Jisc**: https://www.onlinesurveys.ac.uk/).
- Jisc acts as the Data Processor, and is both GDPR compliant and ISO 27001 certified.
- Once the second set of invitations / follow-ups emails are sent out, your email address will be confidentially destroyed.
- Only Bronwyn Sherriff (primary researcher) has direct access to the raw (non-anonymised) survey responses collected via Jisc.
- **All raw data will be anonymised, and any personal information identifying factors removed, prior to such information being exported from the Jisc platform or being shared.**

Page 12: Closing Message

- **Thank you** for choosing to take part in this survey.
- I am truly **grateful for your time** and invaluable insights.
- If you have **colleagues** who may also be **interested in participating**, **please** may I ask you to **forward the survey link**.

Researcher's Contact Details:
Please do not hesitate to contact me if you have any queries or would like to be kept updated on the findings of this study.

Ms Bronwyn Sherriff: bsherriff@bournemouth.ac.uk
Alternatively, you are welcome to contact one of my PhD supervisors instead:

- Prof. Carol Clark: cclark@bournemouth.ac.uk
- Prof. David Newell: dnewell@aecc.ac.uk
- Dr Clare Killingback: c.killingback@hull.ac.uk

(iv) Copy of Delphi Survey – Round 2 (DS-R2)

Page 1: Welcome and Introduction

Welcome to the second round of this Delphi-consensus survey.

- Thank you for your invaluable input on the previous survey, it has informed the development of the second round of this Delphi-study.
- This research seeks to investigate manual and physical therapists' perceptions of the influence of five main types of contextual factors during the management of patients with chronic or persistent low back pain (LBP), namely:

1. **practitioner's beliefs and characteristics** (e.g., beliefs, expertise, appearance);
2. **patient's beliefs and characteristics** (e.g., beliefs, expectations, previous experiences);
3. **patient-practitioner relationship** (e.g., overt communication, patient-centred approach);
4. **treatment features / characteristics** (e.g., overt therapy, appointment features);
5. **treatment environment / setting** (e.g., layout, interior design).

Next Steps:

- If you are willing to participate, please select the **Consent Statement checkboxes** at the bottom of the page **and then *'next'*** to begin.
- The questionnaire takes approximately **15 to 20 minutes** to complete.
- You may select the ***'finish later'*** option and email yourself a link or leave the browser window open to continue at a later time.
- Survey **responses are collected over encrypted SSL** (TLS) connections to ensure information is transmitted securely.
- You will be able to provide your email address at the end of the questionnaire if you would like to receive a summary of the findings.

Researcher's Contact Details:
This Delphi-study forms part of a broader research project which is being conducted in order to obtain a PhD qualification from Bournemouth University, in partnership with AECC University College.

Please do not hesitate to contact me if you have any additional questions or specific concerns.
Ms Bronwyn Sherriff: bsherriff@bournemouth.ac.uk
Alternatively, you are welcome to contact any one of my PhD supervisors:

- Prof. Carol Clark: cclark@bournemouth.ac.uk
- Prof. David Newell: dnewell@aecc.ac.uk
- Dr Clare Killingback: c.killingback@hull.ac.uk

1. Consent to Participate *Required*

☐ I confirm that I have read and understood the information provided.

☐ I agree to take part in the study on the basis set out in the Information Sheet provided to me via email.

Page 2: Demographics

2. Age: (years) *Required*

Please enter a number.

3. Gender: *(please select option from drop-down menu) Required*

(drop-down menu)

Male
Female
Non-binary
Prefer not to disclose
Other

a. If you selected Other, please specify:

4. Practitioner Type: *(please select one option) Required*

- Chiropractor
- Osteopath
- Physiotherapist
- Sports Therapist
- Other

a. If you selected Other, please specify:

5. Years of Clinical Experience (Post-Qualifying)**:** (years) *Required*

Please enter a number.

6. Practice Setting: *(please select one option)*

Note: The following question relates to your **pre-COVID-19 practice setting** rather than how you may currently be practising.

- Private practice
- Public (NHS setting)
- Combination of both
- Educational organisation
- Charity / Non-profit organisation
- Other

a. If you selected Other, please specify:

7. Current Practice Region: *(please select option from drop-down menu) Required*

(drop-down menu)

Northern Ireland
Scotland
Wales
North East and Cumbria
North West
Yorkshire and the Humber
West Midlands
East Midlands
London
East of England
South East
South West
Other

a. If you selected Other, please specify:

Page 3: (1) Practitioner's Beliefs and Characteristics

- Below is a list of care approaches for patients with chronic or persistent low back pain (LBP).
- Please indicate whether you **have intentionally used** each approach **believing it could influence patient's** LBP **outcome(s)**.

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

8. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Remaining attentive and fully focused on the patient throughout the appointment.	☐	☐	☐	☐	☐	☐	☐
2. Being genuine and honest to instil a sense of trustworthiness and authenticity.	☐	☐	☐	☐	☐	☐	☐
3. Displaying self-confidence without appearing dismissive.	☐	☐	☐	☐	☐	☐	☐
4. Being calm and compassionate throughout the appointment.	☐	☐	☐	☐	☐	☐	☐
5. Displaying a professional and caring (not only "curing") attitude.	☐	☐	☐	☐	☐	☐	☐
6. Creating a caring atmosphere (e.g., appear to have all the time in the world; ensure each patient feels like a priority).	☐	☐	☐	☐	☐	☐	☐

7. Actively build rapport with each patient (e.g., discuss common interests / hobbies; enquire about their lives).	☐	☐	☐	☐	☐	☐	☐
8. Administering treatments you expect to be effective.	☐	☐	☐	☐	☐	☐	☐
9. Clearly communicating your expectations (i.e., what you anticipate will occur) whilst administering care.	☐	☐	☐	☐	☐	☐	☐
10. Using indicators to display your expertise or credibility (e.g., qualifications, insurance, professional memberships) in reception / office, website, or correspondence.	☐	☐	☐	☐	☐	☐	☐
11. Demonstrating professionalism through your general appearance (i.e., being clean, tidy, smart, and presentable).	☐	☐	☐	☐	☐	☐	☐

Page 4: (2) Patient's Beliefs and Characteristics

- Below is a list of care approaches for patients with chronic or persistent low back pain (LBP).
- Please indicate whether you **have intentionally used** each approach **believing it could influence patient's** LBP **outcome(s)**.

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

9. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Actively investigating patient's needs, feelings, preferences, and previous experiences.	☐	☐	☐	☐	☐	☐	☐
2. Supporting the patient in reframing negative memories (e.g., reinterpret an x-ray / scan or explain radiology reports / GP letters).	☐	☐	☐	☐	☐	☐	☐
3. Reframing misinformed beliefs from previous healthcare experiences (e.g., 'my spine is crumbling', 'my spinal curve is abnormal', 'my back is worn out').	☐	☐	☐	☐	☐	☐	☐
4. Exploring the patient's current or pre-existing beliefs about the cause(s) of their LBP.	☐	☐	☐	☐	☐	☐	☐
5. Communicating an intervention is likely to be effective using positive verbal instructions (e.g., 'I expect your pain will improve after treatment').	☐	☐	☐	☐	☐	☐	☐
6. Emphasising positive outcomes such as overall pain-reducing effects (e.g., 'manual or physical therapies are often as effective as painkillers').	☐	☐	☐	☐	☐	☐	☐

7. Being optimistic during treatment by providing a prognosis (e.g., 'I believe you will recover and get back to your usual level of functioning').	☐	☐	☐	☐	☐	☐	☐
8. Instilling genuine hope in patients regarding how their life can change for the better.	☐	☐	☐	☐	☐	☐	☐

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

10. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Reinforcing a shift in patient's negative thoughts to positive ones (e.g., monitor outcomes to highlight progress).	☐	☐	☐	☐	☐	☐	☐
2. Rephrasing negative information (e.g., leg flexion test: 'this procedure might be a bit uncomfortable but only temporarily').	☐	☐	☐	☐	☐	☐	☐
3. Using simple, everyday analogies to alter patient's negative illness perceptions (e.g., rusty hinges often work well despite their appearance).	☐	☐	☐	☐	☐	☐	☐

4. Anticipating and helping reduce patient's anxiety about the treatment / procedure.	☐	☐	☐	☐	☐	☐	☐
5. Allocating time for patients to ask about negative aspects of treatment to address their concerns openly and honestly.	☐	☐	☐	☐	☐	☐	☐
6. Avoiding negative phrases (e.g., 'wear and tear', 'damage', 'degeneration', 'abnormal').	☐	☐	☐	☐	☐	☐	☐
7. Explaining that calming their stress response is a part of everyday self-care for physical pain and healing.	☐	☐	☐	☐	☐	☐	☐
8. Explaining imaging is usually unnecessary because scans may not explain the extent of their pain and/or dysfunction.	☐	☐	☐	☐	☐	☐	☐

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

11. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s).

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Reframing patient's prior misconceptions about their anatomy / physiology (e.g., 'your spine is flexible not fragile').	☐	☐	☐	☐	☐	☐	☐
2. Reframing patient's prior misconceptions about treatment (e.g., 'bed rest does not usually help patients recover faster but modified activity can').	☐	☐	☐	☐	☐	☐	☐
3. Explaining the multi-dimensional nature (biopsychosocial aspects) of pain (i.e., beliefs, emotions, and behaviours (movement and lifestyle)) via suitable educational materials.	☐	☐	☐	☐	☐	☐	☐
4. Explaining basic pain science (i.e., perceived pain is not necessarily actual physical pain from nerve or tissue damage, but whilst very real, is more of a 'learned' response to prior experiences).	☐	☐	☐	☐	☐	☐	☐

5. Explaining routine activities, movement, or exercise can help 'rewire' perceived pain pathways (e.g., some pain or discomfort is normal but is not a sign their LBP is "worsening").	☐	☐	☐	☐	☐	☐	☐
6. Clarifying maladaptive perceptions (e.g., catastrophising: ‘My vertebrae are out of line. I stopped gardening, so I won’t end up in a wheelchair’).	☐	☐	☐	☐	☐	☐	☐
7. Assisting in decreasing fear-avoidance and harm beliefs by recognising, confronting, and correcting them.	☐	☐	☐	☐	☐	☐	☐
8. Helping patients plan and monitor treatment success (e.g., explain outcome measures; co-create short-term and long-term goals or target-driven stages of improvement).	☐	☐	☐	☐	☐	☐	☐
9. Developing patient’s self-confidence in performing or persisting with a new behaviour or goal.	☐	☐	☐	☐	☐	☐	☐

Page 5: (3) Patient–Practitioner Relationship

- Below is a list of care approaches for patients with chronic or persistent low back pain (LBP).
- Please indicate whether you **have intentionally used** each approach **believing it could influence patient's** LBP **outcome(s)**.

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

12. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Being warm, friendly, and relaxed during the appointment.	☐	☐	☐	☐	☐	☐	☐
2. Using eye contact, smiling, caring expressions of support to convey empathy or compassion.	☐	☐	☐	☐	☐	☐	☐
3. Using affirmative head nodding, forward leaning, open body postures / orientations.	☐	☐	☐	☐	☐	☐	☐
4. Not rushing or interrupting the patient; giving them time to tell their story.	☐	☐	☐	☐	☐	☐	☐
5. Applying different forms of touch (e.g., assistive touch, touch to prepare the patient, touch to provide information, touch to reassure the patient).	☐	☐	☐	☐	☐	☐	☐
6. Providing a confident diagnosis (e.g., providing a diagram with simple explanations and/or notes).	☐	☐	☐	☐	☐	☐	☐

7. Explaining improvement(s) can be dynamic, and their condition / symptoms may change throughout treatment.	☐	☐	☐	☐	☐	☐	☐
8. Providing a meaningful explanation of the patient's LBP (i.e., cognitive reassurance) which is clear, understandable, and can be referred to after treatment.	☐	☐	☐	☐	☐	☐	☐
9. Asking questions about the meaning of the patient's symptoms (i.e., what symptoms indicate to them).	☐	☐	☐	☐	☐	☐	☐
10. Examining the patient fully using appropriate therapeutic 'hands on' touch during the clinical examination.	☐	☐	☐	☐	☐	☐	☐

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

13. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Using verbal expressions of empathy, support, and language reciprocity (e.g., using the patient's words).	☐	☐	☐	☐	☐	☐	☐
2. Compassionately expressing your understanding of how LBP affects them (e.g., 'I understand how frustrating it is not to be able to walk your dog / go dancing / garden' etc).	☐	☐	☐	☐	☐	☐	☐
3. Ensuring the patient feels listened to and heard (e.g., active listening or noting their responses).	☐	☐	☐	☐	☐	☐	☐
4. Adopting psychosocial talk or partnership statements (e.g., we, us, together).	☐	☐	☐	☐	☐	☐	☐
5. Demonstrating you trust or respect the patient and their opinions.	☐	☐	☐	☐	☐	☐	☐
6. Individualising the interaction style according to a patient's preference (e.g., collaborative or authoritative).	☐	☐	☐	☐	☐	☐	☐

7. Engaging in collaborative decision-making together (e.g., mutually agreed and flexible goals).	☐	☐	☐	☐	☐	☐	☐
8. Promoting the patient's sense of relatedness and partnership with you (i.e., therapeutic alliance).	☐	☐	☐	☐	☐	☐	☐
9. Confirming the patient not only heard but also understood the content of your communication.	☐	☐	☐	☐	☐	☐	☐

Page 6: (4) Treatment Characteristics

- Below is a list of care approaches for patients with chronic or persistent low back pain (LBP).
- Please indicate whether you **have intentionally used** each approach **believing it could influence patient's** LBP **outcome(s)**.

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

14. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Overtly encouraging patients to engage in therapy / exercise with an optimistic mindset to try establish positive associations with pain relief.	☐	☐	☐	☐	☐	☐	☐
2. Encouraging patients to find suitable incentives / reinforcement strategies to increase daily activity (e.g., personalised activities, exercise partners).	☐	☐	☐	☐	☐	☐	☐
3. Clearly explaining the difference between a clinical examination and treatment.	☐	☐	☐	☐	☐	☐	☐
4. Demonstrating whether functional change has occurred immediately after treatment (e.g., pain, range of motion, or strength).	☐	☐	☐	☐	☐	☐	☐

5. Explaining your treatment advice in line with the patient's treatment expectations.	☐	☐	☐	☐	☐	☐	☐
6. Ensuring the patient is cared for by the same practitioner / therapist (i.e., continuity of care).	☐	☐	☐	☐	☐	☐	☐
7. Increasing the frequency and/or duration of appointments (i.e., provide extra time / attention).	☐	☐	☐	☐	☐	☐	☐
8. Providing patients with clear milestones or signposting to indicate their progression through the treatment programme.	☐	☐	☐	☐	☐	☐	☐
9. Administering treatments along with visual feedback (e.g., using mirrors during exercises).	☐	☐	☐	☐	☐	☐	☐
10. Providing self-management materials (e.g., videos, rehabilitation booklets) or email / telephone support to promote a patient's engagement in physical activities.	☐	☐	☐	☐	☐	☐	☐
11. Displaying feedback from other patients to provide reassurance (i.e., testimonials displayed on TV in waiting area, or online via website).	☐	☐	☐	☐	☐	☐	☐
12. Sharing positive stories of other (anonymous) patients with similar problems or goals.	☐	☐	☐	☐	☐	☐	☐

Page 7: (5) Treatment Environment / Setting

- Below is a list of care approaches for patients with chronic or persistent low back pain (LBP).
- Please indicate whether you **have intentionally used** each approach **believing it could influence patient's** LBP **outcome(s)**.

- Select **1** or **2** if you **did not believe** it could improve outcome(s).
- Select **3** if you were **unsure** if it could improve outcome(s).
- Select **4** or **5** if you **believed it could** improve outcome(s).
- Select '**Not Valid**' if you **do not think it is a suitable approach** for patients with chronic LBP.

15. Please indicate how much you agree or disagree with the influence of each approach on patient's outcome(s). *Required*

	1 – Strongly Disagree	**2 – Disagree**	**3 – Neither Agree nor Disagree**	**4 – Agree**	**5 – Strongly Agree**	**Not Valid**	**Do Not Recall / Use**
1. Ensuring treatment facilities have ample natural light or windows, and are suitably heated / ventilated (i.e., comfortable temperature).	☐	☐	☐	☐	☐	☐	☐
2. Ensuring treatment facilities have privacy provisions (e.g., private changing area and treatment room, curtains / blinds on windows).	☐	☐	☐	☐	☐	☐	☐
3. Rearranging the furniture or seating provisions in the treatment office (e.g., relative position to desk, additional chairs for carer).	☐	☐	☐	☐	☐	☐	☐
4. Ensuring waiting areas and treatment facilities are uncluttered and tidy.	☐	☐	☐	☐	☐	☐	☐

5. Providing visual indicators or cues to signify it is a medical setting (e.g., model of spine, patient information brochures, medicalised décor).	☐	☐	☐	☐	☐	☐	☐
6. Creating a positive ambience or atmosphere (e.g., flowers, plants, interesting magazines, friendly staff, relaxing background music, warm lighting).	☐	☐	☐	☐	☐	☐	☐
7. Using nature artworks that include green vegetation, flowers, or water features.	☐	☐	☐	☐	☐	☐	☐

16. On a scale ranging from **1 (no control)** to **6 (full control)**, please indicate how much personal control or input you have on the overall layout and design of the treatment room (i.e., usual care setting **prior to the COVID-19 pandemic**). *Required*

- ○ 1 – No control
- ○ 2 – Almost no control
- ○ 3 – Little control
- ○ 4 – Some control
- ○ 5 – Almost full control
- ○ 6 – Full control
- ○ Not Applicable

Page 8: Contextual Factors

17. On a scale ranging from **1 (not at all important)** to **7 (extremely important)**, based on your experience and beliefs, please **rate the importance of each contextual factor to the patient's treatment** during the healthcare encounter. *Required*

Higher ratings indicate you believe the contextual factor is important.
You may choose to select the same rating for different contextual factors.

	1 – Not at all important	**2 – Low importance**	**3 – Slightly important**	**4 – Neutral**	**5 – Moderately important**	**6 – Very important**	**7 – Extremely important**
Practitioner's beliefs and characteristics (e.g., beliefs, expertise, appearance)	☐	☐	☐	☐	☐	☐	☐
Patient's beliefs and characteristics (e.g., beliefs, expectations, previous experiences)	☐	☐	☐	☐	☐	☐	☐
Patient-practitioner relationship (e.g., overt communication, patient-centred approach)	☐	☐	☐	☐	☐	☐	☐
Treatment features / characteristics (e.g., overt therapy, appointment features)	☐	☐	☐	☐	☐	☐	☐
Treatment environment / setting (e.g., layout, interior design)	☐	☐	☐	☐	☐	☐	☐

a. Please **explain why** you have chosen the above ratings. *Optional*

18. Based on your experience and beliefs, please indicate which contextual factor you feel is the **most important to the patient's treatment** during the healthcare encounter. *Required*

(drop down menu)
Practitioner's beliefs and characteristics
Patient's beliefs and characteristics
Patient-practitioner relationship
Treatment features / characteristics
Treatment environment / setting

19. Based on your experience and beliefs, please indicate which contextual factor you feel is the **least important to the patient's treatment** during the healthcare encounter. *Required*

(drop down menu)
Practitioner's beliefs and characteristics
Patient's beliefs and characteristics
Patient-practitioner relationship
Treatment features / characteristics
Treatment environment / setting

Page 9: Consultation Approach

Note: The following questions relate to your **pre-COVID-19 consultation approach** rather than how you may currently be practising during the global pandemic.

Although there are a range of consultation approaches and styles, which may differ depending on the patient and context, please try to place yourself on the continuum below.

20. On a scale ranging from **mainly hands-on** (i.e., biomechanical orientation) to **mainly hands-off** (i.e., psychosocial orientation), please **rate your typical engagement style** during the treatment of patients with chronic or persistent LBP. *Required*

- ○ 10 – Mainly hands-off
- ○ 9
- ○ 8
- ○ 7
- ○ 6
- ○ 5 – Combined approach
- ○ 4
- ○ 3
- ○ 2
- ○ 1
- ○ 0 – Mainly hands-on

a. Please **explain why** you have chosen the above rating. *Optional*

21. Please select any of the following factors which you believe has **mainly influenced** or shaped **your consultation approach**. *Required*

Please select as many factors as apply to your **pre-COVID-19** consultation approach.

- ☐ Pre-qualifying education / training
- ☐ Pre-qualifying clinical experience(s)
- ☐ Post-qualifying / postgraduate education (e.g., PG Certificate or Diploma, Masters)
- ☐ Post-qualifying training (e.g., CPD seminars, short courses and/or workshops)
- ☐ Post-qualifying clinical experience(s)
- ☐ Clinical guidelines
- ☐ Professional registrations / memberships
- ☐ Professional Indemnity insurance policies
- ☐ Workplace Code of Conduct
- ☐ Current research and/or Evidence-Based Practice (EBP)
- ☐ Mentorship and/or clinical supervision
- ☐ Other

a. If you selected Other, please specify:

22. Please elaborate on your personal interaction style or consultation approach if you have additional comments. *Optional*

23. On a scale ranging from **1 (not at all)** to **5 (very large extent)**, please indicate to what **extent the COVID-19 pandemic has impacted your consultation approach** for patients with chronic or persistent LBP. *Required*

Please select at least 1 answer.
You may select up to 3 answer(s) (e.g., '4 - Large extent' and 'Currently unable to practice').

	1 – Not at all	**2 – Small extent**	**3 – Moderate extent**	**4 – Large extent**	**5 – Very large extent**	**Unsure**	**Currently unable to practice**	**Have not treated patients with chronic LBP**
Impact of COVID-19 on your consultation approach	☐	☐	☐	☐	☐	☐	☐	☐

a. **Please elaborate** on your response if you have additional comments.

Research Findings

If you are interested in receiving a **summary of the findings**, please include your **email address** in the textbox below:

*24.*Please **DO NOT** provide your **NHS** email address: *Optional*
Please enter a valid email address.

- Your email address will be securely stored on this password protected online survey platform (**hosted by Jisc**: https://www.onlinesurveys.ac.uk/).
- Jisc acts as the Data Processor, and is both GDPR compliant and ISO 27001 certified.
- Once the summary of findings are sent out, your email address will be confidentially destroyed.
- Only Bronwyn Sherriff (primary researcher) has direct access to the raw (non-anonymised) survey responses collected via Jisc.
- Any personal or identifying information will be removed, prior to such data being exported from the Jisc platform or being shared.

Please click the 'Finish' button to submit your responses, otherwise, they will not be saved.

Page 10: Thank you

- **Thank you** for choosing to take part in this Delphi-study.
- I am truly **grateful for your time** and invaluable **insights**.

Please do not hesitate to contact me if you have any queries or would like to be kept updated on the findings of this study.

Ms Bronwyn Sherriff: bsherriff@bournemouth.ac.uk

Alternatively, you are welcome to contact one of my PhD supervisors instead:

- Prof. Carol Clark: cclark@bournemouth.ac.uk
- Prof. David Newell: dnewell@aecc.ac.uk
- Dr Clare Killingback: c.killingback@hull.ac.uk

(v) Mean 95% Confidence Intervals

The Delphi data presented in Sherriff et al. (2023) were re-evaluated to address concerns regarding the mean 95% Confidence Intervals (CIs) exceeding 5.0 for certain statements (i.e., Item 1 in Tables 6 and 8, respectively). Upon review, it was determined that this issue was not attributable to data errors but rather reflected inherent characteristics of the data. Specifically, responses for these statements were predominantly high (4's or 5's), indicating high levels of agreement among panel members (100% agreement, respectively), as presented in the undernoted bar charts (Figures A and B).

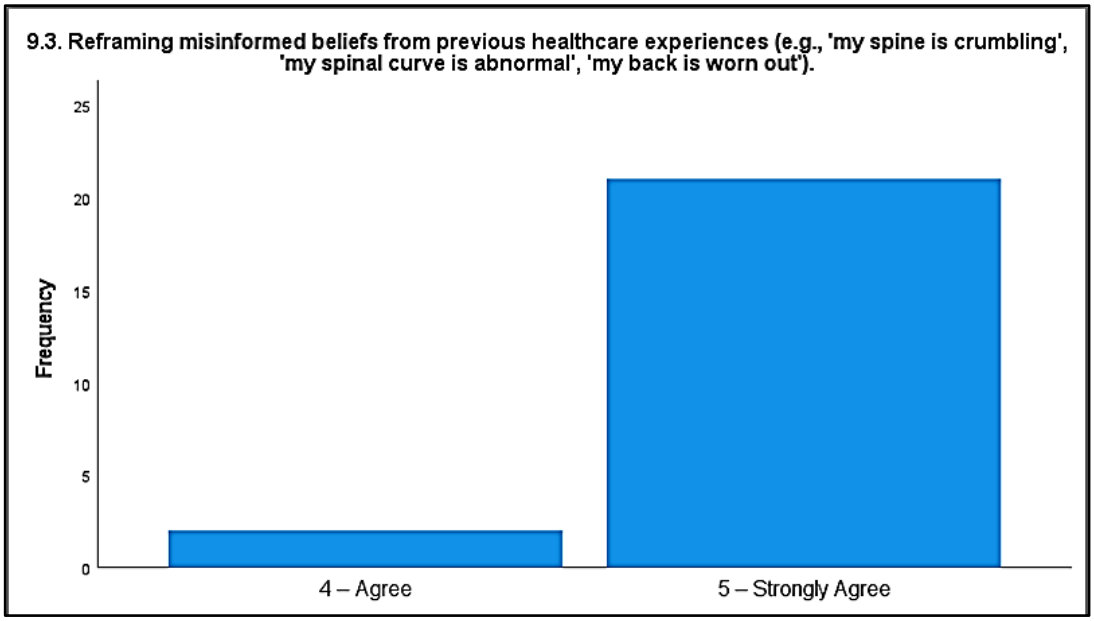

Figure A. Bar chart reflecting panel responses to question 9.3 (n = 23)

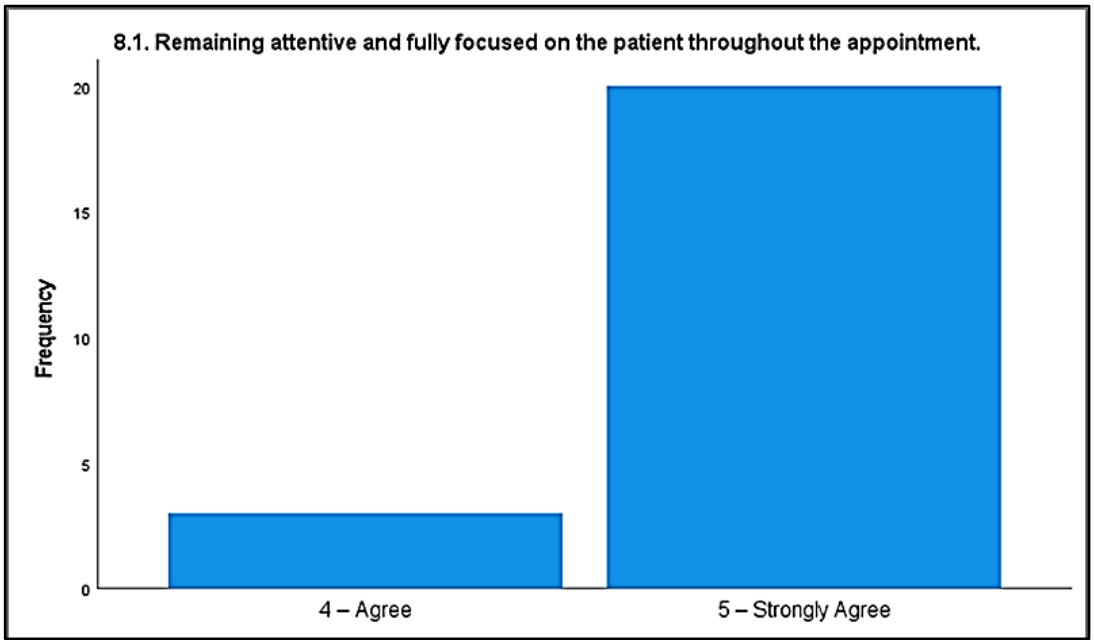

Figure B. Bar chart reflecting panel responses to question 8.1 (n = 23)

Consequently, the point estimate for the mean approached the maximum response value of 5.0, leading to the upper limit of the 95% CI exceeding 5.0. This reflects the data's variability and the uncertainty in estimating the population mean from a small sample (n = 23).

When the sample size is small ($n < 30$) and the population standard deviation is unknown, the *t*-distribution is more appropriate than the *Z*-distribution for calculating the mean CI. To calculate a mean CI using the *t*-distribution, the following formula is used:

$$\bar{x} \pm t_{\text{df-1}} * (s / \sqrt{n})$$

This approach accounts for the additional uncertainty arising from the estimation of the population standard deviation from the sample. To ensure the accuracy of the computation in SPPS, the mean 95% CIs were recomputed using an online calculator, yielding results identical to those previously reported in the Delphi study, as reflected in Table A below.

Table A. Mean 95% CI computations per relevant Delphi statement

	Delphi Item (Table 6) Q9.3	**Delphi Item (Table 8) Q8.1**
Mean ($\bar{x}$)	$\bar{x}$ = 4.9130	$\bar{x}$ = 4.8696
Margin of Error (MOE) [a]	MOE = 0.1246	MOE = 0.1489
Standard Deviation (s)	s = 0.2881	s = 0.3444
Sample size (n)	n = 23	n = 23
Standard Error (SE)	SE = 0.06007	SE = 0.0718
Mean 95% Confidence Interval	[4.7885, **5.0376**]	[4.7207, **5.0185**]
$\bar{x}$ ± MOE	4.9130 ± 0.1246	4.8696 ± 0.1489
Where: $t_{(22)}$ = 2.0739 mean CI is: $\bar{x}$ ± Margin Of Error (MOE). [a] MOE = ± 2.0739 * (0.2881 / √23) and MOE = ± 2.0739 *(0.3444 / √23) respectively		

In both cases, the mean 95% CI exceeds 5.0 since the upper limit is $\bar{x}$ plus the Margin Of Error (MOE). Accordingly, Table A reaffirms the validity of the reported Delphi findings.

Bootstrapping is typically considered a useful technique that can provide reliable estimates of statistics and CIs when the underlying distribution is unknown or non-normal. However, it may not effectively address the limited variation of responses, which was a characteristic of the Delphi data. This limitation arises because the bootstrapped CIs are derived from re-sampling subsets of the original Delphi dataset, which is likely to lead to comparable results and unlikely to change the overall variance.

Although data transformation is sometimes used to address skewed distributions, it would also be inappropriate in this context. Transforming the data to meet inferential test assumptions would deviate from the Delphi study's objective. The main analysis did not involve parametric tests but reported descriptive statistics to reflect the Delphi panel members' perceptions. Transforming the data could therefore complicate the interpretation of the results given the nature of the study, since the data has been ordered to reflect the degree of consensus.

The median might have provided a more robust measure of central tendency, considering the ordinal nature of the data. However, the use of the mean was justified for ranking the Delphi statements across the main CF domains given the limited variability observed in the data. This was because the median was not a sensitive enough indicator to rank the Delphi statements since it was typically 4.0 or 5.0 for most statements.

Most importantly, the reported 95% CIs were not used to draw inferences about the population mean or inform the Delphi study's main findings. The 95% CIs were included for completeness and are unlikely to affect the overall conclusions. Therefore, the use of the mean and associated CIs was appropriate given the nature of the data and the aims of the Delphi study.

Appendix III – Supplementary Materials (Qualitative study)

The following supplementary materials are included in this Appendix:

(i) Copy of the patient information sheet;
(ii) Copy of the patient agreement form;
(iii) Copy of the practitioner information sheet;
(iv) Copy of the patient agreement form;
(v) Copy of the pre-interview tasks (patient and practitioner versions);
(vi) Copy of the interview guides (patient and practitioner versions);
(vii) Extracts from the field notes;
(viii) COREQ Checklist; and
(ix) Assessment of thematic analysis research quality

(i) Patient Information Sheet

Ref: CFVC-Px_V1.3 Ethics ID: 33506 Date: 15-04-2021

Bournemouth University

Participant Information Sheet

The title of the research project

Exploring patients' and practitioners' experiences of consultations for persistent low back pain.

Invitation to take part

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who is organising/funding the research?

This research is match-funded by Bournemouth University and the AECC University College for the purpose of obtaining a postgraduate (PhD) qualification.

What is the purpose of the project?

This study investigates both patient's and practitioner's experiences of the same consultation. The aim is to enhance our understanding of contextual elements of these healthcare interactions, specifically for patients experiencing persistent low back pain. These insights may help to inform practice and improve current approaches to treatment in the future. Conducting these interviews will help identify and describe specific or common elements of the interaction which could be beneficial for recovery.

Why have I been chosen?

You are being asked to participate as we would like to understand patients' experiences of consultations for recurring or persistent low back pain. We are seeking between 8 and 10 adult patients (aged between 18 and 65 years) with non-specific persistent or chronic low back pain (symptoms for at least 3 months), who recently attended a face-to-face, telephone, or virtual / online consultation with a private practice Chiropractor, Physiotherapist, Osteopath, or Sports Therapist in the UK. Understanding patient perceptions and experiences is important because of the limited research evidence currently available.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a participant agreement form. We want you to understand what participation involves before you make a decision on whether to participate.

All information shared with the researcher will be kept strictly confidential which means: no information will not be disclosed with any person at the participating clinic. Only the researcher will

know what you have shared about the consultation or your personal experiences unless you disclose information about unprofessional conduct. If this were to occur, the researcher will contact you via email to provide you with information to lodge a complaint if you wish to do so. The researcher may also need to share details of the reported misconduct with the research supervisors and the Clinical Director (where appropriate) so corrective action can be taken if necessary. However, none of your personal details will be shared with them ensuring your anonymity will be protected. Participating in this research will not influence any future treatment you will receive at the clinic and will also not affect your relationship with any staff at the clinic in any way.

If you or any family member have an on-going relationship with BU or the research team, e.g., as a member of staff, as student or other service user, your decision on whether to take part (or continue to take part) will not affect this relationship in any way.

What would taking part involve?

Taking part will involve two main activities. Firstly, completing a short online survey (consisting of a brief pre-interview task and providing basic demographic details e.g., age-group, gender) at a time convenient to you. This task is expected to take between 5 and 10 minutes but you may also opt to *'finish later'* and either email yourself a copy of the link or leave the browser window open and continue at a later time. Secondly, participating in a 25 to 30 minute online or telephone interview at a pre-arranged date and time which is convenient for you. **Please note** both you and your therapist will be interviewed separately. You will receive a £15.00 *Love2Shop voucher* as a token gesture for your time after the interview (redeemable at a participating high street retailer).

The pre-interview task is optional, but it gives you an opportunity to provide some brief notes about any aspect of the consultation you felt was important before the interview takes place. It can be helpful to have time to think about the experiences you wish to share before the interview. Your notes can also be shared with you during the interview to remind you what notes you made which is useful if the interview takes place several days later.

Can I change my mind about taking part?

Yes, you can stop participating in study activities at any time and without giving a reason.

You can withdraw from participating before you complete the pre-interview task, as well as during the pre-interview task (via the online survey) at any time and without giving a reason. You may also withdraw from the study by declining to be interviewed even if you have already completed the pre-interview task.

If I change my mind, what happens to my information?

After you decide to withdraw from the study, we will not collect any further information from or about you.

As regards information we have already collected before this point, your rights to access, change or move that information are limited. This is because we need to manage your information in specific ways in order for the research to be reliable and accurate. Further explanation about this is in the Personal Information section below.

If you decide to withdraw during the online pre-interview task, you can simply close the browser page, and this will remove any data collected about you from the study. Once you have completed and submitted your pre-interview task, we are unable to remove anonymised responses from the study. However, if you provided an email address for purposes of arranging the follow-up interview, then your responses will be identifiable, and can be removed.

Please note that once you have taken part in an interview, it may not be possible for this data to be removed from the study analysis, as this might affect the ability to complete the research appropriately or may impact the accuracy and reliability of the research findings.

What are the advantages and possible disadvantages or risks of taking part?

Whilst there are no immediate benefits to you for participating in the project, it is hoped that this work will help improve treatment outcomes for other patients with persistent low back pain in the future. The research findings may provide valuable insights into both practitioners' and patients' views and experiences will help researchers better understand elements of the consultation which might be therapeutic. This information may also help to improve treatment approaches in the future.

There are no anticipated disadvantages of taking part in the study, other than the time required to complete the voluntary activities. Whilst we do not anticipate any risks to you in taking part in this study, you may simply decline to answer any questions posed during the interview if you do not feel comfortable responding.

What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?

The pre-interview task collects a few brief thoughts or notes you wish to voluntarily share about your experience of the consultation. Collecting this information in advance will help you to remember specific aspects of the consultation which may be more difficult to recall at the time of the interview and can readily be shared with you during the interview. You will also be asked to provide your age-group, gender, and select preferences for when you would prefer the interview to be scheduled.

During the interview, you will be asked questions related to various aspects of your experience of the consultation, as well as some initial information regarding your low back pain, specifically how long you have been experiencing symptoms during your most recent episode and how long you have been experiencing problems overall. This information will help to us better understand elements of the consultation which both patients and practitioners believe to be important and /or beneficial as well as identify common aspects of the interaction which could be improved for the design of future treatment approaches or interventions.

Please note that if you tell the researcher about unsatisfactory or unprofessional care during the interview, this information may be anonymously disclosed to the research supervisors as well as the Clinical Director (where appropriate) to ensure corrective action is taken if necessary. You may also be provided with information about how to lodge a formal complaint via email after the interview has taken place. However, none of your personal details will be shared with these individuals ensuring your anonymity will be protected.

Will I be recorded, and how will the recorded media be used?

The interview will only be audio recorded. The audio recordings made during this research will be used only for analysis and the transcription of the recording(s) for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

How will my information be managed?

Bournemouth University (BU) is the organisation with overall responsibility for this study and the Data Controller of your personal information, which means that we are responsible for looking after your information and using it appropriately. Research is a task that we perform in the public interest, as part of our core function as a university.

Undertaking this research study involves collecting and/or generating information about you. We manage research data strictly in accordance with:

- Ethical requirements; and
- Current data protection laws. These control use of information about identifiable individuals, but do not apply to anonymous research data: "anonymous" means that we have either removed or not collected any pieces of data or links to other data which identify a specific person as the subject or source of a research result.

BU's Research Participant Privacy Notice sets out more information about how we fulfil our responsibilities as a data controller and about your rights as an individual under the data protection legislation. We ask you to read this Notice so that you can fully understand the basis on which we will process your personal information.

Research data will be used only for the purposes of the study or related uses identified in the Privacy Notice or this Information Sheet. To safeguard your rights in relation to your personal information, we will use the minimum personally identifiable information possible and control access to that data as described below.

Publication

You will not be able to be identified in any external reports or publications about the research without your specific consent. Otherwise, your information will only be included in these materials in an anonymous form, i.e., you will not be identifiable.

Security and access controls

BU will hold the information we collect about you in hard copy in a secure location and on a BU password protected secure network where held electronically.

Personal information which has not been anonymised will be accessed and used only by appropriate, authorised individuals and when this is necessary for the purposes of the research or another purpose identified in the Privacy Notice. This may include giving access to BU staff or others responsible for monitoring and/or audit of the study, who need to ensure that the research is complying with applicable regulations.

Once you have signed the participant agreement form, you will be given a unique identifier code to use to pseudo-anonymise both your pre-interview task and your interview data. Only the researcher will be able to attribute your identifier code to your data. Please note all online survey responses are

collected over encrypted SSL (TLS) connections and the service provider (JISC) is both GDPR Compliant and ISO 27001 certified.

Sharing your personal information with third parties

As well as BU staff and the BU student working on the research project, we may also need to share personal information in non-anonymised format with external collaborators (namely, Professor Dave Newell and Dr Clare Killingback), as well as the PhD studentship co-funder (AECC University College).

Further use of your information

The information collected about you may be used in an anonymous form to support other research projects in the future and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. To enable this use, anonymised data will be added to BU's online Research Data Repository: this is a central location where data is stored, which is accessible to the public.

Keeping your information if you withdraw from the study

If you withdraw from active participation in the study, we will keep information which we have already collected from or about you, if this has on-going relevance or value to the study. This may include your personal identifiable information. As explained above, your legal rights to access, change, delete or move this information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. However, if you have concerns about how this will affect you personally, you can raise these with the research team when you withdraw from the study.

You can find out more about your rights in relation to your data and how to raise queries or complaints in our Privacy Notice.

Retention of research data

Project governance documentation, including copies of signed **participant agreements**: we keep this documentation for a long period after completion of the research, so that we have records of how we conducted the research and who took part. The only personal information in this documentation will be your name and signature, and we will not be able to link this to any anonymised research results.

Research results:

We will keep your personal information in identifiable form for a period of three (3) years after the award of the degree. Although published research outputs are anonymised, we need to retain underlying data collected for the study in a non-anonymised form to enable the research to be audited and/or to enable the research findings to be verified.

You can find more specific information about retention periods for personal information in our Privacy Notice.

We keep anonymised research data indefinitely, so that it can be used for other research as described above.

Contact for further information

If you have any questions or would like further information, please either contact the researcher, Bronwyn Sherriff (bsherriff@bournemouth.ac.uk) or the project supervisors: Prof. Carol Clark (cclark@bournemouth.ac.uk), Prof. David Newell (dnewell@aecc.ac.uk), or Dr Clare Killingback (c.killingback@hull.ac.uk).

In case of complaints

Any concerns about the study should be directed to Professor Vanora Hundley, Faculty of Health and Social Sciences, Bournemouth University by email to researchgovernance@bournemouth.ac.uk.

Finally

If you decide to take part, you will be given a copy of the information sheet and a signed participant agreement form to keep.

Thank you for considering taking part in this research project.

(ii) Patient Agreement Form

Ref: CFVC-Px_V1.3
Ethics ID: 33506
Date: 15-04-2021

Bournemouth University

Participant Agreement Form

Full title of project: Exploring patients' and practitioners' experiences of consultations for persistent low back pain.

Name, position, and contact details of researcher: Bronwyn Sherriff, Postgraduate Researcher, bsherriff@bournemouth.ac.uk

Name, position and contact details of supervisors: Professor Carol Clark, Head of Department Rehabilitation and Sport Sciences, cclark@bournemouth.ac.uk;Professor David Newell, Director of Research, AECC University College, dnewell@aecc.ac.uk; and Dr Clare Killingback, Physiotherapy Programme Lead, University of Hull, c.killingback@hull.ac.uk).

To be completed prior to data collection activity

Section A: Agreement to participate in the study

You should only agree to participate in the study if you agree with all of the statements in this table and accept that participating will involve the listed activities.

I have read and understood the Participant Information Sheet (CFVC-Px_V1.3) and have been given access to the BU Research Participant Privacy Notice which sets out how we collect and use personal information (https://www1.bournemouth.ac.uk/about/governance/access-information/data-protection-privacy).
I have had an opportunity to ask questions.
I understand that my participation is voluntary. I can stop participating in research activities at any time without giving a reason and I am free to decline to answer any particular question(s).
I agree that BU researchers may process my confidential medical information as described in the Participant Information Sheet.
I understand that taking part in the research will include the following activity/activities as part of the research:
• Being audio recorded during the interview;
• My words will be quoted in publications, reports, web pages and other research outputs without using my real name.
I understand that, if I withdraw from the study, I will also be able to withdraw my data from further use in the study **except** where my data has been anonymised (as I cannot be identified) or it will be harmful to the project to have my data removed.
I understand that my data may be included in an anonymised form within a dataset to be archived at BU's Online Research Data Repository.
I understand that my data may be used in an anonymised form by the research team to support other research projects in the future, including future publications, reports, or presentations.

I acknowledge the following:

I understand that if I tell the researcher about unsatisfactory or unprofessional care during the interview, then: • Details of this may be anonymously disclosed to the research supervisors, and the Clinical Director where appropriate, so corrective action may be taken if necessary. • However, my identity or identifying features will not be revealed to these parties. • I may also be provided with information to lodge a formal complaint if I wish to do so.	
	Initial box to agree
I consent to take part in the project on the basis set out above (Section A)	

Section B: The following parts of the study are optional

You can decide about each of these activities separately. Even if you do not agree to any of these activities you can still take part in the study. If you do not wish to give permission for an activity, do not initial the box next to it.

	Initial box to agree
• Completing an online survey (i.e., pre-interview task) prior to the interview	

I confirm my agreement to take part in the project on the basis set out above.

Name of participant (BLOCK CAPITALS)	Date (dd/mm/yyyy)	Signature
Name of researcher (BLOCK CAPITALS)	Date (dd/mm/yyyy)	Signature

(iii) Practitioner Information Sheet

Ref: CFVC-Prac_V1.3 Ethics ID: 33506 Date: 15-04-2021

Bournemouth University

Participant Information Sheet

The title of the research project

Exploring patients' and practitioners' experiences of consultations for persistent low back pain.

Invitation to take part

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Who is organising/funding the research?

This research is match-funded by Bournemouth University and the AECC University College for the purpose of obtaining a postgraduate (PhD) qualification.

What is the purpose of the project?

This study investigates both patient's and practitioner's experiences of the same consultation. The aim is to enhance our understanding of contextual elements of these healthcare interactions, specifically for patients with persistent low back pain. These insights may help to inform practice and improve current approaches to treatment in the future. Conducting these interviews will help identify and describe specific elements of the interaction which could be beneficial for a patient's recovery.

Why have I been chosen?

You are being asked to participate as we would like to understand Chiropractors', Physiotherapists', Osteopaths', and Sports Therapists' experiences of contextual factors during these consultations. We are seeking between 8 and 10 UK-based practitioners, who are currently providing face-to-face, telephone, or virtual / online consultations for patients with non-specific persistent or chronic low back pain. Practitioner perceptions and experiences are important because of the limited research evidence currently available.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a participant agreement form. We want you to understand what participation involves before you make a decision on whether to participate.

If you or any family member have an on-going relationship with BU or the research team, e.g., as a member of staff, as student or other service user, your decision on whether to take part (or continue to take part) will not affect this relationship in any way.

What would taking part involve?

Taking part will involve three main activities. Firstly, to assist with recruiting patients eligible to participate (detailed information will be emailed to you once you have signed and returned a participant agreement form). The guidance will include a recruitment flowchart to help you initiate the discussion with eligible patients. It will also include general information about the study to answer their questions, and a research invitation you can email to your patient if they would like to find out more. Your main role will be to provide initial information about the study to eligible patients and email them a research invitation if they express interest. **You will not need to obtain your patient's consent to participate. Patients should be aware they are not required to take part in this study unless they choose to.**

Secondly, completing a short online survey (consisting of a brief pre-interview task and providing basic demographic details e.g., age-group, gender) at a time convenient to you. This task is expected to take between 5 and 10 minutes but you may also opt to *'finish later'* and either email yourself a copy of the link or leave the browser window open and continue at a later time. The pre-interview task is optional, but it gives you an opportunity to provide some brief notes about any aspect of the consultation you felt was important before the interview takes place. It can be helpful to have time to think about the experiences you wish to share before the interview. Your notes can also be shared with you during the interview to remind you what notes you made which is useful if the interview takes place several days later.

Lastly, the third activity involves participating in a 25 to 30 minute online or telephone interview at a pre-arranged date and time which is convenient for you once your patient has consented to be interviewed. Both you and your patient(s) will be interviewed separately. If more than one of your patients consents, you will be invited to take part in a second interview but doing so is optional. You will receive a £15.00 *Love2Shop voucher* as a token gesture for your time after the interview (redeemable at a participating high street retailer).

Please note that if your patient discloses that they believed they received improper or unprofessional care from you during their interview, then this information may be anonymously disclosed to the research supervisors to determine whether your patient should be provided with information to lodge a formal complaint. If you were recruited through your Clinical Director then this information will also be anonymously disclosed to them to ensure corrective action is taken if necessary. However, this will be done anonymously without disclosing either your or your patient's name or identifying features. If you have any concerns or unanswered questions about this, please discuss these with the researcher.

Can I change my mind about taking part?

Yes, you can stop participating in study activities at any time and without giving a reason.

You can withdraw from participating before you complete the pre-interview task, as well as during the pre-interview task (via the online survey) at any time and without giving a reason. You may also withdraw from the study by choosing not to assist with recruiting patients, and/or declining to be interviewed even if you have already completed the pre-interview task.

If I change my mind, what happens to my information?

After you decide to withdraw from the study, we will not collect any further information from or about you.

As regards information we have already collected before this point, your rights to access, change or move that information are limited. This is because we need to manage your information in specific ways in order for the research to be reliable and accurate. Further explanation about this is in the Personal Information section below.

If you decide to withdraw during the online pre-interview task, you can simply close the browser page, and this will remove any data collected about you from the study. Once you have completed and submitted your pre-interview task, we are unable to remove anonymised responses from the study. However, once you have signed the participant agreement form, you will be given a unique identifier code to pseudo-anonymise your pre-interview and interview data. If you included this code in your survey response or provided an email address for purposes of arranging the follow-up interview, then your responses will be identifiable, and can be removed.

Please note that once you have taken part in an interview, it may not be possible for this data to be removed from the study analysis, as this might affect the ability to complete the research appropriately or may impact the accuracy and reliability of the research findings.

What are the advantages and possible disadvantages or risks of taking part?

Whilst there are no immediate benefits to you for participating in the project, it is hoped that this work will help improve outcomes for patients with chronic or persistent low back pain in the future. The research findings may provide valuable insights into both practitioners' and patients' views and experiences of contextual factors which may inform evidence-based practice.

There are no anticipated disadvantages of taking part in the study, other than the time required to complete the voluntary activities. Whilst we do not anticipate any risks to you in taking part in this study, you may simply decline to answer any questions posed during the interview if you do not feel comfortable responding.

Only the researcher will know what you have shared about the consultation or your personal experiences. However, if your patient discloses information about improper or unprofessional conduct, the researcher may contact your patient via email to provide them with information about how they can lodge a complaint if they wish to do so. The researcher may also need to share details of the alleged misconduct with the research supervisors and your Clinical Director (where applicable) so corrective action can be taken if necessary. However, this will be done anonymously without disclosing either your or your patient's name or identifying features.

What type of information will be sought from me and why is the collection of this information relevant for achieving the research project's objectives?

The pre-interview task collects a few brief thoughts or notes you wish to voluntarily share about your experience of the consultation. Collecting this information in advance will help you to remember specific aspects of the consultation which may be more difficult to recall at the time of the interview

and can readily be shared with you during the interview. You will also be asked to provide your age-group, gender, and select preferences for when you would prefer the interview to be scheduled.

During the interview, you will be asked questions related to various aspects of your experience of the consultation, as well as some initial information regarding your clinical expertise. This information will help to us better understand elements of the consultation which both patients and practitioners believe to be important and /or beneficial as well as identify common aspects of the interaction which could be improved for the design of future treatment approaches or interventions.

Will I be recorded, and how will the recorded media be used?

The interview will only be audio recorded. The audio recordings made during this research will be used only for analysis and the transcription of the recording(s) for illustration in conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

How will my information be managed?

Bournemouth University (BU) is the organisation with overall responsibility for this study and the Data Controller of your personal information, which means that we are responsible for looking after your information and using it appropriately. Research is a task that we perform in the public interest, as part of our core function as a university.

Undertaking this research study involves collecting and/or generating information about you. We manage research data strictly in accordance with:

- Ethical requirements; and
- Current data protection laws. These control use of information about identifiable individuals, but do not apply to anonymous research data: "anonymous" means that we have either removed or not collected any pieces of data or links to other data which identify a specific person as the subject or source of a research result.

BU's Research Participant Privacy Notice sets out more information about how we fulfil our responsibilities as a data controller and about your rights as an individual under the data protection legislation. We ask you to read this Notice so that you can fully understand the basis on which we will process your personal information.

Research data will be used only for the purposes of the study or related uses identified in the Privacy Notice or this Information Sheet. To safeguard your rights in relation to your personal information, we will use the minimum personally identifiable information possible and control access to that data as described below.

Publication

You will not be able to be identified in any external reports or publications about the research without your specific consent. Otherwise, your information will only be included in these materials in an anonymous form, i.e., you will not be identifiable.

Security and access controls

BU will hold the information we collect about you in hard copy in a secure location and on a BU, password protected secure network where held electronically.

Personal information which has not been anonymised will be accessed and used only by appropriate, authorised individuals and when this is necessary for the purposes of the research or another purpose identified in the Privacy Notice. This may include giving access to BU staff or others responsible for monitoring and/or audit of the study, who need to ensure that the research is complying with applicable regulations.

Once you have signed the participant agreement form, you will be given a unique identifier code to use to pseudo-anonymise both your pre-interview task and your interview data. Only the researcher will be able to attribute your identifier code to your data and this will also try to ensure your patients cannot be easily linked back to you. Additionally, online survey responses are collected over encrypted SSL (TLS) connections and the service provider (JISC) is both GDPR Compliant and ISO 27001 certified.

Sharing your personal information with third parties

As well as BU staff and the BU student working on the research project, we may also need to share personal information in non-anonymised format with external collaborators (namely, Professor Dave Newell and Dr Clare Killingback), as well as the PhD studentship co-funder (AECC University College).

Further use of your information

The information collected about you may be used in an anonymous form to support other research projects in the future and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. To enable this use, anonymised data will be added to BU's online Research Data Repository: this is a central location where data is stored, which is accessible to the public.

Keeping your information if you withdraw from the study

If you withdraw from active participation in the study, we will keep information which we have already collected from or about you, if this has on-going relevance or value to the study. This may include your personal identifiable information. As explained above, your legal rights to access, change, delete or move this information are limited as we need to manage your information in specific ways in order for the research to be reliable and accurate. However, if you have concerns about how this will affect you personally, you can raise these with the research team when you withdraw from the study.

You can find out more about your rights in relation to your data and how to raise queries or complaints in our Privacy Notice.

Retention of research data

Project governance documentation, including copies of signed **participant agreements**: we keep this documentation for a long period after completion of the research, so that we have records of how we conducted the research and who took part. The only personal information in this documentation will be your name and signature, and we will not be able to link this to any anonymised research results.

Research results:

We will keep your personal information in identifiable form for a period of three (3) years after the award of the degree. Although published research outputs are anonymised, we need to retain

underlying data collected for the study in a non-anonymised form to enable the research to be audited and/or to enable the research findings to be verified.

You can find more specific information about retention periods for personal information in our Privacy Notice.

We keep anonymised research data indefinitely, so that it can be used for other research as described above.

Contact for further information

If you have any questions or would like further information, please either contact the researcher, Bronwyn Sherriff (bsherriff@bournemouth.ac.uk) or the project supervisors: Prof. Carol Clark (cclark@bournemouth.ac.uk), Prof. David Newell (dnewell@aecc.ac.uk), or Dr Clare Killingback (c.killingback@hull.ac.uk).

In case of complaints

Any concerns about the study should be directed to Professor Vanora Hundley, Faculty of Health and Social Sciences, Bournemouth University by email to researchgovernance@bournemouth.ac.uk.

Finally

If you decide to take part, you will be given a copy of the information sheet and a signed participant agreement form to keep.

Thank you for considering taking part in this research project.

(iv) Practitioner Agreement Form

Ref: CFVC-Prac_V1.3
Ethics ID: 33506
Date: 15-04-2021

Bournemouth University

Participant Agreement Form

Full title of project: Exploring patients' and practitioners' experiences of consultations for persistent low back pain.

Name, position, and contact details of researcher: Bronwyn Sherriff, Postgraduate Researcher, bsherriff@bournemouth.ac.uk

Name, position and contact details of supervisors: Professor Carol Clark, Head of Department Rehabilitation and Sport Sciences, cclark@bournemouth.ac.uk;Professor David Newell, Director of Research, AECC University College, dnewell@aecc.ac.uk; and Dr Clare Killingback, Physiotherapy Programme Lead, University of Hull, c.killingback@hull.ac.uk).

To be completed prior to data collection activity

Section A: Agreement to participate in the study

You should only agree to participate in the study if you agree with all of the statements in this table and accept that participating will involve the listed activities.

I have read and understood the Participant Information Sheet (CFVC-Prac_V1.3) and have been given access to the BU Research Participant Privacy Notice which sets out how we collect and use personal information (https://www1.bournemouth.ac.uk/about/governance/access-information/data-protection-privacy).
I have had an opportunity to ask questions.
I understand that my participation is voluntary. I can stop participating in research activities at any time without giving a reason and I am free to decline to answer any particular question(s).
I understand that taking part in the research will include the following activity/activities as part of the research:
• Recruiting prospective patient participants on behalf of the researcher;
• Being audio recorded during the interview;
• My words will be quoted in publications, reports, web pages and other research outputs without using my real name.
I understand that, if I withdraw from the study, I will also be able to withdraw my data from further use in the study **except** where my data has been anonymised (as I cannot be identified) or it will be harmful to the project to have my data removed.
I understand that my data may be included in an anonymised form within a dataset to be archived at BU's Online Research Data Repository.
I understand that my data may be used in an anonymised form by the research team to support other research projects in the future, including future publications, reports, or presentations.

I acknowledge the following:

If a patient of mine discloses unsatisfactory or unprofessional care to the researcher during their interview, then: • Details of this may be anonymously disclosed to the research supervisors (and the Clinical Director if recruited through them) so corrective action may be taken if necessary. • However, my and my patient's identity or identifying features will not be revealed to these parties. • My patient may also be provided with information to lodge a complaint should they wish to do so.

	Initial box to agree
I consent to take part in the project on the basis set out above (Section A)	

Section B: The following parts of the study are optional

You can decide about each of these activities separately. Even if you do not agree to any of these activities you can still take part in the study. If you do not wish to give permission for an activity, do not initial the box next to it.

	Initial box to agree
• Completing an online survey (i.e., pre-interview task) prior to the interview	

I confirm my agreement to take part in the project on the basis set out above.

Name of participant (BLOCK CAPITALS)	Date (dd/mm/yyyy)	Signature
Name of researcher (BLOCK CAPITALS)	Date (dd/mm/yyyy)	Signature

(v) Pre-interview tasks

Patient Version

Page 1: Welcome

- This online survey is expected to take **5-10 minutes**.
- You may also opt to ***'finish later'*** and either email yourself a copy of the link or leave the browser window open and continue at a later time.
- The survey collects **a few brief thoughts** you wish to share about your recent appointment and some general information about you and your low back pain history.

Please provide your **unique identifier** code: *Required*

Note: If you have not been given a unique code yet then **please use your initials** and the **date of your consultation**.

For example: Amy Smith, 10th September will be **AS-10-09** or **AS-10-Sept**.

How long have you been **experiencing** low back pain **symptoms**?
(*please state whether your answer is in **weeks, months,** or **years***) *Required*

More info
Please provide an estimated time in **weeks, months,** or **years**. For example, you can write **12 weeks** or **four months** or **3 years**.

Please select your **gender**.

- Male
- Female
- Non-binary
- Prefer not to say
- Other

Please select your **age group**. *Required [drop-down menu]*

- 18-24 years
- 25-29 years
- 30-34 years
- 35-39 years
- 40-44 years
- 45-49 years
- 50-54 years

55-59 years
60-64 years
65+ years

Page 2: Pre-interview Task

N.B. Please **click on the 'Finish' button** in the bottom right corner to submit your answers.

Please tell me about your **low back pain history**
(*e.g., how it began, main symptoms, treatment you prefer, why you need therapy etc.*)

Why did you choose to seek treatment with your therapist?

Thinking about your recent appointment for your low back pain, please briefly **describe up to 5 (five) experiences or aspects of the consultation** you feel may be important to your recovery.

- These can **either be positive or negative** moments, such as your thoughts or views about the examination, diagnosis, treatment, or advice received, or your general experience with your therapist during your treatment.
- There are **no right or wrong answers**, so please feel free to mention anything you would like to share.

Please share your experience in the text box below. *Required*

N.B. Please click the 'Finish' button to submit your answers.

Next Steps

Download my responses

You have 15 minutes to view this data

- **Thank you** for taking the time to complete this online survey.
- If you have agreed to a follow-up interview, Bronwyn will be in touch with you soon.

If you have any questions or would like further information, please either contact Bronwyn Sherriff (bsherriff@bournemouth.ac.uk) or the project supervisors: Prof. Carol Clark (cclark@bournemouth.ac.uk), Prof. David Newell (dnewell@aecc.ac.uk), or Dr Clare Killingback (c.killingback@hull.ac.uk).

Practitioner Version

Welcome

- This pre-interview task is expected to take **5-10 minutes**.
- You may also opt to ***'finish later'*** and either email yourself a copy of the link or leave the browser window open and continue at a later time.
- The task collects **a few brief thoughts** or notes you wish to share about your recent consultation.
- Collecting this in advance will **help you to remember** specific aspects of the consultation which may be more difficult to recall at the time of the interview.
- Your notes can also be shared with you during the interview.

Please provide your **unique identifier** code: *Required*

Note: If you have not been given a unique code yet then **please use your initials and the date of your consultation.**
For example: Amy Smith, 10th November will be **AS-10-11** or **AS-10-Nov**.

Pre-Interview Task

Thinking about your recent appointment, please briefly **describe up to 5 (five) moments or experiences** you feel were important.

- These can **either be positive or negative** feelings, thoughts, views, experiences, or shared moments during the LBP appointment / consultation.
- There are **no right or wrong answers**, so please feel free to mention anything you would like to tell me more about during the interview.

Please add a few brief notes in the text box below.

Please select your **age group**. *Required [drop-down menu]*

- 20-24 years
- 25-29 years
- 30-34 years
- 35-39 years
- 40-44 years
- 45-49 years
- 50-54 years
- 55-59 years
- 60-64 years
- 65-69 years
- 70+ years
- Prefer not to say

Please select your **gender**.

- Male
- Female
- Non-binary
- Prefer not to say
- Other

Interview Preferences

Please indicate the **most convenient week(s)** to be interviewed.
You may select more than one. Required

[Option of several different weeks included]

- Other

Which **day(s) of the week** usually suits you best?
You may select more than one.

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday
- Other

N.B. Please **click on the 'Finish' button** to submit your answers

Next Steps

Download my responses

You have 15 minutes to view this data

- **Thank you** for taking the time to complete the pre-interview task and demographic survey.
- Bronwyn will be in touch soon to arrange and confirm the date and time of your interview via email.

If you have any questions or would like further information, please either contact Bronwyn Sherriff (bsherriff@bournemouth.ac.uk) or the project supervisors: Prof. Carol Clark (cclark@bournemouth.ac.uk), Prof. David Newell (dnewell@aecc.ac.uk), or Dr Clare Killingback (c.killingback@hull.ac.uk).

(vi) Interview Guides

Patient Version

Initial Questions

- Is this the first time you have experienced pain in your lower back region?
- Please try to recall how long you have experienced problems or pain in your lower back region.
- Which healthcare professional do you most prefer to help treat your low back pain?
- Have you previously seen or consulted with [*insert practitioner's name*] before?

[*Confirm any missing demographic details from pre-interview survey*]

Main Question

- Tell me about the pre-interview notes you provided regarding your recent consultation.

[*Use screensharing to prompt participant if they cannot recall their notes*]

If no pre-interview task notes, then:

- Tell me a little bit about how your consultation went on [*insert day/date*].

Supplementary Questions

[*Adapted prior to interview based on pre-interview task*]

- Tell me what you thought about the consultation setting or the treatment atmosphere.
- What was your impression of the therapist?
- During this consultation, how do you feel you got along with the therapist?
- Tell me how the therapist discussed or explained your low back pain symptoms with you.
- How confident did you feel about the treatment or advice you were offered during this consultation?
- How did it feel not having any physical examination or contact compared to a face-to-face consultation? [For telehealth or virtual consultations only]
- How did you feel about your physical examination or the treatment you received?
- Tell me about any personal qualities or characteristics you feel might be important to your treatment or recovery?

Closing Question

- Is there anything about your consultation you would have preferred to be different?

Practitioner Version

Initial Questions

- Please confirm the type of practitioner you are.
- How many years of clinical experience do you have?
- Have you previously consulted with [*insert patient's name*] before?

[*Confirm any missing demographic details from pre-interview survey*]

Main Question

- Tell me about the pre-interview notes you provided regarding your recent consultation.

[*Use screensharing to prompt participant if they cannot recall their notes*]

If no pre-interview task notes, then:

- Tell me a little bit about how your consultation went on [*insert day/date*].

Supplementary Questions

[*Adapted prior to interview based on pre-interview task*]

- Was there anything specific you did to adapt or change the consultation environment or setting?

- Thinking about your characteristics or appearance as a practitioner, tell me whether you believe these may have influenced the consultation.

- During this consultation, what was your experience of the relationship (or connection) between you?

- Although all patients are different, in your opinion, was there anything about their characteristics that may have influenced the consultation?

- How did you think the discussion went when explaining their low back pain?

- How confident did you feel about the treatment or advice you gave during this consultation?

- Tell me how it felt being unable to perform a physical examination compared to a face-to-face consultation? [For telehealth or virtual consultations only]

- How did you feel about your physical examination or the hands-on treatment you provided?

Closing Question

- Reflecting on this appointment, would you have done anything differently?

(vii) Field notes extracts

Interviewing versus Counselling

- Considering my previous experience as a counsellor, I found the transition to an interviewing role quite challenging.
- I struggled with finding the balance between acknowledging participants' expressions, demonstrating empathy, and following the interview guide.
- It was uncomfortable to simply follow the interview guide because it felt robotic or somewhat dismissive of what participants were sharing.
- The semi-structured format and the pre-interview tasks helped me stay engaged and really listen to what participants had to say.
- I wanted the participants feel like they were leading the discussion but still keep things on track without cutting them off or being abrupt.
- Since I experienced empathy for the patient participants, I recognised the importance of maintaining my role as an interviewer and refrain from offering any educational insights or intervening in their healing process.
- Trying to let the participants share while keeping to the time limit proved challenging but I asked for permission to continue if I thought the interview might exceed the timeframe (about 30 minutes).
- Throughout the interviews, I recognised similarities in the challenges practitioners may have faced in balancing clinical reasoning processes and maintaining patient engagement, which I found to be quite challenging.
- I think I established a rapport with most interviewees, but the virtual format made the process trickier, especially if they opted for audio-only, which presented difficulties in interpreting body language and experienced occasional audio/visual delays.
- I believe a pilot phase for the interview schedules might have been useful.

Insider versus Outsider

- I recognised that there were potential power dynamics at play during the interviews.
- All patient participants were female, and I felt this might have made the interviews a bit less intimidating for them, especially when we started with a brief video introduction.
- Although I did not disclose it beforehand, I deeply empathised with the patients' experiences as I have my own experience with persistent pain (i.e., insider status).
- Having never personally visited a Chiropractor, only observed initial consultations, I wondered whether my outsider status might influence the practitioner interviews.
- Despite being an outsider, the Chiropractors treated me like a colleague, casually using jargon (e.g., diagnostic phrases) as if they expected I would understand.
- Although practitioners indicated they were a bit nervous about the interview process, they gradually relaxed and opened up as we went along.
- This may have been because they indicated that they had not previously participated in qualitative research.
- I sensed the practitioners were a bit apprehensive, perhaps worried about being judged or negatively evaluated or were concerned that a patient may have said something unfavourable about them.
- I wasn't sure if my foreign accent was obvious to all participants, but I had concerns that it might create cultural or language-related barriers to understanding and interpretation.
    - For instance, there was one participant with a fairly strong accent, which made transcribing a bit difficult, especially when certain phrases or words were slightly obscured because of muffled audio or interruptions/lags.

Analytical notes / initial ideas and insights

- Patients have shared complex journeys with LBP which appears to have significantly impacted their lives and coping abilities.
- Seeking treatment seems to have been their only option or last resort because of the pervasive impact of LBP symptoms interfering with their daily lives.
    - *It is possible the Covid-19 pandemic potentially delayed their willingness to seek treatment?*
- Some patients recounted multiple interactions with other healthcare professionals in the past and expressed dissatisfaction and/or distrust.
- Patients seem to contrast negative experiences in the past with more positive experiences with their current treatment.
- Patients provided fairly detailed accounts of those negative experiences and what they felt went wrong, was dissatisfactory, or reasons for mistrusting other practitioners.
    - *Patients are at various stages of treatment during the interviews; for instance, Beth completed her treatment, while Amelia and Chloe are still undergoing treatment.*
- Practitioners were also mindful of and responsive to patients' past experiences along with demonstrating empathy.
- Practitioners described focusing on understanding patients' needs, actively listening, and allowing patients time to paint a detailed picture of their journey with LBP.

- Practitioners focused on strong interpersonal and communication skills and described demonstrating person-centred approaches to care.
    - *This focus may have been influenced by the interviewer-interviewee power dynamic.*
    - *However, it seems that patients' reports echo similar experiences, indicating congruence between patient experiences and practitioner disclosures.*
- Practitioners use phrases such as "building rapport" and "putting patients at ease" rather than theoretical language such as "working" or "therapeutic alliance".
- Practitioners were aware of the significant role that their communication plays during LBP appointments and described focusing on their use of language and verbal and non-verbal cues.
    - Concerns were raised regarding how PPE affected communication with patients during the pandemic.
- Some practitioners spoke about specific communication strategies they use with all patients rather than simply focusing on the patient involved in the interview.
    - *It may have been easier for some practitioners to recall their general approach to consultations rather than specific details of individual interactions.*
    - *This may be a product of how the questions were phrased or perhaps the number of patients' practitioners engage with.*
- Patients typically offered concrete examples illustrating how the current approach was helping to effectively addresses their needs.
- Patients also described practitioner attributes that they thought were important or valuable during LBP consultations.

(viii) COREQ Checklist

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	155
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	155
Occupation	3	What was their occupation at the time of the study?	155
Gender	4	Was the researcher male or female?	155
Experience and training	5	What experience or training did the researcher have?	155
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	155
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	156
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	197-199
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	148-149
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	150
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	150-151
Sample size	12	How many participants were in the study?	149
Non-participation	13	How many people refused to participate or dropped out? Reasons?	158 & 194
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	155
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	156
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	158
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	155-6 & 380-1
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	157
Field notes	20	Were field notes made during and/or after the inter view or focus group?	156
Duration	21	What was the duration of the inter views or focus group?	155
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	156-157
Description of the coding tree	25	Did authors provide a description of the coding tree?	N/A
Derivation of themes	26	Were themes identified in advance or derived from the data?	156-157
Software	27	What software, if applicable, was used to manage the data?	156
Participant checking	28	Did participants provide feedback on the findings?	193
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	YES
Data and findings consistent	30	Was there consistency between the data presented and the findings?	YES
Clarity of major themes	31	Were major themes clearly presented in the findings?	158 & 178-179
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	N/A

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

(ix) Assessment of thematic analysis research quality

BRAUN & CLARKE CHECKLIST		
Adequate choice and explanation of methods and methodology		**Response**
1.	Do the authors explain why they are using thematic analysis (TA), even if only briefly?	YES; pp. 73-74 & 148-149
2.	Do the authors clearly specify and justify **which *type* of TA** they are using?	YES; pp. 73-74
3.	Is the use and justification of the specific type of TA consistent with the research questions or aims?	YES; p.73
4.	Is there a good 'fit' between the theoretical and conceptual underpinnings of the research and the specific type of TA (i.e. is there conceptual coherence)?	YES; pp. 73-74
5.	Is there a good 'fit' between the methods of data collection and the specific type of TA?	YES; p.74
6.	Is the specified type of TA consistently enacted throughout the paper?	YES
7.	Is there evidence of problematic assumptions about, and practices around, TA? These commonly include: • Treating TA as one, homogenous, entity, with one set of – widely agreed on – procedures. • Combining philosophically and procedurally incompatible approaches to TA without any acknowledgement or explanation. • Confusing summaries of data topics with thematic patterns of shared meaning, underpinned by a core concept. • Assuming grounded theory concepts and procedures (e.g. saturation, constant comparative analysis, line-by-line coding) apply to TA without any explanation or justification. • Assuming TA is essentialist or realist, or atheoretical. • Assuming TA is only a data reduction or descriptive approach and therefore must be supplemented with other methods and procedures to achieve other ends.	NO
8.	Are any supplementary procedures or methods justified, and necessary, or could the same results have been achieved simply by using TA more effectively?	N/A
9.	Are the theoretical underpinnings of the use of TA clearly specified (e.g. ontological, epistemological assumptions, guiding theoretical framework(s)), even when using TA inductively (inductive TA does not equate to analysis in a theoretical vacuum)?	YES
10.	Do the researchers strive to 'own their perspectives' (even if only very briefly), their personal and social standpoint and positioning? (This is especially important when the researchers are engaged in social justice-oriented research and when representing the 'voices' of marginal and vulnerable groups, and groups to which the researcher does not belong.)	YES; pp.197-199
11.	Are the analytic procedures used clearly outlined, and described in terms of what the authors actually did, rather than generic procedures?	YES; pp.156-157
12.	Is there evidence of conceptual and procedural confusion? For example, reflexive TA (Braun & Clarke, 2006) is the claimed approach but different procedures are outlined such as the use of a codebook or coding frame, multiple independent coders and consensus coding, inter-rater reliability measures, and/or themes are conceptualised as analytic inputs rather than outputs and therefore the analysis progresses from theme identification to coding (rather than coding to theme development).	NO
13.	Do the authors demonstrate full and coherent understanding of their claimed approach to TA?	YES
Notes: Extracted from "Table 1. A tool for evaluating thematic analysis (TA) manuscripts for publication: Twenty questions to guide assessment of TA research quality" (Braun & Clarke, 2020b, pp.18-19).		

BRAUN & CLARKE CHECKLIST continued		
A well-developed and justified analysis		**Response**
14.	Is it clear what and where the themes are in the report? Would the manuscript benefit from some kind of overview of the analysis: listing of themes, narrative overview, table of themes, thematic map?	YES; pp.158 & 178-179
15.	Are reported themes topic summaries, rather than 'fully realised themes' – patterns of shared meaning underpinned by a central organising concept? • Have the data collection questions been used as themes? • If so, are topic summaries appropriate to the purpose of the research? • If the authors are using reflexive TA, is this modification in the conceptualisation of themes explained and justified? • Would the manuscript benefit from further analysis being undertaken, with the reporting of fully realised themes? • Or, if the authors are claiming to use reflexive TA, would the manuscript benefit from claiming to use a different type of TA (e.g. coding reliability or codebook)?	NO
16.	Is a non-thematic contextualising information presented as a theme? (e.g. the first theme is a topic summary providing contextualising information, but the rest of the themes reported are fully realised themes). If so, would the manuscript benefit from this being presented as non-thematic contextualising information?	NO
17.	In applied research, do the reported themes have the potential to give rise to actionable outcomes?	YES
18.	Are there conceptual clashes and confusion in the paper? (e.g. claiming a social constructionist approach while also expressing concern for positivist notions of coding reliability, or claiming a constructionist approach while treating participants' language as a transparent reflection of their experiences and behaviours)	NO
19.	Is there evidence of weak or unconvincing analysis such as: • Too many or two few themes? • Too many theme levels? • Confusion between codes and themes? • Mismatch between data extracts and analytic claims? • Too few or too many data extracts? • Overlap between themes?	NO
20.	Do authors make problematic statements about the lack of generalisability of their results, and or implicitly conceptualise generalisability as statistical probabilistic generalisability (see Smith, 2018)?	NO
Notes: Extracted from "Table 1. A tool for evaluating thematic analysis (TA) manuscripts for publication: Twenty questions to guide assessment of TA research quality" (Braun & Clarke, 2020b, pp.18-19).		