School of Physiotherapy and Exercise Science

A prospective, qualitative investigation of pain-related fear in people with chronic low back pain

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Declaration of Originality

"To the best of my knowledge and belief this thesis contains no material previously published by any other person except where due acknowledgment has been made. This thesis contains no material which has been accepted for the award of any other degree or diploma in any university".

Samantha Bunzli

December, 2015

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Abstract

Background: Chronic non-specific low back pain (CNSLBP) is now a leading cause of disability worldwide. Pain-related fear is a strong, potentially modifiable predictor of CNSLBP disability. The Fear Avoidance Model (FAM) describes how the belief that pain is a sign of damage leads to pain-related fear and avoidance behaviour that sustain pain and disability. Since its publication in 2000, a large body of research has supported the relationships proposed by the model. However calls have been made for the next generation of FAM research to address key limitations of the model in its current form. Whilst the FAM conceptualises pain-related fear as a 'phobia' driven by the underlying belief that pain is a sign of damage, it is possible that other 'non-phobic' beliefs and pain processes also trigger pain-related fear and avoidance behaviour. To date, our understanding of the beliefs underlying pain-related fear and the factors contributing to these beliefs remain limited. Further, the FAM assumes a single pathway to fear reduction, mediated by changes to the underlying belief that pain is a sign of damage. However the factors associated with fear reduction have not been fully explored, and it remains unknown if alternative pathways to fear reduction exist. To inform future iterations of the FAM that can help direct targeted intervention, this research aimed to understand the beliefs underlying pain-related fear, the factors associated with these beliefs and the factors associated with improvements in pain-related fear.

Objectives: The research questions guiding this doctoral thesis were:

- 1. What are the beliefs underlying pain-related fear in people with CNSLBP?
- 2. What factors contribute to these beliefs?
- 3. How does pain-related fear change over time?
- 4. What factors are associated with improvements in fear?

Methods: A predominantly qualitative approach was selected to provide a nuanced understanding and novel insight into the lived experience of pain-

related fear through the lens of the FAM. A mixed-methods component was also

included. Three phases of research were conducted.

1. A review of the existing qualitative literature exploring the lived experience

of pain-related fear in people with CNSLBP was conducted to gain insight into

the beliefs underlying pain-related fear, factors associated with these beliefs

and change in pain-related fear over time.

2. A cross-sectional qualitative investigation employing an Interpretive

Description framework and semi-structured interviews explored beliefs

underlying pain-related fear and factors associated with these beliefs in 36

individuals with CNSLBP and high scores on the Tampa Scale of Kinesiophobia

(mean = 47/68).

3. Participants were followed over four months in a prospective mixed-methods

investigation exploring change in pain-related fear and factors associated with

improvements in fear. Validated self-report questionnaires, in addition to semi-

structured interviews, were administered at baseline and four-month follow-up.

The results of the qualitative and quantitative strands were merged to assess

convergence, divergence, contradictions or relationships between the two.

Findings: Four manuscripts are presented.

The publication: "Lives on hold. A qualitative synthesis exploring the experience

of chronic low back pain" reviewed findings from 18 qualitative studies. It

conceptualises the experience of CNSLBP as biographic suspension in which

three aspects of suspension are described: suspended "wellness", suspended

"self", and suspended "future". However, findings from the review provided

limited insight into the potential factors contributing to pain-related fear and

change in fear in people with CNSLBP.

The publication: "What do people who score highly on the Tampa Scale of

Kinesiophobia really believe? A mixed-methods investigation of people with

chronic non-specific low back pain" identified heterogenous beliefs underlying high levels of pain-related fear. Some participants in the sample believed that pain was a sign of damage, others believed pain was a sign of suffering/functional loss and a minority of participants believed pain was a sign of both. Results of an itemised analysis of Tampa scores supported a multifactorial model of the Tampa Scale of Kinesiophobia, but highlighted limitations in the ability of the scale to differentiate between underlying beliefs.

The publication: "The beliefs underlying pain-related fear and how they evolve. A qualitative investigation in people with chronic back pain and high pain-related fear" describes the overarching theme of a pain experience that did not make sense to the participants. The experience of back pain as unpredictable, uncontrollable and intense made it threatening. In an attempt to make sense of their 'threatening' pain, participants with damage beliefs underlying their fear, drew on past personal experiences of back pain, societal beliefs, and sought diagnostic certainty. Met with diagnostic uncertainty, or diagnoses of an underlying pathology that couldn't be fixed, they were left fearful of damage and confused about how to 'fix' it. Participants with suffering/functional beliefs drew on past personal experiences of back pain and sought help from clinicians to control their pain. Failed treatments and the repeated failure to achieve functional goals left them unable to make 'sensible' decisions of what to do about their pain.

The manuscript: "Gaining control over the low back pain experience. Patients' perspectives of improvements in pain-related fear" reports how some of the participants experienced an improvement in pain-related fear over a four-month period. The overarching theme underpinning improvement in fear was 'gaining control over the pain experience'. Participants who experienced an improvement in fear described gaining control over the pain experience through a reduction in the threat value of pain; some described gaining a conceptual understanding of pain that made sense coupled with targeted management; and others described reduced goal conflict. The processes involved in achieving these differed between individuals, and appeared to be

influenced by the beliefs underlying their pain-related fear. In support of the qualitative findings, the mixed-methods analysis found that 'improvers' were more likely to experience clinically significant improvements in quantitative measures of back beliefs, pain control and pain intensity.

Conclusions: The Common Sense Model is offered as a framework to understand the study findings. By incorporating a Common Sense perspective, the FAM may be extended to capture the dynamic nature of pain-related fear and to account for the multiple factors associated with pain-related fear and the multiple pathways to fear-reduction in people with CNSLBP.

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Abbreviations

AEM Avoidance Endurance Model

ASI Anxiety Sensitivity Index

BBQ Back Beliefs Questionnaire

CNSLBP Chronic non-specific low back pain

CSQ Coping Strategies Questionnaire

CSQ-CC Coping Strategies Questionnaire – Cognitive Coping

CSQ-Control Coping Strategies Questionnaire - Control

DASS Depression Anxiety Stress Scale

FABQ Fear Avoidance Beliefs Questionnaire

FAM Fear Avoidance Model

HCP Healthcare Professional

IPQ Illness Perceptions Questionnaire

IPQ-R Illness Perceptions Questionnaire-Revised

LBP Low back pain

MCID Minimally Clinically Important Difference

NRS Numerical Rating Scale

PCS Pain Catastrophising Scale

PSEQ Pain Self-Efficacy Questionnaire

RCT Randomised Controlled Trial

TSK Tampa Scale of Kinesiophobia

TSK-AA Tampa Scale of Kinesiophobia – Activity Avoidance

TSK-SF Tampa Scale of Kinesiophobia – Somatic Focus

Chapter 1. Introduction

"It is your spine, that entire structure where everything comes from. Where you bend, where you move, where you sit, when you walk. Every single movement is derived from your back. And then out of nowhere comes the stabbing pain, when you least expect it. That overwhelming, shocking, frightening pain" (51 year old female, 2 years experience of low back pain)

Low back pain (LBP) is common. In Australia, most people will have experienced LBP in the past six months or know someone who has (Walker, Muller, and Grant 2004), and will have developed their own beliefs and attitudes about it (Buchbinder, Jolley, and Wyatt 2001).

Low back pain is largely self-limiting. Most people will not seek care for their LBP (Walker, Muller, and Grant 2004) and those who do seek care report similar levels of pain intensity as those who do not (Mannion, Wieser, and Elfering 2013). Whilst the vast majority of care-seekers will have stopped seeking care within three months (Croft et al. 1998), 65 per cent will still be experiencing LBP symptoms 12 months later (Itz et al. 2013). Around 10 per cent of care-seekers will experience chronic, disabling LBP (Croft et al. 1998, Cassidy, Carroll, and Cote 1998) and will account for the large majority of healthcare and societal costs (Krismer and van Tulder 2007).

Low back pain causes more disability than any other condition (Hoy et al. 2014). In a recent estimate of the global burden of disease, LBP was found to be the sixth highest burden out of 291 conditions studied (Hoy et al. 2014). An 'epidemic' of LBP has been described (Waddell 1996) as the prevalence and cost of disabling LBP in western societies continues to rise (Freburger et al. 2009). This is in the context of continuing scientific advances in, for example, imaging technology.

Indeed, contrary to common belief amongst the general population (Darlow et al. 2014) and even healthcare professionals (HCPs) (Buchbinder, Staples, and Jolley 2009), approximately 85 per cent of people with chronic disabling LBP

will not have any observable pathological explanation for their pain (Deyo 2002). This large majority will be considered to have chronic non-specific LBP (CNSLBP) defined as pain in the lumbar region lasting >3 months, without an identifiable pathology (Airaksinen et al. 2006). Chronic non-specific LBP has substantial impact on an individual's physical, psychological and social wellbeing. It is associated with reduced functional activity (Smith et al. 2012), reduced cardiovascular health (Hestbaek, Leboeuf-Yde, and Manniche 2003), reduced mental health (Demyttenaere et al. 2007), social withdrawal (de Souza and Frank 2011), lost work productivity (Wasiak, Kim, and Pransky 2006) and reduced quality of life (Nolet et al. 2015).

"They can put a man on the moon, why can't they cure my pain?" (54 year old male, 6 years experience low back pain)

The impact of CNSLBP underscores the need for effective CNSLBP treatment and management. However to date, our understanding of effective CNSLBP treatment and management remains limited. A systematic review of randomised controlled trials (RCTs) for non-specific LBP found similar patterns of initial improvement, followed by a plateau, irrespective of treatment: be it active, passive, usual care or placebo; pharmacological, psychological, manual therapy or multidisciplinary pain management (Artus et al. 2010). Similar findings led Pransky et al. (2010) to conclude at the end of their review that the only thing 'certain' about CNSLBP management into the future is that HCPs will continue to be faced with the challenge of choosing between a diverse array of possible treatment options and optimising outcome.

To help guide HCPs in deciding what works best for whom, an understanding of the multi-dimensional mechanisms underlying CNSLBP is needed (Turk 2005).

The multi dimensions of LBP

Pain, as an experience, is essential for survival. 'Adaptive' pain functions as an alarm system to protect us from potential or actual physical threat. When the brain receives a pain signal from a hand in boiling water, it initiates and executes defensive responses to pull the hand out of harms' way (Melzack 2001). Pain also alerts us that something is wrong that requires attention, such

as an unseen tumour (Church 2013). However, pain can persist beyond normal healing times and in the absence of nociception (Shimo et al. 2011). In this case, it may no longer be considered 'adaptive' but rather 'maladaptive' pain and is commonly associated with considerable suffering and disability.

"Pain may be the warning signal that saves the lives of some people, but it destroys the lives of countless others" (Melzack 2001, p.1378).

Serious underlying causes of LBP are rare. Whilst the prompt identification of pathologies such as malignancy, infection, inflammatory disorders, fracture or cauda equina compression is important to facilitate treatment and in some cases prevent the progression of disease, the prevalence of these pathologies amongst people presenting with LBP in primary care is low. Approximately 0.7 per cent have an underlying malignancy, 0.01 per cent have a spinal infection, <1 per cent have an inflammatory back disease, 1-4 per cent have a spinal fracture, and 0.04 per cent have cauda equina syndrome (Deyo, Rainville, and Kent 1992, Jarvik and Deyo 2002, Underwood and Dawes 1995).

For the large majority of cases, LBP is thought to be a multidimensional condition involving a complex interaction between biological, psychological and social factors (Waddell 2004). Research has explored LBP from a variety of perspectives including genetics, neuro-physiological, patho-anatomical, physical, psychological, cognitive behavioural, lifestyle, inter-personal and societal perspectives.

From a genetic perspective, research has suggested that between 30 and 46 per cent of LBP may be heritable (Battie et al. 2007). Studies have identified genes implicated in, for example, enhanced pain perception and pain sensitisation (Reimann et al. 2010, Tegeder and Lotsch 2009), genes associated with intervertebral disc herniation (Tegeder et al. 2006) and genetic markers that may have a modulatory effect on depression and physical function in people with LBP (Lebe et al. 2013).

From a neuro-physiological perspective, LBP may occur through direct activation of nociceptors in the spinal structures (nociception). Increased activity in the neural pain pathways (sensitisation) is normal in the early phases

of LBP when there may be a source of on-going nociception post injury. However, some people may continue to show tissue sensitisation beyond normal healing times. This may be due to a sustained source of nociception, such as for example, altered movement patterns and muscle guarding placing strain on sensitised tissue (Hodges and Smeets 2015). Sensitisation may also occur in the absence of on-going nociception. For some people, increased activity in the neural pain pathways may be driven by psychological states such as fear, anxiety and depression as well as by lifestyle factors such as sleep disruption. This may serve to amplify the perception of pain by, for example, interfering with normal cortical processes that inhibit pain processing (Rabey et al. 2015) and altering function of the neuro-immune-endocrine system that may influence tissue hypersensitivity (McFarlane 2007).

From a patho-anatomical perspective, a variety of patho-anatomical structures of the spine have been implicated in LBP, including (but not limited to) modic changes linked to bone oedema in the vertebral endplate, foraminal and spinal stenosis with associated nerve pain (Albert et al. 2008, Merckaert et al. 2015). However targeting interventions on the basis of a patho-anatomical 'diagnosis' alone can be problematic as patho-anatomical findings correlate poorly with the clinical presentation of LBP and disability (Deyo 2013). While significant associations between LBP and findings on imaging scans such as disc degeneration and disc herniation have been reported at a population level (Cheung et al. 2009), the presence of so-called "abnormalities" is high amongst the asymptomatic population and is a poor predictor of future LBP (Endean, Palmer, and Coggon 2011).

From a physical perspective, injury models propose an association between biomechanical stress, nociception and LBP (McGill 2004). High physical demands in sporting and work contexts have been found to be associated with an increased risk of LBP (Nyman et al. 2009). However systematic reviews have found no evidence that normal activities and movements in daily living such as sitting (Roffey et al. 2010b), lifting (Wai et al. 2010) or awkward postures (Roffey et al. 2010a) are independently associated with an increased risk of LBP. Other potential sources of on-going nociception may include altered movement

patterns (Hodges and Smeets 2015) and/or tension due to sustained 'guarding' of the back muscles in response to pain and /or distress (O'Sullivan 2005).

From a psychological perspective, diathesis-stress models have been used to explain the high correlation between LBP and depression, early life stress, post-traumatic stress disorder, and other anxiety disorders (Banks and Kerns 1996, Turk 2002). These models propose that individuals may develop negatively biased cognitive schemas of themselves when they are exposed to stressful life events, particularly at an early age. When these individuals are confronted with stressful events in later life such as pain, these schemas may become activated, eliciting catastrophic thoughts about themselves and their ability to cope. There is evidence that early exposure to trauma is associated with dysregulation of the stress response system that may result in impaired habituation to physical or psychosocial challenges such as pain (Gupta and Silman 2004).

From a cognitive behavioural perspective, the relationship between cognitions and behaviour has been shown to play a key role in the transition from acute to chronic LBP (Boersma and Linton 2005a). The central tenant of this perspective is that what people believe and do about their LBP will predict how long it will last and how disabled they will be by it (Turk, Meichenbaum, and Genest 1983). The Fear Avoidance Model (FAM) describes how the belief that pain is a sign of damage leads to pain-related fear and the avoidance of activities associated with pain (Vlaeyen and Linton 2000). Pain-related fear has been identified as one of the strongest potentially modifiable predictors of LBP disability (Picavet, Vlaeyen, and Schouten 2002, Swinkels-Meewisse et al. 2006). Therefore clinical practice guidelines recommend that the first line of treatment in all individuals presenting with LBP in the absence of 'red flags' should address erroneous/unhelpful beliefs about LBP and the meaning of pain, and promote the early resumption of normal activities (Delitto et al. 2012). Whilst a large body of research has supported the tenants of the FAM, gaps remain in our understanding of what people with LBP believe and how to effectively target these beliefs to ensure a return to normal function (Wideman et al. 2013, Crombez, Eccleston, et al. 2012, Pincus et al. 2010).

From a lifestyle perspective, the prevalence of LBP is highest during middle age (Hoy et al. 2012), the most productive working years of life. Lifestyle factors that have been associated with increased risk of developing LBP include smoking (Chou and Shekelle 2010), low levels of physical activity (Teichtahl et al. 2015), poor sleep hygiene (Kaila-Kangas et al. 2006) and high levels of everyday stress (Hayden et al. 2009). There is evidence that these lifestyle factors have an accumulative effect on the risk of LBP (Mikkonen et al. 2015). On the other hand, a 'healthy lifestyle' defined as non-smoking, low alcohol intake, high levels of leisure physical activity and a balanced diet, has been shown to decrease the risk of developing persistent, disabling LBP in women with occasional LBP by 52 per cent (Bohman et al. 2014).

From an interpersonal perspective, theory suggests that people with LBP may display overt pain behaviours in order to communicate their suffering to others (Sullivan 2012). People are more likely to engage in communicative pain behaviours when they perceive themselves as having low levels of social support (Buenaver, Edwards, and Haythornwaite 2007); perceive that the validity of their pain is being questioned by others (Cano et al. 2009); and/or perceive that that they have been the subject of injustice (Sullivan, Scott, and Trost 2012). They may also be more likely to engage in communicative pain behaviours if they have an overly supportive spouse that reinforces the 'sick role' (Flor, Kerns, and Turk 1987). It has been suggested that pain behaviours are learnt from watching others in the family and wider cultural context (Goubert et al. 2011). This may help to explain, in part, familial (O'Sullivan et al. 2008) as well as cultural links of disabling LBP. International, multi-centre research suggests that the widespread awareness of disabling LBP (knowing someone else with disabling LBP) may predispose to its occurrence (Coggon et al. 2013).

From a societal perspective, patho-anatomical and injury models of LBP continue to dominate health and compensation systems in Western countries, despite the lack of evidence to support these models in the large majority of cases (Pransky, Buchbinder, and Hayden 2010). This has contributed to the stigmatisation of people with chronic and/or disabling LBP who, in the absence

of an observable underlying pathology, may be accused of malingering and seeking secondary gains (the financial and/or social rewards of disability) and/or accused of somatisation (LBP of 'psychological' origin). Social security provisions and cultural differences in health beliefs may help to explain international variance in the prevalence of disabling LBP (Coggon et al. 2013). Socio-economic factors such as lower education level and/or low health literacy may reduce one's ability to seek, understand and utilise LBP information, and access care in a timely way (Thelin, Holmberg, and Thelin 2008, Briggs et al. 2010).

In summary, the multi-dimensional mechanisms underlying LBP can be examined and understood from multiple perspectives. Each contributes substantially to our evolving understanding of LBP as a unique experience characterised by an individual's genetic, neuro-physiological, structural and psychological make-up, their beliefs, lifestyle, inter-personal relationships and societal context.

A cognitive behavioural perspective through a physiotherapy lens

"Fear of pain and what people do about pain may be more disabling than pain itself" (Waddell 1996, 2821)

This thesis adopts a cognitive behavioural perspective to explore LBP associated with high pain-related fear. This perspective was chosen for having ecological validity with contemporary clinical physiotherapy practice, whose main objective is to optimise function through a bio-psycho-social model of care (Foster and Delitto 2011).

However, I acknowledge that a cognitive behavioural perspective is not mutually exclusive. Whilst cognitive behavioural mechanisms describe the influence of pain-related fear on the persistence of LBP and disability, pain-related fear and fear avoidance behaviour may be understood from a variety of perspectives. From a neurophysiological perspective it has been proposed that an altered cortical representation of the back may result in a distorted body schema, producing unexpected bodily sensations and motor responses that may fuel pain-related fear and pain (Wand and O'Connell 2008). From a physical

perspective, it has been proposed that motor adaptation in response to an acute LBP episode such as altered muscle activation to 'splint' the painful part, may persist and become maladaptive in some people and become a source of ongoing nociception fuelling the fear avoidance cycle (Hodges and Smeets 2015). From a psychological perspective, it has been suggested that personality vulnerabilities such as anxiety sensitivity and intolerance of uncertainty may predispose some individuals to pain-related fear (Carleton, Sharpe, and Asmundson 2007). Exploring pain-related fear from these multiple perspectives provides us with a deeper understanding that can inform clinical management of pain-related fear and associated LBP disability.

Missing in the literature to date is the patients' perspective of the experience of pain-related fear associated with LBP. Little is known about what people with high pain-related fear believe about their LBP and how pain-related fear is experienced over time. Understanding the lived-experience of pain-related fear may provide novel insights into how pain-related fear develops, persists and responds to treatment. Such understanding may lend support to develop more targeted fear-reduction interventions that can help reduce the burden of LBP disability.

To date, the FAM is the predominant cognitive behavioural model of LBP disability. First applied to the context of CNSLBP research by Vlaeyen and Linton in 2000, (Vlaeyen and Linton 2000), their seminal paper has been cited 1560 times at the time of writing (Scopus, accessed 29th June, 2015). The FAM describes how beliefs about pain may catalyse a vicious cycle of pain-related fear, avoidance behaviour and disability. The tenants of the FAM have been largely supported by research. Pain-related fear is amongst the strongest predictors of LBP disability (Picavet, Vlaeyen, and Schouten 2002) and reductions in pain-related fear are associated with improvements in pain and disability (Wertli et al. 2014). However RCTs based on the FAM have reported modest effect sizes for fear reduction and disability, and high drop out rates (Linton et al. 2008, Leeuw et al. 2008). Indeed, the FAM describes a pathway into pain-related fear, but does not provide a working model of the pathway(s) out of pain-related fear.

This prospective, qualitative study, with a mixed-methods component, responds to calls for the next generation of FAM research to explore the "personal narratives and explanations for the acquisition of fear, and beliefs about movement and avoidance" (Pincus et al. 2010, p.744). It seeks to inform future iterations of the FAM that can direct more targeted fear-reduction interventions to people with LBP (Wideman et al. 2013, Vlaeyen and Linton 2012b, Crombez, Eccleston, et al. 2012). Conducted by a physiotherapist, this study aims to provide novel insights into the beliefs underlying pain-related fear, what contributes to these beliefs, and how and why pain-related fear may change over time.

Motivation for research

A priori statement 5.4.12

The beliefs and attitudes towards LBP that I have acquired through 10 years of clinical work with LBP patients require explicit a priori documentation in order for inference to be made on how these shape the design, analysis and interpretations of this study.

I graduated in physiotherapy from Otago University, New Zealand in 2000 and spent 8 years working in musculoskeletal physiotherapy in a variety of settings both public and private in New Zealand, the United Kingdom and Australia. In clinical practice I was drawn to the LBP patients that were not responding to the 'standard' manual or exercise therapy. I wanted to help the individuals who were not fitting inside the 'box'.

I realized that despite my 'poor' manual therapy skills, many of these patients improved through our treatment sessions. The non-specific treatment factors appeared to me the most influential. By asking the right questions and listening to my patients, I gained insight into their personal context and the effect pain had on their life. I understood their beliefs, attitudes and goals. I sensed what they needed of me as their physiotherapist, both in terms of treatment expectations and a listening, empathetic ear. Fears, anxieties, frustrations and tears were revealed through the course of our 'physical' therapy sessions.

When the opportunity arose to undertake this PhD I was excited at the thought of spending the foreseeable mid-term future studying the psychosocial context of pain that had engaged me clinically.

I write this at the point of embarking on participant recruitment. I have familiarised myself with the qualitative and quantitative literature exploring the biopsychosocial dimensions of LBP and it's management. I see that empirical evidence exists for my clinical intuition – the 'non-specific' treatment effects of a strong, detailed clinical examination to give context to the individuals pain, the

importance of ensuring the individual feels understood, validated and hopeful for the future.

In the process of gaining both candidacy and ethical approval for this study, I have had to defend my position as a physiotherapist conducting a qualitative study based on the FAM that has roots in psychology. I have argued the ecological validity of this study. I am not asking of the participants any questions that are beyond the scope of a physiotherapy assessment, seeking to understand the experience of a patient presenting with chronic pain. I have also highlighted the inter-disciplinary nature of this research team, in particular my associate supervisor Rob Schütze (Clinical Psychologist) without whose knowledge, perspective and insight this study would not be possible.

Whatever the outcome of this research process, be it that the blurring of professional boundaries is an inevitable consequence of LBP management, or acknowledging that physiotherapists are indeed under-skilled to cross into the 'cognitive' territory of 'cognitive-behavioural' experience of pain, I believe this research is important in order for i) Physiotherapists and other HCPs to better understand pain-related fear and ii) To convert my clinical intuitions into something that can be done to improve the lives of other people with LBP.

Structure of thesis

This thesis is comprised of nine chapters.

In Chapter one I have provided background information on LBP and pain-related fear, and argued the significance of this study. I have also provided an *a priori* statement of the personal motivation for this research written prior to data collection.

In Chapter two I present a review of the literature on pain-related fear. I introduce the FAM and use this as a framework for exploring the role that pain-related fear plays in sustaining LBP and disability. Potential mechanisms underlying pain-related fear and the potential process involved in fear-reduction are discussed. The chapter concludes by summarising the gaps in the FAM literature.

In Chapter three I present a review of the qualitative literature exploring the experience of LBP from the perspective of individual sufferers. The chapter begins with a brief introduction outlining the aims of the review. It then presents the published manuscript: "Lives on hold: a qualitative synthesis exploring the experience of chronic low back pain". As there have been several new publications since the completion of the qualitative review, an updated review of the qualitative literature is also presented. The chapter concludes with a discussion of the review findings in relation to the study aims.

In Chapter four, I provide details on the methodology of this research. The aims, approach, data collection and data analyses are described. The computer assisted qualitative data sorting software used in this study is presented and examples are provided of how it was used to assist in the analysis of qualitative data. A description of the mixed-methods analysis is presented, with further details provided in the mixed-methods manuscripts presented in Chapters five and seven.

In Chapter five, I present findings from the analysis of baseline data. An introduction is followed by the published manuscript: "What do people who score highly on the Tampa Scale of Kinesiophobia really believe? A mixed-

methods investigation in people with chronic non specific low back pain". The chapter concludes with a discussion of the baseline mixed-methods findings in relation to the study aims.

In Chapter six, I present the findings from the qualitative data analysis of baseline data. An introduction is followed by the published manuscript: "The beliefs underlying pain-related fear and how they evolve. A qualitative investigation in people with chronic back pain and high pain-related fear". The chapter concludes with a discussion of the baseline qualitative findings in relation to the study aims.

In Chapter seven, I present the findings from the analysis of follow-up data. An introduction is followed by the submitted manuscript: "Gaining control over the low back pain experience. Patients' perspectives of improvements in pain-related fear". The chapter concludes with a discussion of the follow-up mixed-methods findings in relation to the study aims.

In Chapter eight, I discuss the key research findings. I present the Common Sense Model as a framework to understand the findings and discuss the theoretical and clinical implications of including a Common Sense perspective into the FAM. The chapter concludes with a reflection on the research methodology and suggestions for future research.

In Chapter nine, I present concluding comments and a 'call for action' for the next generation of the FAM to incorporate a 'Common Sense' perspective.

Chapter 2. Literature review on pain-related fear

Fear, like pain, is an experience that is essential for survival. Pain-related fear is an emotional reaction to the pain experience which initiates a flight or escape response away from the noxious input (Wall 1979). Pain-related fear is adaptive and protective in the context of acute tissue damage and pathology. However fear that persists beyond the termination of the noxious input, normal tissue healing times and in the absence of pathology, becomes maladaptive with significant negative consequences for the homeostasis of the individuals' biopsychosocial processes (Leeuw, Goossens, Linton, et al. 2007). To paraphrase Melzack (2001): pain-related fear may be the warning signal that saves the lives of some people, but it destroys the lives of countless others.

The Fear Avoidance Model of chronic pain (FAM)

Aristotle, over 2000 years ago recognized an association between fear and pain: "Let fear, then, be a kind of pain or disturbance resulting from the imagination of impending danger, either destructive or painful" (Eysenck 1997).

Amid the behaviouralism movement of the 1970's, Fordyce published the first model of avoidance learning (Fordyce 1976). This model proposed that avoidance behavior following an acute injury reduces the likelihood of (re)injury and gives damaged tissue a chance to heal. The key tenant of the model was that avoidance behavior is reinforced through reduced suffering associated with nociception. It proposed that for most people avoidance behavior following an acute injury will gradually reduce, but for a subset of individuals, the reinforcement contingency 'reduced pain' shifts to other reinforcement contingencies such as 'reduced work'. These individuals learn that avoiding activities they associate with pain such as work, reduces the likelihood of experiencing pain.

Fordyce's model was extended by Linton et al. (1984) to include classical

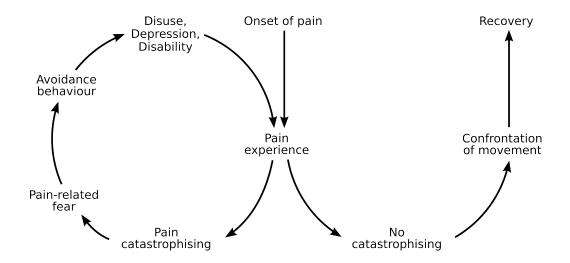
conditioning elements to explain the persistence of avoidance behavior post injury. Classical conditioning describes a process by which a previously neutral activity such as bending becomes associated with pain and elicits a sympathetic activation and fear response. Through operant conditioning, the activity 'bending' comes to predict pain and activates a fear response even in the absence of pain. Individuals then learn that avoiding bending reduces the likelihood of experiencing pain and fear and the avoidance behavior is maintained, leading to disability. However as these models assume that an injury has been sustained, they do not account for avoidance behavior in individuals with LBP who cannot relate their pain to a specific injury, who may believe that their pain is caused by an underlying structural abnormality or damage.

The behaviouralist movement gave way to the cognitive behavioural movement, which ascribed a central role to pain-related beliefs and cognitions in the persistence of avoidance behavior. Early models of 'fear avoidance' emerged, suggesting that chronic pain disability could be explained by a vicious cycle between avoidance behavior and cognition (Lethem et al. 1983, Philips 1987, Slade et al. 1983). Drawing on the phobia literature, these early models equated pain-related fear with kinesiophobia: "an excessive, irrational and debilitating fear of physical movement and activity" (Kori, Miller, and Todd 1990, p.37). From these foundations, Vlaeyen and Linton (2000) proposed their fear avoidance model (FAM) which continues to be the leading cognitive behavioural model of LBP disability today.

The FAM presented in Figure 2.1 illustrates how the experience of LBP initiates a set of cognitive, emotional and behavioural responses. In line with the theory that cognitive factors precede emotional reactions (Lazarus 1982) the FAM proposes that people who 'catastrophise' that their pain is "a sign of serious injury or pathology" (Crombez, Eccleston, et al. 2012, p.476) may become fearful and avoidant of physical activity that they presume worsens their problem. The avoidance of activity prevents opportunities to challenge negative expectations through positive disconfirmatory experiences, and may exacerbate

pain and disability. On the other hand, people who do not catastrophise, i.e. who interpret pain as non-threatening, will resume normal activities that promote recovery.

Figure 2.1. Fear Avoidance Model adapted from Vlaeyen and Linton (2000)



Since the publication of the FAM, research has lent empirical support to the claim that "Fear of pain and what we do about pain may be more disabling than pain itself" (Waddell 1996, p.2821). A review of 46 cross sectional studies involving a total of 9,579 people with chronic pain investigated the association between pain-related fear and disability. The meta-analysis found a large positive relationship between pain-related fear and disability that was stable across demographic and pain characteristics (Zale et al. 2013). A prospective study involving individuals without LBP at baseline found that pain-related fear predicted disabling LBP at six-month follow-up (Odds Ratio: 3.4; 95% Confidence Interval (CI): 1.3,8.7) (Picavet, Vlaeyen, and Schouten 2002). Amongst individuals with LBP at baseline, prospective studies have shown that pain-related fear predicts disabling LBP at six months (Odds Ratio: 4.4; 95%CI: 2.5,7.9) (Picavet, Vlaeyen, and Schouten 2002) and 12 months (Relative Risk: 1.5; 95%CI: 1.2,1.7) (Jensen et al. 2010). Employing a structural equation modeling approach, Goubert et al. (2004) found support for the relationships between pain catastrophising, pain-related fear and pain severity proposed by the FAM, in a cross-sectional study involving people with CNSLBP. Also employing a structural equation modeling approach, Wideman et al. (2009) explored the relationships proposed by the FAM in a prospective study involving people with work-related musculoskeletal injuries participating in a disability management intervention. The study found that reductions in catastrophising early in the intervention were predictive of return to work, as were reductions in pain-related fear and pain severity later in the intervention. However, inconsistent with the FAM, the study found that early reductions in catastrophising were not related to later reductions in pain-related fear, raising questions about the sequential predictions of the FAM.

Indeed, twelve years on from the original FAM publication, experts have called for the next generation of the FAM to address some of the limitations of the model in its current form (Crombez, Eccleston, et al. 2012, Vlaeyen and Linton 2012a, Pincus et al. 2010). A key limitation is that whilst the FAM is grounded in psychopathological models, pain-related fear does not seem to be necessarily grounded in psychopathology. The belief at the core of the model, that pain is 'a sign of serious injury or pathology', is common amongst the general population, people with acute LBP and CNSLBP (Darlow et al. 2014). This is also common amongst HCPs, who frequently prescribe spinal imaging for low-risk patients and advise them to avoid activity due to pain or fear of doing harm (Lurie, Birkmeyer, and Weistein 2003). This suggests that rather than being irrational or 'phobic', this belief may be 'normal' and culturally, often *medically*, endorsed, in spite of it being contrary to clinical guidelines. Further, catastrophising and fear-avoidance behavior are only moderately correlated (Wideman, Adams, and Sullivan 2009), suggesting that there may be some individuals with high painrelated fear who do not catastrophise about pain as a sign of serious injury or pathology (Pincus et al. 2010).

Indeed, experts have indicated that there may be other 'non-phobic' processes that trigger pain-related fear and fear avoidance behaviours (Rainville et al. 2011). For example, it is possible that central pain processes that sensitise spinal structures lead to increased pain intensity during movement. Increased pain intensity during movement may prompt avoidance through simple

classical conditioning, reinforcing the belief that avoidance is preferable to suffering (Gay et al. 2015). Other 'non-phobic' beliefs that have been suggested may underlie pain-related fear include the belief that: 'pain must be resolved to resume activity' and: 'pain will impact on valued life goals' (Crombez, Eccleston, et al. 2012, Pincus et al. 2010). Rather than being 'psychopathological' it is recognized that such beliefs occur in a motivational context and would therefore implicate self-regulatory processes in future iterations of the FAM (Crombez, Eccleston, et al. 2012). Self-regulatory processes refer to the adjustment of emotions and behaviours depending on the appraisal of goal outcome (Karoly 1993). Such feedback processes are currently lacking in the FAM which assumes that pain-related fear and fear avoidance are stable across contexts and time (Crombez, Eccleston, et al. 2012).

If heterogenous processes could trigger the emotional and behavioural responses described by the FAM, this would have implications for the clinical management of people with CNSLBP and high pain-related fear (Rainville et al. 2011). Currently, interventions based on the FAM target the belief that pain is a sign of serious injury or pathology (Vlaeyen et al. 2012). These interventions have successfully reduced fear in some individuals with high pain-related fear, but a significant proportion fail to respond to treatment (Linton et al. 2008, Leeuw et al. 2008, Woods and Asmundson 2008). It is possible that some individuals fail to respond to interventions targeting beliefs about serious injury or pathology because this is not the predominant driver of their pain-related fear. Indeed, in some cases pain-related fear and avoidance may be driven by altered pain processing such as central sensitization, resulting in exposure interventions being pain-provoking for some individuals (Sullivan et al. 2009). To date, the processes underlying pain-related fear in people with CNSLBP remain poorly understood. Given the central role that beliefs play in the current FAM, it is logical that the next generation of FAM research begins with an indepth exploration of the beliefs underlying pain-related fear.

In addition to understanding what beliefs underlie pain-related fear, it is also important to understand the factors contributing to these beliefs (Wideman et al. 2013, Vlaeyen and Linton 2012a). Pincus et al. (2010) propose two extensions to the FAM describing how beliefs may evolve: 1. A social-beliefs pathway describing how individuals acquire unhelpful beliefs about LBP through information from health culture, significant others and HCPs, and 2. A depression pathway describing how a trait-like vulnerability to negative affect makes individuals more likely to ruminate and catastrophise about the meaning of their symptoms. The authors tentatively suggest that beliefs acquired through different pathways may require different emphasis in treatment; that socially acquired beliefs may benefit from educational approaches, whilst individuals with high negative affect who catastrophise about the meaning of their symptoms may benefit from behavioural approaches (Pincus et al. 2010). However, in addition to social factors and underlying vulnerabilities, other factors may influence the evolution of beliefs underlying pain-related fear. For example, whilst the FAM at present assumes a linear one-directional pathway from the pain experience to cognitive-behavioural processes, it has been suggested that there may be a bi-directional relationship between pain intensity and pain-related fear (Werneke et al. 2009, Sullivan et al. 2009). It is also possible that the experience of increased pain intensity during movement may reinforce the belief that avoidance is preferable to suffering. To date the myriad of factors that may influence beliefs underlying pain-related fear have not been explored.

The current state of the FAM

The section that follows is a review the current evidence based on the existing FAM. It begins with a description of the roles of pain catastrophising, pain-related fear and fear avoidance behaviour in the FAM; followed by a description of the assessment and treatment of pain-related fear based on the FAM.

The role of pain catastrophising in the FAM

Catastrophising has been defined as an "exaggerated negative 'mental set' brought to bear during an actual or anticipated pain experience" (Sullivan 2001, p.53). It involves the rumination and magnification of pain and feelings of helplessness (Sullivan, Bishop, and Pivik 1995).

Catastrophising may impact on pain outcomes through various interpersonal and psychological (Cano 2004, Sullivan, Rodgers, and Kirsch 2001), physiological (Wolff et al. 2008) and neuroanatomical (Gracely et al. 2004) processes. The Communal Coping Model posits that catastrophising serves an interpersonal communicative function to place emotional distress associated with suffering within a social/interpersonal context. It suggests that people who catastrophise engage in overt pain behaviours to convey information about their internal state and that these pain behaviours which include guarding, bracing and avoidance, will sustain disability (Sullivan, Rodgers, and Kirsch 2001). At a psychological level, catastrophising may amplify the pain experience via attention biases to pain-related information and an inability to suppress pain-related thoughts. Van Damme et al. (2004) found that people who scored highly for pain catastrophising were slow to disengage from cues that threatened pain and painful stimuli and overestimated the probability of experiencing pain. Individuals who catastrophise about the meaning of pain may be more likely to interpret ambiguous physical sensations as threatening or painful (Arntz and Claassens 2004). Attentional bias implications may mean that less attention is available for non-pain-related tasks resulting in a heightened pain experience (Berryman et al. 2014). At a physiological and neuroanatomical level, hypervigilance to pain-related cues may 'prime' the pain system (George et al. 2007) by sensitizing areas of the brain involved in modulating the affective components of pain (Rhudy et al. 2009, Seminowicz and Davis 2006).

The role of pain-related fear in the FAM

Pain-related fear may function in a similar way to catastrophising, by sensitising the pain system through activating the same areas in the brain that encode sensory and affective aspects of the pain experience (Porro et al. 2002, George et al. 2007).

There is some debate as to whether individuals with CNSLBP show typical phobic 'fight or flight' responses when confronted with threatening activity.

Two experimental studies exposing participants with CNSLBP to pictures of back-stressing movements have failed to support the 'phobic' component of the FAM. Despite rating the pictures as aversive, the participants with high self-reported pain-related fear did not show typical startle responses (Kronshage, Kroener-Herwig, and Pfingsten 2001) or activation in the areas of the brain typical of a phobic response (Barke et al. 2012) when compared to people with low pain-related fear and control groups. Interpreting their findings as absence of a 'phobic' response, the authors suggested that it was not fear that motivates avoidance behaviour, but rather an individual's beliefs and attitudes towards back-stressing movements.

A more recent study investigated the physiological response patterns of individuals with high and low pain-related fear made to believe that they would perform a back-stressing movement demonstrated by the researcher (Glombiewski et al. 2015). They found evidence of two different response patterns: 1. A stress response characterised by a moderate increase in skin conductance and heart rate deceleration together with increased muscle tension in 42 per cent of participants; and 2. A phobic response characterised by high skin conductance and heart rate acceleration together with increased muscle tension in 58 per cent of participants. Self-report measures of pain-related fear did not distinguish between the phobic and non-phobic individuals. This supports a 'phobic' model of pain-related fear in some but not all individuals with CNSLBP and high pain-related fear. It also highlights the challenge of identifying phobic and non-phobic individuals in the clinical setting who may respond differentially to intervention.

The role of fear-avoidance behaviour in the FAM

Fear avoidance behaviour is inherent in the definition of fear itself and is likely to sustain pain-related fear by reducing the opportunities the individual has for positive exposure (Lethem et al. 1983). During tasks perceived as threatening, individuals with LBP and high pain-related fear has been linked to increased muscle activity, altered movement patterns, or avoid the task altogether (Geisser et al. 2004, Thomas and France 2007, Huijnen et al. 2010).

Increased muscle tension may be a stress-induced physiological reaction in some people with LBP and high pain-related fear (Flor and Turk 1989). Observable 'bracing' and 'guarding' may serve a communicative function as an outward sign of suffering in some people (Sullivan 2012). These behaviours may also be perceived as serving a protective function, based on the belief that the spine is vulnerable during movements perceived as threatening (Glombiewski et al. 2015). However rather than being 'adaptive' in people with CNSLBP, these altered patterns may increase tissue loading leading to muscular fatigue and potentially, sustaining peripheral nociceptor activation (Norton and Asmundson 2003, O'Sullivan 2005, Sullivan et al. 2009).

The submaximal performance and avoidance of activity have well-documented functional, emotional and social consequences (Boersma and Linton 2005b, Samwel et al. 2007). However whilst the FAM posits that fear avoidance is a stable response to cognitive processes, there is evidence that some individuals with CNSLBP and high levels of pain-related fear will avoid certain tasks associated with pain but persist in other tasks despite pain (Huijnen et al. 2011). This suggests that fear avoidance responses are dynamic and highly context-specific (Verbunt, Smeets, and Wittink 2010, Demoulin et al. 2013).

There is evidence of other individuals with high pain-related fear who rigidly respond with task persistence instead of avoidance (Hasenbring and Verbunt 2010). McCracken and Samuel (2007) suggest that this rigid task persistence may be considered a form of 'psychological avoidance', the avoidance of experiences that come with making change or facing limitations. Indeed, whilst confrontation of activity is thought to be adaptive and associated with positive outcome in CNSLBP, an inflexibility to disengage with the task until completion in spite of pain escalation is considered maladaptive (Hasenbring et al. 1999, McCracken 2013).

To capture this range of behavioural responses to pain-related fear, the Avoidance Endurance Model (AEM) (Hasenbring and Verbunt 2010) has evolved as a descendent of the FAM. The AEM proposes two opposing pathways to pain chronicity, fear avoidance responses and endurance responses. Chronicity is thought to arise from the rigid, time-stable pattern of either of

these maladaptive responses. Fear avoidance responses are consistent with those described by the FAM. In contrast, endurance responses refer to task persistence behavior despite pain, through thoughts of suppression, distraction from pain or minimization. According to the AEM, when the interruption of painful activity is postponed, an eventual interruption, such as a short rest, will not calm over-loaded physical structures and therefore pain will not decrease. When repeated over time, the perception of poor control over increasing pain intensity levels will eventually force the avoidance of painful activity. The authors of the AEM propose different behavioural responses may require different intervention approaches. They suggest that individuals with fear avoidance responses may benefit from exposure interventions, whilst individuals with endurance responses may benefit from cognitive behavioural approaches aimed at reducing thought suppression and encouraging a more flexible response pattern (Hasenbring and Verbunt 2010). However to date, this hypothesis has not been tested in RCTs involving people with CNSLBP. As a descendent of the FAM, the AEM similarly lacks explicit consideration for the fact that behavioural responses appear to be dynamic and context-specific.

Assessment of pain-related fear

Practice guidelines recommend the use of self-report questionnaires to aid in the clinical assessment of pain-related fear (Delitto et al. 2012). Several questionnaires have been used to assess pain-related fear in people with CNSLBP, all measuring slightly different constructs (see Table 2.1). These include the Avoidance Endurance Questionnaire (Hasenbring, Hallner, and Rusu 2009), Fear Avoidance Beliefs Questionnaire (FABQ) (Waddell et al. 1993), the Fear of Pain Questionnaire (Lethem et al. 1983), the Pain Anxiety Symptoms Scale (McCracken, Zayfert, and Gross 1992), the Photograph Series of Daily Activity-short electronic version (Leeuw, Goossens, van Breukelen, et al. 2007) and the Tampa Scale of Kinesiophobia (TSK) (Miller, Kori, and Todd 1991).

Table 2.1 Self-report questionnaires used to assess pain-related fear

Questionnaire	No items	Construct	Subscales	Example items
Avoidance Endurance	C	Avoidance and	Fear-Avoidance	I avoid physical strenuous activities
Questionnaire	28	Endurance responses to pain	Endurance	I carry on doing what I am doing, no matter what
Fear Avoidance	10	Foor arraidance holiofe	Physical Activity	Physical activity might harm my back
Beliefs Questionnaire	10	real -avolualice beliels	Work	I should not do my normal work with my present pain
			Fear of minor pain	How fearful are you of experiencing pain associated with having a muscle cramp?
Fear of Pain Questionnaire	30	Fears about pain	Fear of severe pain	How fearful are you of experiencing pain associated with breaking your leg?
			Fear of medical pain	How fearful are you of experiencing pain associated with having one of your teeth drilled?
			Somatic Anxiety	I can stay relaxed when I hurt
Dain Annioty		Fear and anxiety	Cognitive Anxiety	I worry when I am in pain
Symptoms Scale	20	behaviours related to	Fear	I think that pain is a signal that means I am damaging myself
			Escape/Avoidance	I try to avoid activities which cause pain
Jo seine Dieser et all				Please look at each photograph and try to imagine
Photograph series of Daily Activities –		Perceived levels of		yourself performing the same movement. Place the
short electronic	40	harmfulness		photograph on the scale from 0-100 according to the
Version				extent to which you feel that this movement is harmful
101512				to your back
		Kinosionhobia	Comatic Focus	My body is telling me I have something dangerously
Tampa Scale of	17	Milesiophobia	Somatic rocus	wrong
Kinesiophobia	ì		Activity Avoidance	If I were to try and overcome it, my pain would increase

With the exception of the Avoidance Endurance Questionnaire (that has only relatively recently been validated (Hasenbring, Hallner, and Rusu 2009)), a limitation of the questionnaires is that they predate the FAM and lack a theoretical framework (Lundberg et al. 2011). This raises questions regarding the clinical interpretation of individual scores. A recent critical review of measures of pain-related fear concluded that the construct validity of available questionnaires remains to be established; a gold-standard measure of pain-related fear is lacking; and that at present, the most widely used tool, the TSK, may be the best available measure of 'kinesiophobia' (Lundberg et al. 2011).

Kinesiophobia

Kinesiophobia was first described by Kori et al. (1990). The authors suggested that many, if not all, individuals presenting with chronic pain of unknown medical cause that exhibit avoidance of activity are suffering primarily from a 'phobia'. They defined kinesiophobia as: "an excessive, irrational and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or reinjury" (p.37). Miller, Kori and Todd (1991) presented a measure of kinesiophobia, the TSK. The scale was adopted by Vlaeyen et al. (1995), and since then has been applied to the CNSLBP research as a measure of pain-related fear, or more specifically, fear of movement/(re)injury, defined as a specific fear of movement and physical activity that is (wrongfully) assumed to cause (re)injury.

Whilst originally presented as a one-dimensional scale, factor analytic studies have suggested that the TSK may be better described as a two-dimensional scale, consisting of a Somatic Focus subscale and an Activity Avoidance subscale (Roelofs et al. 2004, Goubert et al. 2004, French et al. 2007). However the definitions of the subscales vary between authors. For example, the Somatic Focus subscale has been described as "the belief in underlying and serious medical problems" (Clark, Kori, and Brockel 1996) and "the belief that pain is a sign of bodily harm" (French et al. 2007). The Activity Avoidance subscale has been defined as "the belief that activity may result in (re)injury or increased pain (Clark, Kori, and Brockel 1996) and "the belief that activities that promote

pain should be avoided" (French et al. 2007). A conceptual and operational definition of the TSK in the literature is lacking (Lundberg et al. 2011).

Despite this, the TSK has been widely used to test the assumptions of the FAM. High scores on the TSK have been found to be associated with and predictive of increased pain severity (Sullivan et al. 2009), pain duration (Picavet, Vlaeyen, and Schouten 2002) and increased CNSLBP disability (Picavet, Vlaeyen, and Schouten 2002, Crombez et al. 1999). Intervention studies have used the TSK to identify individuals with high pain-related fear for interventions aimed at reducing fear of movement/(re)injury (Vlaeyen et al. 2012). A recent systematic review investigating the role of pain-related fear as a prognostic factor for LBP outcome, found that based on the existing literature it was not possible to identify a specific cut-off value for 'high' pain-related fear on the TSK as cut-off values vary between studies, but proposed a 'pragmatic' cut-off of >37/68 based on a median split in the populations used to validate the TSK (Wertli et al. 2013). However based on median scores amongst the chronic pain population, Vlaeyen et al (2012) suggest that scores >40/68 may constitute high levels of pain-related fear.

While clear levels of clinically important change for the TSK are lacking, longitudinal analysis has shown that reductions in TSK scores predict improvements in disability (Wideman, Adams, and Sullivan 2009). Luning Bergsten et al. (2012) found that patients with CNSLBP improving ≥ 8 points on the TSK were more likely to increase their physical activity levels than individual with <8 points improvement. This is in contrast to a previous study involving individuals with acute LBP which suggested that a change score of <9 on the TSK is likely to be due to fluctuations in pain-related fear in the absence of real change (Ostelo et al. 2007).

The widespread use of the TSK is illustrated in Table 2.2 which summarises findings from intervention studies involving individuals with high pain-related fear. With the exception of Woby et al. (2004) and O'Sullivan et al. (2015), all the intervention studies involving individuals with high pain-related fear use the TSK as a screening tool and as an outcome measure. However, to date it is

unclear how individual scores on the TSK should be interpreted in research and clinical settings. Calls have been made for future research to reach an agreement on the conceptual and operational definition of the TSK construct(s) (Lundberg et al. 2011). A deeper understanding of the beliefs underlying high scores on the TSK may assist in comprehending why some people with high scores respond to certain fear reduction treatments while others do not.

Treating pain-related fear

Consistent with the FAM, reductions in pain-related fear in people with high fear at baseline are associated with improvements in self-reported physical activity levels (Lüning Bergsten et al. 2012) disability (Leeuw et al. 2008) and pain intensity (Woby et al. 2008). There is evidence that changes in pain-related fear mediate disability outcomes, making fear reduction a treatment priority for people with CNSLBP (Wertli et al. 2014).

A search of the literature identified 11 studies that involved participants with high pain-related fear (mean \geq 40/68 TSK (Vlaeyen et al. 2012); mean \geq 15 FABQ-physical activity subscale (Williamson 2006)) undergoing an intervention for CNSLBP and reported pain-related fear as an outcome measure. Ten of the studies involved interventions specifically targeting pain-related fear, whilst one did not

(Lüning Bergsten et al. 2012). The 11 studies are summarised in Table 2.2.

Table 2.2. Intervention studies assessing changes in pain-related fear in individuals with CNSLBP and high pain-related fear

Study	Design	Intervention	Sample	Outcome	Change in pain-related fear post intervention
			size	measures	
Vlaeyen et al. (2001)	Replicated cross over single case study	Exposure Graded activity	n=4	TSK	Reduction in fear following exposure therapy: 19-24 points TSK
Vlaeyen et al. (2002)	Replicated cross over single case study	Exposure Graded activity	9=u	TSK PHODA	Mean reduction in fear following exposure therapy: 23 points TSK; 55 points PHODA
Boersma et al. (2004)	Multiple baseline single case study	Exposure	9=u	TSK	Mean reduction in fear following exposure therapy at 3 months: 21 points TSK
Woby et al. (2004)	Case-series	Cognitive Behavioural Therapy	n=83	FABQ	Mean reduction in fear following cognitive behavioural therapy: 5 points FABQ - Physical Activity subscale
De Jong et al. (2005)	Replicated single case study	Education Exposure Graded activity	9=u	TSK	Mean reduction in fear following exposure therapy: 20 points TSK; 48 points PHODA
Linton et al. (2008)	Randomised controlled trial	Exposure Waiting list controls Usual treatment	n=46	TSK	Mean reduction in fear following exposure therapy: 8 points TSK
Leeuw et al. (2008)	Randomised controlled trial	Exposure Graded activity	n=85	РНОБА	Mean reduction in fear following exposure therapy: 30 points PHODA Mean reduction in fear following graded activity: 13 points PHODA
Woby et al. (2008)	Case series	Cognitive Behavioural Therapy	n=166	TSK	Mean reduction in fear following cognitive behavioural therapy: 5 points TSK
Woods & Asmunds- on (2008)	Randomised controlled trial	Exposure Graded activity Waiting list controls	n=44	TSK FABQ PASS	Mean reduction in fear following exposure therapy: 8 points TSK, 11 points FABQ, 8 points PASS Mean reduction in fear following graded activity: 4 points TSK, 2 points FABQ, -1 point PASS

I Dougeton of		0.000	60-5	тст/	Man and action in four fall arrive and within holy and
runing bergsten et	case series	Cognitive	79=U	ISK	Mean reduction in lear following cognitive denavioural
al. (2012)		Behavioural			therapy:
		Therapy			9 points TSK
Monticone et al.	Randomised	Cognitive	06=u	TSK	Mean reduction in fear following cognitive behavioural
(2013)	controlled trial	Behavioural			therapy:
		Therapy			23 points TSK
		Exercise group			
O'Sullivan et al.	Case series	Cognitive	n=26	FABQ	Mean reduction in fear following cognitive functional
(2015)		Functional			therapy:
		Therapy			13 points FABQ - Physical Activity subscale
		Waiting list			
		controls			
FABQ = Fear Avoidan	ce Beliefs Questionn	iaire; PASS = Pain A	Anxiety Sym	ptoms Scale; l	FABQ = Fear Avoidance Beliefs Questionnaire; PASS = Pain Anxiety Symptoms Scale; PHODA = Photograph Series of Daily Activities; TSK =
Tampa Scale of Kinesiophobia	lophobia				

The most common intervention that appears in Table 2.2 is Exposure in vivo. Exposure in vivo was designed to specifically target fear by providing highly fearful individuals with the opportunity to create new associations between feared activities/movements and outcome. Thus a cognitive learning process is thought to take place in which patients learn that their expectations of pain and/or damage are the result of catastrophic overestimation (Vlaeyen et al. 2012). Early single case design studies showed promising preliminary results that Exposure in vivo could effectively reduce pain-related fear and improve disability and pain more effectively than a graded activity intervention in selected highly fearful individuals with CNSLBP (Vlaeyen et al. 2001, Vlaeyen et al. 2002, Boersma et al. 2004). In these studies, the rapid reductions in painrelated fear observed suggested that insight learning was occurring through Exposure in vivo rather than gradual trial and error learning (Rachman and Whittal 1989). In the study by de Jong et al. (2005) modest reductions in fear were reported following the education component of Exposure in vivo but improvements in fear behaviour only occurred following the exposure component of Exposure in vivo. This is consistent with the theory that behavioural modification constitutes a potent strategy for cognitive restructuring (Bandura 1977).

Subsequent attempts to extend these findings in larger prospective studies (Woby et al. 2008) and RCTs (Linton et al. 2008, Leeuw et al. 2008, Woods and Asmundson 2008) revealed more modest effect sizes for fear reduction which were reportedly, highly variable from patient to patient, and incurred a high drop out rate (31-47 per cent). Of note, whilst cut-offs determining eligibility for each study differed, and in one study may have captured individuals with moderate levels of fear rather than high fear (Linton et al. 2008), all three RCTs involving Exposure in vivo reported a sample mean of \geq 40/68 on the TSK, indicating high pain-related fear. In the only study to explore the factors mediating changes in fear, Leeuw et al. (2008) reported that improved beliefs about the harmful consequences of activity mediated reductions in fear through a graded exposure in vivo intervention relative to a graded activity intervention.

Cognitive Behavioural Therapy aims to change the content of pain-related thoughts and beliefs and improve behavioural participation in daily life through a variety of strategies including education and physical activation. Improvements in fear are thought to be mediated by changes in pain catastrophising (Spinhoven et al. 2004). In two early before-after observational studies involving highly fearful individuals with CNSLBP undergoing a physiotherapy led Cognitive Behavioural Therapy, Woby et al. (2004, 2008) showed small to moderate reductions in pain-related fear were associated with reductions in disability but not reductions in pain intensity. Similar to trials of Exposure in vivo, they also reported a high drop out rate of 25-35 per cent. Luning Bergsten et al. (2012) conducted a prospective cohort study of a multidisciplinary Cognitive Behavioural Therapy program for CNSLBP that did not specifically target pain-related fear. Dividing their sample into the subgroups based on TSK scores, they found that the highly fearful subgroup had a clinically significant reduction in fear, which was associated with improvements in activity levels and sustained at six months post intervention. The authors suggested that interventions did not specifically need to focus on pain-related fear but that exposure to physical activity and exercise itself may be sufficient to reduce fear in highly fearful people with CNSLBP.

The study by Monticone et al. (2013) compared: i) A 5-week multidisciplinary Cognitive Behavioural Therapy targeting pain-related fear combined with monthly 'reinforcement' meetings with a psychologist for the following 12 months, to ii) A 5-week manual therapy and exercise training combined with 'reinforcement' telephone calls to continue exercising for the following 12 months. In remarkable results, with no drop-outs at 12 months, the authors reported extremely large effects with almost a complete resolution of pain-related fear, disability and pain in the Cognitive Behavioural Therapy intervention and no change in pain-related fear, disability and/or pain in the exercise group at 12 months. These findings are unusual given the absence of drop-outs, large effects for Cognitive Behavioural Therapy and no change in the manual therapy group in contrast with previous studies, and should perhaps be considered with caution until reproduced by other authors.

Cognitive Functional Therapy is person-centred behavioural intervention that challenges maladaptive beliefs and associated maladaptive functional behaviours, targeting feared or pain provoking postures and/or movements (Vibe Fersum et al. 2013). O'Sullivan et al. (O'Sullivan et al. 2015) report findings from a case series involved 26 individuals with CNSLBP and high scores on the FABQ-physical activity subscale. Participants took part in a three-month baseline, measurement phase; a 12 week Cognitive Functional Therapy intervention; followed by a 12 month no treatment follow-up. Large reductions in on the FABQ-physical activity (13 points) were reported post-treatment that remained clinically and statistically significant at 12 months. A RCT comparing Cognitive Functional Therapy to manual therapy and exercise in 121 people with moderate levels of pain-related fear similarly reported large reductions on the FABQ that were sustained at 12 month follow-up (five points FABQ-physical activity; six points FABQ-work) (Vibe Fersum et al. 2013). These findings suggest that individualised treatment targeting maladaptive beliefs and functional behaviours related to pain in parallel may be an effective way to reduce pain-related fear. However to date, the mechanism(s) underlying fear reduction through Cognitive Functional Therapy remains uncertain.

Another category of intervention may also have potential to reduce pain-related fear in CNSLBP. Acceptance and Commitment Therapy (McCracken, Vowles, and Eccleston 2005), based on the concepts of mindfulness, acceptance and values-based action (Hayes, Strosahl, and Wilson 1999), is thought to indirectly reduce pain-related fear through a shift in attention away from pain and its consequences towards things of greater life value, a skill known as 'psychological flexibility' (Vowles and McCracken 2008). There is early evidence that Acceptance and Commitment Therapy based interventions may reduce pain catastrophising and pain anxiety in people with CNSLBP (Schütze et al. 2014, Vowles et al. 2014). These changes may be mediated by changes in reduced pain vigilance (Vowles et al. 2014) and /or by encouraging people to resume valued activities of daily life (den Hollander et al. 2010). However to date no studies of Acceptance and Commitment Therapy efficacy have been conducted in people with CNSLBP and high pain-related fear.

It is notable that, with the exception of Monticone et al.(2013), all of the studies included in Table 2.2 report reductions in pain-related fear for all intervention arms. While it is possible that this reflects the natural progression of pain-related fear over time, the lack of comparative control group in all but two studies (Linton et al. 2008, Woods and Asmundson 2008) makes it difficult to study interventional effects. However, as avoidance behaviours may prevent opportunities to confront and challenge beliefs underlying pain-related fear, there is some suggestion that pain-related fear is a relatively stable construct in individuals with CNSLBP, that is unlikely to spontaneously change over time without intervention (Wertli et al. 2014).

It is also possible that the reductions in pain-related fear observed in these studies could be due to 'non-specific' treatment effects. These treatment effects are those that exist outside of the specific intervention; the contextual factors which may be common across diverse interventions (Miciak, Gross, and Joyce 2012). Two non-specific treatment effects that have been found to influence CNSLBP outcomes are the therapeutic alliance between the HCP and patient (Hall et al. 2010) and patients' expectations of treatment (Heymans et al. 2006). The role that non-specific treatment effects may play in fear reduction for people with CNSLBP and high pain-related fear was explored in the study by Woods and Asmundson (2008) which included a measure of therapeutic alliance and treatment credibility at two time-points through the graded exposure and graded activity interventions. They found that the quality of the therapeutic alliance did not differ between the two intervention arms, suggesting that this did not differentially influence the outcome of the interventions. Participants were more likely to rate graded exposure as more credible than graded activity, however treatment credibility was not measured at the start of the intervention and the difference in rating may reflect the participant's perception of improved outcomes through the course of graded exposure.

It is likely that some individuals respond to certain interventions that suit their particular circumstances, while others do not. This is the premise behind an emerging approach to CNSLBP management known as stratified care which involves targeting treatment to subgroups of people based on prognostic risk factors (Foster et al. 2013). Hill et al. (2011) conducted a large RCT involving 1573 individuals presenting to General Practice with LBP. Based on a risk-assessment tool, the STarT Back Screening Tool, individuals were grouped low, medium and high risk of poor outcome. Individuals were then randomised to the control group or the intervention arm. In the intervention arm, three different treatment pathways were developed to match the risk groups: all groups received a single session of advice to keep active; in addition to this, the medium and high risk groups were referred to standard physiotherapy or psychological-informed physiotherapy respectively. Improvements on the TSK were reported for all groups in both intervention arms. Statistically significant differences in scores on the TSK in favour of the intervention arm were reported. However the differences in change scores on the TSK for the intervention arm compared to control arm were of low clinical significance, (0.7, 2.4 and 3.6 points for the low, medium and high groups respectively).

To date our knowledge of the mechanisms underlying improvements in fear in people with CNSLBP and high pain-related fear remains limited. The question "what works best for whom?" in people with CNSLBP and high pain-related fear remains under-explored. Treatment guidelines for CNSLBP do not recommend one fear-reduction intervention over another (Reese and Mittag 2013) and HCPs are left uncertain about how best to manage patients presenting with CNSLBP and high pain-related fear (Slade, Molloy, and Keating 2011, Synott et al. 2015). Research is required to guide HCPs in determining what fear reduction treatment works best for whom, and why (Thorn and Burns 2011, Asmundson, Vlaeyen, and Crombez 2004).

Chapter conclusion

There is clear evidence that a vicious cycle of pain-related fear and fear-avoidance plays a key role in CNSLBP disability. To date, the variety of factors that may trigger the cycle, including behavioural and pain sensitisation processes remains poorly understood. Given the central role that beliefs play in

the current FAM, it is logical that the next generation of FAM research begins with an in-depth exploration of the beliefs underlying pain-related fear.

This chapter has highlighted three key knowledge gaps in the literature:

- It remains unknown whether all individuals with high pain-related fear believe that pain is a sign of serious injury or pathology. Any alternative beliefs that may underlie pain-related fear have not been investigated
- It is unknown how beliefs underlying pain-related fear evolve
- The mechanisms underlying improvements in fear in people with CNSLBP and high pain-related fear remain unknown.

To provide an evidence-based platform for future iterations of the FAM that may help direct targeted intervention, research is needed to:

- 1. Explore the beliefs underlying pain-related fear and the factors that may contribute to these beliefs
- 2. Explore how and why pain-related fear may improve over time

Qualitative research may assist in building this evidence base for the next generation of FAM research. Pincus et al. (2010) claim that in order to improve the clinical utility of the FAM, there is a need for future research in people with high fear to explore the "personal narratives and explanations for the acquisition of fear and beliefs about movement and avoidance" (p. 744). Vlaeyen and Morley (2005) suggest that evidence based medicine may not be well suited to the epidemiology of large RCTs; rather in order to understand what works best for whom, we must turn our focus to the individual as the unit of analysis. In Chapter three of this thesis we will therefore turn our attention to the qualitative literature to determine if novel insights into pain-related fear may be gained by exploring the subjective experience of CNSLBP.

Chapter 3. Qualitative synthesis

Introduction

Exploring pain-related fear from the perspective of the individual experiencing CNSLBP may help inform a more nuanced understanding of pain-related fear. To gain insights into individuals' perceptions of factors contributing to pain-related fear and/or changes in fear, a review of the qualitative literature investigating the experience of CNSLBP was conducted.

However, in the course of conducting the review it became apparent that although pain-related fear is a critical factor in the genesis of CNSLBP, there was insufficient research that has explicitly examined pain-related fear qualitatively. Therefore the aim was broadened to explore the lived experience of CNSLBP, which could then inform the qualitative interviewing conducted in the subsequent stages of this research.

Published manuscript

Lives on Hold

A Qualitative Synthesis Exploring the Experience of Chronic Low-back Pain

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Objectives: Chronic nonspecific low-back pain (CLBP) is a prevalent, costly condition that is remarkably resistant to intervention. Substantial evidence suggests that a mismatch exists between the biomedical beliefs held by clinicians and patients and the biopsychosocial nature of CLBP experience. The aim of this metasynthesis of qualitative studies was to provide clinicians with a richer understanding of their patients' CLBP experience to highlight the importance of moving away from biomedical paradigms in the clinical management of CLBP.

Methods: Qualitative studies exploring the CLBP experience from the perspective of the individual were included. Twenty-five articles representing 18 studies involving 713 participants were subjected to the 3-stage analytic process of extraction/coding, grouping, and abstraction.

Results: Three main themes emerged: the social construction of CLBP; the psychosocial impact of the nature of CLBP; and coping with CLBP.

Discussion: The authors conceptualize the experience of CLBP as biographical suspension in which 3 aspects of suspension are described: suspended "wellness," suspended "self," and suspended "future". The implications of improved clinician understanding of the CLBP experience and directions for future research are discussed.

Key Words: low-back pain, qualitative research, chronic pain,

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hronic nonspecific low-back pain (CLBP) is one of the -leading causes of disability in western countries incurring substantial personal and societal cost. 1 Statistics show that the societal costs of CLBP are increasing rather than decreasing² making effective and efficient CLBP management a priority for the medical and allied health care professions (HCP).

Limitations in a purely biomedical approach to CLBP management has led to a paradigm shift towards a clientcentered approach, which recognizes the complex interactions between an individuals' biopsychosocial contexts, which influence their disability. 3,4 Qualitative methods are well suited to investigate this biopsychosocial paradigm. By exploring how individuals make sense of their situation, qualitative methods provide insight into behavior, deepening our understanding of CLBP disability.⁵ Qualitative metasynthesis is "an interpretive integration of qualitative findings that are themselves interpretive syntheses of data." More than a summary of findings, they offer a novel interpretation of the data that may contribute to the development of clinically orientated theory.

Despite its limitations, research shows that many HCP endorse a biomedical paradigm over a biopsychosocial approach in the clinical management of CLBP. 8,9 Similarly, biomedical beliefs are widely held by lay and chronic pain populations. ^{10,11} However, the chronic pain literature has identified tensions created by the biomedical paradigm in relation to the legitimization of pain and suffering, uncertainty, and fear and anxiety for the future. 12-14 These tensions may sustain physical and psychological disability in CLBP. Providing HCP with a richer understanding of the subjective CLBP experience may assist in resolving this apparent discord between widely endorsed biomedical conceptualizations of CLBP and the lived experience of CLBP. In recent years a substantial number of qualitative studies exploring the subjective CLBP experience have been published. The aim of this metasynthesis is to integrate findings from these studies with the vision that providing HCP with a richer understanding of the CLBP experience will highlight the importance of moving away from biomedical paradigms in the clinical management of CLBP.

METHODS

Identification of Studies

The databases MEDLINE, EMBASE, AMED, CINAHL, PsychINFO, Sociological Abstracts, and Scopus were searched twice over the period from January 2011 to October 2011 using the MeSH headings "back pain" and "qualitative research" as broad search terms to maximize findings. In addition, a sensitive search strategy in Medline (through OvidSP) was performed using the combination: interview*[Title/Abstract] OR interviews[MeSH:noexp] OR experience*[Text Word] OR qualitative[Title/Abstract] AND low back pain[MeSH:noexp]. Titles were screened and abstracts were read where appropriate. Cross-referencing of relevant articles was undertaken simultaneously.

Inclusion Criteria

Studies involving individuals with a diagnosis of CLBP defined as low-back pain (LBP) of duration ≥ 3 months, not attributed to pathologic entities such as

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infection, tumor, osteoporosis, inflammatory disorders, fractures, radicular syndrome, or cauda equina syndrome¹⁵ were included in this review. Where the diagnosis of nonspecific was not clear, but no specific causes of LBP were reported by the authors, studies were included. This is justified by evidence that 85% to 90% of LBP patients are diagnosed with nonspecific LBP.16 Studies involving individuals aging from 18 to 65 years were included to capture the chronic pain experience of working aged adults, which may differ from that of older adults in whom age-associated expectations and anticipation of declining physical health may moderate the pain experience. 17,18 Studies that included perspectives from the individual with CLBP in addition to other parties (such as partners and HCPs) were included, where the findings from the individual were clearly separated. Studies needed to meet the criteria of "qualitative research," that is, the findings represented some degree of transformation of data, that is, interpretation, rather than remaining as rewordings or summaries of participants' voices. 19 Studies reported in English, French, and Spanish were eligible for inclusion, consistent with the language capacities of the authors and available resources.

Assessment of Trustworthiness

Trustworthiness in this metasynthesis is defined as the degree of confidence that the results and conclusions of a study are based on sound methodological processes. However, as a lack of consensus exists with regard to criteria for the judgment of trustworthiness in qualitative research, 6 no study was excluded from this synthesis on this basis. Where concern over aspects of trustworthiness existed, this was documented and considered in the discussion of findings.

Trustworthiness criteria were adapted from Popay et al.²⁰ As in Sim and Madden's²¹ qualitative metasynthesis of the experience of fibromyalgia syndrome, these criterion were selected as they were considered the most applicable across a spectrum of methods and epistemological stances.

- A focus on, and privileging of, the subjective experience of CLBP.
- (2) Use of methods that are intrinsically adaptive and/or adaptiveness in choice or sequencing of stages in the research process. Adaptive refers to the responsiveness of the research design to the real life social contexts encountered during the course of the study.²¹
- (3) Choice of informants whose knowledge or experience is relevant to the substantive focus and theoretical framework of the study.
- (4) Appropriate presentation of primary data and description of context.
- (5) Consideration of >1 perspective on the topic of inquiry, including a reflexive concern for the researchers' standpoint, that is, consideration of how the professional background, beliefs, and attitudes of the researchers have shaped the study's methodology, analysis, and interpretation.
- (6) Evidence of analysis and interpretation of data at a conceptual and theoretical level.
- (7) Findings are related to broader theoretical concerns and/or other empirical contexts.

Data Analysis

Data extraction was performed using a purposedesigned form. Extracted data consisted of a description of the participants, description of the setting, the aims of the study, the research disciplines of the authors, the methodological approach, data collection methods, fulfillment of trustworthiness criteria, and extracted findings (Table 1). Extracted findings were separated from presentations of data used to provide evidence for findings, for example, quotations; imported findings from other studies referred to by the authors, and the researchers' discussions of the meaning or significance of their findings.⁶

Synthesis of Studies

The analytic process was adapted from Sandelowski and Barroso.⁶ It involved the following 3 stages.

- (1) Extraction of findings and coding of findings for each article.
- (2) Grouping of findings (codes) according to their topical similarity to determine if findings confirm, extend, or refute each other.
- (3) Abstraction of findings—analyzing the grouped findings to identify additional patterns, overlaps, comparisons, and redundancies to form a set of concise statements, which capture the content of all findings.

These 3 stages were not performed sequentially but rather simultaneously. Through a process of constant comparative analysis,⁴⁷ emerging groupings from early codings were checked with ongoing coding and used to guide later coding. Emerging abstraction was checked for suitability of fit with groupings and through theoretical sampling. Theoretical sampling involved the selection of 2 articles from an earlier date of publication^{23,24} to see if and how changes in contemporary chronic pain models influenced the experience of CLBP or interpretation of the experience.

Consideration of Metasynthesis' Trustworthiness

The authors of this review are clinical and research physiotherapists and a clinical psychologist. Their research and clinical interests lie in the implementation of biopsychosocial models of pain management. This metasynthesis draws on the literature review work of the first authors' (S.B.) doctoral studies. The search strategy was performed twice by the first author (S.B.). Two authors (S.B. and A.S.) independently assessed retrieved titles and abstracts against the inclusion criteria.

The coding, grouping, and abstraction process was performed by the first author (S.B.). A subset of articles was randomly selected for cross-coding by another author (R.W.), who performed a second-level grouping and thematic description on the subset while remaining blinded to the results of the metasynthesis. No discrepancies were identified in this process, strengthening the claim that the findings of this metasynthesis are based on the primary data.

The abstraction process was presented by S.B. (a physiotherapist) to the other authors (research and clinical physiotherapists and a clinical psychologist) to prompt discussion/debate about the suitability of fit of the final model to the early codes/grouping. Any disagreement was resolved by discussion and consensus agreement among the 5 authors.

RESULTS

A total of 871 articles were scanned in the databases. Seventy articles were retrieved, of which 46 did not meet the inclusion criteria. One article was identified through cross-referencing. Twenty-five articles were included representing

TABLE 1. Description of Included Studies

References	No. Participants	Female	Age (y)	Duration	Employment	Setting	Methodology	Research Discipline	Data Source	Unfulfilled Trustworthiness Criteria
Ashby et al ²²	11	0	23-59	> 8 mo	Unemployed	Australia work hardening program	Thematic analysis embedded in ethnographic study	Occupational therapy	Individual semistructured interviews and participant observation	Category 5
Bowman ²³ Bowman ²⁴	15	40	Unknown	> 6 mo	Mixed	US pain clinic	Phenomenology	Nursing	Indepth interviews	Category 4 Category 5 Category 4 Category 5
Busch ²⁵	30	Unknown	26-59	> 3 mo	Employed	Swedish pain clinic	Grounded theory	Physiotherapy	Semistructured interviews	category 5
Campbell and Guy ²⁶	16	Unknown	34-78	> 1 y	Unknown	Secondary care UK	Thematic analysis	Unknown clinician in pain clinic	2x focus groups meeting 4 times each	
Coole et al ²⁷	25	52	22-58	3 mo-35 y	Employed	UK pain clinic	Thematic analysis	Unknown clinician in	Semistructured interviews	Category 5
Corbett et al ²⁸	6	50	19-59	> 3 mo	Unknown	UK community	Thematic analysis	pain clinic Physiotherapy	Semistructured interviews	
Crowe et al. ²⁹	64	48	25-80	> 12 wk	Unknown	Community	Inductive thematic analysis	Nursing/ physiotherapy	Semistructured interviews	Category 5
de Souza and Frank ³⁰ ; de Souza and Frank ³¹	11	55	27-79	> 6 mo	5 unemployed 1 retired	UK rheumatology clinic	Framework approach using thematic content analysis	Physiotherapy		Category 5 Category 5
Holloway et al ³² ; Holloway et al ³³ ; Walker et al ³⁴ ; Walker	20	40	28-80	2-52 y	1 participant employed	UK pain clinic	IPA	Health psychology, nursing	Indepth unstructured interviews	Category 5 Category 4 Category 5
et al ³⁵ May et al ³⁶	12	50	20-55	> 1 y	Unemployed	UK pain clinic	Content analysis	Unknown	Semistructured interviews	Category 5 Category 4
Osborne and Smith ³⁷ ; Osborne and Smith ³⁸ ; Smith and Osborne ³⁹	6	30	36-52	5-15 y	Unemployed	UK pain clinic	IPA	Psychology	Semistructured interviews	Category 4
Raak and Wahren ⁴⁰	10	67	Working age	> 13 mo	Unknown	Sweden community	Content analysis	Nursing	Indepth interviews	
Satink et al ⁴¹	7	57	42-70	10-29 y	Unemployed	The Netherlands pain clinic	Narrative approach	Occupational therapy	Semistructured interviews	
Snelgrove and Liossi ⁴²	10	70	39-66	> 4 y	Unknown	UK pain clinic	IPA	Nursing/ psychology	Semistructured interviews	Category 5
Strunin and Boden ⁴³	414	Unknown	age	Unknown Described as "chronic" verage of 22 wk	Unknown	US community	Ethnography	Medical anthropology	Semistructured phone interviews	
Toye and Barker ⁴⁴	20	65	29-67	off work "Persistent" pain, involved in treatment over several months to years	Mixed	UK pain clinic	Grounded theory	Physiotherapy	Semistructured interviews	
White and Siebold ⁴⁵	5	100	32-44	> 6 mo	Unknown	Community Australia	Narrative autoethnography	Nursing	Open-ended interviews	
Young et al ⁴⁶	31	45	20-65	"Time off work for LBP in last year" Demographic data describe long history over several years	Mixed	Community Canada	Phenomenology	Health science		

IPA indicates interpretative phenomenological approach; LBP, low-back pain; US, United States; UK, United Kingdom.

18 studies (Fig. 1). Four articles from 3 studies included participants aged older than 65 years. The study by Holloway and colleagues^{32–35} separated findings from the 2 participants aged older than 65 that were included in their study. The large study by Crowe et al²⁹ included 64 individuals aged 18 to 80 and, although no information is given regarding the number of individuals aged older than 65, the findings are consistent with the CLBP experience of working age adults in the other studies included in this metasynthesis and therefore the article was included, as were 2 other studies. ^{26,30,31} Studies exploring the treatment experiences of people with CLBP were not included in this metasynthesis where the objectives were to improve treatment programs rather than understand the CLBP experience itself. Likewise, studies exploring the workplace experiences of people with CLBP were not included where the purpose was to, for example, identify workplace challenges and barriers to return to work rather than understand the CLBP experience.

A summary of the included studies are presented in Table 1. The 25 included articles were published between 1991 and 2011. All studies took place in western countries, primarily in the pain clinic setting, ^{26,22–27,30–39,41,42,44} with 6 taking place in the community. ^{28,29,40,43,45,46} A total of 713 participants were involved in the 18 studies (Table 1).

Criterion of trustworthiness are presented for the readers to consider (Table 1). Twelve articles failed to fulfill all trustworthiness criterion. Eleven articles failed to fulfill Category 5^{22–24,27,29–31,33,35,36,42} and 4 failed to fulfill Category 4.^{23,24,34,36}

Initial coding of included studies resulted in 27 codes, which were reduced to 11 categories and finally arranged into 3 themes (Tables 2 and 3). These themes were: CLBP as a socially mediated experience; the psychosocial impact of the nature of CLBP; and coping with CLBP.

Although no refutations of findings were found, the findings from 1 study included in this metasynthesis require extra consideration. Bowman²⁴ found that participants attributed other physical symptoms to their CLBP such as nausea and faintness. Although this finding was not replicated by any other studies, it is noted that our contemporary understanding of the physiological effects of stress and anxiety has advanced considerably since 1991 and thus the authors of this synthesis justify the inclusion of this finding into the theme "Psychosocial impact of pain."

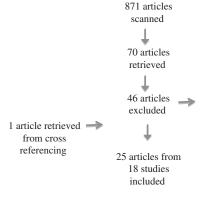
Findings

The Social Construction of CLBP

Participants in the studies held biomedical beliefs about their back pain. A biomedical explanation for the CLBP was critical for an individual to establish their pain as being a legitimate disability, which could then receive the support of the family, workplace, and welfare agencies. ²⁶–²⁸,³²–³⁴,³⁶,³⁷,⁴⁰,⁴²,⁴⁴ The lack of a satisfactory etiological explanation for their "invisible" pain meant participants in many studies felt at risk of not being believed. 23,24,26,32–34,37,42,44 Without a valid explanation for their pain, the participants' belief in the linear diagnosistreatment-cure model was shaken, fueling feelings of anxiety in the face of an uncertain future. 25-28,32,42,46 "Health where participants sought opinions from a range of different health professionals in the hope of finding a satisfactory etiological explanation, was a commonly employed practice among participants in the included studies. 25,26,32,34,46 The participants' experience in the health care system was repeatedly described with feelings of anger and frustration towards professionals who could not fulfill expectations of a diagnosis-treatment-cure pathway. 26,28,32,34,42,44, However, despite disenchantment with the medical system, it seemed that individuals maintained "hope" that advancements in medical technology would mean a diagnosis could be found and their pain subsequently resolved. 25,26,28,34,36,41,42

Iatrogenic distress was described in several studies. Walker et al³⁴ found that the biomedical model adopted by the participants' doctors encouraged passivity and avoidance. They claimed that the medical system encouraged participants to seek a nonexistent cure. Corbett et al²⁸ also found that the participants' doctors painted a bleak future, leading to participant anxiety, pessimism, hypervigilence, and hopelessness. Holloway et al³³ found that age-related explanations intended by doctors to legitimize pain or support the benign nature of their CLBP were interpreted by participants as implying progressive deterioration of their condition and conferring stigma of the aging body. Ashby et al²² reported that participants' erroneous biophysical interpretations of their pain acquired from HCPs lead to fear of movement and subsequent avoidance behavior.

Stigmatization of CLBP was a theme in almost all included studies. The role of the media was highlighted as



Reasons for Exclusion:
Other chronic pain conditions included
(n=13)
Not nonspecific LBP (n=1)
Not chronic LBP (n=9)
Not only from perspective of person with
CLBP (n=6)
Did not meet criteria of qualitative research
(n=1)
Individuals aged<18 included (n=1)
Focus on treatment experience not on pain
experience (n=8)
Focus on return to work/workplace

FIGURE 1. Flow chart of study identification. LBP indicates low-back pain.

TARLE 2 Identification of Themes From Initial Coding

Themes		Categories	Codes
CLBP as a socially mediated experience	CLBP as a socially mediated experience	Stigma	Stigma; biomedical model pain; not being believed; psychogenic pain
•	-	Experience with health system	Experience with health system; health shopping; iatrogenic distress; hope
		Establishing credibility	Establishing credibility; social comparisons; pain behaviors; concealing pain
The psychosocial impact of the nature of CLBP	The nature of pain	Omnipresence of pain	Omnipresence of pain
		Fluctuating/ unpredictable	Fluctuating/ unpredictable pain
	Effect of pain	Life disruption	Disrupted curriculum vitae; disrupted activities of daily living change in social roles
		Psychological	Fear for job; fear for future; effect of psychosocial factors; changing self; psychological effects of pain
		Other physical symptoms	Other physical symptoms
Coping with CLBP	Coping	Acceptance	Acceptance
		Coping strategies	Coping strategies; hypervigilance; social withdrawal

CLBP indicates chronic nonspecific low-back pain.

painting an image of people with CLBP as fraudulents seeking secondary gains.^{33,45} Participants felt that society viewed people with CLBP as burdens, without value or virtue and thus threatening social order. 32,33,39 HCPs were identified as painting an image of the demanding, difficult, and drug-seeking CLBP patient. ⁴⁵ Any inference by HCPs of the pain being psychological in origin was felt by participants in several studies to be labeled with the stigma of questionable integrity. 34,36,37,46 In the workplace, some studies commented that participants felt employers viewed them as lazy, unreliable, and undesirable employees thus leading to the dilemma of disclosure and its impact on sickness records and job security. 24,27,32,34,35,46

Strategies to gain credibility. Feeling the validity of their pain experience being doubted by others, participants felt the need to establish themselves as credible characters. Some studies found that participants took care to portray themselves as virtuous, moral, and previously active people who were in no way culpable for their pain, which they invariably attributed to an underlying pathology^{36,42,44} or even to the fault of others. ^{26,34} Studies found that participants felt the need to justify their pain was real and not

TABLE 3. Example Extract From Within the Category: Stigma

	Biomedical Model	
References	of Pain	Not Being Believed
Toye and Barker ⁴⁴	Diagnosis important to have a legitimate reason for the pain	Not believed by HCP, friends, family, or colleagues
	Diagnosis so others can believe them	Invisibility of condition challenges credibility
	Want a positive test result although they acknowledge this is counter-intuitive—why be disappointed with a result showing there is nothing wrong?	Back pain is common and varies greatly in severity, therefore it is difficult to appear genuine
	Insistent on getting a scan. Shocked, disappointed when nothing is wrong	Cultural stereotypes of someone with unexplained back pain
Snelgrove and	Psychosocial explanations from doctor contradict attempts to establish legitimacy Participants concerned to express pain as biomechanical in origin and because of no fault of their own	Invisibility of condition
Liossi ⁴²	Sensory, biological core of pain emphasized rather than affective response to it	Uncertain etiology and prognosis mean problems maintaining integrity
	The participants biomedical understanding of pain made failings of HCP difficult to understand	Not being believed
	Still adhered to medical model of understanding despite disenchantment with medical system	
Coole et al ²⁷	Physically centered coping strategies—avoidance, positioning Keen to justify symptoms by acceptable biomedical explanations backed up by investigations	Afraid of not being believed
	Uncertainty among participants as to cause Developed own explanations for their pain—wear and tear, degeneration, arthritis, history of heavy work, and age	

HCP indicates health care professionals.

psychogenic in origin.^{35–37} One study commented on the late sequencing of emotional responses to pain during interviews, only divulging such information after they had established themselves as credible people.⁴²

A recurrent theme in the included studies was the importance of the outward appearance of pain in establishing and maintaining the credibility of their CLBP. ^{24,27,33–35,37,44,45} The consistency or persistence of pain behaviors was considered important in judging if the pain was genuine or not, however, this proved difficult in light of the fluctuating nature of pain. ^{27,44} Appearing healthy or mobile while remaining in pain was to risk "being branded a fake" and therefore participants felt obliged to appear ill and disabled. ³⁷ Several studies, however, highlighted a dilemma for participants who felt they needed to negotiate not looking too ill but ill enough. ^{27,37,44,45} Thus, excessive overt distress was also seen to threaten their credibility and participants in some studies concealed their pain to avoid appearing like "that type of person (with CLBP)." In several studies, this dilemma was overcome by social withdrawal, thus avoiding the scrutiny of others. ^{23,32,33,37,39,41}

Comparison of the self with others with chronic pain was identified in several studies as a strategy to gain credibility. ^{23,35,37,39,44} The existence of other people with chronic pain gave an element of legitimacy to their experience. Comparison of their situation to that of others allowed participants to "rank" their level of disability or loss. In 1 study, participants found it important to their credibility that they distinguish themselves from the typical chronic pain "malingerer." ⁴⁴

Psychosocial Impact of the Unpredictable, Omnipresent Nature of Pain

The nature of pain. In the studies reviewed, pain was described as omnipresent, salient, and characterized by unpredictable fluctuations in intensity during both waking and sleeping hours. Osborn and Smith³⁸ describe the ability of pain to disrupt even the smallest and most mundane activities of daily living: "These activities had now to be done carefully, effortfully, and with forethought and in some cases had gone from being unconscious and thoughtless to planned, fearful ,and threatening" (p. 220). Two studies describe lack of sleep and disrupted sleep as a consequence of pain. ^{30,40} Studies commented on the uncertainty associated with the fluctuating nature of pain, which posed challenges to coping on a daily basis and making plans for the future. ^{28,29,40,42,46} This had a significant impact on daily functioning particularly in the workplace and family context.

In the workplace, recurrent flare-ups disrupted the consistency of work ability. The struggle to retain work was described in several studies with participants expressing fear about job loss and future financial insecurity. 22,24–29,31,32,34

Studies widely reported changing roles within the family context. ²²⁻²⁴, ^{28,31-33,35,37,39,41-43,45} Unreciprocated dependency on family members associated with feelings of helplessness was described in several studies. ^{23,26,30-32,35,43,45} Loss of the conjugal relationship and marital strain and breakdown were identified. ^{23,35,43,45}

The nature of pain and its effect on social functioning had significant psychological consequences. Studies described participants experiencing disbelief at why they were suffering, prompting feelings of frustration, anger, guilt, and despair. 24,25,29,31,32,37,42 Negative emotions in response to pain were felt to be so strong that they became directed outwards at others, with participants in several studies describing themselves as "short tempered." 23,26,35,39,42,43 Corbett et al²⁸ found that the psychological aspects of back pain were inextricably linked to the physical side with fluctuations in pain directly related to fluctuations between hope and despair. Anxiety and distress, in light of an uncertain future, were widely described by study participants. 24-26,28,29,35,41,46 These changes in attitude and mood were reported to result in feelings of depression. 23-25,32,42,43

The changing sense of self. The psychological effects of pain amounted to an "assault on the self." Many included studies described a dichotomy between the past and present self, the ideal and perceived self. 29,32,33,35,37–39,42–44 Perceived changes in identity resulted in feelings of self-denigration, self-loathing, and shame by participants in the studies. 25,37,39,42,43 One study involving highly disabled individuals found that the battle to retain the self was more distressing than pain itself. Many studies described a battle lost, where a new, altered identity emerged as a consequence of pain. 35,37,39,43,44 This new "me but not me" was met with feelings of distress and grief 37,39,44,46 and in 1 study, suicidal ideation. 43

Coping With CLBP

Strategies to control the omnipresent, unpredictable nature of pain reflected the biomedical belief systems held by the studies participants. Physically centered strategies were widely cited, the most common being hypervigilence to painful or threatening movements²⁴,29,38 and activity restriction or avoidance. ²³,25,28,30,45,46 Medication use to control pain was common, with participants in several studies highlighting concerns around dependency, side effects, and their impact on the "self." ²⁷,42,46

Strategies to control the "assault on the self" consistently included avoidance and withdrawal. Withdrawal from social contact to avoid "letting others down" and perceived stigmatization were widely employed despite participants acknowledging that isolation exacerbated feelings of depression. 22,23,25,31-33,35,37,41 Persistent strategies were also cited whereby participants exceeded their perceived functional capacities in an attempt to fight back against the pain. 23,25,28,31,39 Findings from several studies described participants partaking in a cost analysis or risk assessment where contextual demands influenced whether to engage in activities or not, with or without pain. 41,45,46

Acceptance. Although in many studies participants described a "battle" or "fight" to control the pain and the assault on the self, 24,38,39,41,44 participants also acknowledged the need to learn to live with the pain. 24,25,28,32,40,41,44 Participants in the study by Bowman²⁴ acknowledged the need to live with pain but expressed despair at the thought of pain always being present. In another study, participants highlighted difficulties in accepting pain when fluctuations in pain meant continuous adjustment had to be made, leaving them feeling insecure and uncertain. 32 Corbett et al²⁸ found that learning to live with the pain facilitated the turning point from a trajectory of despair to one of hope for the future.

DISCUSSION

This metasynthesis identified 3 major themes describing the CLBP experience: the social construction of CLBP; the psychosocial impact of the unpredictable and

omnipresent nature of pain; and the strategies employed to cope with the pain and protect against the "assault on the self." These themes are consistent with Bury's⁴⁸ notion of biographical disruption, which suggests that LBP is an experience in which the structures of everyday life and the belief upon which they rest are disrupted. Three main aspects of disruption have been described: the disruption of taken for granted assumptions and behaviors; the disruption of explanatory frameworks from an existential perspective; and the mobilization of resources to face their altered situation.

Although the notion of biographical disruption is a widely acknowledged description of the chronic illness experience and indeed 5 of the included studies cite it in their discussions, ^{28,35,38,39,44} it has also been argued that biographical disruption is a fact of life. Similar to life events such as divorce or retirement, self-redefinition and life restructuring have been reported with chronic illnesses such as human immunodeficiency virus or diabetes. ^{49,50}

Soklaridis et al⁴⁹ propose that biographical disruption in individuals with CLBP requires a different kind of self-restructuring because unlike experiences of loss or other chronic illnesses, there is the underlying hope that once the pain is gone, life can get back to normal. Indeed, the inability of individuals with CLBP to accommodate pain in their lives, to accept pain, and the tendency to regard the past self as the preferred self may represent a biography suspended in time.

CLBP Experience as Biographical Suspension

The experience of CLBP, a chronic illness of uncertain etiology, may be conceptualized as biographical suspension. It may be argued that individuals with CLBP live a life "on hold," one in which the "pause" button has been pressed until such time as the "play" button will return them to their former, pain-free lives. Three main aspects of suspension are described as suspended "wellness", suspended self, and suspended future.

Suspended Wellness

The biopsychosocial model of CLBP conflicts with the biomedical beliefs individuals with CLBP hold. Glenton¹³ claims that whilst one is fighting to prove they are sick, they cannot get better. It is possible that until such time as legitimacy is established, lives are suspended in the chronic pain sick role, characterized by a constant and ongoing battle for legitimacy. Individuals with CLBP feel the credibility of their pain is judged on the consistency and persistence of observable pain behaviours and therefore appearing healthy or mobile whilst remaining in pain is to risk being branded "a fake." ^{37,44} Wellness is thus suspended until legitimacy is achieved.

Suspended Self

The psychological effects of the CLBP experience amount to an assault on the self. 39,51 The sense of "not being me" infers the existence of a former true self. Individuals engage in an "ongoing, futile battle to preserve the preillness identity." They maintain faith that the medical system will eventually fulfill their expectations of the diagnosis-treatment-cure pathway, thus the present self may be viewed as a temporary imposter and hope is maintained that one will eventually return to their former true self. This is consistent with self-pain-enmeshment theory, 53 which states that when pain elimination is the primary but

unobtainable goal in individuals with chronic pain, the movement towards future selves is blocked, leading to a sense of entrapment. 54

Suspended Future

Sociological research claims that individuals develop new projections of their future that correspond to their projected illness trajectory,⁵⁵ thus the ability to make future plans is likely to be contingent on a pain prognosis. The absence of an etiological explanation combined with the fluctuating nature of their pain mean individuals with CLBP face an uncertain illness trajectory. This uncertainty affects short-term, mid-term, and long-term planning with consequences for social and occupational activities. Individuals with CLBP engage in a day by day battle to control their pain and suspend future plans until such time as they may receive a viable prognosis and with it, a tangible future.

Clinical Implications

A substantial body of evidence suggests that a discord exists between biomedical paradigms and the lived experience of CLBP. 12-14 To improve outcomes and patient satisfaction, it is important for patients and clinicians to cocreate a shared narrative around CLBP. Conceptualizing the CLBP experience as biographical suspension may facilitate this.

At the core of biographical suspension in CLBP is diagnostic uncertainty. Biomedical beliefs about CLBP appear deep rooted in western society and difficult to change.³ It is therefore important that patients receive a diagnostic explanation for their pain, which is acceptable to them, providing them with the legitimacy they are seeking.⁵⁶ This legitimacy may remove the need for pain behaviors thus permitting the pathway to wellness. Butler and Moseley's⁵⁷ "Explain Pain" paradigm, for example, may provide patients with a valid physiological explanation for their pain and has been shown to have positive effects on outcome measures in CLBP.⁵⁸

Two important elements of biographical suspension, the reluctance to concede a biomedical explanation for pain, and the battle to preserve the preillness identity have also been identified as important to the construct of acceptance in chronic pain research.⁵⁹ Similar to Toye and Barker,44 we emphasize that acceptance does not imply "resignation or quitting," rather it seems that an individuals' acceptance of a credible explanation for their pain and the acceptance of a new identity are essential in enabling individuals to engage in meaningful life activities both in the present and future despite pain. A recent review has found some evidence that acceptance-based interventions may be of benefit for people with chronic pain, although reported effects are small and based on few high-quality studies. 60 Future research is needed to determine the role that acceptance-based interventions may play in the management of CLBP. 60,61 In particular, it remains to be seen how distinct and effective these so-called third-wave psychological interventions are compared with more established psychological treatments such as cognitive-behavioral therapy, which has a much greater body of evidence suggesting positive effects on pain, disability, and mood, albeit with similarly small effect sizes. ⁶²

Design Considerations

This qualitative metasynthesis has roots in subtle realism, which argues that although qualitative research involves subjective perceptions, there is some underlying reality that may be studied.⁶³ The authors acknowledge the emphasis qualitative investigation places on idiographic knowledge and the complexities and contradictions of individual experiences that appear resistant to "summing up."64 However, the authors also adhere to the opinion that qualitative health research involves the identification of patterns in experiences that can inform clinical practice⁶⁵ and therefore perceive qualitative metasynthesis to be "a cross-case generalization created from the generalizations made from and about individual cases."64 Richardson and Lindquist7 have made calls for qualitative metasynthesis to allow knowledge gained from individual qualitative studies to inform evidence-based medicine in physiotherapy practice. This present paper is among the first to answer their call. Although the findings of this metasynthesis are not novel, the synthesis of these findings and conceptualization of the CLBP experience as "biographical suspension" constitute a unique and important contribution to the clinical management of CLBP.

Trustworthiness was not considered in the inclusion criteria of this metasynthesis, however, it is important to consider that the 2 least fulfilled trustworthiness criteria were Categories 4 and 5, indicating that these studies could be at risk of overinterpreting their qualitative data. The repetition among findings, however (Table 4), lends support to the rigor of the articles included and limits the influence that this potential source of bias may have had on the results of this metasynthesis. In the interest of enhancing trustworthiness in future qualitative studies, authors are urged to (1) declare their standpoint to allow judgements to be made as to how these shape their study; and (2) present sufficient primary data, that is, quotes, to assure readers that study findings are grounded in the participants' voices.

The search strategy in this metasynthesis employed wide search terms to enable the maximum return of titles. However, multiple synonyms exist in the literature for "qualitative research," often involving methodologies such as "phenomenology," "narrative autoethnography." It is thus possible that relevant studies may have been missed. A saturation of themes was reached, however, with a striking repetition of findings among included studies (Table 4). As the data from all included studies was incorporated into the final model, it is considered unlikely that the inclusion of further

TABLE 4. Number of Contributing Statements and Articles to Grouped Codes

Grouped Codes	No. Contributing Statements	No. Contributing Articles
Psychological effects of pain	134	24
Stigma	96	21
Life disruption	60	20
Establishing credibility	55	17
Experience with health system	44	12
Coping strategies	36	18
Social withdrawal	18	11
Fluctuating/ unpredictable pain	16	9
Omnipresence of pain	12	8
Acceptance	11	7
Other physical symptoms	1	1

studies would impact on the results. This claim is supported by the theoretical sampling of 2 publications, which predated contemporary biopsychosocial models of pain.^{23,24}

The exclusion of 1 study requires further discussion. Lillrank¹⁴ conducted a narrative analysis of submissions for an autobiographic writing competition on CLBP. As the author has a sociology background, no medical professionals were involved in the recruitment process and some women report specific LBP diagnoses (tumor) this study was excluded from the metasynthesis. It is pertinent to note, however, that the search for diagnostic certainty detailed in this study lends compelling support to the synthesis findings.

The authors make no claim that the experience of CLBP as presented here is representative of all people with CLBP. The need for future research exploring the experience of CLBP in other age groups and societies is emphasized. However, some level of generalizability of the findings to other working aged adults with CLBP in western societies is supported by: (1) empirical studies in CLBP in which higher pain acceptance and feelings of life control are associated with reduced disability and "future-directed orientations in life" 18,66; (2) strong commonalities among the findings of included studies; and (3) resonation of the synthesis' findings and interpretation with claims from experts in this field of research. 67-70

Future Research

Although this synthesis has highlighted the strength of evidence among qualitative studies exploring the CLBP experience in working aged adults in western societies, it has also highlighted the gaps in our current understanding of the CLBP experience. In addition to future research involving patients from other age groups and societies, we also identify a need for future longitudinal qualitative studies that will allow for a better understanding of the relationship between time and the CLBP experience.

CONCLUSIONS

A deeper contextual understanding of the individuals' pain experience as provided by qualitative research is of fundamental importance in evidence-based health care. This metasynthesis of qualitative studies identified 3 themes describing the CLBP experience: the social construction of CLBP; the psychosocial impact of the nature of CLBP; and coping with CLBP. Interpretation of these findings resulted in a novel theory of biographical suspension in which suspended wellness, suspended self and suspended future represent "lives on hold" for individuals with CLBP.

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Updated review of qualitative literature

Since the literature search performed in Bunzli et al. (2013) was completed, other studies that might be relevant to this review may have been published. The search strategy from Bunzli et al. (2013) was therefore repeated in January 2015 (see Figure 3.1). Six further articles from four studies met the inclusion criteria for the review. A description of these studies and findings from these articles are presented in Tables 3.1 and 3.2 and are considered in the discussion below.

Figure 3.1. Flow chart of study identification in updated search

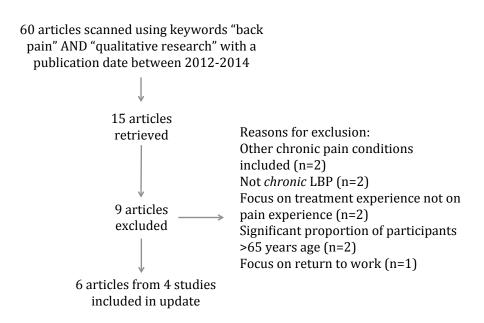


Table 3.1. Description of studies included in updated synthesis

Reference	Number	Female (%)	Age (years)	Duration	Employment	Setting	Methodology	Research discipline	Data source
Darlow et al. 2013	11	64%	25-67	>3 months	9 working, 1 retired, 1 sick benefit	New Zealand primary care	Interpretive Description	Physiotherapy	Semi structured interviews
Lin et al. 2012	22	70176	64 96	54+40 m 6 ×	Mirrod	Regional and remote	Clinical	Dhymiothomaxy	Semi structured
Lin et al. 2013	76	24%	77-07	SIIIOIIII CA	nayen	Australian communities	ethnography	rnysiotnerapy	interviews using 'yarning'
Snelgrove & Liossi 2013	10	20	39-66	>4 years	Unknown	United Kingdom pain clinic	Interpretive Phenomenol- ogical Analysis	Nursing/ psychology	Semi structured interviews 3 times over 2 years
Toye and Barker 2012a Toye and Barker 2012b	. 20	65%	29-67	'Persistent LBP'	Mixed	United Kingdom pain clinic	Grounded theory	Physiotherapy	Semi structured interviews 3 times over 1

Table 3.2. Findings of studies included in updated synthesis

Reference	Key findings
Darlow et al. 2013	 Biomedical, structural beliefs influenced by observing others with back pain but mostly by encounters with HCPs. Participants changed behaviour as result of advice from HCPs to change posture or strengthen muscles. Resulted in hypervigilence, avoidance and feelings of frustration and guilt when these strategies didn't work
Lin et al. 2012	 Impact of pain on familial and societal roles Biomedical beliefs leading to fear of damaging spine, anger at stigmatization, frustration at lack diagnosis
Lin et al. 2013	 Biomedical, structural beliefs originating from encounters with HCPs Pessimistic expectations for future associated with structural beliefs and diagnostic uncertainty
Snelgrove & Liossi 2013	- At follow-up, "windows of opportunity" following treatment that improved pain levels. Reduced pain levels enabled participants to reengage with core selves and hope for future without pain
Toye and Barker 2012a	 Biomedical beliefs Iatrogenic distress through lack of validation, conflicting diagnoses Perceptions of stigmatization by general practitioners
Toye and Barker 2012b	 Restoring hope through changing beliefs, deconstructing fear and accepting new self Replacing biomedical beliefs with new explanatory model of pain: "bringing my body back into balance Deconstructing fear of movement through communication with PT and exposure to feared movement Making acceptable changes to self in terms of activity levels

Discussion of synthesis findings

The findings of this synthesis are supported by the publication of two other qualitative syntheses exploring the experience of CNSLBP published since Bunzli et al. (2013). A synthesis by MacNeela et al. (2015) included 38 articles from 28 studies without excluding studies on the basis of participants' age. Four themes related to the subjective experience of CNSLBP were identified: the undermining influence of pain; its disempowering impact on all levels; unsatisfying relationships with HCPs; and learning to live with the pain. A synthesis by Snelgrove and Liossi (2013) included 33 articles from 28 studies, also without excluding studies on the basis of participants' age. Three themes were identified: the impact of CNSLBP on 'self'; relationships with HCPs and family; and coping with CNSLBP. Consistent with Bunzli et al. (2013), the discussion of both these syntheses highlight the discordance between HCPs attitudes and patients experiences and suggest that improved communication between HCPs and patients is necessary to reduce distress associated with the CNSLBP experience.

In all studies included in this synthesis, the CNSLBP experienced was predominantly lived through the lens of biomedical beliefs about pain. Whilst none of the included studies specifically aimed to explore the experience of pain-related fear, descriptions of fear and anxiety were salient in all studies. Beliefs in the structural vulnerability of the spine and fear avoidance beliefs that painful activities and postures should be avoided were commonly reported in the included studies.

One study identified in the updated search explored the formation of beliefs held by people with acute and chronic LBP (Darlow et al. 2013). Darlow et al. (2013) described how fear avoidance beliefs amongst the participants were influenced by explicit advice from HCPs to avoid certain movements. The study also suggested that fear avoidance beliefs were influenced by the treatment approaches HCPs selected such as strengthening exercises to 'protect' the 'vulnerable' spine.

The finding that biomedical beliefs, particularly beliefs related to pain as a sign of damage, play a role in the experience of fear and anxiety in LBP is not new. However the suggestion that HCPs may play a role in the formation of fear avoidance beliefs is a valuable finding supporting suggestions of causality that have been implied in cross sectional studies employing self-report measures to explore associations between the beliefs of HCP and their patients (Darlow et al. 2012). The studies included in this review did not specifically recruit participants with high pain-related fear and it remains unknown how transferable the findings are to the population of individuals with CNSLBP and high fear. In addition, as the included studies did not aim to explore the factors contributing to pain-related fear, it is unlikely that this theme was explored to saturation. It remains unknown whether other factors contributing to pain-related fear may also be identified in future qualitative studies.

Only one study, included in the updated search, identified factors that may be associated with changes in fear. Toye and Barker (2012) explored the factors contributing to positive outcome following a biopsychosocial intervention for CNSLBP in a study that followed on from a baseline study investigating the experience of CNSLBP in the same sample (Toye and Barker 2010). The authors identified 'restoring hope' as the central ingredient for positive outcome at follow-up. Contributing to the restoration of hope, was a reduction in fear of damage achieved through good communication with the physiotherapist and challenging negative expectations through exposure to feared movements.

That exposure to feared movements may result in reductions in fear is well established and whilst education plays an important role in exposure based interventions (de Jong et al. 2005), the suggestion that good communication on behalf of the HCP is necessary in order to encourage confrontation of feared movements has not been made explicit in intervention studies involving exposure based treatments. However it is unknown how representative these findings are to the population of individuals with CNSLBP and high pain-related fear at baseline. Toye and Barker (2012, 2010) did not include a quantitative measure of fear in the descriptive data at baseline and fear was not identified as a salient theme in the baseline findings. Further, Toye and Barker did not aim to

explore the factors contributing to changes in fear in detail and therefore it is possible that other factors may also be identified in future qualitative studies exploring changes in pain-related fear.

In summary, the findings of this synthesis highlight the salience of biomedical beliefs as well as diagnostic and prognostic uncertainty in the lived experience of CNSLBP. However the findings provide limited insights into the potential factors contributing to fear and change in fear from the perspective of people with CNSLBP and high pain-related fear. In addition to highlighting gaps in the qualitative literature, the findings of this synthesis helped inform the interview schedule used in the subsequent stages of this research, as outlined in the following chapter.

Chapter 4. Methodology

Research questions

To fill gaps identified in the literature and inform future iterations of the FAM, the following research questions were investigated:

- 1. What are the beliefs underlying pain-related fear in people with CNSLBP?
- 2. What factors contribute to these beliefs?
- 3. How does pain-related fear change over time?
- 4. What factors are associated with improvements in fear?

Approach

To investigate these questions, a prospective qualitative study with a mixed-methods component was conducted.

Qualitative approach

A qualitative approach was selected in order to explore how individuals make sense of their own situation. This provided the opportunity to gain novel insights into the factors contributing to pain-related fear at baseline and improvements in pain-related fear at follow-up, rather than simply relying on the *a priori* selection of factors based on empirical research.

Previous qualitative studies exploring aspects of the LBP experience have used various methodological frameworks including Grounded Theory (Slade, Molloy, and Keating 2008), Phenomenology (Bowman 1994), Interpretive Phenomenological Analysis (Snelgrove and Liossi 2009) and Interpretive Description (Darlow et al. 2013). In selecting a methodological framework for this study, the aim of the research and the role of the researcher were considered (Table 4.1).

Table 4.1. Qualitative methodological frameworks compared

Methodological framework	Aim	Role of researcher
Grounded Theory (Glaser and Strauss 1967)	To understand a social process going on. To develop a substantive theory to explain social process	Researcher has knowledge, so will influence interpretation but tries to bracket knowledge to allow findings to emerge inductively. The researcher begins with no pre-existing theory or hypothesis or expectation of findings, the theory is grounded in data.
Phenomenology (Giorgi 1985)	To live in another persons shoe. To describe the essential elements of an experience, to give voice to the experience. Not aiming for generalisability	Researcher attempts to bracket all prior knowledge so not to influence explanation.
Interpretive Phenomen- ological Analysis (Smith and Osborn 2003)	Not to live in another persons shoes, but to take their side. Aims to capture and explore meanings of experiences of individuals in detail, not to generalize to larger populations	The researchers' own conceptions required to make sense of the other persons' world through interpretation.
Interpretive Description (Thorne, Reimer Kirkham, and MacDonald-Emes 1997)	To describe in detail a phenomena which extends current knowledge and has real clinical applications	Researcher has knowledge and will use this knowledge to design and conduct and interpret research.

The research questions were designed through the 'expert' lens of the doctoral candidate and the PhD supervisors to answer a clinical question with implications for clinical practice. The doctoral candidate is a Physiotherapist with ten years clinical experience in musculoskeletal physiotherapy, working with people with chronic pain. The PhD supervisors include clinical and research Physiotherapists and a Clinical Psychologist with clinical and research expertise in the management of CNSLBP. The standpoint of the researchers, as clinicians and researchers who wished to inform clinical practice, was considered unsuitable to grounded theory and phenomenology in which investigators "bracket", i.e. set aside, their pre-existing assumptions and beliefs. Whilst Interpretive Phenomenological Analysis does not necessarily involve "bracketing", it aims to gain a detailed phenomenological understanding of a small sample, rather than seeking to inform clinical practice. An Interpretive Description approach denotes an explicit role for the a priori beliefs of the researchers and aims to yield insights that may inform clinical practice (Thorne, Reimer Kirkham, and MacDonald-Emes 1997). Interpretive Description was therefore deemed to be the most suitable framework aligning with the aims of the study.

Interpretive Description has its groundings in subtle realism (Oliver 2012). The tenants of subtle realism are that there is some underlying reality that may be studied. The role of research, either qualitative or quantitative, is to attempt to represent that reality, not to imagine the existence of an attainable 'truth' (Blumer 1969). The logic of this approach is that a mixed-method design may "expand the scope of enquiry by accessing a wider range of data" (Cathain and Thomas 2006, p.102) to gain a richer, deeper understanding of that reality.

The mixed-method design of this study is consistent with the philosophy of the Interpretive Description framework whereby "a solid and substantive logic derived from the disciplinary orientation justifies the application of specific techniques and procedures outside of their conventional context" (Thorne 2008, p.35). In the clinical physiotherapy setting, the subjective assessment of patients in pain involves the convergence of interview findings with scores from relevant

self-report questionnaires. Thus the design of this study, involving both qualitative interviews and self-report questionnaires, has ecological validity.

The Interpretive Description framework acknowledges that the health researcher necessarily brings theoretical and practical knowledge to the study. This knowledge provides the theoretical scaffolding on which the researcher embarks on the research inquiry. The influence of *a priori* beliefs and assumptions of the researcher on the design and development of the research is visible. Thus the possibility of a relationship between qualitative and quantitative findings is proposed, whilst acknowledging that the potential findings from the qualitative component are unknown. It is possible that no patterns will be identified in the experience of pain-related fear and therefore analysis with quantitative findings will not be possible.

Interpretive Description also acknowledges that at the foundation of clinical knowledge is the recognition that health experiences are comprised of complex interactions between bio, psycho and social phenomena. Shared patterns of such experiences are at the core of clinical knowledge, whilst the application of clinical knowledge will be individualized for each patient (Thorne, Reimer Kirkham, and MacDonald-Emes 1997). In this context, Interpretive Description seeks to reveal shared patterns of experiences that have clinical application but "remain amenable to reconsideration in the light of varying contexts, new concepts, new ways of understanding, and new meanings" (Thorne, Reimer Kirkham, and MacDonald-Emes 1997, p.172).

Mixed-methods approach

Qualitative and quantitative data were collected at the same time in a concurrent, mixed-methods design (Driscoll et al. 2007).

The study of mediating factors in fear reduction is important as it provides knowledge of how treatment effects occur, however to date few studies have explored factors mediating LBP outcomes (Mansell, Kamper, and Kent 2013). The mixed-method design of this study expanded the scope of enquiry by enabling access to a wider range of data to facilitate a deeper understanding (Cathain and Thomas 2006). The inclusion of the quantitative component

served to 'triangulate' the qualitative findings, to ensure that the account was rich, robust and comprehensive (Patton 1999).

Trustworthiness considerations

By demonstrating the steps taken to arrive at the results, the trustworthiness of the study findings may be judged.

Whilst the design of this study was influenced by *a priori* knowledge, interpretations were the result of inductive analysis, rather than based on *a priori* hypotheses. Various strategies were employed to enable judgements to be made on the way that data was gathered and analysed, and to reassure that the interpretations were grounded in the data, as outlined below.

The doctoral candidate was trained in qualitative interviewing techniques and had the opportunity to apply these techniques in her role as a research assistant conducting qualitative phone interviews to explore the experiences of people with LBP accessing care in remote Australian communities (Briggs et al. 2012). This role enabled the doctoral candidate to cultivate interviewing skills prior to commencing data collection for her doctoral research.

To further cultivate the doctoral candidates' interview skills, all baseline transcripts were read by the PhD supervisors. This provided an opportunity for feedback on the interview style and content. At baseline a random sample of eight transcripts was selected and the four supervisors independently coded two transcripts each. Whilst cross-coding is not considered a pre-requisite for the rigour of a qualitative study (Charmaz 2006, Smith, Flowers, and Larkin 2009), comparisons between the coding performed by the doctoral candidate and the supervisors helped to reassure that early interpretations were based in the raw data. In addition, it enabled the doctoral candidate and supervisors to check on the reliability of the 'quantitization process' (Tashakkori and Teddlie 1998) which was performed in the mixed-methods analysis and involved the transformation of qualitative data into dichotomous variables based on the presence or absence of codes. At follow-up, a random sample of six follow-up transcripts was selected and three supervisors independently coded two each. The doctoral candidate and the PhD supervisors were satisfied that the

identification and interpretation of key extracts in the transcripts did not differ between the candidate and the supervisors, therefore no additional transcripts were cross-coded.

The use of a data sorting software helped establish an audit trail (Mays and Pope 2006). This data sorting software was purpose-designed by the doctoral candidate to facilitate discussion between the candidate and PhD supervisors through the sharing of a hyperlinked pdf file. Three levels of context were permitted through hyperlinks in the pdf file: the code, the extract, and the location of the extract in the original transcript. This facilitated the process of constant comparative analysis (cycling back and forth between emerging concepts and raw data), helping to ensure that the process of data reduction stayed true to the meanings as originally intended by the participants (Strauss and Corbin 1990). Further detail on the software is provided under the heading 'Qualitative data analysis'.

Theoretical sampling was employed by specifically seeking ambiguous or negative cases to test emerging patterns in the data (Draucker et al. 2007, Strauss and Corbin 1990). For example, during the process of data collection and early data analysis, in order to further explore the role that beliefs about the meaning of pain had on pain-related fear, two nurses and one physiotherapist with CNSLBP and high fear who might hold alternative pain beliefs due to a more detailed understanding of pain physiology, were recruited.

The prospective design of this study provided an opportunity for 'respondent validation' (Whittemore, Chase, and Mandle 2001). In the follow-up interviews, participants were asked to clarify or expand on findings from their baseline interviews where necessary. Participants were also asked to comment on emerging findings.

Supporting extracts from interviews are presented in the findings of Chapters five, six and seven to further ensure that the interpretations offered are supported by the data (Whittemore, Chase, and Mandle 2001).

Qualitative analysis of interview data was conducted before quantitative data analysis to further ensure that interpretations were grounded in the raw data.

Recruitment

The inclusion criteria for this study were:

- Age: working age individuals 18-65 years. This age bracket was chosen at
 it may be the population most responsive to intervention (Henschke et al.
 2010). This population was also chosen to minimize the potential
 involvement of important comorbidities that may accompany older age
 and interfere with the capture of information in this study.
- Diagnosis: A primary complaint of non-specific LBP defined as pain primarily localized below the lowest ribs and above the inferior gluteal folds for which no specific cause is detectable, such as infection, neoplasm, metastasis, osteoporosis, rheumatoid arthritis, fracture, inflammatory process, or radicular syndrome (van Tulder et al. 1997).
 - Duration and Intensity: ≥6 months duration with an average score of ≥3 on the Numerical Rating Scale (NRS) over the preceding three months.
 - Fear: A score of ≥40 on the Tampa Scale of Kinesiophobia (TSK) (Miller, Kori, and Todd 1991). This scale measures fear of movement/(re)injury construct but is also associated with general measures of fear, anxiety, depression, catastrophising, fear avoidance behaviour and work related disability compensation (Gauthier et al. 2006, Vlaeyen et al. 1995). A score of ≥40 is considered a clinically significant cutoff for fear of movement identified from the literature (Vlaeyen et al. 2012).
 - Language: Good understanding of written and spoken English.
 - Exclusion: Pregnancy and/or current acute episode of psychosis as diagnosed by a medical doctor.

Ethics approval was gained from three different Human Research Ethics Committees (see Appendices 5, 6 and 7) to recruit participants from a range of private and public clinics located in different sociodemographic regions in the Perth metropolitan area. These included private physiotherapy and chiropractic clinics, General Practice clinics, public physiotherapy outpatient clinics and multidisciplinary pain clinics. Participants were purposively sampled (Patton 1990) from a range of different clinical settings, from different geographical

areas and on gender. This ensured that individuals with a range of experiences of pain-related fear were included. Purposive sampling was facilitated by maintaining close contact with HCPs in the recruiting clinics. For example after approximately one third of the interviews had been conducted and analysed, the researchers decided that more male participants were required to ensure a more balanced representation of gender. At this time, HCPs were specifically asked to stop handing the study information sheets to female patients and only hand them to males who fit the inclusion criteria until the gender representation had been addressed. Throughout the data collection and analysis period, theoretical sampling was undertaken. Theoretical sampling is the process of data collection directed by emerging ideas and theories rather than by predetermined population characteristics (Strauss 1987). To do this, cases of ambiguity and negative cases were specifically sought (Glaser and Strauss 1967). An example is illustrated below under the heading 4: 'Identification of emerging themes'.

Participants were recruited between May 2012 and May 2013. Healthcare professionals identified potential candidates as instructed by the PhD candidate. Healthcare professionals handed potential candidates the study information sheet and an invitation together with a statement to the effect of: "Our clinic is involved in a research study being run through Curtin University involving people with chronic low back pain. You may be suitable to participate in this study. If you are interested in finding out what participation would involve, please contact the researchers as indicated on the invitation". The HCPs were instructed to in no way make the individual feel pressured to contact the researchers. It is unknown how many individuals were handed study invitations by the HCPs and thus the response rate is unknown. However as this study was not seeking generalizability, this was not considered important for the integrity of the study design. Recruitment continued until it was considered that subsequent interviews would not change the themes identified during the concurrent analysis of baseline data. Whilst thematic saturation for the prospective component of this study could not be foreseen, consideration was given to potential loss to follow-up by oversampling.

All individuals who met the inclusion criteria, contacted the researchers and gave verbal consent were invited to participate in an interview at a time and location convenient to them.

Data collection

Qualitative and quantitative data were collected at baseline and four month follow-up. Consistent with previous studies assessing mediators of change in chronic illness, a four-month follow-up time frame was chosen as this was considered to be a sufficient period of time for fear reduction to occur (Boersma et al. 2004, Woby, Watson, and Roach 2004).

Descriptive and demographic data was collected for each participant. This included pain duration, age, sex, marital status, occupation, employment status and compensation status. At follow-up information was also collected on the nature and duration of any interventions they had received during the study period.

Qualitative data collection

Semi-structured interviews were conducted in the participants' homes or a private meeting room at the School of Physiotherapy and Exercise Sciences, Curtin University. Phone interviews were conducted at baseline with two participants living in remote locations. The length of interviews between those conducted in person or over the phone did not differ. Interviews lasted between 45 -120 minutes at baseline, and 30 - 60 minutes at follow-up. Content analysis showed that the content of interviews conducted in person or over the phone was similar.

The semi-structured interview schedules at baseline and follow-up are detailed in Tables 4.2 and 4.3. The content of both interviews was informed by the findings from the qualitative synthesis presented in Chapter 3. For example, at baseline, questions were included to explore the participants' beliefs about the structural integrity of the spine and to explore what they had been told about

their LBP from any HCPs they had consulted. At follow-up, questions were included to explore the role of the therapeutic alliance and expectations related to their LBP.

At baseline, all interviews opened with the question: "Can you please tell me the story of your LBP?" This was intended to assist the participant to feel at ease and for the interviewer (the doctoral candidate) to gain a contextual understanding of the individuals' experience. At baseline, interviews with the first participants recruited were guided by opening questioning, whereas later interviews functioned to challenge emerging themes from concurrent data analysis and therefore involved more refined questioning. At follow-up, all interviews opened with the question: "Can you please tell me how you have been since we last spoke?" Subsequent questions exploring experiences at follow-up involved consideration of each individual's baseline findings.

At baseline and follow-up, interviews were flexible to explore new concepts as they arose.

Table 4.2. Baseline interview schedule

Research question	Themes to explore	Example interview questions
	Nature of pain	Can you put me in your shoes and tell me how your back pain feels?
	Impact of pain	How does your back pain affect your day to day life?
What does this	Pain behaviour	When you feel the pain in your back, what do you do? Why do you do this? How well do you think you can cope with the pain?
about their back	Pain beliefs	When you feel the pain in your back, what do you think it is telling you? Why do you think this?
	Back beliefs	What do you think the function of the spine is? Why? How is back pain different from other pain you have experienced in the past?
		How do you think your back pain will be in 6 months time? In 12 months time? In 10 years
	Expectations	time? Do you think your back pain will get better?
		What do you think it will take to get better?
	Experience of fear	Can you give me an example where you were afraid or worried about your pain? Why were you worried? What did you do? Why did you do this?
	Healthcare	What healthcare professionals have you seen for your back pain?
Why is this person	encounters	What have they told you about your back pain?
fearful?	Other societal	Where/who else do you turn to for advice on your back pain? Why?
	influences	Have you been around other people who have had back pain? How did they cope with their pain?
	Previous experiences	Can you tell me about any previous experiences of back pain you have had? How did your experiences then compare to your experience now?
	Vulnerabilities	Back pain can be a stressful experience. Can you please tell me how you cope with other
		stressful events in your life?

Table 4.3. Follow-up interview schedule

Research	Themes to	Example interview questions	
question	estion explore		
	Change in pain	How have you been since we last spoke?	
	experience	Would you describe your back pain experience as the	
		same, better or worse since we spoke? In what way? Why	
		do you think this?	
		How predictable is your pain now?	
		How much control do you feel you have over your pain	
		now?	
	Change in fear?	Last time you described being afraid or worried of (the	
		damaging or functional/suffering consequences) in x	
		situation. Have you found yourself in the same/a similar	
		situation since we last spoke?	
		What did you do? Why did you do this?	
		If you were presented with situation x now, do you think	
		you would be as afraid/worried, less afraid/worried or	
		more afraid/worried than when we last spoke? Why do	
Has this person		you think this? What do you think is the reason for any	
experienced an		change?	
improvement		When you feel the pain in your back now, what do you do?	
in fear?	D . 1 1 .	Why do you do this?	
	Pain behaviour	How well do you think you can cope with the pain now?	
Factoria		Do you think this is the same/better or worse than when	
Factors associated with		we last spoke? Why do you think this? When you feel the pain in your back now, what do you	
improvement	Pain beliefs	think it is telling you? Why do you think this?	
in fear		When we last spoke you mentioned that you were	
in lear	Back beliefs	uncertain about the cause of pain/ you thought that x was	
	Back beliefs	the cause of pain. Do you still think that?	
		How do you think your back pain will be in 6 months time?	
	Expectations	In 12 months time? In 10 years time?	
		Do you think your back pain will get better?	
		What do you think it will take to get better?	
	Treatment	Can you describe to me any treatment/management you	
	received	have received since we last spoke?	
		How often did you receive it?	
		Have you had any investigations on your back?	
		Are you still receiving treatment?	
		Do you think that the treatment has any effect? What?	
		Why do you think this?	
		Can you tell me about your interactions with the	
		clinician(s) you saw?	

Quantitative data collection

The week prior to the baseline and follow-up interviews, participants were sent a series of self-report questionnaires. They were asked to complete these and hand them or send them to the researchers in a sealed envelope at the time of the interview. Participants were advised that they could take breaks as often as they needed whilst completing the questionnaires. The researchers remained blinded to all questionnaire scores until after the completion of baseline and follow-up interview data analysis so as not to influence the analytic and interpretive process of qualitative analysis. One exception to this was scores on the Depression Anxiety Stress Scale (DASS) that were assessed at the time of the interview. It was a requirement stipulated by the ethics committees that reviewed this research (see Appendices 5, 6 and 7), that any participant scoring above cut-offs for moderate symptoms of depression would have a letter sent to their General Practitioner informing them of this finding. Therefore, potential participants were made aware of this referral process and were asked for consent to contact their General Practitioner in the case that they scored above the cut-off (see more under heading: 'DASS' below).

Potential constructs contributing to changes in fear were identified based on the FAM and a review of intervention studies involving individuals with CNSLBP and high pain-related fear (see Table 2.2). To assess these constructs, self-report questionnaires that had been validated for use in a CNSLBP or chronic pain population were selected. In accordance with ethical considerations, an effort was made to minimize participant burden by limiting the number of questionnaires included.

A measure of disability was not included in this study as disability was considered to be an outcome variable rather than a mediating variable for fear reduction (Leeuw et al. 2008, Kamper et al. 2012). A measure of pain intensity was included as there is evidence that changes in pain intensity contribute to changes in fear (Gheldof et al. 2010, Gay et al. 2015, Crombez, Viane, et al. 2012). Based on the studies described in Table 2.2, catastrophising, back pain beliefs, self efficacy beliefs and coping strategies were identified as potential

contributing factors to change in fear in this study as they are constructs targeted in fear reduction interventions. In addition, symptoms of depression, anxiety and stress in the past week and anxiety sensitivity were identified as potential contributing factors to change in fear. These symptoms reflect negative states that may influence fear reduction (Meulders, Meulders, and Vlaeyen 2014) and have shown to change through the course of fear reduction interventions for CNSLBP (Woby et al. 2008).

The eight self-report questionnaires selected were:

The Anxiety Sensitivity Index (ASI)

The ASI (Peterson and Reiss 1992) was included as anxiety sensitivity has been identified as a vulnerability factor for pain-related fear (Asmundson and Taylor 1996). It was used to assess changes in the individuals' fear of symptoms of anxiety. The psychometric properties of the ASI are sound and the ASI has been commonly used in pain research (Zvolensky et al. 2001, Ocanez, McHugh, and Otto 2010). The questionnaire consists of 16 items and individuals indicate their level of agreement on a 5-point scale (0= very little; 4 = very much). Higher scores reflect higher levels of anxiety sensitivity. No MCID has been established.

Back Beliefs Questionnaire (BBQ)

The BBQ (Symonds et al. 1996) was used to assess changes in the individuals' beliefs that pain has negative consequences on the structure and function of the spine. It has been shown to have good internal consistency and test-retest reliability in people with LBP (Symonds et al. 1996). The questionnaire consists of 14 statements that individuals indicate their level of agreement with on a five point scale (1=completely disagree; 5=completely agree). The scores of nine statements are reversed and summed for a total score ranging from 9-45 with higher scores reflecting more positive back beliefs. Buchbinder et al. (2001) found that a change of 1.9 was associated with a decreased rate of compensation claims following a mass media campaign targeting public LBP

beliefs. A change of two points is suggested to be clinically significant (Buchbinder, Jolley, and Wyatt 2001)

Coping Strategies Questionnaire (CSQ-24)

The CSQ-24 (Harland and Georgieff 2003) was used to assess change in positive thinking about pain and control over pain. The CSQ-24 has been found to be a reliable measure of coping in individuals with CNSLBP (Harland and Georgieff 2003, Harland and Martin 2014). The CSQ-24 consists of five subscales -Catastrophising, Reinterpreting, Diversion, Cognitive Coping and Control. Only the subscales Cognitive Coping and Control were selected for inclusion in the study, as a measure of Catastrophising was already included and there is evidence that the Reinterpreting and Diversion subscales may have poor construct validity (Harland and Georgieff 2003). The Cognitive Coping subscale (CSQ-CC) includes items such as "I see (the pain) as a challenge and don't let it bother me". Individuals are asked to indicate the frequency with which they employ the strategy on a seven point scale ranging from *Never do that* to *Always* do that yielding a total score ranging from 0-35. Higher scores reflect higher levels of cognitive coping, considered to be a positive strategy in the literature (Harland and Gerard Ryan 2013). The single item Control (CSQ-Control) may be a clinically useful indication of perceived control over pain (Harland and Georgieff 2003). Assessed on a seven point scale ranging from "No control" to "Complete control", it yields a total score ranging from 0-6. Higher scores reflect greater control over pain. Currently no MCID has been established for the CSQcontrol and CSQ-CC scales.

Depression Anxiety Stress Scale-21 item (DASS-21)

The DASS-21 (Lovibond and Lovibond 1995) was used to assess symptoms of depression, anxiety and stress in the past week. The DASS can be administered and scored by non-psychologists as part of the broader clinical assessment (www2.psy.unsw.edu.au/dadd/over.htm). The psychometric properties of the DASS-21 have been established (Antony et al. 1998) and it is valid for use in chronic pain populations (Wood et al. 2010). Participants are asked to rate the extent to which they have experienced symptoms in the past week on a scale of 0-3 of frequency/severity. Three scores are generated, one for each scale:

Depression, Anxiety and Stress. Individuals who scored above 14 on the Depression subscale of the DASS (moderate levels of depressive symptoms) had a letter sent to their General Practitioner informing them of this finding and recommending further assessment as they saw appropriate.

Numerical rating scale (NRS)

The NRS (Jensen and Karoly 1992) was used to assess change in pain intensity. The validity and sensitivity of the NRS have been established (Jensen and Karoly 1992). Participants were asked what their average pain intensity over the past week had been on a scale of 0-10 where 0 indicates "no pain" and 10 indicates "pain as bad as it could be". An MCID of two points on the NRS is recommended in the literature (Ostelo et al. 2008).

Pain Catastrophising Scale (PCS)

The PCS (Sullivan, Bishop, and Pivik 1995) was used to assess changes in negative cognitive-affective responses to pain. The PCS consists of 13 items which individuals are asked to indicate the frequency with which they experience thoughts or feelings on a five point scale (where 0=not at all and 4= all the time). The total score is derived from the sum of all 13 items, yielding a score from 0-52. The sum of items on the subscales rumination, magnification and helplessness may also be calculated. Higher scores on the PCS reflect higher levels of pain catastrophising The scale and subscales have been shown to have sufficient internal consistency and validity (Sullivan, Bishop, and Pivik 1995). Currently no MCID has been established for the PCS in people with chronic musculoskeletal pain.

Pain Self Efficacy Questionnaire (PSEQ)

The PSEQ (Nicholas 1989) was used to assess changes in the individual's belief that they had the tools to manage their pain and confidence in their ability to use these tools to control pain (Nicholas 1989). Scores range from 0 (low self-efficacy beliefs) to 60 (strong self-efficacy beliefs), with scores of >40 indicating a high confidence in ability to manage pain (Nicholas 2007). The PSEQ has been

found to be reliable and valid in people with CNSLBP (Nicholas 2007). An MCID of nine points on the PSEQ has been suggested (Maughan and Lewis 2010).

Tampa Scale of Kinesiophobia (TSK)

Quantitative change in fear was measured by the TSK (Miller, Kori, and Todd 1991). Participants are asked to what extent the agree with 17 items on four point Likert scale ranging from "strongly disagree" to "strongly agree". A total score is summed after reversing the scores of items 4, 8, 12 and 16. Higher scores reflect higher levels of pain-related fear. Whilst the TSK English version has received little psychometric scrutiny, the TSK Swedish and Dutch versions have been found to be reliable and valid in the CNSLBP population (Roelofs et al. 2004, Lundberg, Styf, and Carlsson 2004). An MCID of eight has been suggested in the literature (Lüning Bergsten et al. 2012).

Transcription

Having gained consent, interviews were recorded by a small voice recorder placed between the subject and the interviewer. Recorded interviews were transcribed by the doctoral candidate for several reasons:

- 1. It assisted the doctoral candidate to reflect on her own interviewing style
- 2. Having conducted the interviews the doctoral candidate had a deep understanding of the emotional aspects of the interview situation which could be reawakened in the transcription
- 3. It involved emersion in the raw data, enhancing familiarity. This facilitated early stage analysis of meaning
- 4. Transcribing each interview soon after having conducted it sped up the transcription process as the content remained fresh in mind

All participants were assigned a code to protect their identity. Audio recordings from the interviews were transcribed verbatim. Verbatim transcription was chosen to translate from oral to written language in order to allow for the richest representation of data. It allowed for meaning to be revealed not only in the spoken word but the way in which it is said. This assisted not only the doctoral candidate during data analysis but it also enabled the PhD supervisors

who were not present at the interviews and did not listen to audio data to have a deeper understanding of the interview. Following transcription, an attempt was made to formalise speech into grammatically correct sentences with full stops and comma's to make it easier for an audience to read and understand. Full stops were used where clear pauses in speech denote the end of one concept and start of a new.

Interviews were indexed via code and in instances where the interviewee referenced their own name, it was replaced by their code bracketed such as (010). Names of all other people, institutions and places were replaced with a capital letter.

Transcripts were typed using Microsoft Word.

Qualitative data analysis

A data sorting software was purpose-designed by the doctoral candidate and implemented by Pascal Buenzli (Buenzli 2012). Transcripts were uploaded into the software, and manual coding was performed by highlighting extracts of the transcript and assigning it an appropriate 'code'. The software then grouped extracts by code. A single pdf file was produced, with hyperlinks between i) The coded transcripts, ii) Extracts grouped according to code, and iii) A list of codes for each transcript. This rendered the process of data analysis visible, and facilitated the sharing of coded data between the doctoral candidate and supervisors more easily than hand-coding or existing commercial softwares such as NVivo (2000) which can be difficult to share (Mangabeira, Lee, and Fielding 2004).

Data analysis at baseline and follow-up was based on an inductive approach described by Thorne et al. (2004) and involved five steps:

- 1. Open coding
- 2. Intra-subject analysis: Salient coding
- 3. Inter-subject analysis: Search for patterns between participants
- 4. Identification of emerging themes
- 5. Interpretive description of findings

Data analysis occured concurrently with data collection. Steps were repeated several times to explore new directions as they arose. Baseline data was analysed before that of follow-up data. Findings from the analysis of baseline data informed the content of follow-up interviews and the analysis of follow-up data.

1. Open coding

Codes were derived from the raw data rather than being determined *a priori*. Coding was guided by the question: "How is this relevant to this individuals' pain-related fear?" This process of inductive open coding led to the development of a 'code-book' which listed the codes relevant to the participants' fear. This code-book was added to, refined and updated in the data sorting software during the analysis of subsequent interviews. The refined code-book had a tree-like structure and was able to describe all the raw data, with no new codes emerging from the analysis of subsequent interviews. All transcripts were then re-coded using the refined code-book. As an example, the refined code-book for the baseline data analysis is presented in Figure 4.1 where 'stem' codes are represented in bold font and 'branch' codes are represented in normal font.

Figure 4.1. Example code-book from baseline data analysis

Fear

Damaging consequences of pain Suffering consequences of pain Functional consequences of pain

Explanatory model of pain

Biomedical/structural beliefs BPS beliefs

Coping response to pain

Avoidance beliefs
Persistence beliefs
Rumination
Hypervigilance
Hopeful expectations future
Poor expectations future
Low self efficacy beliefs
High self efficacy beliefs

LBP threat

Predictability of pain Controllability of pain Pain intensity

Contributing factors

Societal beliefs
Familial beliefs
Negative info HP
Positive info HP
Diagnostic uncertainty
Conflicting information
Scans
Failed treatment
Positive past experience
Negative past experience
Underlying vulnerability
Contextual stress
Conflicting goals
Repeated goal failures
Therapeutic alliance

In order to consider alternative perspectives and interpretations of the raw data at baseline, a person not involved in the study randomly selected eight transcripts from a sample of 20 that had been transcribed to date. Each of the four PhD supervisors then independently analysed two transcripts each. At follow-up, due to the unavailability of one of the PhD supervisors, six transcripts from follow-up interviews were randomly selected from a sample of 30 and each of the three supervisors independently analysed two. Variations in terminology used for coding existed, but the doctoral candidate and supervisors were in agreement that the meaning of the codes used was consistent.

2. Intra-subject analysis: Salient coding

Once the refined code-book had been applied to each transcript, 'salient codes' were identified for each transcript. These were the concepts considered to be most relevant and important to that individuals' experience of pain-related fear at baseline and of change in fear at follow-up. For example, fear related to

beliefs about the damaging consequences of pain was identified as a salient code for participant 017 at baseline:

```
[Yeah well I think what was happening was I thought that any time it hurt I thought that
150 I was doing more damage. Like I really thought if it hurts it is getting worse and I am
151 killing, I am breaking down, I am killing myself so I would do anything I could to stop it
152 from hurting.]
```

As with the open coding, the supervisors were asked to identify salient codes for each of the transcripts that had been randomly selected. Salient codes identified by the supervisors were found to be consistent with those identified by the doctoral candidate.

3. Inter-subject analysis: Search for patterns between participants

Once all transcripts had been coded and salient codes identified, the data sorting software produced the single hyperlinked pdf file that consisted of the coded transcripts, extracts grouped by code and list of codes for each transcript. In addition, the software produced a 'code-plot' for each transcript. An example of a code-plot from baseline analysis is provided below. In Figure 4.2 the code-book is presented as a code-plot with all refined codes listed. The dark lines separate 'stem' codes from each other. In Figure 4.3 the codes used in the analysis of transcript 017 are presented in the code plot with salient codes represented in red font. The presentation of content in this form aided the search for patterns in the data.

Figure 4.2. Code-book from baseline data presented as a code-plot

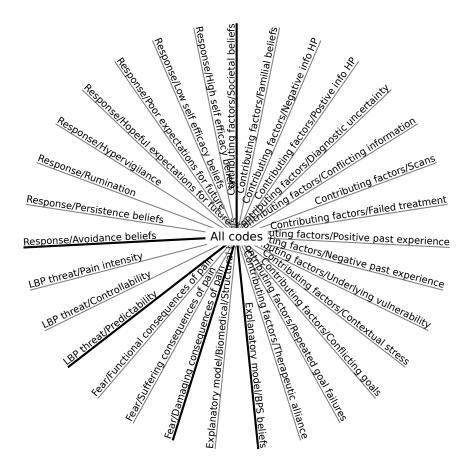
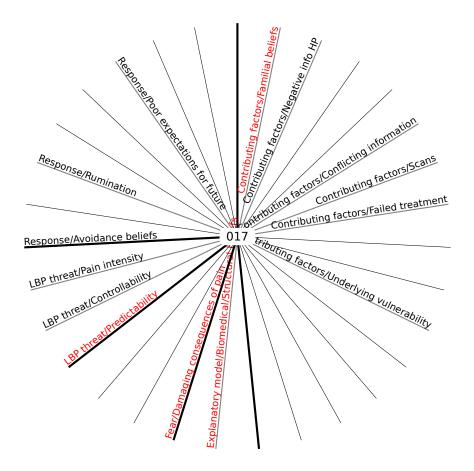


Figure 4.3. Code-plot for Participant 017



Code-plots assisted the identification of recurring codes, recurring salient codes and relationships between them. Grouped extracts were analysed to check and confirm that recurring codes and salient codes described common aspects of participants' experiences. For example, the above extract from Participant 017, was grouped with other extracts assigned the 'Damaging consequences of pain' code that described a similar fear associated with causing damage to the structural integrity of the spine.

[Fear/Damaging consequences of pain]

- "Yeah well I think what was happening was I thought that any time it hurt I thought that I was doing more damage. Like I really thought if it hurts it is getting worse and I am killing, I am breaking down, I am killing myself so I would do anything I could to stop it from hurting." [017], line 149
- "there is something about the back it is that fear of my god I don't want to do something to my spine because if I hurt my spine I am not going to be able to walk, I am not going to be able to mobilise and what if I am an invalid and I cant do anything" [013], line 9

4. Identification of emerging themes

Patterns of salient codes between participants were identified as emerging themes. Grouped extracts were analysed to develop understanding and construct a description of the emerging theme. Emerging themes were challenged in a four step process comprising of: 1. The re-analysis of transcripts which did not fit the pattern to check that they were correctly coded, 2. Group discussion with the PhD supervisors to consider alternative perspectives and insights, 3. Specific questioning during interviews with subsequent participants, 4. Theoretical sampling in which cases of ambiguity and negative cases were specifically sought.

To illustrate this process, the following example is provided from the baseline analysis. The 'damaging consequences of pain' was identified as a recurring salient code in many transcripts, but was absent from the transcripts of others. Extracts grouped as "damaging consequences of pain" appeared to reflect underlying biomedical beliefs that pain was a sign that tissue/structural damage was occurring to the spine. Re-analysis of transcripts confirmed that some participants did not believe pain was a sign of tissue/structural damage. Group discussions highlighted the possibility that the absence of the "damaging consequences of pain" code did not necessarily mean that individuals did not endorse biomedical concepts, but rather that these did not emerge in the interview as salient to their experience. Interviews with subsequent participants included questioning regarding the 'meaning' of pain and specific questioning as to whether individuals believed that their pain was a sign of tissue/structural damage. Theoretical sampling involved the recruitment of two

nurses and one physiotherapist with CNSLBP and high fear scores who were considered to hold alternative pain beliefs due to a more detailed understanding of pain physiology. Transcripts in which the code "damaging consequences of pain" was absent were analysed to identify patterns of salient codes between them. Through this process, 'beliefs related to the damaging consequences of pain' and 'beliefs related to the suffering/functional consequences of pain' were identified as themes describing the salient beliefs underlying fear in this sample.

5. Interpretive description

The final stage of abstraction involved the interpretation of the meaning of the findings. This was performed through the 'expert' lens of the doctoral candidate and the supervisors who had experience in the clinical management of people with CNSLBP and were familiar with the fear avoidance literature. Interpretation was guided by two key questions: 1. How may this finding influence the current clinical management of people with CNSLBP and high pain-related fear? 2. How might this finding inform future iterations of the FAM?

Data collection and data analysis continued until the research questions could be answered in a way that would yield useful knowledge for clinical practice and it was considered that the inclusion of further participants would not alter the main themes identified (Thorne, Reimer Kirkham, and O'Flynn-Magee 2004).

Steps 1-5 of the qualitative analysis were performed separately for the analysis of baseline data and follow-up data.

Mixed-methods analysis

In addition to the qualitative analysis at follow-up, a mixed-method analysis was included to explore how pain-related fear changes over time and the factors associated with improvement in fear.

Based on the interview data, individuals were considered to have experienced an improvement in pain-related fear at follow-up if they expressed being less fearful and/or described a reduction in the threat that pain posed to them, AND described a reduction in protective/avoidance behaviours compared to baseline.

The transcripts were then 'quantitized' (Tashakkori and Teddlie 1998), by allocating 0 = 'non-improver' and 1 = 'improver'. This process of transforming qualitative data into quantitative data, known as quantitizing (Tashakkori and Teddlie 1998) has been applied previously in the health literature (Borkan, Quirk, and Sullivan 1991). Quantitized data could then be merged with quantitative questionnaire data as described in further detail below.

In addition to qualitative improvements in pain-related fear, change scores on the TSK at follow-up were calculated. A reduction on the TSK of \geq 8-points was considered to be clinically significant, as consistent with the literature (Lüning Bergsten et al. 2012). Qualitative improvements in pain-related fear were compared to changes scores on the TSK to triangulate the findings by assessing convergence, divergence and contradictions between the two (Creswell and Piano Clark 2007). Instances where individuals achieved a \geq 8-point reduction on the TSK but were not identified as an 'improver' in the qualitative analysis, or vice versa, were discussed between the doctoral candidate and the supervisors and considered in the findings.

The transcripts of 'improvers' were analysed following steps 1-5 of the qualitative analysis described above. Coding was guided by the question: "What are the factors that appear to be associated with an improvement in pain-related fear for this individual?" Salient codes were identified for each 'improver' and patterns of salient codes amongst 'improvers' were identified as themes. The transcripts of 'non-improvers' were also analysed for the presence of absence of these salient codes to better understand their role in fear reduction.

In addition to the qualitative analysis, change scores on the self-report questionnaires were calculated as the difference in score at follow-up compared to baseline for each individual. For the mixed-method analysis, differences in scores between 'improvers' and 'non-improvers' on each questionnaire were analysed using independent t-tests or Mann Whitney U tests in the case of ordinal data with less than 10 categories.

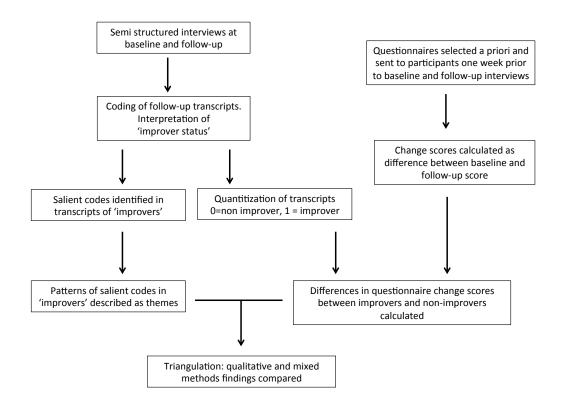
Differences between the percentages of individuals in the improver versus nonimprover group who achieved clinically significant changes on each of the questionnaires was calculated using Chi-squared tests. Once again, this provided a means of triangulating the findings and increased the clinical utility of the qualitative findings by facilitating comparison with the existing quantitative literature.

Interpretations of clinically significant changes were made based on the existing literature. Where no clinically significant change score had been established, a 30 per cent change in score from baseline to follow-up was interpreted as clinically important as recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (Dworkin, Turk, and Wyrwich 2008).

The analysis of quantitative data was performed using SPSS Statistics Version 21.0 (IBM Corp). Statistical significance was set at $p \le 0.05$.

The mixed-method analysis is summarized in Figure 4.4.

Figure 4.4. Mixed-methods analysis



Chapter conclusion

A deeper understanding of the lived experience of pain-related fear is needed to fill key gaps in the fear avoidance literature. Through a qualitative paradigm using an Interpretive Description framework, the lived experience of pain-related fear is explored in a sample of individuals with CNSLBP and high scores on the TSK. Semi-structured interviews conducted at baseline and four-month follow-up explore the beliefs underlying pain-related fear, the factors contributing to these beliefs; how pain-related fear changes over time and the factors associated with improvements in fear. Self-report questionnaires administered at baseline and follow-up are merged with the qualitative data to access greater insights into change in fear and factors associated with improvements in fear. By providing a deeper understanding of the cycle into

fear and the cycle out of fear in people with CNSLBP, interpretations of the findings will inform future iterations of the FAM.

Whilst in the design protocol for this study the mixed-methods analysis was planned only at follow-up, an opportunity was identified to also perform a mixed-methods analysis of baseline data. This resulted in the publication: 'What beliefs underlie high scores on the Tampa Scale of Kinesiophobia?' presented in the following chapter.

Chapter 5. What beliefs underlie high scores on the Tampa Scale of Kinesiophobia?

Introduction

The first aim of this research was to explore the beliefs underlying pain-related fear amongst participants with CNSLBP and high pain-related fear.

Participants with high pain-related fear were identified for inclusion in this study based on scores on the TSK, widely believed to be a measure of fear of movement/(re)injury, defined as a specific fear of movement and physical activity that is (wrongfully) assumed to cause (re)injury (Vlaeyen et al. 1995).

During the participant interviews, it became apparent that not all of the participants selected on the basis of a high TSK score were afraid that movement and physical activity would cause (re)injury. This raised the question: what does the TSK measure?

A lack of conceptual and operational definition of the TSK has been highlighted previously by Lundberg et al. (2011) who called for future research combining psychometric procedures with qualitative approaches that incorporate the patients' perspective to help reach an agreement on the definitions of construct(s) measured by the TSK.

The publication that follows answers this call. In addition to describing the beliefs underlying high pain-related fear, a mixed-methods analysis explores the construct validity of subscales on the TSK.

Published manuscript

What Do People Who Score Highly on the Tampa Scale of Kinesiophobia Really Believe?

A Mixed Methods Investigation in People With Chronic Nonspecific Low Back Pain

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Robert Schütze, MPsych(Clinical),‡
and Peter O'Sullivan, PhD*

Objectives: The Tampa Scale of Kinesiophobia (TSK) has been used to identify people with back pain who have high levels of "fear of movement" to direct them into fear reduction interventions. However, there is considerable debate as to what construct(s) the scale measures. Somatic Focus and Activity Avoidance subscales identified in factor analytic studies remain poorly defined. Using a mixed methods design, this study sought to understand the beliefs that underlie high scores on the TSK to better understand what construct(s) it measures.

Methods: In-depth qualitative interviews with 36 adults with chronic nonspecific low back pain (average duration = 7 y), scoring highly on the TSK (average score = 47/68), were conducted. Following inductive analysis of transcripts, individuals were classified into groups on the basis of underlying beliefs. Associations between groups and itemized scores on the TSK and subscales were explored. Frequencies of response for each item were evaluated.

Findings: Two main beliefs were identified: (1) The belief that painful activity will result in damage; and (2) The belief that painful activity will increase suffering and/or functional loss. The Somatic Focus subscale was able to discriminate between the 2 belief groups lending construct validity to the subscale. Ambiguous wording of the Activity Avoidance subscale may explain limitations in discriminate ability.

Discussion: The TSK may be better described as a measure of the "beliefs that painful activity will result in damage and/or increased suffering and/or functional loss."

Key Words: chronic low back pain, fear avoidance model, painrelated fear, Tampa Scale of Kinesiophobia, qualitative research, mixed methods

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n a survey of Australian adults, 65% reported at least 1 episode of low back pain in the previous 6 months, with 16% reporting chronic disabling low back pain. Estimates suggest that only 8% to 15% of patients with chronic low back pain have an identified pathoanatomic diagnosis, leaving > 85% being classified with chronic nonspecific low back pain (CNSLBP).³

The theory of reasoned action states that beliefs about the consequences of behavior have a strong influence on behavioral intention. Consistent with this, a leading explanation of pain persistence and disability in CNSLBP is the fear avoidance model (FAM). This cognitive-behavioral model describes how the "catastrophic" interpretation of pain as a sign of damage catalyses a vicious cycle of fear and avoidance. The avoidance of movement or activities associated with pain reduces opportunities for positive exposure, sustaining pain and disability.

The Tampa Scale of Kinesiophobia (TSK)⁶ is a widely used measure of pain-related fear beliefs.⁷ High scores on the TSK have been found to be associated with and predictive of increased pain severity,⁸ pain duration,⁹ and increased CNSLBP disability.^{9,10} Longitudinal analysis has shown that reductions in scores for pain-related fear predict reductions in disability.¹¹

However, there is considerable debate as to what construct(s) the TSK actually measures. ¹² The TSK was developed before publications of the FAM and was initially designed as a 1-dimensional scale of Kinesiophobia: "an excessive, irrational and debilitating fear of physical movement and activity resulting from a feeling of vulnerability to painful injury or re-injury." ¹³ In the context of CNSLBP, it is more widely considered a measure of fear of movement/(re)injury defined as a specific "fear of movement and physical activity that is (wrongfully) assumed to cause (re)injury." ¹⁴

Further, rather than being a 1-dimensional scale, factor analytic studies involving people with CNSLBP have favored a 2-factor model of the TSK in which the broader construct fear of movement/(re)injury is represented by the subscales Somatic Focus (TSK-SF) and Activity Avoidance (TSK-AA). ^{15–17} The subscales, however, have been inconsistently described. ¹² The TSK-SF has been described as: "the belief in underlying and serious medical problems" ¹⁸ as well as "the belief that pain is a sign of bodily harm or damage." ¹⁹ The TSK-AA has been described as: "the belief that activity may result in (re)injury or increased pain" ¹⁸ as well as "the belief that activities that promote pain should

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be avoided."¹⁹ Further, French et al¹⁹ found the TSK-SF and the TSK-AA highly correlated with each other and other measures including catastrophizing and depression questioning the clinical utility of distinguishing between them. These definitions remain to be confirmed through rigorous qualitative investigation.

Interventions studies have used the TSK as an assessment tool to identify individuals with high fear of movement/(re)injury for interventions aimed at reducing fear of movement/(re)injury such as cognitive-behavioral therapy, graded exposure, and graded activity. 20-22 There is some evidence that these interventions are effective in reducing fear of movement/(re)injury. 21,23 However, the literature has highlighted substantial costs associated with highly personalized treatment such as graded exposure, and calls have been made for treatment matching to ensure that valuable resources are not wasted. 24 Treatment matching infers that only people with "specific characteristics" receive tailored fear reduction treatments. 24 However, there is little guideline in the literature as to what these specific characteristics are, beyond scoring highly for fear of movement/(re)injury.

This study sought to understand the beliefs that underlie high scores on the TSK to better understand what construct(s) the TSK measures. The first aim of this paper was to describe how individuals scoring highly on the TSK interpret the CNSLBP experience and its consequences in qualitative one-on-one interviews. The second aim was to explore how individual variance in qualitative interview data relates to elevated scores on the TSK and scores on the TSK-AA and TSK-SF subscales.

METHOD

Interpretive Description (ID) is a qualitative methodological framework based on the epistemological foundations of client-centered health research. It adheres to the systematic reasoning of health disciplines with the aim of vielding legitimate knowledge for clinical practice. Rather than loosely adapting methodological frameworks borrowed from disciplines such as sociology or anthropology, ID makes explicit its departure from traditional qualitative methodologies. Foremost, in contrast to phenomenological approaches, ID acknowledges that the health researcher necessarily brings theoretical and practical knowledge to the study and lays visible the a priori beliefs and assumptions of the researchers that influence the design and findings of the study. The authors of this paper are clinical and research physiotherapists and a clinical psychologist with interests in the clinical application of biopsychosocial models of chronic pain. S.B., a physiotherapist, conducted and transcribed all interviews and led the data analysis, with input from all 4 coauthors. The ID framework allowed the researchers to use their knowledge of the FAM, both evidence-based and empirical, to design a study that could investigate individuals' interpretation of the CNSLBP experience and its consequences, with implications for clinical practice.

ID also acknowledges that at the foundation of clinical knowledge is the recognition that health experiences comprise complex interactions between biological, psychological, social phenomena. Shared patterns of such experiences are at the core of clinical knowledge, while the application of clinical knowledge will be individualized for each patient.²⁵ In this context, ID seeks to reveal shared

patterns of experiences that have clinical application but "remain amenable to reconsideration in the light of varying contexts, new concepts, new ways of understanding, and new meanings."²⁵p.172

Approval for this research was granted by the Curtin University Human Research Ethics Committee (approval number HR65/2011) and local hospital ethics committees in Perth, WA.

Sample

Purposive sampling was used to recruit participants seeking care from a variety of musculoskeletal practitioners including general practitioners, physiotherapists, chiropractors, and multidisciplinary pain centers in Perth, WA. A wide sample frame was used as pain-related fear and has been shown to be associated with increased care-seeking in an Australian sample.¹

Adults aged 18 to 65 years with a CNSLBP of \geq 6 months duration and pain intensity \geq 3/10 on the Visual Analogue Scale were eligible for inclusion. Individuals who presented with specific causes of low back pain including red flags, radicular pain with nerve compression, and spondylolisthesis and pregnancy-related back pain were excluded. Individuals who met the inclusion criteria were screened with the 17-item TSK 13 to identify those with high pain-related fear defined as a score of \geq 40. This cutoff is above suggestions from a recent review paper that a score of \geq 37 reflects high pain-related fear, 26 but aligns with previous research by Vlaeyen et al. 23

Procedure

Individuals meeting the inclusion criteria were identified by clinicians at the participating centers between May 2012 and May 2013. They were provided with the study information sheet and were invited to contact the researchers if they were interested in participation.

Purposive sampling was used to ensure that participants seeking care from a range of health settings were included. This paper describes the experiences of 36 individuals who gave written informed consent and participated in the study. The participants were 69% female with an average of 42 years of age. The mean duration of CNSLBP was 7 years and the mean score on the TSK was 47/68. Demographic data for each participant are presented in Table 1.

Data Collection

Data were provided from semistructured interviews in which the interviewer opened with the question "Can you please tell me your pain story?" This assisted the participant to feel at ease and gave the researcher a deeper contextual understanding of the individuals' experience. The interviews explored the nature of their pain, their pain beliefs, and their beliefs about the function of their back and the causes and consequences of their back pain. An interview schedule used as a guide to prompt discussion can be seen in Table 2.

Interviews were held predominantly in the participants' homes. In 2 cases interviews took place in the office of the first author (S.B.) and phone interviews were conducted with 2 participants living in a rural location. Interviews lasted between 45 minutes to 2 hours. No differences were noted between the content or depth of the interviews conducted in the participants' home, the researchers' office or phone interviews.

Code	Sex	Age	Marital Status	Occupation	TSK Score	Duration LBP (y)
				1		
010	Male	39	Married	Disability pension	42	13
011	Female	39	Married	Administration/grocery stockist	65	0.5
012	Female	33	Single	Administration	53	12
013	Female	51	Single	Nurse	56	2
014	Female	39	Married	Relief teacher	42	4
015	Female	25	De Facto	Nurse	46	0.5
016	Female	41	Married	Construction management	48	0.75
017	Male	42	Married	Teacher	50	2
018	Male	54	Single	Unemployed	46	6
019	Male	33	Single	Air conditioning mechanic	45	8
020	Female	33	Partner	Forensic police	46	0.5
022	Female	60	Married	Market Research	51	13
024	Female	61	Married	Task manager	45	10
025	Female	61	Married	Administration	42	0.5
026	Male	49	Single	Disability pension	48	20
027	Female	23	Single	Physiotherapy student	42	10
028	Male	19	Single	Student	47	2
029	Female	53	Single	Carer	46	2
030	Female	58	Single	Unemployed	46	19
031	Female	27	Single	Rigging engineer	42	0.75
032	Female	46	Married	Catering company	47	0.75
033	Male	43	Single	Unemployed	40	14
036	Female	41	Married	Horse trainer	41	7
037	Female	43	Married	Unemployed	46	1
038	Female	45	Married	Unemployed	40	12
039	Female	38	Divorced	Unemployed	46	4
042	Female	45	Divorced	Unemployed	55	27
043	Female	47	Single	Unemployed	48	2
044	Female	42	Married	Part time work	46	11
045	Male	29	Single	Unemployed	41	2
046	Male	64	Divorced	Small business from home	53	8
047	Female	41	Married	Sick leave, administration	53	1
048	Female	39	Separated	Unemployed	42	29
049	Female	37	Married	Business administration	40	4
050	Male	38	Separated	Sick leave, electrician	46	6
052	Male	30	Single	Primary school teacher	44	6

Qualitative Analysis and Consideration of Trustworthiness

Consent was given by all participants to record the interviews. Interviews were subsequently transcribed verbatim by the first author (S.B.).

Inductive analytic techniques were used in which the data were used to generate ideas rather than confirm or negate ideas.²⁷ The identification of codes from the raw data was guided by broad questions such as "what is going on here?" rather than detailed line by line coding.²⁸ A list of codes was compiled and refined in an ongoing process of constant comparative analysis throughout the data

analysis.²⁹ The refined "code book" had a tree-like structure that was able to describe all raw data. Coded raw data were entered into a computer program that sorted the extracts by code. For example, all extracts to which the researcher had assigned the code "damage beliefs" were grouped together. This provided an audit trail by which all authors could reflect on the sensitivity of the codes to the meanings and interpretations of the individual participant.³⁰

After each transcript had been coded, main codes were identified. These were the codes considered most relevant to the research question for that individual, reflected by the

	Themes to	
Research Question	Explore	Interview Questions
What does this person believe about their back pain?	Nature of pain	Can you put me in your shoes and tell me how your back pain feels?
•	Impact of pain	How does your back pain affect your day to day life?
	Pain behaviour	When you feel the pain in your back, what do you do? Why do you do this How well do you think you can cope with the pain?
	Pain beliefs/object of fear	When you feel the pain in your back, what do you think it is telling you? Wh do you think this?
	Back beliefs	What do you think the function of the spine is? Why? How is back pain different from other pain you have experienced in the past

salience of the code to that individual's experience, rather than the frequency with which the code occurred. Recurring main codes, emerging themes, were then explored in subsequent interviews. This process is exemplified below:

017: If I am hurting, I am probably making a really bad back even worse

S.B.: What makes you think that?

017: Cos it stands for I mean, if something hurts it is for a reason, it is your body saying don't do it.

In this early interview, "damage beliefs" were considered a key interpretation of the CNSLBP experience in this individual. This belief was explored in subsequent interviews, in which it consistently emerged as a main code.

The first author, S.B., coded all raw data and identified main codes for each participant. A random sample of 8 transcripts was analyzed by the coauthors, and the intercoder consistency of main codes was high. Emerging themes were discussed between authors and challenged through theoretical sampling in which cases of ambiguity and negative cases were specifically sought. For example, to explore the emerging theme "damage beliefs" we recruited and included in this sample 2 nurses and 1 physiotherapist with CNSLBP and high TSK scores who we thought might hold alternative pain beliefs because of a more detailed understanding of pain physiology.

As this study is part of a larger prospective study, scheduled follow-up interviews were conducted with 30 of the participants 4 months after the initial interview. Six participants were not contactable for follow-up. The authors did not consider the experiences reported at baseline by the 6 participants lost to follow-up to differ substantially from those who participated in the follow-up interviews. Follow-up interviews lasted approximately 30 minutes and provided an opportunity for member checking³¹ of main codes identified for individual participants and emerging themes across participants.

Once the authors considered the final themes to be representative of the participants' experience, they were then subjected to a process of interpretation in which they were considered in the context of current understanding from the literature. Two main themes that were identified through this process reflecting the beliefs that: (1) painful activity will result in damage; and (2) painful activity will increase suffering and/or functional loss.

Qualitative Findings

The Belief That Painful Activity Will Result in Damage

Many participants in the study believed pain to be a sign of tissue damage, reflecting the biomedical belief that "hurt" is correlated with pathology. Pain as a danger or harm made sense to them. In words of a participant:

"If something hurts, it is for a reason. It is your body saying don't do it" (017).

Many participants reported reducing activity in response to pain believed to be a sign that damage was occurring to their physical structure:

"I stop because I am basically trying to not do more damage to it, that is what is going through my mind" (038).

"I would never bend over to pick something up. I try to brace myself on any move (...) because any time it hurts I think that I'm doing more damage. Like if it hurts it is getting worse and I am killing, I am breaking down, I am killing myself" (017). This image of disintegration and dying is an extreme example of the catastrophic belief that pain signaled damage.

Pain as a threat to the structure of the spine was a theme endorsed by many participants in the study and was associated with explicit back beliefs. Many participants conceived of the spine as the "core of the body" that housed the "nerves":

"The spine is the core of your body, the spine is a no go zone because of all the nerves and everything... it is your spine, it holds your structure together" (011).

"That is where the nerves are and everything else you know, you play around with that then that is it you know" (018).

The belief that the spine was of fundamental importance for the rest of the body's function is well illustrated in the following extract with a 50-year-old woman told by her General Physician that she had an unstable spine:

S.B.: "When you hear the word unstable, what does that mean to you?"

013: I literally felt like I was falling apart. I felt like my structure, I had nothing holding me together. I remember one time getting out of bed and I literally felt as though I was going to fall apart, I thought oh my god I am so weak, I literally felt like I was going to fall apart, that my structure wasn't going to hold me up."

She elaborates:

"It is your spine, it's that entire structure where everything comes from, where you bend, where you move, where you sit, when you are walking, every single movement is derived from your back" (013).

The threat value of back pain is therefore high:

"There is something about the back it is that fear of my god I don't want to do something to my spine because if I hurt my spine I am not going to be able to walk, I am not going to be able to mobilise and what if I am an invalid and I can't do anything?" (013).

Pain interpreted as a sign of damage had implications for the future for many participants. This is exemplified in the following extract by a 60-year-old lady who said that she had degenerative changes in her spine, and was avoiding carrying her shopping bag in the fear of "doing more damage" or "overloading" her "crumbling spine."

S.B.: "How does the word degeneration make you feel?"

022: "Disgusting. The fact that it is just in there crumbling and I can't do anything about it. It is falling apart. It is an old persons' spine. 80 year olds' spine. Which is upsetting... The future scares me. Big time, because I feel that it will get worse. And then I may be confined to a wheelchair or I will have a walking frame earlier than that might be the case."

Beliefs that pain signaled damage were influenced by uncertainty surrounding diagnosis, a danger of the unknown. This 38-year-old lady had L4/5-L5/S1 surgically

fused 4 years ago and continued to experience CNSLBP, which her specialist described as "unexplained":

"As far as, I am caught between 2 really bizarre places in the fact that I studied 3 science degrees, I know the realities, but the brain wouldn't work that way, so I know that my spine is fused, there is no damage that can occur to it, but the pain was so intense that I couldn't walk and I didn't know why that was happening. I was told when I went in for surgery that even though they had released the bolt, the bolt could still move, so when the pain shoots down my leg and I collapse, I think well has it moved? Have I actually hurt myself more?" (039).

This physiotherapist presenting with a small disk protrusion without nerve compression who was not considered to be a candidate for surgical intervention reported avoiding work-related tasks for fear that pain meant she was making her "structure" worse:

"I think there is something structurally wrong ...I was disappointed a little bit cos I have a lot of pain, why do I have just this protrusion?" (027). When asked what it would take to reduce her fear of structural damage she says she needs to know what is causing her pain.

The Belief That Painful Activity Will Increase Suffering and/or Functional Loss

Not all participants believed painful activity would result in damage. Some believed painful activity would increase suffering and functional loss.

Painful Activity Will Increase Suffering:

This participant describes the sensory discomfort associated with pain while explicitly refuting the idea that pain signified damage:

"I am mainly just scared of the pain, that the pain will get worse. Not so much of my back because I know that exercise won't make it worse, but I am scared that if I do the wrong movement, the pain will get worse...Cos I know how bad the pain is and I don't want to aggravate that area because I know that will cause the pain" (015).

As a 25-year-old nurse with a good understanding of structural anatomy and pain physiology she describes her pain as:

"...intense, sharp pain that it is almost like I am paralysed for the moment it is happening.... and it will take a good five minutes to fully recover afterwards it is so painful" (015). The experience of intense sharp pain lasting 5 minutes is so aversive to her that she reported making all attempts to avoid it.

The wish to avoid emotional suffering associated with pain rather than fearing potential damage is expressed below:

"It just means pain, I don't think I am going to end up in a wheelchair or anything like that, I don't think it will do any permanent damage, it just feels pain, I can't walk it off, there is nothing I can do to make it better once it is there, so I avoid it" (043).

This 40-year-old man similarly describes his lack of control over pain during an activity-related flare-up that lasts 3 days:

"I am beside myself on what to do and I get to the point where I am like why should I be suffering this much pain and I always think of what I can do to try and ease it but a lot of the time there is nothing you can do, there is just nothing you can do...I can't sleep, I can't do anything" (033).

Painful Activity Will Increase Functional Loss

The effect that a flare up of pain would have on functional ability was widely cited as a reason for the avoidance of tasks associated with pain provocation. Participant 033 goes on to describe the importance of avoiding flaring up his pain:

"(A flare up) is very disruptive to my whole week, I won't get my sleep, it just compounds other things later on that I have to do or, as they say, you can't live on fresh air, you have to do your shopping.... It took me a long time to sort of slow down a bit and accept the fact that righteo it is not going to get any better but you can make life more bearable if you take your time and spread things over a few days rather than do them all in the same day" (033).

A similar sentiment is expressed by these participants:

"Well the doctor said ignore it and get on with things... but I know if I bend over and pick up that pen, that pen is going to irritate me for the next half an hour. Why would I do that? If it is going to irritate me for half an hour when I could have an hour pain free why would I do that? I can achieve a lot in half an hour if I am not in agony" (032).

"There is something in my mind going if I wake up tomorrow and I am in that much pain and I can't walk what do I do you know cos I have got to function for my family" (011).

This mother of 5 describes feelings of panic associated with the functional consequences of performing a paineliciting task:

039: "I know the pain is there and it turns into a panic because of the consequences of doing what I am doing."

S.B.: "What would the consequences be?"

039: "That I couldn't walk. I wouldn't be able to even cook dinner, I wouldn't' be able to function, I couldn't' even have the kids sit on my knee."

When asked what pain means to her she says:

"Just that I am not able to do the stuff that I want to do" (039).

These extracts reflect an underlying belief that avoidance would mitigate subsequent loss of function associated with pain exacerbations.

Several participants expressed concerns over their ability to cope with pain if/when contextual demands changed and they could no longer avoid activities they perceived as pain provoking. This 39-year-old mother, who had experienced an episode of debilitating back pain before having children, expressed:

"I was so scared because I kept thinking of the first experience I kept thinking I won't be able to cope, I won't be able to cope now I have two children, I won't be able to go through what I went through again, I thought it was all going to happen again, the same experience" (014).

Concerns over the ability to cope with pain with increasing age were expressed by this lady approaching retirement:

"I don't actually feel my structure is going to get worse. I am just worried about it not getting any better. I think my back is where it is now and it is not going to get worse but I think if I don't learn how to cope with it... If this is my back as it is now when I am 60 what is it going to be like when I am 70? This is the time that my husband and I want to start travelling and doing things. He wants to travel around Australia and I think how am I going to stay in a tent?" (024).

Mixed Methods Analysis

In the mixed method analysis, interview transcripts for each participant were analyzed with the question "Does this person predominantly believe that painful activity will result in damage (damage beliefs) or believe that painful activity will increase suffering and/or functional loss (suffering/functional loss beliefs)?" Each transcript was classified as "damage beliefs" or "suffering/functional loss beliefs" by the first author (S.B.). Classification was based on the salience of the theme in each transcript, rather than the frequency of endorsement. This method of "quantitizing" qualitative data has been described in the mixed methods literature³² and successfully applied previously.33 To assess the reliability of this classification process, the remaining 4 authors performed independent analysis on a randomly selected sample of 8 transcripts. Classification agreement was 100%. Table 3, columns 1 and 2 display the classification for each participant, and an extract from their transcription.

We acknowledge that beliefs are likely to function on a continuum and that some individuals believe painful activity will result in both damage and suffering and/or functional loss. Analysis of interview transcripts identified 14 individuals who strongly believed that painful activity would result in damage and were therefore classified in the "damage beliefs" group. Seventeen individuals who strongly believed that painful activity would result in suffering and/or functional loss (and who explicitly denied the belief that painful activity would result in damage) were placed in the "suffering/functional loss beliefs" group.

Five individuals clearly described both "damage beliefs" and "suffering/functional loss beliefs." In 3 of these instances, individuals were concerned about the functional impact that performing a painful activity would have, but in describing their experiences, they appeared to be more concerned that damage might occur while performing the activity. These individuals were therefore placed in the "damage beliefs" group. In 2 cases, individuals believed that pain was a sign of damage but in describing their experiences they appeared to be more concerned about the functional impact of activity than the damage that might occur while performing it. These individuals were therefore placed in the "suffering and/or functional loss beliefs" group. These interpretations were supported by independent analysis of the transcripts and group discussion between the researchers, in addition to confirmation by the individuals in follow-up interviews. Therefore, for purposes of analysis, 17 people were classified as "damage beliefs" and 19 as "suffering/functional loss beliefs." Extracts supporting the classification of each individual is found in Table 3.

Once the individual transcripts had been classified, associations between "damage beliefs" and "suffering/

functional loss beliefs" and itemized scores on the TSK were explored. Differences between the 2 groups were evaluated for the total TSK scores as well as the TSK subscales, using independent t tests. The TSK-SF comprised items 3, 5, 6, 7, and 11. Two different versions of the TSK-AA have been described in the literature and so both versions were analyzed in this study. The TSK-13-AA comprised items 1, 2, 9, 10, 13, 14, 15, 17^{18} and TSK-11-AA comprised items 1, 2, 10, 13, 15, $17^{.34}$ These versions were the result of factor analytic studies that eliminated low item-total correlations, including the reverse-scoring items.

To better understand differences between the 2 groups on the TSK-SF and TSK-AA subscales, frequencies of each ordinal response item were evaluated between the 2 groups using the Mann-Whitney U test. In addition, the endorsement of each item was reflected by a median score of ≥ 3 . Data analysis was performed using SPSS Statistics Version 21.0 (IBM Corp.). Statistical significance was set at $P \leq 0.05$.

"Damage beliefs" may be captured by the construct: "the belief that pain is a sign of bodily harm or damage" as measured by the TSK-SF, 19 whereas "suffering/functional loss beliefs" may be captured by the construct: "the belief that activities that promote pain should be avoided" as measured by the TSK-AA. 19 We therefore hypothesized that:

- (1) Individuals in the "damage beliefs" group would score significantly higher on the TSK-SF, and lower on the TSK-AA, than individuals in the "suffering/functional loss beliefs" group.
- (2) Individuals in the "suffering/functional loss beliefs" group would be more highly ranked on TSK-AA items, whereas individuals in the "damage beliefs" group would be more highly ranked on the TSK-SF scale items.

Mixed Method Findings

Participants in the "damage beliefs" group scored significantly higher on the TSK total score than individuals in the "suffering/functional loss beliefs" group. Participants in the "damage beliefs" group agreed more strongly with items on the TSK-SF than the "suffering/functional loss beliefs" group, with differences in items 3, 7, and 11 being statistically significant. In contrast, participants in the "suffering/functional loss beliefs" group did not agree more strongly with items on the TSK-AA than individuals in the "damage beliefs" group. Participants in the "damage beliefs" group agreed significantly more strongly with item 13 of the TSK-11-AA and item 9 on the TSK-13-AA (Tables 4 and 5).

DISCUSSION

Results from this qualitative study described 2 distinct beliefs in participants with CNSLBP scoring highly on the TSK: (1) The belief that painful activity will result in damage to their spine; and (2) The belief that painful activity will increase suffering and/or functional loss. The belief that painful activity will result in damage is consistent with the construct fear of movement/(re)injury as described in the literature. However, the finding of a second belief associated with the TSK, not directly related to fear of movement/(re)injury, raises the question of whether the TSK is best described as a measure of fear of movement/(re)injury.

Participant		
Code	Belief Group	Supporting Extract
010	SFB	"I am not scared about it, it is just pain that's all it is." "Sometimes I just do something even if I know it will be sore, and deal with the consequences afterwards I try to live as much of a normal life as possible."
011	DB	"The way I felt was if I continued to do what I was doing, my back would break. That I was actually destroying my back, making it worse by continuing."
012	DB	"I still have an unknown fear in me that it is going to be a disc that has blown. Because I can't tell you a any time in those 12 y when one of them ruptured, it happened so gradually. I think that is where m hesitation comes from and my anxiousness – from not knowing when it is going to happen. Is that goin to happen? Is that what it felt like before? All those thoughts"
013	DB	"I stopped everything when I felt pain because I literally felt like I was falling apart. That is just how I felt I literally felt like I was going to fall apart, that my structure wasn't going to hold me up"
014	SFB	"Now I see that the pain is not causing me major damage at all". "Pain is threatening to me because I think that I am not going to be able to complete the daily tasks I nee to do."
015	SFB	"For me I am not worried about the structure of my spine getting worse, for me it is just the pain". "I mean it is fear because I am scared of the pain literally but I think it is because I know the structure of the back I understand exactly where it is"
016	SFB	"I don't think my back is going to break or anything. It is just like there is something that is really hurtin me and I want that hurting to stop. My back is not going to break anymore I just want my pain t stop."
017	DB	"I thought that any time it hurt, I was doing more damage. Like I really thought if it hurts it is gettin worse and I am killing, I am breaking down, I am killing myself so I would do anything I could to sto it from hurting."
018	DB	"I am worried about my back pain, because that is where your nerves are and everything else you know you play around with that then that is it you know."
019	SFB	"I mean I don't think that there is something dangerously wrong. The psychologist explained pain pathways to me. I understand it is just my body telling me I have got something dangerously wrong. "When I feel pain Like I worry if I sleep in the wrong position that I will be in pain the next day."
020	DB	"When it seizes that is when I go ooh I wonder what has happened, has something moved in my back? "I have some medications but I try to avoid taking them because if I don't feel the pain I won't know if am doing something to aggravate it. Obviously when it spikes I need to do something to change, but if have taken the medication and it spiked I might not know that I have done something wrong."
022	DB	"Pain tells me something is getting worse in there. I feel like it is just in there crumbling and I can't deanything about it. It is falling apart."
024	SFB	"I feel that it overwhelms me. It overwhelms me. I don't think it is going to get worse, but I don't think is going to get better. I think my back is where it is now and it is not going to get worse. I do believ that. But if I don't learn how to cope with it"
025	DB	"I think just wait I will go to the doctor one day and they will finally do a scan and say oh look you hav got cancer but we are talking about when you get those moments and it is really ridiculous." "I don't think about it I just do it and if I have a pain afterwards I think oh damn I shouldn't have don that, what have I done to my back now?"
026	SFB	"I know the pain is coming from inflammation. It is just a warning sign that just back off for a bit and tr not to do anything to aggravate it. Because when I do aggravate it the pain gets worse and that pain intolerable. It is the incapacity. You are too scared to move. You feel like every time you go to stand upon someone is stabbing a knife into your back."
027	DB	"I think pain is telling me there is something structurally wrongthis problem with the structure if I don't have a direction to solve the problem it can become even worse to the point I cannot work anymore."
028	SFB	"I don't think pain is to be scared of, I think it is there and it happens. I am scared if it goes beyond a leve I expect it because then it might stop me doing the limited exercise I can do. I am not scared of the pair just the limitations of pain."
029	SFB	"I just don't want to live with that sort of pain, everything just stops you are just so consumed with that pain level. I am writhing, I cant cope and it is just not good and so I avoid it. I don't want to deal wit that pain. I don't want it, I don't want it."
030	SFB	"Well if I stop doing something it is because I am sick of the pain, I want it to ease. I don't think that it i going to cause more damage or it is going to stop me doing something tomorrow or whatever else. I ar just so sick and tired of the pain, just being there."
031	SFB > DB	"I was just in a lot of pain. I wasn't scared just worried that I wouldn't make the meeting! I am mor scared of the consequences of pain - stopping me doing things." "I guess pain is a sign of damage – when do you get pain when you haven't injured yourself?"
032	SFB > DB	"If I bend I know I will irritate my back, so I choose not to irritate it If it is going to irritate me for hal an hour when I could achieve half an hour painfree why would I do that? I can achieve a lot in half a hour if I am painfree." "I am afraid of damaging my back. Because you don't understand it, if I was some sort of doctor I woulknow what you can or can't do."

(Continued)

TARLE 3	(continued)

Participant Code	Belief Group	Supporting Extract
033	SFB	"Now when pain gets up to that level I think to myself, I haven't made it worse previously, why would it get any worse now, or really could it get any worse?"
		"I try to avoid flaring up my pain because it is very disruptive to my whole week, I won't get my sleep, it just compounds other things later on that I have to do. As they say you can't live on fresh air, you have to do your shopping"
036	SFB	"I thought ok I have done this and made it sore, but I don't have time for a sore back. I have still got to get other things done. I can't sit around all day. Which is why I got cleaners, there is no point in me cleaning and getting sore and sitting around all day and not being able to spend time with my family."
037	DB > SFB	"I worry about the future. I think am I going to end up in a wheelchair or in one of those little scooter things." "In a way I am worried about causing damage to my structure because I don't' know what is causing it, it
		is out of my control." "It also worries me when my back flares up because, you just sort of don't want to go out anywhere just in
038	DB	case your back is going to flare up and then you know I get embarrassed." "Worst case scenario would be if it I guess if it herniated and um you know I would be in a lot more pain and a lot more disabled."
		"I feel like I am doing more damage when I feel pain."
039	DB > SFB	"I am very clear in my mind that there is a great possibility that I will end up in a wheelchair or unable to function. Because it will eventually just start to deteriorate, unless I have the support structure in there mechanically, to prevent that from happening."
		"It stopped being about the pain and started to be a nauseas feeling. Um because I knew the pain was there and it turned into panic because of the consequences of doing what I was doing that I wouldn't be able to function."
042	DB	"I am worried that the swelling is putting pressure on and is it interfering with some other problem I have got like nerves, is it squashing a nerve somewhere? I think pain is the body is telling you that there is something wrong."
043	SFB	"It just means pain. I don't think I am going to end up in a wheelchair or anything like that, I don't know that it is going to do any permanent damage, I just feel the pain, I can't walk it off, there is nothing I can do to make it better once it is there."
044	DB	"I got scared then I was thinking what is going to happen am I going to be in a wheelchair and when it gets that bad and I can't walk that is when I get really scared."
		"Yeah when it is that, when you get in a position where you are bending down or holding my boy for too long then I am thinking, that is not doing my back any good doing that."
045	SFB	"I don't want my pain to flare up because then I wouldn't be able to function. Even though my function is limited, I don't think I would be able to function to my capacity with this condition."
0.4.5		"I don't think I am damaging my spine"
046	DB DB	"If you have pain it means something is damaged."
047 048	SFB	"To me back pain means damage-nerve-spinal cord-wheelchair." "Doing that does hurt my back, it doesn't stop me but I pay for it it has to be done so I do it. I don't feel it at the time but it is half an hour later that it really hurts. I am not thinking what have I done to my back, it just hurts."
		"I can't afford to be off, I have to keep going. But with the severe pain I can't cope it is that painful. I will
049	SFB	do anything to avoid that severe pain." "I avoid bending because it would mean more pain which would mean being flat on my back again and I don't have time for it."
050	DB	"If I push it too far it could, there is such fine tolerances in there, at the end of the day if something happens it is going to be a lot more serious, I could end up severely damaging the nervous systems going down."
052	DB > SFB	"There is a strong relationship between my instability and pain. When I don't have the belt on, I limp to try and protect things, to protect what damage has been done."
		"I am worried about the consequences of pain, that I might not be able to work. I do think about that when I decide to do an activity or not."

 $DB > SFB = Participant \ describes \ mixed \ beliefs. \ Damage \ beliefs \ considered \ more \ salient \ than \ suffering/functional \ loss \ beliefs.$ $SFB > DB = Participant \ describes \ mixed \ beliefs. \ Suffering/functional \ loss \ beliefs \ considered \ more \ salient \ than \ damage \ beliefs.$ $DB \ indicates \ "Damage \ beliefs" \ group; \ SFB, \ "Suffering/functional \ loss \ beliefs" \ group.$

Beliefs about the consequences of performing a behavior are thought to be key determinants of behavioral intention. The belief that painful activity will increase suffering and/or functional loss is consistent with suggestions by Crombez et al³⁵ that pain is "more than a sign of bodily harm; it is an obstacle to be coped with in the daily pursuit of valued activities and goals that matter" (p. 477). Negotiating the dynamic between the attainment of important

functional goals and pain control involves considered decision making.³⁶ Participants in this study described how they negotiated this dynamic through the avoidance of feared or provocative movements and activities or the modification of the way they performed them. Although we recognize that self-reports of behavior may differ from actual behavior, these findings suggest that it is important that interventions not only target beliefs about pain, but also focus on the

TABLE 4. Independent t Tests

	M	ean (Range)	
Scale	Damage Beliefs	Suffering/Functional Loss Beliefs	Independent t Test
TSK total score	49.3 (40-65)	44.1 (40-48)	0.002*
TSK-SF	14.8 (11-20)	12.7 (9-16)	0.008*
TSK-13-AA TSK-11-AA	24.2 (17-31) 18.4 (13-24)	22.6 (14-26) 17.7 (9-23)	0.136 0.503

TSK = Tampa Scale of Kinesiophobia.

TSK-11-AA = 11-item Activity Avoidance subscale of TSK.

TSK-13-AA = 13-item Activity Avoidance subscale of TSK.

TSK-SF = Somatic Focus subscale of TSK.

*Statistically significant difference between groups.

development of pain control strategies that are linked to individuals' functional goals.

This suggestion of heterogenous beliefs associated with the TSK may have important implications for fear reduction interventions. At present, these interventions assume and target fear of movement/(re)injury beliefs.³⁷ However, directing all individuals scoring highly on the TSK into interventions aimed at reducing fear of movement/(re)injury may result in a dilution effect due to the inclusion of individuals in whom fear of movement/(re)injury is not the predominant belief underlying their CNSLBP experience. This may represent a misuse of valuable health resources and help explain the small to moderate effect sizes for some of these interventions.³⁸

To explore how these distinct beliefs were related to elevated scores on the TSK and scores on the TSK-AA and TSK-SF subscales, this study included a mixed method analysis. The process of "quantitizing" the qualitative findings showed that individuals could be reliably placed into 1 of 2 "belief" groups. Results showed that the "damage beliefs" group agreed significantly more strongly with items on the TSK-SF than did the "suffering/functional loss beliefs" group. This supports our first hypothesis and lends construct validity to the existence of a TSK subscale describing the belief that pain is a sign of damage. However, contrary to our second hypothesis, the TSK-AA subscale was also endorsed by the "damage beliefs" group, with no difference on item agreement between the "damage beliefs" group and the "suffering/functional loss beliefs" group on either version of the TSK-AA.

A closer consideration of the itemized analysis may give insights into the lack of discriminative ability of the TSK-AA. Of particular note is the endorsement by both groups of items 1, 9, 13, and 15 of the TSK-AA, which all contain the word "injure." Endorsement of these items by the "damage beliefs" group may reflect the interpretation of the word "injure" as synonymous with "damage." However, results from the qualitative study found that 17 of the 19 individuals in the "suffering/functional loss beliefs" group explicitly denied damage beliefs during the qualitative interview. This was supported by a lack of endorsement of items 3, 8, 11, and 16 by the "suffering/functional loss beliefs" group all of which contain the word "dangerous." We therefore speculate that individuals in the "suffering/functional loss beliefs" group may interpret

"injure" as "increase pain"; however, this should be the subject of further investigation.

The TSK-AA is widely defined as "the belief that activity may result in (re)injury or increased pain. ^{15,18} The inclusion of the "or" in this phrase deems the definition nonspecific: whereas "the belief that activity may result in increased pain" might reflect well the "suffering/functional loss beliefs" group; "the belief that activity may result in (re)injury" is likely to capture "damage beliefs." Indeed, strong correlations between the TSK-SF and the TSK-AA have been reported, leading one paper to conclude that there was little value in distinguishing between the 2.¹⁹ We argue that the present findings suggest these strong intersubscale correlations may in part reflect ambiguously worded items as a consequence of poorly defined constructs.

The results of this study support a 2-factor model of the TSK, one factor being the TSK-SF. Although the TSK-AA was unable to discriminate between the "damage beliefs" and the "suffering/functional loss beliefs" groups, we propose that in the clinical setting, high scores on the TSK combined with low scores on the TSK-SF may assist in identifying individuals who are less likely to respond to fear reduction interventions. These individuals may respond more favorably to alternative pain control strategies linked to their functional goals.

Design Considerations and Future Research

The authors declare their clinical experience treating people with CNSLBP and familiarity with the chronic pain literature. This knowledge was fundamental in the design of this study and helped to guide the interpretive process as consistent with an Interpretive Description framework.²⁵ Measures to establish trustworthiness as outlined previously helped to ensure the findings were grounded in, and reflective of, the participants' experiences. Although the authors acknowledge the emphasis qualitative investigation places on the uniqueness of the pain experience, the search for patterns in experiences that can inform clinical practice reveals the philosophical standpoint of these health researchers.

This study highlights the important role that qualitative inquiry plays in the area of chronic pain research. Through the application of methodologies specifically suited to the field of health research, qualitative studies may be particularly well placed to explore the validity of theoretical knowledge derived from positivist approaches given the subjective nature of pain.

We acknowledge that in the process of reducing qualitative data, some of the depth and meaning of the participants' experiences has been lost. We also reiterate our acknowledgement that beliefs exist on a continuum rather than being dichotomous. However, the positivist approach taken allowed us to increase the clinical utility of the qualitative findings, given that the TSK is a tool widely used in clinical practice. The approach also allowed us to contribute to the existing literature exploring the psychometric dimensions of the TSK.

We further acknowledge that the process of classifying individuals into 1 of 2 groups is at risk of bias. We have attempted to minimize the risk of classification bias through the reliability testing and inclusion of Table 2.

Finally, the sampling strategy used in this study has implications for the generalizability of the study findings. Although all participants scored highly on the TSK, we used a purposive and theoretical sample to include

TABLE 5. F	Frequency	of Item	Response
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				N	(%)				
	TSK Item	Group	SD	D	A	SA	U statistic	P †	Endorsement‡
TSK-11-AA									<u> </u>
1	I'm afraid that I might injure myself if I exercise	DB SFB	0	3 (18) 5 (26)	7 (41) 12 (63)	7 (41) 2 (11)	112.500	0.088	Yes Yes
2	If I were to try and overcome it, my pain would increase	DB	0	4 (23)	6 (35)	6 (35)	159.500	0.946	Yes
10	Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening	SFB DB	1 (5) 1 (6)	3 (16) 3 (18)	9 (47) 6 (35)	6 (32) 6 (35)	161.000	0.986	Yes Yes
	, ,,	SFB	0	3 (16)	12 (63)	4 (21)			Yes
13	Pain lets me know when to stop exercising so that I don't injure myself	DB	0	1 (6)	7 (41)	9 (53)	93.000	0.012*	Yes
	, ,	SFB	1 (5)	1 (5)	15 (79)	2 (11)			Yes
15	I can't do all the things normal people do because it's too easy for me to get injured	DB	0	5 (30)	6 (35)	6 (35)	155.500	0.841	Yes
		SFB	2 (11)	3 (16)	6 (32)	8 (42)			Yes
17	No one should have to exercise when he/she is in pain	DB	1 (6)	8 (47)	6 (35)	2 (12)	142.500	0.520	No
marr 42 4 4		SFB	1 (5)	8 (42)	5 (26)	5 (26)			Yes
TSK-13-AA 9	I am afraid that I might injure myself accidentally	DB	0	1 (6)	6 (35)	10 (59)	97.500	0.025*	Yes
	accidentary	SFB	0	3 (16)	12 (63)	4 (21)			Yes
14	It's really not safe for a person with a condition like mine to be physically active	DB	2 (12)	9 (53)	4 (23)	2 (12)	106.500	0.054	No
		SFB	6 (32)	11 (58)	1 (5)	1 (5)			No
TSK-SF 3	My body is telling me I have something dangerously wrong	DB	0	3 (18)	7 (41)	7 (41)	83.000	0.009*	Yes
	dangerously wrong	SFB	3 (16)	7 (37)	7 (37)	2 (11)			No
5	People aren't taking my medical condition seriously enough	DB	3 (18)	7 (41)	5 (30)	2 (12)	123.500	0.207	No
		SFB	2 (11)	5 (26)	8 (42)	4 (21)			Yes
6	My accident has put my body at risk for the rest of my life	DB	1 (6)	0	11 (65)	5 (30)	122.500	0.169	Yes
		SFB	0	6 (32)	9 (47)	4 (21)			Yes
7	Pain always means I have injured my body	DB	0	5 (30)	6 (35)	6 (35)	98.000	0.033*	Yes
		SFB	2 (11)	8 (42)	8 (42)	1 (5)		0.00 54	No
11	I wouldn't have this much pain if there weren't something potentially dangerous going on in	DB	0	4 (23)	9 (53)	4 (23)	77.500	0.005*	Yes
	my body	SFB	3 (16)	11 (58)	3 (16)	2 (11)			No
Other Items		Group	SA	A	D	SD	U Statistic	P^{\dagger}	Endorsement‡
4	My pain would probably be relieved if I were to exercise	DB	0	9 (53)	4 (23)	4 (23)	136.000	0.387	No
0	Total because a modeling of the state of the	SFB	3 (16)	8 (42)	5 (26)	3 (16)	1.40.000	0.650	No
8	Just because something aggravates my pain does	DB	0	7 (41)	8 (47)	1 (6)	140.000	0.659	Yes
12	not mean it is dangerous	SFB	0	11 (58)	5 (26)	3 (16)	100 000	0.070	No
12	Although my condition is painful, I would be better off if I were physically active	DB	3 (18)	, ,	6 (35)	1 (6)	108.000	0.070	No
16	* * *	SFB	7 (37)	9 (47)	3 (16)	0	66 500	0.002*	No Vas
16	Even though something is causing me a lot of pain, I don't think it's actually dangerous	DB	2 (12)	1 (6)	9 (53)	4 (23)	66.500	0.003*	Yes
	pain, I don't tillik it's actually daligerous	SFB	4 (21)	10 (53)	5 (26)	0			No

TSK-11-AA = 11-item Activity Avoidance subscale of TSK.

participants with a wide variation of experiences. This enabled us to explore pain-related fear in more depth; however, it limits the generalizability of the present findings. Further, the sample size in this study is small and the findings need to be replicated with larger, more representative samples. Despite these limitations, support for the

TSK-13-AA = 13-item Activity Avoidance subscale of TSK. TSK-SF = Somatic Focus subscale of TSK.

TSK-SF = Somatic Focus subscare of 15K.

† P value = Mann-Whitney U test of item response on 1-4 scale.

‡Endorsement = Median score ≥ 3.

*Statistically significant difference of rank of scores between groups.

A indicates agree; D, disagree; DB, "Damage beliefs" group; SA, strongly agree; SD, strongly disagree; SFB, "Suffering/functional loss beliefs" group.

multidimensional model of the TSK described in this study is lent by convergence with other psychometric studies utilizing different methodological approaches.

Future research exploring what represents a low TSK-SF score may be of clinical utility in distinguishing between individuals who are likely to respond well to interventions aimed at modifying damage beliefs, from those who are less likely to respond. Addressing ambiguously worded items in the TSK-AA such as those containing the word "injure" may increase the sensitivity of the scale to discriminate between the "damage beliefs" group and "suffering and/or functional loss beliefs" groups. Alternatively, there may also be scope for the development of a new scale that better addresses the underlying beliefs of people suffering from chronic pain.

CONCLUSIONS

Through qualitative interviews, this study identified 2 key beliefs underlying high scores on the TSK: (1) The belief that painful activity will result in damage; and (2) The belief that painful activity will increase suffering and/or functional loss. The mixed method findings support a multidimensional model of the TSK. The TSK-SF was able to discriminate between individuals in the "damage beliefs" group and those in the "suffering/functional loss beliefs" group, lending construct validity to the subscale. The TSK-AA was not able to discriminate between these groups. Ambiguous wording of items in the TSK-AA may explain this poor discriminate ability. Although the findings of this mixed method study require replication in larger, more representative samples, we propose that rather than a measure of "fear of movement/(re)injury," the TSK is better described as a measure of the "beliefs that painful activity will result in damage and beliefs and/or increased suffering and/or functional loss.

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Discussion of chapter findings

Whilst experts have suggested that other beliefs besides damage beliefs, may trigger pain-related fear in people with CNSLBP, to my knowledge this is the first qualitative study to describe what a sample of people with high pain-related fear believe about their LBP. The heterogenous beliefs described in this study are not accounted for in the current FAM which assumes damage beliefs underlying fear. Future iterations of the FAM may draw on these findings and consider how to incorporate suffering/functional loss beliefs as alternative pathways to pain-related fear.

Understanding the factors contributing to these beliefs and how these beliefs evolve may inform future fear-reduction interventions targeted to these factors. We will explore this further in Chapter six.

Chapter 6. The beliefs underlying pain-related fear and how they evolve: A qualitative investigation in people with chronic back pain and high pain-related fear

Introduction

Experts have called for research to explore personal explanations for how and why beliefs underlying pain-related fear evolve. Therefore, having described the beliefs underlying pain-related fear in this sample, the second aim of this research was to investigate the participants' perceptions of the factors contributing to their beliefs underlying pain-related fear.

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BMJ Open Beliefs underlying pain-related fear and how they evolve: a qualitative investigation in people with chronic back pain and high pain-related fear

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ABSTRACT

Objectives: The fear-avoidance model describes how the belief that pain is a sign of damage leads to painrelated fear and avoidance. But other beliefs may also trigger the fear and avoidance responses described by the model. Experts have called for the next generation of fear avoidance research to explore what beliefs underlie pain-related fear and how they evolve. We have previously described damage beliefs and suffering/ functional loss beliefs underlying high pain-related fear in a sample of individuals with chronic back pain. The aim of this study is to identify common and differential factors associated with the beliefs in this sample.

Design: A qualitative study employing semistructured interviews.

Setting: Musculoskeletal clinics in Western Australia. Participants: 36 individuals with chronic back pain and high scores on the Tampa Scale (mean 47/68). **Results:** The overarching theme was a pain experience that did not make sense to the participants. The experience of pain as unpredictable, uncontrollable and intense made it threatening. Attempting to make sense of the threatening pain, participants with damage beliefs drew on past personal experiences of pain, societal beliefs, and sought diagnostic certainty. Met with diagnostic uncertainty, or diagnoses of an underlying pathology that could not be fixed, they were left fearful of damage and confused about how to 'fix' it. Participants with suffering/functional loss beliefs drew on past personal experiences of pain and sought help from healthcare professionals to control their pain. Failed treatments and the repeated failure to achieve functional goals left them unable to make 'sensible' decisions of what to do about their pain.

Conclusions: The findings raise the suggestion that sense-making processes may be implicated in the fearavoidance model. Future research is needed to explore whether fear reduction may be enhanced by considering beliefs underlying fear and providing targeted intervention to help individuals make sense of their pain.

INTRODUCTION

Pain-related fear is one of the strongest modifiable predictors of disability in low

Strengths and limitations of this study

- Interviews with 36 individuals with high painrelated fear (mean 47/68 on the Tampa Scale) provide insight into the beliefs underlying fear and how they evolve.
- Findings from the 'lived experience' of people with high pain-related fear provide an evidencebased platform for future iterations of the fearavoidance model.
- This study employed purposive sampling to capture a range of experiences of pain-related fear; it is unknown how representative this finding is to the greater population of individuals with chronic low back pain and high pain-related

back pain (LBP). 1 2 In line with the theory that cognitive factors precede emotional reactions,³ the fear-avoidance model (FAM)⁴ proposes that individuals with LBP who believe their pain is 'a sign of serious injury or pathology' may become fearful and avoidant of physical activity that they presume worsens their problem. The avoidance of activity prevents opportunities to challenge negative expectations and may exacerbate pain and disability.

Since its publication, research has largely supported the relationships proposed by the FAM. 6-9 However experts have identified limitations in the current FAM and made suggestions for how research may inform the next generation of FAM. $^{5\ 10\ 11}$ One such suggestion is that while the FAM assumes that all individuals with LBP interpret pain as a sign of damage, it is possible that other beliefs trigger the fear and avoidance responses described by the FAM.⁵

Currently, interventions based on the FAM target the belief that pain is a sign of serious injury or pathology. ¹² These interventions have successfully reduced fear and disability

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in some individuals with LBP and high pain-related fear, but a significant proportion fail to respond to treatment. 13–15 Understanding what beliefs underlie pain-related fear and how they evolve may assist in directing fear reduction interventions that target specific beliefs.

Several qualitative studies have investigated the beliefs of people with LBP. Stenberg et al¹⁶ explored pain beliefs in relation to physical activity (including exercise and work) in participants with acute and chronic neck pain and LBP. They identified 'fear of hurting the fragile body' as the salient theme and found that earlier experiences of pain and activity undermined fear of damage. Similarly, Darlow et al¹⁷ explored the factors involved in the development of LBP beliefs in participants with acute and chronic LBP and found strong social influences, particularly that of healthcare professionals (HCPs), on the genesis of positive and negative LBP beliefs. While providing insight into potential factors contributing to LBP beliefs, these studies included participants with acute and chronic pain whose beliefs have been shown to differ¹⁸ and the studies did not select for individuals with high pain-related fear.

In a previous publication we reported on the beliefs of individuals with chronic non-specific LBP (CNSLBP) scoring highly for pain-related fear on the Tampa Scale of Kinesiophobia (TSK). In a qualitative study of 36 people, Bunzli *et al*¹⁹ found that some individuals believed painful activity had damaging consequences for the structural integrity of the spine (damage beliefs); while others believed painful activity would increase suffering and/or lead to subsequent functional loss (suffering/functional loss beliefs); and some held both beliefs. In the report we stopped short of investigating the factors that contribute to these beliefs and to date our understanding of why individuals with CNSLBP and high pain-related fear associated LBP with damage, suffering and/or functional loss remains limited.

To build an evidence-base for future iterations of the FAM that may direct targeted fear reduction interventions, this study aimed to identify common and differential factors associated with beliefs underlying fear in individuals with CNSLBP and high scores on the TSK.

METHODS

All participants read the study explanatory sheet and gave written informed consent prior to participation.

An Interpretive Description framework²⁰ was chosen for this study as it adheres to the systematic reasoning of health professions with the objective of informing clinical practice. This paradigm acknowledges the theoretical and practical knowledge the health researchers brings to the study, laying visible their assumptions and beliefs that influence the design and findings. In this study, the Interpretive Description framework enabled the researchers to draw on their clinical and theoretical knowledge of biopsychosocial processes and the FAM to design a study that could explore the factors

contributing to damage beliefs and suffering/functional loss beliefs among individuals with CNSLBP with implications for clinical practice.

The authors of this paper are clinical and research physiotherapists and a clinical psychologist with interests in the clinical application of biopsychosocial models of chronic pain. This study is part of the first authors' (SB) doctoral studies. SB is a physiotherapist with 10 years of clinical experience.

This study followed the consolidated criteria for reporting qualitative research (COREQ) guidelines²¹ (see online supplementary material).

Sample

This study involves the same sample as has been previously described in Bunzli *et al.*¹⁹ The sample is described in detail below.

Participants seeking care from a range of musculoskeletal practitioners (general practitioners, physiotherapists, chiropractors and pain clinics) in Perth, Western Australia were recruited through purposive sampling.

Adults aged 18–65 years with CNSLBP of ≥6-month duration and pain intensity ≥3/10 on the visual analogue scale were eligible for inclusion. Individuals who presented with specific causes of LBP including red flags, radicular pain with nerve compression and spondylolisthesis and pregnancy-related LBP were excluded. Individuals with high fear were eligible for inclusion. High pain-related fear was identified by scores ≥40 on the 17-item TSK (R Miller, S Kori, D Todd. The Tampa Scale. Unpublished, 1991)as consistent with previous literature. 22

Recruitment

Participating clinics identified individuals meeting the inclusion criteria between May 2012 and May 2013. Individuals were provided with the study information sheet and invited to contact the researchers if they were interested in participating in a study being conducted by a doctoral student at the school of physiotherapy investigating pain-related beliefs and emotions of people with CNSLBP. Purposive sampling involved regular contact between the researchers and participating clinics throughout the study period. In this way sampling was adjusted in response to data emerging from the simultaneous processes of recruitment, interviews and data analysis. For example, after approximately one-third of the interviews had been conducted and analysed, the researchers decided that more male participants were required to ensure a more balanced representation of gender. At this time, clinicians were asked to only hand the invitations to males who fit the inclusion criteria until the gender representation had been addressed. Recruitment continued in this way until saturation was reached. Saturation was reached when the authors considered that the inclusion of further participants would not influence the main themes identified in this study.²³ Purposive sampling was performed in order to capture a wide range of experiences of pain-related fear. As such it is unknown how representative the final sample is of the larger population with CNSLBP and high pain-related fear.

All participants who contacted the researchers were included. This paper describes the experiences of 36 individuals who gave written informed consent and participated in the study. The participants were 69% female with an average of 42 years of age. The mean duration of CNSLBP was 7 years and the mean score on the TSK was 47/68. Participant characteristics are presented in table 1.

Data collection

Semistructured interviews were conducted by SB, a female physiotherapist and PhD candidate with experience in conducting qualitative interviews. Prior to the interviews, SB was not working as a clinical physiotherapist and was not known to the participants and therefore

had no pre-existing relationship with them. Participation involved a single one-to-one interview conducted in the participants' homes or a private university office. Phone interviews were conducted with two participants living in remote locations. An interview schedule guide is outlined in table 2. The content of the interviews was informed by the findings from a review of the qualitative literature exploring the lived experience of CNSLBP.²⁴ For example, it has been suggested that fear avoidance beliefs may be influenced by advice from HCPs to avoid certain movements to 'protect' the spine,¹⁷ therefore the questions: 'What health professionals have you seen for your back pain?' What have they told you about your back pain?' were included in the interview schedule.

Early interviews were guided by opening questioning. Later interviews involved both opening questioning and more refined questioning as a result of concurrent data analysis of previous interviews. Participants were able to give opinions freely during the interviews. All interviews

Code	Sex	Age	Marital status	Occupation	TSK score	Duration LBP (years)
010	Male	39	Married	Disability pension	42	13
011	Female	39	Married	Administration	65	0.5
012	Female	33	Single	Administration	53	12
013	Female	51	Single	Nurse	56	2
014	Female	39	Married	Teacher	42	4
015	Female	25	De facto	Nurse	46	0.5
016	Female	41	Married	Construction	48	0.75
017	Male	42	Married	Teacher	50	2
018	Male	54	Single	Unemployed	46	6
019	Male	33	Single	Mechanic	45	8
020	Female	33	De facto	Police officer	46	0.5
022	Female	60	Married	Market research	51	13
024	Female	61	Married	Task manager	45	10
025	Female	61	Married	Administration	42	0.5
026	Male	49	Single	Disability pension	48	20
027	Female	23	Single	Physiotherapy student	42	10
028	Male	19	Single	Student	47	2
029	Female	53	Single	Carer	46	2
030	Female	58	Single	Unemployed	46	19
031	Female	27	Single	Engineer	42	0.75
032	Female	46	Married	Caterer	47	0.75
033	Male	43	Single	Unemployed	40	14
036	Female	41	Married	Horse trainer	41	7
037	Female	43	Married	Unemployed	46	1
038	Female	45	Married	Unemployed	40	12
039	Female	38	Divorced	Unemployed	46	4
042	Female	45	Divorced	Unemployed	55	27
043	Female	47	Single	Unemployed	48	2
044	Female	42	Married	Teacher	46	11
045	Male	29	Single	Unemployed	41	2
046	Male	64	Divorced	Small business	53	8
047	Female	41	Married	Sick leave, administration	53	1
048	Female	39	Separated	Unemployed	42	29
049	Female	37	Married	Administration	40	4
050	Male	38	Separated	Sick leave, electrician	46	6
052	Male	30	Single	Teacher	44	6

Research question	Examples of open questioning
What factors are associated with beliefs underlying fear?	You have said that you worry about the consequences of low back pain—Can you please give me an example of this? Why were you worried? What did you do? Why did you do this? What would you do if you were in a similar situation again? Why would you do this?
	Examples of refined questioning
	Which healthcare professionals have you seen for your back pain? What have they told you about your back pain?
	Can you tell me about any investigations for example, scans you have had on your back Where/who else do you turn to for advice on your back pain? Why?
	Have you been around other people who have had back pain? How did they cope with their pain?
	Can you tell me about any previous experiences of back pain you may have had?

were flexible to explore any new themes that arose. The interviews lasted between 45 min and 2 h.

Analysis and consideration of trustworthiness

Interviews were audio recorded and transcribed verbatim by SB immediately following the interview.

This study was designed to answer two separate research questions. In our previous paper we answered the first research question and described the beliefs underlying high scores on the TSK. We found that 14 individuals scoring highly on the TSK clearly endorsed only damage beliefs, whereas 17 individuals clearly endorsed only suffering/functional loss beliefs, and 5 individuals clearly endorsed both beliefs. ¹⁹ In this paper we answer the second research question and explore the common and differential factors associated with beliefs underlying fear in this sample.

Data analysis was based on an inductive analytic approach described by Thorne *et al*²³ and involved five steps: (1) open coding, (2) intrasubject analysis: salient coding, (3) intersubject analysis: search for patterns between participants, (4) identification of emerging themes and (5) interpretive description of findings. Data analysis occurred concurrently with data collection. Steps were repeated several times to explore new directions as they arose. SB led the data analysis through steps 1–5 with input from coauthors at all stages. The transcripts were read by at least two authors. Group discussion of each transcript was conducted to familiarise all authors with the content.

In step 1, SB conducted open coding on all transcripts. A random sample of eight transcripts was selected for independent analysis by the coauthors. Comparison of coding performed by SB and the coauthors on each of the eight transcripts was done through group discussion. In this way any dissent between the interpretations made by SB and the relevant coauthor could be handled by reaching consensus among the remaining two coauthors who acted as independent arbiters. The authors were in agreement that the extracts and codes identified were consistent between SB and the coauthors. No new concepts were identified by

the coauthors so no further cross-coding was performed. This is consistent with previous qualitative studies in this field where a single author coded all data, with corroboration by coauthors. 17 $^{25-27}$

Codes were derived from the raw data rather than being determined a priori. Coding was guided by the question: 'How is this relevant to this individuals' pain-related fear?'. A list of codes relevant to the participants' fear was devised. This 'code-book' was added to and refined during the analysis of subsequent interviews, in an on-going process of constant comparative analysis throughout the data analysis.²⁸ The refined code-book had a tree-like structure that described all the raw data, with no new codes emerging from the analysis of subsequent interviews. The refined code-book was reapplied to all transcripts by SB.

In step 2, the codes considered to be most relevant and important to each individuals' experience of painrelated fear were identified as salient codes. SB identified salient codes for all transcripts and the coauthors identified salient codes on a random sample of eight transcripts. The identification of salient codes by SB and the coauthors was consistent. The coauthors reviewed and agreed on the full list of salient codes in group discussion.

In step 3, a data-sorting programme (purpose-designed by SB during her doctoral studies) grouped the extracts by code. Grouped extracts were checked by two authors to confirm that recurring codes described common aspects of participants' experiences.

In step 4, patterns of salient codes between participants were identified as emerging themes. Grouped extracts were analysed by SB to develop understanding and construct a description of the emerging theme. Emerging themes were challenged by: (1) the reanalysis of transcripts that did not fit the pattern to check that they were correctly coded, (2) group discussion among the authors to consider alternative perspectives and insights, (3) specific questioning during interviews with subsequent participants and (4) theoretical sampling in which cases of ambiguity and negative cases were specifically sought.²⁸

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In step 5, through group discussion among all authors, the authors interpreted the meaning of the findings by considering: (1) How may this finding influence the current clinical management of people with CNSLBP and high pain-related fear? (2) How might this finding inform future iterations of the FAM?

Data collection and data analysis continued until the research questions could be answered in a way that would yield useful knowledge for clinical practice and the authors considered that the inclusion of further participants would not alter the main themes identified.

The grouping of salient codes into themes is presented in table 3.

RESULTS

The overarching theme was a LBP experience that did not make sense. For all participants, the experience of LBP as unpredictable, uncontrollable and/or intense made it threatening to them (theme 1). In an attempt to make sense of the threatening pain:

Participants with damage beliefs described drawing on past personal experiences of LBP (theme 2), societal beliefs (theme 3) and sought diagnostic certainty from HCPs. Met with diagnostic uncertainty, or diagnoses of an underlying pathology that could not be fixed (theme 4), these participants were left fearful of damage and confused about how to 'fix' it.

Participants with suffering/functional loss beliefs described drawing on past personal experiences of LBP (theme 2), and sought help from HCPs to control their pain. The repeated experience of 'failed' treatment and the failure to achieve functional goals (theme 5) left them unable to make 'sensible' decisions of what to do about their pain. Themes are described in detail below, with supporting quotes labelled by participant code and the line numbers corresponding to where the quotes appeared in the interview transcripts.

THEME 1: THE PREDICTABILITY, CONTROLLABILITY AND INTENSITY OF PAIN

Common to the accounts of all participants was the experience of LBP as intensely painful, unpredictable and/or difficult to control.

The intensity of LBP made it something scary, to be feared. Participants with damage beliefs described intense pain as an evolutionary warning signal that they should stop what they were doing to avoid damaging or (re)injuring their spine, while participants with suffering/functional loss beliefs described their distress associated with suffering intense pain:

When my back was completely bad, 10/10 pain, I got scared then, thinking what is going to happen am I going to be in a wheelchair and yeah when it gets that bad and I can't walk then that is when I do get really scared. (044, line 233)

You just don't want to live with that sort of pain...everything just stops you are just so consumed with that pain level. I am writing, I am really distressed and can't cope. It is just not good and so I avoid it. (029, line 350)

Most participants experienced their LBP as unpredictable. They described difficulties predicting what would trigger their pain, how long it would last and how well they would be able to control it. Pain that was unpredictable and uncontrollable was difficult to make sense of:

There is no set pattern when it is going to happen. And I can do things today that won't trigger it, tomorrow I do exactly the same things and it will trigger it. So nothing causes it and I can't control it. That is what is so frustrating and scary. (032, line 124)

Because it is unpredictable, it is out of your control...you don't know what you are doing to exacerbate it, you are

Overarching theme	Themes	Salient codes
Inability to make sense of pain	Damage beliefs underlying fear Suffering/functional loss beliefs underlying fear LBP threat	Damage beliefs Suffering/functional loss beliefs Pain predictability Pain controllability Pain intensity
	Negative past experience of pain Societal back beliefs	Negative past experience of pair Societal beliefs Family beliefs
	Process of seeking diagnostic certainty	Diagnostic uncertainty Negative information HCP Conflicting information Scans
	Repeated experience of failure to control pain	Failed treatment Repeated goal failures Persistence behaviour

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just kind of moving so you have no control and that is the scary thing, (013, line 767)

In a few divergent cases, LBP was described as highly predictable. For example, participant 032 knew what movements/activities would flare up her pain. For her, the uncontrollability rather than unpredictability of pain appeared to be associated with her pain-related fear:

If I bend, I know I will irritate my back...if it is going to irritate me for half an hour when I could achieve half an hour painfree, why would I do that? (032, line 293)

THEME 2: NEGATIVE PAST PERSONAL EXPERIENCES OF PAIN

In an attempt to try and make sense of the threatening pain experience, participants drew on their previous personal experiences of LBP. While the experience of, and recovery from, mildly debilitating LBP in the past may function to reduce fear, the previous experience of severe, debilitating LBP appeared to reinforce beliefs about the on-going weakness of the spine that is vulnerable to re-injury, and influence negative expectations of suffering/functional loss associated with pain:

I think that is where my hesitation and anxiousness comes from...no no I do not want to blow another disc... so I am just super cautious. (012, line 697)

If you (feel pain) you panic because you don't know if the pain is going to go away. You don't know if you have gone backwards...I don't want to go back to the original pain. (032, line 311)

THEME 3: THE INFLUENCE OF SOCIETAL BACK BELIEFS

Participants with damage beliefs described drawing on societal beliefs and attitudes to make sense of their pain. However the salience of damage beliefs appeared to be high among the family members, friends and colleagues that they turned to as sources of information. This reinforced their 'fear of damage' and their uncertainty about how to address it:

I guess we all have that fear of the spine...there is something about the back, that fear of my god I don't want to do something to my spine, because if I hurt my spine I am not going to be able to walk, I am not going to be able to mobilise and what if I am an invalid and I can't do anything. (013, line 11)

You grow up hearing horror stories about back surgeries and how it makes things ten times worse. (012, line 26)

THEME 4: PROCESS OF SEEKING DIAGNOSTIC CERTAINTY

Participants with damage beliefs described undiagnosed pain as 'petrifying'. For these participants receiving a diagnosis from a HCP was important in order to understand what was causing their pain and how they could 'fix' it. However many participants who consulted a HCP did not receive a diagnosis and the lack of explanation left them confused:

It could be my discs but they say not, so I am very confused and that is a big deal for me, that I don't know what it is. (038, line 190)

When you look at everything that says there is nothing to show, how can you treat it? How can you treat it when tests come back negative? (025, line 427)

Other participants did receive a diagnosis of an underlying pathology from their HCP. A poor understanding of the diagnostic jargon used by HCPs meant some participants interpreted the diagnostic 'label' they had been given as a serious underlying pathology. For example, when asked to describe how they interpreted their diagnosis of 'degeneration' these participants described a process of deterioration in the integrity of the spine:

The way I understood what they say about my back, degeneration was something about breaking down. (049, line 57)

They told me that I had degeneration...so it is a slow progressive issue that will only get worse over time. (050, line 160)

The 'diagnosis' of an underlying pathology led to confusion when participants realised that there was no option to 'fix' the underlying pathology. This participant who was told that his pain was caused by 'degeneration' and that he was not a candidate for surgery, said:

The injury is bone on bone. You know they can do hip replacements and all that sort of thing, why can't they do anything for your spine? (018, line 284)

Similarly, this participant who was told her LBP was due to 'ligament issues' said:

Why is it that you hear stories about people with cruciate ligament issues and they are back playing footie in 6 months? Like a clear path—clear diagnosis, clear treatment option with a high success rate and resolution of the problem. What makes this joint different from the other joints? Why does that treatment path not exist for this joint? (036, line 299)

THEME 5: REPEATED EXPERIENCE OF FAILURE TO CONTROL PAIN

Participants with suffering/functional loss beliefs described consulting HCPs in search of strategies to gain control over their pain. However the strategies they were provided with had limited effectiveness:

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He says we need to get you back in to the gym and moving and I say yeah but on Friday I tried to exercise again and I was down and out the weekend. I don't have time to be down and out. I have to work. (049, line 236)

When they failed to meet their expected treatment outcomes despite adhering closely to the recommendations of their HCPs, this reinforced the unpredictability and uncontrollability of their pain and left them uncertain of what to do next:

That's the point that I couldn't understand like I am doing everything they want me to do. I am doing physio, I am moving and trying all this and the pain isn't dying. This is crazy. (010, line 128)

I've been blown off by everyone and stuff I had sought for myself hadn't really worked. I don't know what to do. (016, line 455)

With a lack of strategies to control pain, participants with suffering/functional loss beliefs described being 'stuck' trying to make sensible functional choices when all options had undesirable outcomes. This participant provided an example of how she 'weighed up' whether walking home with heavy groceries would cause her more pain than sitting in the car:

Its always a weigh-up: how many groceries am I getting, therefore can I walk back with the shopping? Versus sitting in the car to drive. (016, line 635)

Some participants decided to ignore pain and persist with functional tasks despite pain. However persistence inevitably resulted in flare-ups of pain that forced them to abandon the task:

So you have a cramp but it is 5 o'clock and there are a billion things to get done...I just get on with it. But within an hour I have to get heat on it because it starts to ache, deep in the bone it...Every night I sit on the couch and put heat packs on it. (049, line 590)

The repeated experience of failing to achieve functional goals due to exacerbations in pain reinforced the participants' inability to make sense of their pain:

I don't know what to do, it doesn't make sense to me. (024, line 20).

DISCUSSION

We have previously documented two predominant beliefs in this sample of individuals with CNSLBP and high pain-related fear.¹⁹ The aim of this study was to explore factors associated with these underlying beliefs. The overarching theme across all participants was the experience of a threatening pain that they could not make sense of. Participants described attempts to make sense of pain that varied depending on their beliefs underlying fear.

Pain that does not make sense

That sense-making processes may play a role in pain-related fear is a novel suggestion that is in contrast to the 'phobic' processes described by the FAM. An inability to make sense of CNSLBP symptoms has been documented in other qualitative investigations of the CNSLBP experience. Studies have described 'the riddle of the puzzling pain'²⁹ and the 'bewildering situation' of repeatedly unmet expectations of CNSLBP treatment.³⁰ A metasynthesis of qualitative studies described how an inability to make sense of pain placed 'lives on hold', suspending biographical timelines in people with CNSLBP.²⁴ There is some evidence that individuals with chronic widespread pain and chronic musculoskeletal pain who cannot make sense of their symptoms are more likely to catastrophize about them.³¹

Predictability, controllability and intensity of pain

Predictability, controllability and stimulus intensity have been described as common to the pathways to, and maintenance of, all specific fears.³² However despite being central to the experiences of the participants in this study, the current FAM does not ascribe a role to the nature of the pain experience in pain-related fear. Emerging evidence from experimental studies in healthy participants also suggests that predictability, controllability and pain intensity may influence pain-related fear. An experimental study involving healthy participants found that the absence of safety cues makes unpredictable pain more threatening than predictable pain, resulting in increased pain-related fear. 33 Another experimental study in healthy participants found that having control over pain and then losing it may result in more pain-related fear than never having had control, through heightened hypervigilance.³⁴ A recent study involving participants with chronic pain found that in moments of more intense pain, fearful thinking about pain increased.³⁵ These findings suggest that rather than being a static response to a stable belief,⁵ pain-related fear may be dynamic and responsive to changes in the pain experience.

Attempts to make sense of the threatening pain experience

Expectations from past personal experiences of pain, cultural beliefs about LBP in the general population, treatment expectations and goal context were all found to influence underlying beliefs. Considering these influences in future iterations of the FAM may be warranted. For instance, the high prevalence of pathoanatomical beliefs about LBP in society suggests that these may be 'normative' rather than being 'exceptional or irrational' as is currently inferred by the FAM.⁵ A population-based cross-sectional study of people living in New Zealand found that of the 602 respondents, 89% believed their back was easy to injure and 89% believed if they ignored back pain, they may cause damage to their back. 57% of respondents believed that back pain meant they had

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injured their back and 64% believed that a 'twinge' in their back could be the first sign of serious injury.³⁶ Similar findings have been reported in Australia.³⁷

The influence that competing goals had in this study suggests that self-regulatory processes may be implicated in future iterations of the FAM.⁵ Self-regulatory processes refer to the adjustment of emotions and behaviours depending on the appraisal of goal outcome.³⁸ Such feedback processes are currently lacking in the FAM and therefore the model does not account for the fact that pain-related fear and fear avoidance may vary depending on context.⁵ ¹⁰

Clinical implications

For individuals presenting with CNSLBP and high painrelated fear, it may be important to consider their beliefs underlying fear and provide targeted interventions to help them make sense of their pain.

Where possible, strategies that improve pain controllability, predictability and intensity may be effective in reducing the threat LBP poses to individuals. There is currently debate as to whether pain control should be a target of interventions for CNSLBP. For example, approaches such as acceptance and commitment therapy (ACT) recommend that pain controllability should not be a target of treatment, while approaches such as cognitive functional therapy (CFT) explicitly target pain control, where achievable, as a focus of the intervention. To date, ACT has reported modest effect sizes for disability, but little improvement in pain.³⁹ In contrast, a recent randomised control trial reported large effect sizes for pain and disability reduction through CFT. 40 As symptom attenuation is an important construct of recovery for individuals with CNSLBP,41 it would appear unfounded to miss an opportunity to target pain control in the lack of evidence that purely targeting cognitive processes yields superior outcomes. Clearly exploration in this area is warranted.

Individuals presenting with damage beliefs are likely to benefit from an acceptable, individualised, biopsychosocial understanding of CNSLBP using unambiguous language. It is important to question patients with damage beliefs about their past health experiences, including what they have previously been told about their LBP and any scans they have had. The findings highlight a need for further research to better understand how diagnostic jargon commonly used in the LBP context such as 'degeneration' are experienced and interpreted by patients with CNSLBP. Bridging this language gap should be recognised as a LBP research priority to prevent the inadvertent perpetuation of damage beliefs by HCPs.

For all patients presenting with high pain-related fear, asking about any previous negative experiences of LBP can provide insight into how these contribute to expectations of pain and its consequences. Interventions may include strategies that discourage pessimistic expectancies, replacing them with more optimistic attitudes towards the achievement of valued goals. 42

Individuals presenting with suffering/functional loss beliefs may respond to approaches which link pain-control strategies to functional goals. This may be achieved via measures that target the regulation of an individuals' emotional responses to pain and activity pacing, while addressing maladaptive functional behaviours (such as muscle guarding) associated with feared or avoided movements. In some cases combining these strategies with pharmacology may assist the process of dampening pain responses to functional tasks. Combined with approaches which improve goal setting, goal pursuit and goal flexibility this may enhance fear reduction in individuals who repeatedly fail to achieve functional goals due to pain.

Strengths and limitations

The authors make explicit their clinical experience in the area of biopsychosocial CNSLBP management and familiarity with the literature. It is a limitation of this study that only one author performed coding of all transcripts. However, we emphasise the inductive nature of the analytic process and the trustworthy measures employed to ensure that the findings were grounded in the participants' experiences.

Another limitation of this study is that only individuals who contacted the researchers were included. It is possible that this sample differed in important ways to the population from which they came. In this sample we were able to identify a predominant belief underlying fear, with overlap in a minority of cases. It is unknown how representative this finding is to the greater population of individuals with CNSLBP and high pain-related fear.

Future research

Future research is needed to explore the beliefs underlying pain-related fear and how they evolve in larger and more diverse populations of people with CNSLBP.

Future intervention studies involving participants with CNSLBP and high pain-related fear are needed to explore whether sense-making processes play a role in fear reduction. Such studies will require repeated measures throughout the intervention period to better understand the mechanisms involved in sense-making. Including qualitative interviews in the design of future intervention studies would enhance our understanding of how these mechanisms may differ between individuals.

Future randomised controlled trials are needed to better understand the role that pain controllability plays in pain-related fear and fear reduction. Such studies may compare interventions that target pain controllability such as CFT to interventions such as ACT that target pain acceptance over pain controllability.

CONCLUSION

The findings of this study suggest that multiple factors may trigger the vicious cycle of pain-related fear. Future iterations of the FAM may draw on these findings to 6

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consider ascribing a greater role to somatic aspects of the LBP experience on the pathway to pain-related fear. Similarly, future iterations may consider the role that sense-making processes play on the pathways to painrelated fear. Whether, if and how targeting the somatic aspects of the LBP experience and sense-making processes might influence fear reduction remains to be seen.

Contributors All authors were involved in the design of the study. SB conducted the participant recruitment, conducted and transcribed all interviews, performed the coding and led the interpretive process. The coauthors AS, RS and POS read the raw transcripts, independently coded a random sample of eight interviews and were involved in all stages of the data analysis. All authors had input into, and approved, the final manuscript.

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Discussion of chapter findings

The current FAM provides limited direction for the management of pain-related fear. To date, interventions based on the model have targeted underlying damage beliefs as a mediator of fear-reduction. However these findings highlight that alternative beliefs may underlie pain-related fear, raising the likelihood that other pathways to fear-reduction exist. In Chapter seven the prospective component of this study explores whether novel insights can be gained into the factors associated with improvement in pain-related fear, as experienced by the participants in this study.

Chapter 7. Gaining control over the low back pain experience. Patients' perspectives of improvements in pain-related fear.

Introduction

At present, the FAM describes the cycle into pain-related fear, but does not provide a working explanation of fear-reduction. Currently interventions based on the FAM target underlying damage beliefs as the mediator of fear-reduction. However the findings of this research highlight that not all people with high pain-related fear will have underlying damage beliefs.

Gaining a deeper, person-centred understanding of how and why pain-related fear may change over time, may inform future iterations of the FAM that can direct HCPs to deliver targeted intervention. To date no studies have explored the subjective experiences of pain-related fear over time in people with high pain-related fear at baseline. This chapter explores the factors associated with improvement in pain-related fear amongst participants at four-month follow-up. The manuscript that follows is currently under review in a peer-reviewed journal.

Submitted manuscript

"Gaining control over the low back pain experience. Patients' perspectives of improvements in pain-related fear".

Samantha Bunzli, Peter O'Sullivan, Robert Schütze, Anne Smith

Abstract

The Fear Avoidance Model suggests that correcting the belief that pain is a sign of damage, may reduce pain-related fear in people with back pain. However it is possible that alternative pathways to fear-reduction exist. Recently heterogenous beliefs underlying fear have been reported in people with chronic back pain. To investigate the possibility of alternative pathways to fearreduction, we conducted a prospective mixed-methods investigation involving 31 individuals with chronic back pain and heterogenous beliefs underlying high fear. We aimed to assess changes in fear over a four-month period and to explore factors associated with improvements in fear through analysis of qualitative interviews and change scores on self-report questionnaires. Interviews and questionnaires were completed at baseline and four-months. At follow-up, 18/31 participants reported an improvement in fear. 'Improvers' described 'gaining control over the pain experience' through a reduction in the threat value of pain; some described new conceptual understandings of pain coupled with targeted management; and others described reduced goal conflict. The processes involved in achieving these differed between individuals, and appeared to be influenced by their underlying beliefs. The mixed-methods analysis found 'improvers' were more likely to experience clinically significant improvements in quantitative measures of back beliefs, pain control and pain intensity. Whilst the Fear Avoidance Model assumes a single pathway to fearreduction, this study suggests multiple pathways to fear-reduction may exist. Assisting patients to gain control over the pain experience may enhance fearreduction in people with chronic back pain.

Introduction

The fear avoidance model (FAM) proposes that the belief that pain is damaging leads to pain-related fear and avoidance behaviours that sustain pain and disability in chronic non-specific low back pain (CNSLBP) (Vlaeyen and Linton 2000). In support of the FAM, high pain-related fear is associated with, and predictive of, increased pain severity, pain duration and CNSLBP disability (Picavet, Vlaeyen, and Schouten 2002); whilst reductions in fear are associated with improvements in physical activity levels (Lüning Bergsten et al. 2012), disability (Leeuw et al. 2008), and pain intensity (Woby et al. 2008). Pain-related fear is therefore an important target for intervention.

Interventions based on the FAM targeting underlying damage beliefs have been shown to reduce pain-related fear in some people with CNSLBP with high fear on the Tampa Scale of Kinesiophobia (TSK). Exposure in vivo works on the premise that behavioural modification constitutes a potent strategy for cognitive restructuring (Bandura 1977). Early case studies reported promising results (Vlaeyen et al. 2001, Vlaeyen et al. 2002, Boersma et al. 2004), however randomised controlled trials (RCTs) have reported modest effect sizes, high inter-individual variability and high drop-out rates (31-47 per cent) (Leeuw et al. 2008, Linton et al. 2008, Woods and Asmundson 2008). Targeting damage beliefs through cognitive and behavioural strategies in Cognitive Behavioural Therapy has resulted in similar modest effects (Woby, Watson, and Roach 2004, Woby et al. 2008). Current CNSLBP guidelines do not recommend one fear-reduction intervention over another (Reese and Mittag 2013).

To date, the mechanisms involved in fear-reduction remain poorly understood. Intervention studies involving participants with CNSLBP and high fear have largely focused on the comparative effectiveness of different fear-reduction interventions (Linton et al. 2008, Woods and Asmundson 2008) and the cognitive processes associated with changes in pain and disability (Woby et al. 2008, Woby, Watson, and Roach 2004) rather than the mechanisms underlying changes in pain-related fear. The only study to explore the factors mediating changes in pain-related fear found that changes to underlying damage beliefs mediated reductions in fear through Exposure in vivo, consistent with the FAM

(Leeuw et al. 2008). However it is possible that other pathways to fear-reduction exist, not currently described by the FAM.

Calls have been made for the next generation of research to extend the FAM beyond a 'phobia' conceptualisation of fear and consider the role that factors such as pain interference in valued goals and pain-related physiological processes may play in the pathways to pain-related fear and fear-reduction (Wideman et al. 2013, Crombez, Eccleston, et al. 2012). To inform future iterations of the FAM and help understand what works best for whom, Vlaeyen and Morley (2005) call for exploratory methodologies that focus on the individual as the unit of analysis.

Employing a qualitative approach in a recent publication, we reported that not everyone scoring highly on the TSK believes pain is damaging. Interviews with 36 people revealed that some individuals with CNSLBP endorsed damage beliefs; others believed that pain was a sign of suffering and/or functional loss; and a minority held both beliefs (Bunzli et al. 2015). Heterogenous beliefs underlying pain-related fear are not accounted for in the FAM, and may explain why some people respond to interventions based on the FAM and some do not. It is unknown whether individuals with different beliefs underlying pain-related fear respond uniquely to treatment and experience different pathways to fear-reduction.

Prospective qualitative research provides insight into how changing contexts can influence experiences over time (Thomson and Holland 2003) and helps to identify the determinants and direction of any change in experience (Snelgrove, Edwards, and Liossi 2013). Three prospective qualitative investigations have explored the factors influencing treatment outcomes in people with back pain. These studies identified non-specific treatment effects influencing outcomes including diagnostic certainty (Ong et al. 2011), recovery expectations (Toye and Barker 2012) and respites in pain intensity (Snelgrove, Edwards, and Liossi 2013). No qualitative investigation has explored the factors associated with improvements in pain-related fear prospectively amongst individuals with CNSLBP and high pain-related fear.

To inform future iterations of the FAM and targeted interventions, this prospective, mixed-methods study involving people with CNSLBP and high pain-related fear aimed to:

- 1. Identify individuals who experienced an improvement in pain-related fear (improvers), and individuals who did not (non-improvers), at fourmonth follow-up, through analysis of prospective qualitative interviews and scores on the TSK.
- 2. Identify factors associated with improvements in pain-related fear through qualitative analysis of interview data and explore how these might be associated with beliefs underlying pain-related fear at baseline.
- 3. Examine whether change scores in standard questionnaire measures of factors identified in aim 2 differed between improvers and non-improvers.

Methods

This study involved a prospective mixed-methods design. A primarily qualitative exploratory approach was chosen to capture as much information as possible from this sample. The quantitative component served a triangulation function, used alongside the qualitative data to better understand the temporal nature of pain-related fear and change in pain-related fear.

The over-arching framework employed was Interpretive Description, which differs from other qualitative frameworks by its grounding in the epistemological foundations of client centred health research (Thorne, Reimer Kirkham, and MacDonald-Emes 1997). Specifically, it permits the researchers to lay explicit their backgrounds as clinical and research physiotherapists and a clinical psychologist with interests in biopsychosocial models of CNSLBP. The researchers' a priori beliefs and knowledge gained from previous interactions with people with CNSLBP and from the chronic pain literature influenced the study design and formed the lens through which the study findings were interpreted.

Interpretive Description also acknowledges that at the foundation of clinical knowledge is the recognition that health experiences are comprised of complex

interactions between biological, psychological and social phenomena. Shared patterns of such experiences are at the core of clinical knowledge, whilst the application of clinical knowledge will be individualized for each patient (Thorne, Reimer Kirkham, and MacDonald-Emes 1997). In this context, Interpretive Description seeks to reveal shared patterns of experiences that have clinical application but "remain amenable to reconsideration in the light of varying contexts, new concepts, new ways of understanding, and new meanings" (Thorne, Reimer Kirkham, and MacDonald-Emes 1997, p.172).

The mixed-method design of this study is consistent with the philosophy of the Interpretive Description framework whereby "a solid and substantive logic derived from the disciplinary orientation justifies the application of specific techniques and procedures outside of their conventional context" (Thorne 2008, p.35). In the clinical physiotherapy setting, the subjective assessment of pain patients involves the convergence of interview findings with scores from relevant self-report questionnaires. Thus the design of this study, involving both interviews and self-report questionnaires, has ecological validity. The Interpretive Description framework enabled the researchers to answer the clinical research question and yield legitimate knowledge to inform clinical practice.

Approval for this research was granted by the Curtin University Human Research Ethics Committee (approval number HR65/2011) and local hospital ethics committees in Perth, WA.

Procedure

Participants were recruited from musculoskeletal practitioners (general practitioners, physiotherapists, chiropractors and pain specialists) between May 2012 and May 2013. Individuals who met the inclusion criteria were given a participant information sheet by their treating Healthcare professional (HCP) and invited to contact the researchers if they were interested in participating. The recruitment process has been described in detail elsewhere (Bunzli et al. 2015). Data collection and data analysis were performed in parallel, and purposive sampling for sex, socio-demographic region and care-seeking

behaviour ensured a range of experiences was captured. To do this, the researchers kept in close contact with the HCP involved in recruitment. For example, when the researchers had recruited several participants from physiotherapy clinics and wished to recruit more participants from pain clinics, they asked the physiotherapy clinics to stop handing out invitations and informed the pain clinics that they were seeking more participants from their setting. When more male participants were sought, the researchers asked the HCP to stop handing invitations to females and only hand them to males. It is unknown how many invitations were handed out. All participants who contacted the researchers gave informed consent and participated in the study. Recruitment stopped when the researchers considered that the inclusion of further participants would not influence the main themes identified through the qualitative analysis of baseline interviews.

Adults aged 18-65 years, with CNSLBP of ≥ 6 months duration, pain intensity $\geq 3/10$ on the Visual Analogue Scale and high fear as identified by scores ≥ 40 on the 17-item TSK (Kori, Miller, and Todd 1990) were eligible for inclusion. Individuals who presented with specific causes of LBP including red flags, radicular pain with nerve compression and pregnancy related LBP were excluded.

Data Collection

Data was collected at baseline and four month follow-up.

Semi-structured interviews were conducted at baseline and follow-up by the first author, a female physiotherapist and doctoral candidate with experience in qualitative interviewing. SB was not practicing as a physiotherapist at the time of the study and was unknown to the participants prior to the baseline interviews.

Baseline interviews were conducted with 36 participants. Baseline findings have been described elsewhere (Bunzli et al. 2015). Follow-up interviews were conducted with 31 of the 36 participants. The themes identified in the baseline interviews of the five individuals lost to follow-up did not differ from those who participated in the follow-up interviews. Follow-up interviews lasted

approximately 30 minutes. Twenty were conducted in the participant homes, one in the office of the first author and ten over the phone. The content of the interviews conducted over the phone or in person were similar in terms of the themes identified.

In the follow-up interviews, participants were asked to describe any interventions they had received since baseline, including the dose and duration of any intervention and reasons for any drop-out from intervention. Opening questioning explored the participants' perceptions of any improvement in their experience of pain-related fear. Participants were prompted to describe why they thought they had improved or not improved; the factors that they believed may have facilitated any improvement; and the factors that they believed may have presented a barrier to any improvement.

Open questioning was followed by more directed questioning, informed by the findings from baseline interviews. For example, the experience of high pain intensity emerged as salient factor associated with beliefs underlying pain-related fear in all participants at baseline. Therefore at follow-up, participants were specifically asked about any change they had experienced in pain intensity. Similarly, in baseline interviews diagnostic uncertainty was identified as a salient factor associated with beliefs underlying pain-related fear in some participants. Therefore in follow-up interviews, participants who described diagnostic uncertainty at baseline were specifically asked about any change they had experienced in diagnostic uncertainty. The interview schedule is presented in Table 7.1.

Table 7.1. Interview schedule

Follow-up intervie	W	
Research	Themes to	Example interview questions
question	explore	
	Change in pain	How have you been since we last spoke?
	experience	Would you describe your back pain experience as the
		same, better or worse since we spoke? In what way?
		Why do you think this?
		Has the intensity of your pain changed since we last
		spoke?
		How much control do you feel you have over your pain
		now?
	Change in fear?	Last time you described being afraid or worried of (the
		damaging or functional/suffering consequences) in x
		situation. Have you found yourself in the same/a
		similar situation since we last spoke?
		What did you do? Why did you do this?
		If you were presented with situation x now, do you
		think you would be as afraid/worried, less
		afraid/worried or more afraid/worried than when we
Has this person		last spoke? Why do you think this? What do you think is the reason for any change?
experienced an		When you feel the pain in your back now, what do you
improvement in		do?
fear?		Why do you do this?
	Pain behaviour	How well do you think you can cope with the pain now?
		Do you think this is the same/better or worse than
Factors		when we last spoke? Why do you think this?
associated with	- · · · · ·	When you feel the pain in your back now, what do you
improvement in	Pain beliefs	think it is telling you? Why do you think this?
fear	_	When we last spoke you mentioned that you were
	Back beliefs	uncertain about the cause of pain/you thought that x
		was the cause of pain. Do you still think that?
		How do you think your back pain will be in 6 months
	Expectations	time? In 12 months time? In 10 years time?
	Expectations	Do you think your back pain will get better?
		What do you think it will take to get better?
	Treatment	Have you had any treatment for your back pain?
	received	Can you describe to me the treatment have you
		received?
		How often did you receive it?
		Have you had any investigations on your back?
		Are you still receiving treatment?
		Do you think that the treatment has any effect? What?
		Why do you think this? Can you tell me about your interactions with the (s) you
		saw?
	1	Saw:

The week prior to the baseline and follow-up interviews, participants were sent self-report questionnaires. Participants were asked to complete the questionnaires and hand them (or send them in a postage paid envelope) to the researchers in a sealed envelope at the time of the interview. The researchers remained blinded to all questionnaire scores until after the completion of baseline and follow-up interview data analysis so as not to influence the analytic and interpretive process of qualitative analysis. Twenty-eight participants completed self-report questionnaire data at follow-up. One participant completed TSK and NRS only. Two participants failed to send the questionnaire back to the researchers despite two phone call reminders and two email reminders.

Self-report questionnaires were selected a priori, based on previous literature exploring change in pain-related fear (Woby et al. 2008, Meulders, Meulders, and Vlaeyen 2014, Woods and Asmundson 2008) and mediators of fearreduction (Leeuw et al. 2008) in people with CNSLBP. Consideration was made to limit participant burden. The following questionnaires, validated for use in the low back pain population were selected: The Anxiety Sensitivity Index (ASI; (Peterson and Reiss 1992)), Back Beliefs Questionnaire (BBQ; (Symonds et al. 1996)), Coping Strategies Questionnaire (CSQ-24; (Harland and Georgieff 2003)), Depression Anxiety Stress Scale-21 item (DASS-21; (Lovibond and Lovibond 1995)), Numerical rating scale (NRS; (Jensen and Karoly 1992)), Pain Catastrophising Scale (PCS; (Sullivan, Bishop, and Pivik 1995)), Pain Self Efficacy Questionnaire (PSEQ; (Nicholas 1989)) and the Tampa Scale of Kinesiophobia (TSK; (Miller, Kori, and Todd 1991)). The CSQ-24 consists of five subscales - Catastrophising, Reinterpreting, Diversion, Cognitive Coping and Control, however only the subscales Cognitive Coping (CSQ-CC) and Control (CSQ-Control) were selected for inclusion in the study, as a measure of Catastrophising was already included and there is evidence that the Reinterpreting and Diversion subscales may have poor construct validity (Harland and Georgieff 2003).

Data Analysis

Interviews were audio recorded and transcribed by SB.

<u> Aim 1.</u>

1.1 To explore the stability of pain-related fear over a four-month period, qualitative analysis of interview transcripts was guided by the question: "Did this individual experience an improvement in pain-related fear? Why/why not?"

Individuals were considered to have experienced an improvement in painrelated fear at follow-up if they:

1. Explicitly reported being less fearful and/or described a reduction in the threat that pain posed to them at follow-up compared to baseline

AND

2. Described a reduction in protective and or avoidance behaviours at follow-up compared to baseline

Interpretations of 'improver' status (reported improvement in pain-related fear and protective and / or avoidance behaviours = improver; no improvement = non-improver) for each individual were supported by interview extracts. A random sample of six transcripts was selected and three co-authors independently judged improver status. Of the six transcripts, five were considered to be improvers and interpretations of improver status were consistent between authors.

1.2 In addition, change scores on the TSK were calculated. A change score of \geq 8-points was considered to be clinically significant, as consistent with the minimal clinically important difference (MCID) reported in a previous study (Lüning Bergsten et al. 2012). Results of the qualitative and quantitative analysis of improver status were compared on an individual basis. Instances where individuals were interpreted to be an 'improver' but did not achieve the MCID on the TSK, or where individuals were interpreted as being a 'non-improver' but did achieve the MCID on the TSK, were discussed between authors and considered in the findings.

Due to practical and ethical constraints, it was beyond the scope of this study to access the clinical records of the participants. Instead, participants were asked to describe the content of the interventions they had received over the study period.

Aim 2

- 2.1 To explore the factors associated with improvements in pain-related fear, the transcripts of 'improvers' were analysed using inductive analytic coding techniques (Thorne 2000). A list of codes was compiled and refined in an ongoing process of constant comparative analysis throughout the data analysis (Glaser and Strauss 1967). Coding was guided by the question: "What are the factors that appear to be associated with an improvement in pain-related fear for this individual?" The refined list of codes had a tree like structure that was able to describe all raw data. For each individual, the most salient associative factors were identified and assigned as 'salient codes'. Patterns of salient codes amongst 'improvers' were identified as themes.
- 2.2 The transcripts of 'non-improvers' were then analysed to explore whether the factors associated with improvements in pain-related fear were unique to the experience of 'improvers'.

All interview transcripts were coded by SB. A random sample of six follow-up transcripts was selected and three co-authors independently coded two each. This helped to reassure that interpretations were based in the raw data. The salient codes identified in the selected transcripts did not differ between SB and the co-authors.

2.3. Once each transcript had been analysed, transcripts were grouped according to beliefs underlying pain-related fear at baseline in order to explore whether patterns of salient codes differed between individuals with damage beliefs at baseline and individuals with suffering/functional loss beliefs at baseline. The grouping of the participants in this study according to beliefs underlying pain-related fear at baseline has been described in detail elsewhere (Bunzli et al. 2015). Whilst we acknowledge that beliefs exist on a continuum rather than being dichotomous and indeed, several participants described

mixed beliefs, we were able to reliably identify a predominant belief underlying pain-related fear at baseline in this sample.

Aim 3

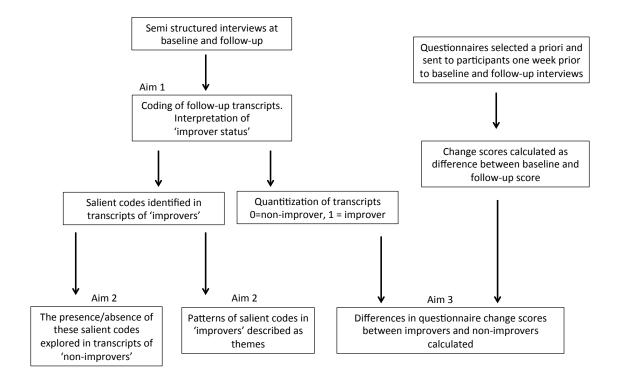
The qualitative interpretation of improver status informed the mixed-methods analysis. This was because there is some debate in the literature as to what change score constitutes an improvement in pain-related fear (Lüning Bergsten et al. 2012), and because individuals with high baseline scores may experience a large reduction on the TSK whilst remaining above cut-offs for high pain-related fear. The transcripts were 'quantitized' (Tashakkori and Teddlie 1998), by transforming the qualitative interpretation of improver status into a dichotomous variable where 0 = 'non-improver' and 1 = 'improver'. This has been performed previously in the health literature (Borkan, Quirk, and Sullivan 1991). Quantitized data could then be merged with quantitative questionnaire data.

- 3.1. Change scores for each self-report questionnaire were calculated as the difference in score at follow-up compared to baseline for each individual. Differences in scores between participants coded as improvers and non-improvers on each of these scales were analysed using independent t-tests or Mann Whitney U tests in the case of ordinal data with less than 10 categories.
- 3.2. Differences between the percentages of individuals in the improver versus non-improver group who achieved clinically significant changes on each of the questionnaires was calculated using Chi-squared tests. Data analysis was performed using SPSS Statistics Version 21.0 (IBM Corp). Statistical significance was set at $p \le 0.05$.

Interpretations of MCID were made based on the existing literature. Where no MCID score had been established, a 30% change in score from baseline to follow-up was interpreted as clinically important as recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) (Dworkin, Turk, and Wyrwich 2008)

The data analysis process is summarised in Figure 7.1:

Figure 7.1. Data analysis process



Results

Demographic and baseline data of the 31 participants who took part in the baseline and follow-up interviews are displayed in Table 7.2.

Table 7.2. Participant characteristics

Code	Sex	Age	Duration LBP (years)	Marital status	Occupation
010	M	39	13	Married	Disability pension
011	F	39	0.5	Married	Administration
012	F	33	12	Single	Administration
013	F	51	2	Single	Nurse
014	F	39	4	Married	Teacher
015	F	25	0.5	De Facto	Nurse
016	F	41	0.75	Married	Construction
017	M	42	2	Married	Teacher
018	M	54	6	Single	Unemployed
019	M	33	8	Single	Mechanic
020	F	33	0.5	Partner	Police officer
022	F	60	13	Married	Market Research
024	F	61	10	Married	Task manager
025	F	61	0.5	Married	Administration
027	F	23	10	Single	Physiotherapy student
028	M	19	2	Single	Student
030	F	58	19	Single	Unemployed
031	F	27	0.75	Single	Engineer
032	F	46	0.75	Married	Caterer
033	M	43	14	Single	Unemployed
036	F	41	7	Married	Horse trainer
037	F	43	1	Married	Unemployed
038	F	45	12	Married	Unemployed
039	F	38	4	Divorced	Unemployed
044	F	42	11	Married	Teacher
045	M	29	2	Single	Unemployed
046	M	64	8	Divorced	Administration
048	F	39	29	Separated	Unemployed
049	F	37	4	Married	Administration
050	M	38	6	Separated	Sick leave, electrician
052	M	30	6	Single	Teacher
M = ma	ale, F = fe	emale		·	

Aim 1

The first aim of this study was to explore the stability of pain-related fear over a four-month period through prospective qualitative interviews and scores on the TSK.

Qualitative analysis of the baseline and follow-up interviews identified 18 of the 31 participants as having experienced an improvement in pain-related fear at follow-up. An example of an 'improver' is Participant 017 who described being less fearful and a reduction in protective behaviours at follow-up compared to baseline:

"I am not frightened... I feel like I can handle the pain that my back will give me if it ever does"

"What changed in me was going from being terrified of hurting myself more anytime I moved to realising that moving was the very thing I needed to do"

An example of 'non-improver' is Participant 015:

"It is still scary that it could come back"

"I am still careful of carrying anything, I don't want to exacerbate any problems"

Twenty-nine participants had baseline and follow-up TSK scores, and of these 16 achieved the MCID on the TSK (see Table 3).

One participant, 011, was considered to be a 'non-improver' but had a \geq 8-point improvement on the TSK. This participant had the highest score on the TSK at baseline (65/68). Whilst at follow-up she scored significantly lower on the TSK (41/68) this score is still above cut-offs of high pain-related fear and did not describe a reduction in protective or avoidance behaviours at follow-up. When asked why she was avoiding painful activity she responded:

"It hurts and I am scared I am going to hurt it more"

Two participants, 049 and 019, were considered to be 'improvers' but only achieved a 7-point reduction on the TSK. Participant 019 described:

"I am ... more relaxed now, this is not going to ruin my life. It will get better"

"I know the things that affect my back, bracing, tensing and stress. And I know the things I have learnt, the relaxation, it will settle it down."

Participant 049 described:

"I am not worried about it. Now when it flares up I know it is actually going to get better"

"I am back in the gym four days a week now. I have even tried running a bit, slowly on the treadmill."

No follow-up TSK scores were available for two participants. Participant 032 was considered to be an 'improver'. She described:

"I am not awake at night worrying anymore. Because I know how to deal with it now"

"If it is really bad I try to do more than less and that really helps a lot." and Participant 015 was considered to be a 'non-improver'. She described:

"I am always scared of it. I am still scared of it"

Improvers reported receiving interventions consistent with both biopsychosocial (e.g. Cognitive Functional Therapy, an individualised behavioural intervention challenging maladaptive beliefs and associated functional behaviours (Vibe Fersum et al. 2013)) and biomedical approaches (e.g. surgery, podiatry). Similarly non-improvers reported interventions consistent with biopsychosocial and biomedical approaches. One improver reported not receiving any intervention during the study period (see Table 7.3).

Table 7.3. Interventions received, TSK scores, salient codes and supporting extracts

				Damage beliefs at baseline	at baseline
Qualit	Qualitative 'Improvers'				
Code	Intervention	TSK s B	TSK score B F	Salient codes	Supporting extract
039*	PT – standard	46	18	Gain biopsychosocial	"I have come to realise my triggers and what causes it and what doesn't
	3 sessions/3			understanding, Improved predictability,	cause it, it makes a change " I am not constantly guarding against it. It used to be that sweeping the
	months			Internal locus of control,	floor I knew would cause the pain so I wouldn't do it where as now it is,
			_	Mindful acceptance	yeah it might cause pain it might not but I will still do it and deal with the
	Psychology				after affects. Why? Because I know my back is not actually being harmed"
	1 x month				"That is how I view everything at the moment, it is well., can I change it - Yes? Then I change it. Can I change it - no? Then stop it. Iust stop worrving
					about it"
046	Chiropractic	53	38	Diagnostic certainty	"Historically wear and tear did mean wheelchair in the future. Until the
	1-2 x week/4			(degeneration)	regenerative medicine came along it wasn't a good future. Now people
	months			External locus of control	are going to be able to have corrective treatment with regenerative
				Hope for the future	medicine"
	Regenerative				"I am confident that the treatment is matching the issue – that we are
	medicine				solving the issue at the source I haven't had time to rebuild the bulk of
	1 x injection				the discs, but it can happen."
012	PT-CFT	53	38	Gain biopsychosocial	"I think it is caused by a Venn diagram of things. I am definitely not
	1 x week/2 months		_	understanding,	telling myself before I do something, "oh this is going to hurt me". I have
				Internal locus of control,	turned that off completely. I am not afraid of doing them and causing
				Understanding negative thoughts	damage".
					"I just said to the physiotherapist bugger it! I just have to flip the switch, I
					have to turn off. I am sick of thinking about it, I am sick of worrying about.

					It is constantly on your mind – am I doing too much, am I doing too little. I am just sick of it. I don't want to think about it anymore, I am just going to do what I want to do."
					"I think that when my nervous system fires I don't have enough control in my mind to know that it is happening in time for me to slow it all the way down."
017	PT - CFT 8 sessions/3	20	36	Gain biopsychosocial understanding	"What changed in me was going from being terrified of hurting myself more anytime I moved to realising that moving was the very thing I
	months				needed to do".
				Reduced pain intensity	"I am not frightened I feel like I can handle the pain that my back will give me if it ever does. But that is just a difference in the level of pain.
					Back then it was an 8 or a 9 out of 10 but now the worst my pain gets is
					probably a 6 and that is only short term. And if I get a good nights' sleep it will probably be a 2 or a 1."
022	Surgery – hip	51	39	Diagnostic certainty (hip labral	"I had a diagnosis! Yay I have a labral tear! It is an orthopaedic surgeon
	labrum repair			tear)	who is acknowledging that I have a problem."
				External locus of control	"I am convinced that it is going to go. It is just I have had a huge
				Hope for future	operation."
					"I am going to see the orthopaedic surgeon in 6 weeks and hopefully it
					Will be repaired
020	PT-CFT	46	26	Gain biopsychosocial	"Before, I was worried it might be the sacroiliac joint and if I did
	4 sessions/8 weeks			understanding	something wrong I would damage it more and need surgery Now I
				Internal locus of control	understand that my back has had enough of the way I sit and stand, my
				Reduction pain intensity	postureNow when the pain happens I will just be mindful again of my
					posture and not worry"
					"I have had moments this week where I haven't had pain which is good"
044	PT- pilates	46	38	Reduction pain intensity	" It doesn't worry me when the pain flares up now. Because it is not as
	1 x week/4 months				bad. I was starting to think am I going to end up in a wheelchair. But I am
					not like that now. It is just not having that excruciating pain anymore."
013	PT-CFT	26	42	Gain biopsychosocial	"Thank goodness the sharp agonizing knife like constant pain in the
	8 sessions/12			understanding	middle of L5/S1 has gone. I still have a different pain, (tightness) across

	weeks			Internal locus of control Reduction pain intensity	my back and in left hip. I know it is muscular not nerve pain, I do know it will settle". "The other night I woke up uncomfortable in the middle of the night with a sharp pain across my back. I got onto the floor, into the child pose posture with outstretched arms to stretch out the lower back and told myself I was safe, all the things (the physiotherapist) has told me to do and I was ok I know it is will settle now, so I am not as anxious or catastrophising to the extent I was."
Qualit	Jualitative 'Non-improvers'	,LS,			
011	PT-CFT 1 x week/4 months	92	41	Gain biopsychosocial understanding Limited controllability	"His philosophy is that I have an ultra sensitive nervous system so whenever I get stressed I flare up. I think ok but how do I get rid of that? I need to find some kind of coping mechanisms if that is what is causing it. How do I get my nervous system back working properly?" "I know my muscles tighten up when I am stressed but it is hard because I don't realise that it is happening." When you said you were not cleaning the shower – what exactly stops you? "It hurts and I am scared I am going to hurt it more."
050	Surgery – disc fusion	46	42	No change understanding, Limited controllability	"There is a bit of stiffness in the morning, I feel that is just from the cold, but other than that it has been going exceptionally well." "I am definitely much more conscious of the things I lift up. Yeah it is always in the back of my mind." "I did have a bit of an episode where I jarred my back and I couldn't move. - it was obviously the next disc up from where I had the operation. So I got quite a bit concerned about that"
052*	Surgery – Sacroiliac joint fusion + PT – standard 3 x week/3 months	44	37	No change understanding Limited controllability	"The worst pain I am having at the moment is the pubic symphysis there is a lot of swellingI was doing the dishes last night and even just the tiny pressure from leaning against the cupboard sent me through the roof. The surgeon said that pretty much wont go away until the other side is fixed because of the movement in my pelvis."

					"It is a really obvious difference between the right side which is really stiff now, and the left side which is not. It just feels weak"
037*	PT-CFT 1 x week/3 months PT-standard 4 x week/3 months Dropped out.	46	44	No change understanding Limited controllability Limited predictability No reduction pain intensity	"Nothing has really changed. Nothing at all. I have stopped going to physiotherapist and all of that because it wasn't working. It is just that I was getting such minimum relief". "It can flare up whenever it likes" "It is because of where the damage is. They can't operate because there is not enough damage there is too much damage done for them to do anything. I am in between a rock and a hard place"
018	PT – standard 1 x week/5 weeks Dropped out	46	45	Limited controllability No reduction pain intensity	"The pain is still there. They were trying to straighten me up a little bit but I have had the pain for so long it is not going to (snap fingers) magic wand." "That is why I went off the 'oxy' stuff - I thought I don't want morphine, opium or whatever they call it I don't want to be addicted to that stuff and it didn't do anything anyway."
027	Participant is a Physiotherapist who undertook post-graduate study biopsychosocial model of chronic pain	42	41	Gain biopsychosocial understanding Limited controllability	"I try not to focus on my back and remember it is not a structural problem. That the problem is caused by stress. I am less afraid than if the pain was being caused by my structure". "I think that it can go away if I find the right solution that I don't have now. I think that I should be more relaxed but there are some factors that I cannot change like my boyfriend is overseas and my father doesn't want me to go. So there are things I can't control". "The more I feel pain the more I worry and the more I worry the more I feel pain".
038	PT- stabilisation exercises 2 sessions/4 months	40	41	No change understanding, Limited predictability, Limited controllability	"I have been doing the stabilisation work but I have had a few set backs I call them in between and that flares it upIt can flare up from a twist that I shouldn't have done or a stumble. It can be just overdoing it when I am out. Doing the house work - whatever I am doing" "I am so protective of my back and I talked to the physiotherapist about that and I said am I causing atrophy in my muscles? Am I causing a pseudo fusion of my back as I am not moving it much I am keeping it

					straight up? And he said well I need you to do that because you need to calm down your joints and the inflammation there by not stressing it out, anything that causes you pain you want to avoid it for a time"
025	Podiatry 3 sessions/2 months.	42	45	Limited predictability Diagnostic uncertainty	"It is like the John Denver song: "Sometimes a diamond sometimes a stone". Sometimes I wake up and it is back and I think what have I done? What is different? If I went and dug in the garden, I could understand why. But that is why it is so difficult - what can I say to people? What can I tell my doctor? I can't even explain it to myself." "I am not going to complain to the doctor and do tests worth an arm and a leg if it will come back with nothing so until I have something concrete that she is going to find, I will just wait."
				Suffering/functional loss beliefs at baseline	s beliefs at baseline
Qualit	Qualitative 'Improvers'				
Code	Intervention	TSK s B	TSK score B F	Salient codes	Supporting extract
016	PT-CFT 1 x week/4 months	48	21	Improved controllability Mindful acceptance	"I am not going out of my way to avoid or anything like that, I am not over thinking it. It is just when it is there I deal with it the best I can but I try not to pander to it". "I am not feeling threatened or anything like that but something has just happened and all of a sudden it is saying a little bit more of a hello". "I use the stop, breathe things to manage it when it is there. I have started addressing things a little bit differently to try and stop it and live a bit more stress free"
048	PT - Standard 1 x 6 weeks/4months Yoga 1 x week Pilates 1 x week	42	20	Improved controllability Improved predictability Hope for the future	"I can control my pain now. No matter how long I sit there and the pain gets worse, as soon as I stretch or walk around it goes away". "I am thinking of becoming a karate instructor - I have done it because of my back because I didn't want any pain anymore and I know that if I keep moving it is good".

031**	PT – CFT 5 sessions/2 months	42	27	Biopsychosocial understanding Improved controllability Internal locus of control Hope for the future	"The physiotherapist explained my pain was being caused by a wound-up nervous system. It totally made sense" "I realised I had the tools in my toolbox now to control a flare up. I got better in 2 weeks - in the past it would have taken me 6 months" "I am confident I can manage any pain that I might experience in the future. I don't think back pain will ever stop me achieving what I want in life"
030	None	46	30	Mindful acceptance	"I know it will rectify itself sooner or later. You have just got to get on with it. Ok to bend or whatever you might go ouch, but you still have to do it. If it hurts it hurts. Simple as that. There is nothing I can do about it, I just have to wait for it to go. I don't revolve my life around it or think about it 24/7". "I know I have to suck it up and get on with it, because no one else is going to do it for me"
036	PT-CFT 1 x week/3months	41	32	Improved controllability Improved predictability	"And I have got the tools now to manage those things that I didn't have before. That is probably the biggest difference. Having the tools to manage it". "The tools I have now are preventative as well as curative Before I would never really know what stirred it up in the first place" "What is different is I don't have to think and plan the logistics. If we want to go to the shops we don't have to think well what time do I have to go to get a parking space out the front? Do I need to bring a cushion? I don't need to think of those things any more I think well I need to go to the shops so I will just go"
049	PT – standard 1 x month/4 months Gym 4 x week/3 month	40	33	Improved controllability Improved predictability, Reduction pain intensity	"I don't get as much grief with my back now, I can get up in the morning without it even hurting. I think I have learnt what actually, I have learnt certain things that makes it worse and what don't the difference is, I am much better at controlling it".
010	PT – CFT	42	34	Improved controllability	"(The pain) comes at least twice a week, which is a lot better - it used to

	4 sessions/4 months			Understanding negative thoughts Mindful acceptance	pop up four or five times a day. So that side of things I'm controlling a lot better. I think like the physical fitness and all of that is really helping". "The more fuel you give it, the more it hurts. The less fuel you give it the better off you are. I don't think about it, like I know I'm in pain but it just it is what it is." "You can't let the pain dominate your life. You've just got to keep going and when it turns up say "gidday, how are you" and continue on."
019	PT - CFT 5 sessions/3 months	45	38	Improved controllability Improved predictability Understanding negative thoughts Hope for the future	"I had made the connection between the stress and that, but I didn't know what to do about it. I didn't have the tools to do what I needed to do". "You sort of have a nano-second when a thought hits your brain of which way you are going to push it. I think in the past my personality, I would grab hold of negative things and hold on to them and dwell on them. Now I am more focused on where I need to go and don't let these things bog me down." "I definitely think in 6 months time I will be a lot better. I know the things that affect my back and I know the things I have learnt will settle it down."
032**	Pain clinic Psychology, physiotherapy, 2 x spinal block injections 1 x week/2 months	47	-	Improved controllability Reduction pain intensity	"I know if I do some of the exercises, it does bring the intensity down. It does help relieve it. If it is really bad I try to do more than less and that really helps a lot. I know how to deal with it now". "Generally it is just like a toothache now and I would rather the constant toothache pain than the vicious one that comes every now and then" "You learn to cope a lot better over a period, I mean it has been quite a while since I hurt my back so you do learn to cope. You learn to deal with the fact that yes you are going to be in pain but yes you can deal with it. You can make it a little bit lesser if you do this exercise, you are a bit more comfortable. There is always a way to get you through it, it is just finding that way that gets you through it."
024	PT - CFT dropped out. 5 sessions/2	45	30	Improved controllability Reduction pain intensity	"Exercise definitely helps, it definitely helps because I know when I am moving that I am not as sore" "I am on the patch and taking a low dose cortisone and everything does

	months				feel better ".
	Gym program 1 x week + medication				"At the end of the day, everybody just wants less pain. Be that by medication or by exercise or by I don't know"
Qualit	Qualitative 'Non-improvers'	ers'			
015	PT - CFT dropped	46		Reduction pain intensity	"I wouldn't say I am normal as I am still feeling pain and still on all the
	out.			Limited predictability	meds. But I am definitely a lot better, the pain is less intense". "I think I have become a lot better after not having the intense nerve pain
	PT – standard and				for a while. I am doing the movements and getting to know how to sit
	hydrotherapy 1 x				properly. But it is still scary that it could come back. I am always scared of
	week 2 months.				it. I am still scared of it".
	Rhisotomy, 2 x				
	cortisone injections				
028	PT – CFT	47	44	No change understanding	"I am worried it is more serious, with more dire consequences because I
	4 sessions/ 2				don't know what it is and with that ambiguity you tend to think of the
	months then			Limited predictability	worse".
	dropped out				"It is 100% unpredictable when it will be a $10/10$ and when it will be
					3/10. But it always takes the same amount of time to calm down."
					"I think the pain has a greater sway than last time. It affects my life more
					severely."
033	PT- CBT	40	98	Limited controllability	"As the months go by we have gone into winter and of course my pain
	$1 \times 2 \text{ weeks}/3$				levels increase automatically without me doing anything".
	months				"I am worse than we last spoke but compared to this time last year, I have
					become more active, the more active I get the more my pain level
					increases, but try to balance it out and try to ignore it a bit"
045	PT – standard	41	38	Limited controllability	"There is still a problem where it gets real intense. I still can't be on my
	1 x 3 weeks/3			No reduction pain intensity	feet for too long, I am still very limited."
	months				"They are trying to get me to use the hot water bottle less so then I can go
					to work and not have to lie down every hour or so".
014	PT – Pilates	42	39	Limited controllability,	"I have not had a representative 4 months - I have been doing these

1 x week/4 months	No reduction pain intensity	renovations and they have stressed me so much! It is like an instant pain
		switch when I am stressed!"
		"Pain is still threatening to me because I am not going to be able to keep
		up with daily life that I need to do. Cos I have a certain standard of
		everything that needs to be done in my mind -it is the high standards I set
		for myself."
* = Participant described 'mixed beliefs'	at baseline. Damage beliefs considered	* = Participant described 'mixed beliefs' at baseline. Damage beliefs considered more salient than suffering/functional loss beliefs
** = Participant described 'mixed beliefs	s' at baseline. Suffering/functional loss b	** = Participant described 'mixed beliefs' at baseline. Suffering/functional loss beliefs considered more salient than damage beliefs
PT = Physiotherapy		
CBT = Cognitive Behavioural Therapy		
CFT = Cognitive Functional Therapy		
B = before		
F = follow-up		

Aim 2

The second aim of this study was to identify factors associated with improvements in pain-related fear through qualitative analysis of interview data and to explore how these factors may be associated with beliefs underlying pain-related fear at baseline. Salient codes and supporting extracts for each participant are presented in Table 7.3, arranged according to improver status and beliefs underlying pain-related fear at baseline. A description of how salient codes were grouped into themes is presented in Table 7.4.

Table 7.4. Identification of themes from inductive coding

Overarching theme	Themes	Salient codes
	Reduction in threat value of pain	Improved controllability Improved predictability Reduction pain intensity
Gaining control over the pain experience	Conceptual understanding of pain that makes sense coupled with targeted management	Diagnostic certainty Biopsychosocial understanding Hope for future Internal locus of control External locus of control
	Reduced goal conflict	Improved controllability Mindful acceptance Understanding negative thoughts

The over-arching theme identified amongst all improvers was 'gaining control' over the pain experience. Gaining control appeared to be achieved by: 1. A reduction in the threat value of pain, described by improvers regardless of beliefs reported at baseline; 2. Conceptual understandings of pain that made sense, coupled with targeted management to control pain, described by improvers who reported damage beliefs at baseline; and 3. Reduced conflict between pain and functional goals, described by improvers regardless of beliefs reported at baseline.

1. Reduction in the threat value of pain

For participants who described an improvement in their perception of pain predictability, pain controllability and/or pain intensity, the threat value of pain appeared to be reduced.

Many improvers perceived an improvement in the predictability of their pain. Individuals perceived pain as more predictable when they knew what triggered an increase in pain intensity and could predict how their symptoms would respond in a given situation. This participant described how she was less worried about pain now that she had learnt what makes her pain worse:

"I don't get as much grief with my back now. I think I have learnt certain things that make it worse" (049)

An awareness of what made pain 'worse' assisted improvers to become aware of what made pain 'better'. Individuals perceived pain as more controllable when they had strategies to control the intensity of their symptoms and the impact of their symptoms. Improvers described a range of strategies that increased perceptions of controllability from more active self-management strategies, to more passive strategies:

"The stretches are the first thing I would do and then drugs are the next thing I would do. If neither of those things would work I would probably call the physiotherapist and say can you talk me through it or can I come in and see you. It hasn't got to that. When I had a flare-up that day and it was really bad, I went to my stretches and that fixed it. I think you build up confidence in your body when the worst happens and you get through it" (017)

Indeed, many improvers described the importance of having the opportunity to 'test' the effectiveness of new strategies during a flare-up. The experience of positive outcome enabled individuals to develop pain self-efficacy:

"You have to be able to have the success of doing it without pain to go actually I can do it. The proof is in the pudding" (036)

Many described an improvement in pain intensity. For some, this appeared to be associated with improvements in pain predictability and controllability. However, not all individuals who experienced an improvement in pain intensity experienced improvements in pain predictability and controllability. It is possible that for some, the follow-up interviews were conducted during a respite in pain intensity, reflecting the fluctuating nature of pain intensity through time:

"It doesn't worry me when the pain flares up now. Because it is not as bad. I was starting to think am I going to end up in a wheelchair. But I am not like that now. It is just not having that excruciating pain anymore" (044)

2. Conceptual understanding of pain that makes sense coupled with targeted management

A biopsychosocial understanding of pain linked to targeted self-management

For some improvers with damage beliefs at baseline, learning that pain was not necessarily a sign of underlying pathology or structural damage, but rather something that could be influenced by their own behaviour, enabled them to develop an internal locus of control over their pain experience. Without the fear of damage, these improvers could confront previously feared movements:

"I went from being terrified of hurting myself anytime I moved to realizing that moving was the very thing I needed to do...What I have learnt about chronic pain is that it is a result of your behavior as much as it is the result of something going on inside you. It is not necessarily the fact that something is busted, it is that you are continually hurting yourself without moving properly" (017)

A biopsychosocial understanding of pain was gained through a combination of education and behavioural experimentation. Behavioural experimentation appeared important to challenge dysfunctional beliefs and to replace negative expectations of moving with pain with positive experiences of moving with pain control. Positive encounters with a confident clinician who established trust and hope, provided a favourable environment for this to occur:

"In my head I thought I would break in half if I did that activity. But the physio said something critically important in one of the early sessions, he said: 'Forget everything you have been told up until now. Your structure is fine. You need to learn how to move again'. And I thought who do I trust? The person that said forget everything, and I am feeling better after one session? Or the people in the past who told me my structure was broken beyond repair?" (036)

"I would never have attempted to touch my toes because I thought I would hurt myself. When he got me to do it on the first day - it wasn't just that I had done it. I could have done it and it hurt like buggery. But my back wasn't hurting. And I had done it on my own, without him. He was just standing there. It changed my mind set instantly. Everything made sense." (017)

Once individuals understood that pain could be influenced by their own behaviour, practicing alternative behaviours and self-management strategies appeared to be linked to improved pain-self efficacy. At baseline this improver believed she had a weak and unstable spine, and worried that 'sharp pain' meant that the structure of her spine was worsening. At follow-up she described her spine as structurally sound and believed that pain was caused by tension in her muscles. She gave an example of how she was less anxious about 'sharp' pain now that she had self-management strategies to 'settle' the pain down:

"I woke up in the middle of the night with a sharp pain across my back. I got onto the floor, into the child pose posture with outstretched arms to stretch out the lower back and told myself I was safe, all the things I have learnt and I was ok. I am not as anxious or catastrophising to the extent I was" (013)

A diagnosis of an underlying structural abnormality linked to targeted biomedical management

Two improvers with damage beliefs at baseline described a strengthening of external locus of control beliefs at follow-up. During the study period they had

received a diagnosis of an underlying structural abnormality and a biomedical intervention to 'fix' the abnormality. This provided them with hope that the structural abnormality causing their pain had been, or could be, resolved.

Having been diagnosed with a labral tear in her hip, Participant 022 was two weeks post labral-repair surgery at the time of the follow-up interview and was experiencing post-operative pain, an average of 7/10 on the NRS. She believed that the labral tear had been the source of her back pain, and that the pain she was experiencing now was an expected consequence of surgery that would resolve with time. She was no longer fearful of engaging in painful activity:

"He said that I can go back to the gym and walk through water. So I did ten lengths and I was fine. I did his exercises... and this morning I have pulled up a little bit sore. But I'm not worried. Because I am convinced that it is going to go. It is just that I have had a huge operation." (022)

The belief that that the damage that had caused her pain for 13 years had now been repaired, restored her hope for the future in spite of on-going pain:

"I have as much pain if not more than I had before, but it is not bothering me in the same way. Because now it makes sense. I have got a guideline. I am going to see the orthopaedic surgeon in 6 weeks and hopefully it will be repaired" (022)

A similar experience was described by Participant 046 who believed that his diagnosis of 'lumbar degeneration' could be reversed through the stem cell injection therapy he was receiving:

"Historically wear and tear did mean wheelchair in the future. Now with regenerative medicine, people are going to be able to have corrective treatment with regenerative medicine" (046)

At follow-up, he reported an improvement in pain-related fear and hope for the future knowing that his issue could be 'solved at the source':

"I am able to be on my feet for longer periods of time... with the gym work I do my muscle bulk is coming back which is terrific. I am confident that the treatment is matching the issue – that we are solving the issue at the source... I haven't had time to rebuild the bulk of the discs, but it can happen." (046)

3. Reduced goal conflict

The improvers who gained a sense of control over what made pain worse and how to make it better during the study period, described reduced conflict between pain and functional goals. Their lives were no longer dictated by pain:

"The difference is I don't have to think and plan the logistics. If we want to go to the shops I don't have to think what time do I have to go to get a parking space out the front? Do I need to bring a cushion? I don't need to think of those things now. If I need to go to the shops I will just go" (036)

Some improvers described a metacognitive shift in their approach to painrelated problem solving that meant they were less engaged in a perseverance loop of worry about unresolved pain. This improver who had received care from a psychologist during the study period described how she had learnt to worry less about the consequences of her pain and other sources of stress in her life:

"How I view everything at the moment is well... can I change it? Yes, ok then I change it. Can I change it - no? Then stop it. Just stop worrying about it" (039)

An improvement in psychological flexibility was described by this improver who learnt to control the negative thoughts and emotions that influenced his pain. Without being 'bogged' down by negative thoughts, he was able to pursue valued life goals:

"I understand you sort of have a nano-second when a thought hits your brain of which way you are going to push it. I think in the past my personality, I would grab hold of negative things and hold on to them and dwell on them. Now I am more focused on where I need to go and don't let these things bog me down." (019)

Through behavioural experimentation, some improvers learned that giving less attention to pain meant it 'hurt' less:

"The more fuel you give it, the more it hurts. The less fuel you give it the better off you are. I don't think about it, like I know I'm in pain but it just is what it is " (010)

A mindful acceptance of the presence of pain in their lives meant that reducing pain was no longer seen as a pre-requisite for achieving functional goals and regaining control over their lives. This improver who described fear of the functional consequences of pain at baseline reported being less worried about the functional consequences of pain at follow-up because:

"I have realized that you can't let the pain dominate your life. You've just got to keep going and when it turns up say 'gidday, how are you' and continue on " (010)

<u>Differences in salient codes between improvers with damage beliefs versus</u> <u>suffering/functional loss beliefs at baseline:</u>

Amongst improvers with damage beliefs at baseline, gaining an understanding of the cause of their pain (biopsychosocial understanding of pain and diagnostic certainty) and an internal locus of control appeared to be the most frequent salient codes. Amongst improvers with suffering/functional loss beliefs at baseline, improved controllability of pain appeared to be the most frequent salient code (see Table 7.3).

Salient codes amongst 'non-improvers':

Amongst non-improvers with both damage beliefs and suffering/functional loss beliefs at baseline, limited controllability of pain appeared to be the most frequent salient code. Of note, three non-improvers with damage beliefs at baseline described gaining a biopsychosocial understanding of pain but the same three individuals described a limited controllability of pain (see Table 7.3).

<u> Aim 3</u>

The third aim of this study was to examine if the changes in quantitative measures ASI, BBQ, CSQ, DASS, NRS, PCS, PSEQ, and TSK differed between those who experienced an improvement in pain related fear and those who did not.

Statistically significant changes between improvers and non-improvers were found on the BBQ, CSQ-Control, NRS, PSEQ and TSK. Significant differences between the percentage of individuals who achieved clinically significant changes in the improver versus non-improver group were seen for the BBQ, CSQ-Control, NRS and TSK (see Table 7.5).

Table 7.5. Baseline, follow-up and change scores of questionnaires in groups with and without an improvement in pain-related fear, and test of differences between grouns in change scores.

Measure		Improvementi	Improvement in pain-related fear		
		No (n=11)	Yes (n=17)	Difference	p-value
ASI (0-64)					
	Baseline (mean, (sd))	20.9 (16)	16.4 (15.6)		
	Follow-up (mean, (sd))	23.4 (11.7)	11.9 (10.5)		
	Change (mean, (sd))	-1.9 (8.7)	2.5 (6.0)	4.4 (-1.3 – 10.1)	0.127a
	Change ≥19 (n(%))	1(9)	0		0.206^{c}
BBQ (9-45)					
	Baseline (mean, (sd))	26.3 (6.3)	26 (5.7)		
	Follow-up (mean, (sd))	26.6 (6.4)	32.4 (6.1)		
	Change (mean, (sd))	0.3(4.9)	6.5(5.1)	6.7 (2.7 – 10.7)	0.002a
	Change ≥2 (n (%))	4 (36)	15 (88)		0.004^{c}
CSQ Cognitive Coping (0-35)*					
	Baseline (mean, (sd))	17.1 (5.5)	16.9 (7.5)		
	Follow-up (mean, (sd))	17.7 (6.4)	19.2 (6.1)		
	Change (mean, (sd))	0.3 (5.8)	3.1(4.8)	2.9 (-1.3 – 7.1)	0.174a
	Change ≥11 (n (%))	0	2 (12)		0.223^{c}
CSQ Control (0-6)*					
	Baseline (Median (min, max))	3 (0,4)	3 (1,4)		
	Follow-up (Median (min, max))	3 (0,4)	5 (2,6)		
	Change (Median (min, max))	0 (-2, 1)	2 (-1, 4)	2	0.003 b
	Change ≥1.8 (n (%))	0	11 (69)		<0.001°
			,		

DASS					
Depression (0-21)	Baseline (mean, (sd))	7.5 (5.2)	4.0 (3.9)		
	Follow-up (mean, (sd))	7.5 (5.1)	1.4(2.0)		
	Change (mean, (sd))	0.6(4.0)	2.2 (3.6)	1.5 (-1.4 - 4.5)	0.297^{a}
	Change ≥6 (n (%))	1 (9)	3 (18)		0.527^{c}
DASS					
Anxiety (0-21)	Baseline (mean, (sd))	5.6 (4.6)	2.9 (4.3)		
	Follow-up (mean, (sd))	5.8 (5.9)	1.3 (1.4)		
	Change (mean, (sd))	0.2 (3.0)	0.9 (2.9)	0.8(-1.6-3.1)	0.506^a
	Change ≥6 (n (%))	0	2 (12)		0.238^{c}
DASS					
Stress (0-21)	Baseline (mean, (sd))	9.6 (6.2)	8.3 (5.3)		
	Follow-up (mean, (sd))	10 (5.5)	5.2 (3.8)		
	Change (mean, (sd))	0.1(4.3)	2.6 (4.4)	2.6 (-0.9 - 6.0)	0.143^{a}
	Change ≥6 (n (%))	1 (9)	3 (18)		0.527c
NRS (0-10) **					
	Baseline (mean, (sd))	5.3 (2.0)	4.7 (1.9)		
	Follow-up (mean, (sd))	4.8 (1.8)	2.9 (2.2)		
	Change (mean, (sd))	0.5(2.0)	1.7 (1.7)	1.2 (-0.2 - 2.6)	0.079a
	Change ≥2 (n (%))	2 (17)	10 (56)		0.033^{c}
PCS total (0-52)					
	Baseline (mean, (sd))	25.7 (10.0)	19.6 (13.8)		
	Follow-up (mean, (sd))	21.9 (10.9)	9.1 (11.4)		
	Change (mean, (sd))	4.6 (7.8)	9.9 (7.5)	5.3 (-0.7 – 11.4)	0.083a
	(n (%)) Change ≥16	1 (9)	5 (29)		$0.201^{\rm c}$

PSEQ (0-60)					
	Baseline (mean, (sd))	28.6 (10.0)	31.7 (11.4)		
	Follow-up (mean, (sd))	33.7 (11.2)	44.8 (9.9)		
	Change (mean, (sd))	5.5 (9.4)	13.2 (8.2)	7.7 (0.9 – 14.6)	0.029a
	(m (%)) (n (%))	4 (36)	12 (71)		0.074^{c}
TSK (17-68)***					
	Baseline (mean, (sd))	45.2(6.5)	46.6 (4.5)		
	Follow-up (mean, (sd))	41.1 (3.1)	31.8 (7.3)		
	Change (mean, (sd))	4.0 (6.8)	14.8 (6.4)	10.8 (5.7 – 15.9)	$< 0.001^{a}$
	Change ≥ 8 (n(%)	1 (8)	15 (88)		<.001 ^c
^a Independent groups t	a Independent groups t-test, b Mann-Whitney test, chi squared test of differences in percentage of individuals achieving minimal clinically	st of differences in perce	ntage of individuals ach	ieving minimal clinically	y
important differences	important differences in improver versus non-improver groups.				

 * Twenty-seven participants completed the CSQ Cognitive Coping and CSQ Control

*** Twenty-nine participants completed the TSK

^{**} Thirty participants completed the NRS

There were some participants who had large improvements in the quantitative measures but were not considered to have experienced an improvement in pain-related fear according to qualitative analysis. A consideration of these cases is provided in Table 7.6.

Table 7.6. Consideration of outliers from mixed-methods analysis

Outlier		Interpretation	Supporting extract from follow-up interview
	finding		
025	6-point	This may be explained by the large fluctuations	"Some days are worse than others. Like the John
	improvement on	she experienced from day to day. It is possible	Denver song "Sometimes a diamond sometimes a stone.
	NRS, but no	that she was experiencing a "good" week (i.e.	That is why I feel that I am not going anywhere now. I
	reduction in fear.	low pain intensity) when she filled in the	could go to the podiatrist and get treatment but I have
		questionnaires, and thus reported low pain	done that and it didn't fix it. I might get short term
		intensity, despite no change in her fear.	relief but who's to say it isn't a good day anyway when I
			go to the podiatrist?"
011	10-point	Participant 011 had the highest fear scores at	"(The physiotherapist's) philosophy is that I have an
	improvement on the	baseline (65/68). Whilst at follow-up she	ultra sensitive nervous system so whenever I get
	TSK-SF and 7-point	scored significantly lower on the TSK (41/68)	stressed I flare up. I think ok but how do I get rid of
	improvement on the	this score is still above cut-offs of high fear. At	that? I need to find some kind of coping mechanisms if
	BBQ but was not	follow-up she described a new biopsychosocial	that is what is causing it"
	considered to have	understanding of pain, but had limited	
	experienced a	strategies to control her response to pain and	SB: When you said you were not cleaning the shower -
	reduction in fear	remained fearful of 'hurting' herself	what exactly stops you?
			011: It hurts and I am scared I am going to hurt it more
018	15-point	An itemised analysis of PSEQ scores at	"That is why I went off the oxy stuff - I thought I don't
	improvement on the	revealed improvements of >2 points on the	want morphine, opium or whatever they call it I don't
	PSEQ but did not	items: "I can enjoy things, despite the pain"; "I	want to be addicted to that stuff and it didn't do
	experience a	can socialise with my friends or family	anything anyway."
	reduction in fear	members as often as I used to do, despite the	"The pain is still there. They were trying to straighten
		pain"; "I can still do many of the things I enjoy	me up a little bit but I have had the pain for so long it is
		doing, such as hobbies or leisure activities,	not going to go with a magic wand."
		despite pain". It is possible that the responses	
		to these items are influenced by, for example,	
		participation in a recent social event, rather	

		than reflecting a reduction in fear avoidance behaviour. Endorsement of the item: "I can cope with my pain without medication" is consistent with the participants' qualitative reports of stopping medication, however he continued to lack strategies to control his pain	
052	16-point improvement in PSEQ but did not experience a reduction in fear.	At follow-up the participant had recently undergone surgery to fuse his right sacroiliac joint. His improved score may reflect the belief that he now has a way of controlling damage by surgery	"It is a really obvious difference between the right side which is really stiff now, and the left side which is not. It just feels weak. I know that it would feel better doing the operation on the left side, because I know how the right side feels"
050	Large improvements on the rumination and helplessness subscales of the PCS but did not experience a reduction in fear.	His experience of recent 'successful' surgery to 'fix' his spine may have meant that he now believed he had an effective way of controlling future pain by surgery. As a result he may not have felt as helpless and worried about his pain at follow-up	"I think if I hadn't had surgery I would be considerably in pain, taking a lot more medication and maybe in a wheelchair or something like that" (050) "I did have a bit of an episode where I jarred my back and I couldn't move. It was obviously the next disc up from where I had the operation. After the second day (of pain) I was actually contemplating on ringing up the surgeon again and seeing if I could come back and get an appointment." (050)
027	10 points higher on the CSQ-CC but did not experience a reduction in fear.	This participant, had undertaken post-graduate physiotherapy course in which she learnt about biopsychosocial models of chronic pain. She believed running was important to control her stress, but running flared up her pain and made her worry about her subsequent functional capacity. An itemised analysis of the CSQ-CC scores revealed a >3	"I try not to focus on my back and remember it is not a structural problem. That the problem is caused by stress. I am less afraid than if the pain was being caused by my structure". "Well usually I still run because I find it important and I don't think about my body. Then when I relax my body I feel the pain and I know it is too late and then I worry I am afraid that I might not be able to work –I

	point improvement on the items: "I tell myself I	am not afraid of the present pain, I am worried about
	can't let my pain get in the way of what I have	tomorrow."
	to do"; "No matter how bad the pain gets I	"(Once the pain has flared up) I don't know what to do.
	know I can handle it"; "I just go on as if nothing	Like stretching – I am not so sure it is a solution, so I
	happened". It is possible that the CSQ-CC	prefer to do nothing. Doing something that I am not
	captured a maladaptive 'persistence' coping	sure about - it is worse than not doing anything. So I
	strategy. The participant continued to run	prefer to avoid it and do something else distracting."
	because she prioritised controlling the stress	
	that she knew influenced her pain. In turn, the	
	running flared up her pain and she lacked	running flared up her pain and she lacked
	strategies to control the flare up.	

Discussion

This study supports the existing literature showing that improvements in pain-related fear may occur over a four-month period for some individuals with CNSLBP and high pain-related fear (Vlaeyen et al. 2001, Boersma et al. 2004, Woby et al. 2008). However, it extends the existing literature by proposing that different pathways to fear-reduction may exist and that these pathways may be influenced by the beliefs underlying pain-related fear.

Common to all improvers was 'gaining control' over the pain experience.

Participants with suffering/functional loss underlying pain-related fear at baseline described a pathway to improvement that involved gaining adaptive self-management strategies to increase pain controllability, predictability and intensity and reduce goal conflict. The opportunity for 'mastery experiences' in which individuals could apply self-management strategies during a flare-up, appeared to be an important step on the pathway, instilling hope and confidence that future flare-ups could be controlled. Increased pain self-efficacy may have meant that these individuals were more likely to engage in previously avoided activities, providing them with positive, 'disconfirmatory' experiences that reduce pain-related fear and encourage the pursuit of valued goals (Woby et al. 2008). This is a putative mechanism by which behavioural interventions facilitate cognitive changes associated with fear-reduction (Foa and Kozak 1986).

Participants with damage beliefs underlying pain-related fear at baseline, described pathways to improvement that involved an understanding of pain that made sense linked with a targeted intervention, delivered by a confident clinician, that strengthened their locus of control beliefs. Two main pathways were identified: a biopsychosocial understanding of pain with a targeted intervention to strengthen internal locus of control beliefs and a biomedical understanding of pain with a targeted biomedical intervention that strengthened external locus of control beliefs.

Recent literature emphasises the importance of providing patients with a neurophysiological understanding of pain, through interventions such as Explain Pain (Butler and Moseley 2003, Traeger et al. 2014). Whilst there is some evidence that these interventions may improve short-term pain outcomes for people with CNSLBP (Clarke, Ryan, and Martin 2011), they have not been trialled in the subgroup of individuals with high pain-related fear. In support of an educational approach, a previous qualitative investigation embedded in a Cognitive Behavioural Therapy intervention suggested acceptance of a biopsychosocial explanation alone is the main prerequisite for positive treatment outcome in people with CNSLBP (Toye and Barker 2012). However, the findings of this study suggest that for individuals with high pain-related fear, a biopsychosocial understanding may need to be linked with the development of an internal locus of control on the pathway to fear-reduction. This is supported by conclusions from a mediation analysis embedded in an RCT that changing beliefs in the damaging effects of pain *and* strengthening internal locus of control beliefs constitute an important pathway to improved CNSLBP outcomes regardless of the type of treatment (Spinhoven et al. 2004).

In contrast, participants who had their damage beliefs endorsed and described a strengthening of external locus of control beliefs, expressed hope that the underlying pathology could be fixed. Individuals who expect a treatment to successfully 'cure' them may be more likely to engage in and adhere to treatment (Main, Foster, and Buchbinder 2010) and may experience expectation-related improvements in affective and cognitive dimensions of the pain experience (Wager et al. 2004). Findings from an RCT suggest that an improvement in pain-related fear may occur in response to a surgical intervention perceived as having been 'successful' (as having 'helped one's back problem') (Havakeshian and Mannion 2013). However, in the present study, two of the four participants who received biomedical interventions targeting an underlying pathology and described an external locus of control, were classified as 'non-improvers' (050 and 052). Both individuals continued to experience pain and to describe their spines as vulnerable. Furthermore, biomedical interventions for CNSLBP may have limited lasting efficacy (Walker et al. 2011, B13 2004) and the experience of unmet treatment expectations repeated over time may eventually exacerbate pain-related fear (Aldrich, Eccleston, and

Crombez 2000, Crombez et al. 2008, Havakeshian and Mannion 2013).

A few participants from both belief groups described how they had learnt to accept the presence of pain without fighting against it on their pathway to improvement. This supports Acceptance and Commitment Therapy in the management of people with CNSLBP and high fear. Acceptance and Commitment Therapy is thought to indirectly reduce pain-related fear through a shift in attention away from pain and its consequences towards focussing on valued life activities, a skill known as 'psychological flexibility' (Vowles and McCracken 2008, Vowles et al. 2014). Whilst Acceptance and Commitment Therapy explicitly emphasises the acceptance of pain rather than control over pain (McCracken and Keogh 2009), a meditational analysis embedded in an RCT found that improved perceptions of pain controllability mediated improvements through both Cognitive Behavioural Therapy and Acceptance and Commitment Therapy (Wetherell et al. 2011). It is possible that for some individuals, acceptance functions as a strategy to control pain-related fear.

The limited pain controllability described by 'non-improvers' in this study, supports the suggestion that a key factor on all pathways to improvement in pain-related fear is gaining control over the pain experience.

Mixed-methods analysis confirmed that improvers had greater improvements in quantitative measures of beliefs about the inevitability of back pain (BBQ), control (CSQ-control item), pain intensity (NRS), pain self-efficacy (PSEQ), and pain-related fear (TSK) than non-improvers. Improvers were also more likely to experience clinically significant improvements on the BBQ, CSQ-control and NRS than non-improvers. Whilst improvers had greater reductions in pain catastrophising (PCS) than non-improvers, this difference was not statistically significant (p=0.083).

The lack of difference between improvers and non-improvers on the ASI and DASS is consistent with the qualitative findings that did not identify affective factors such as stress, anxiety and depression as salient codes associated with improvements in pain-related fear in this group.

The lack of difference in the percentage of improvers and non-improvers with clinically significant improvements on the CSQ-CC and PCS may be due to the fact that no published MCIDs exist for the CSQ-CC or PCS, and the MCID value of 30% may have been too high.

The mixed-methods findings revealed participants who had large improvements on the BBQ, CSQ-CC, NRS, PCS and PSEQ but did not experience an improvement in pain related fear. An analysis of item endorsement in the context of the individual qualitative context provided some insight into this finding. The findings in Table 7.6 highlight limitations in interpreting improvement based on self-report questionnaires. For example, the PSEQ appeared unable to distinguish between an internal and external locus of control and may have been influenced by unrelated contextual events.

It is important to note that whilst improvers and non-improvers had similar scores on the TSK at baseline, non-improvers had worse scores on most self-report questionnaires at baseline, particularly the PSEQ, PCS, DASS and ASI. Whilst these differences in baseline scores between improvers and non-improvers were not statistically significant, this may have presented a potential barrier to change in pain-related fear amongst non-improvers.

Clinical implications

These findings highlight that the pathway to improvement in pain-related fear differs between individuals. The findings suggest that fear-reduction may be enhanced by considering and addressing the underlying beliefs of individuals presenting with high pain-related fear, and providing individualised treatment and/or management to gain control over the pain experience. The findings suggest a close relationship may exist between perceived 'pain control' and reported levels of pain-related fear, although the means by which pain control is achieved may differ between individuals.

The results suggest that for individuals who endorse damage beliefs, providing them with a biopsychosocial explanation of pain to change damage beliefs, assisting them to realise that pain is within their control *and* empowering them to develop self-management skills may facilitate fear-reduction. Alternatively, providing them with an explanation of pain that strengthens their damage beliefs may facilitate fear-reduction if they are assisted to believe there is a way to resolve the damage. However, given that internal locus of control beliefs have been shown to mediate outcome of LBP treatment (Turner, Holtzman, and Mancl 2007, Spinhoven et al. 2004), it would seem preferable that individuals are encouraged to develop self-management strategies to gain independent control over pain, rather than encouraging individuals to be reliant on a healthcare provider to 'fix' them.

In contrast, targeting damage beliefs may not be helpful as a pathway to fear-reduction in people with suffering/functional loss beliefs underlying pain-related fear. To enhance fear-reduction in this group, interventions may need to target pain predictability, controllability and intensity; to provide self-management strategies that build pain-self efficacy; teach skills to think more positively about pain and develop a mindful acceptance of pain.

While speculative, for individuals who lack the capacity to control pain or where pain intensity is a barrier for management, integrating targeted pharmacological management may assist in fear-reduction and functional activation.

Design considerations

A limitation of this study is the reliance on participant's descriptions of the interventions they received during the study period. As such we are only able to comment on patients' perspectives of change. Further limitations include the lack of repeated measures to provide insight into when and how changes occur, and to reduce memory bias. This study had a relatively short follow-up and trajectories of changing pain-related fear may not have been captured at the single follow-up. As there is no consensus in the literature as to what constitutes an improvement in pain-related fear on the TSK, we chose to determine

improver status based on qualitative data. We were able to reliably classify people as improvers or non-improvers based on the pre-determined criteria. Readers are referred to Table 7.3 for reassurance that these judgements were grounded in raw data.

The a priori selection of questionnaires for the mixed-method analysis means that questionnaires measuring constructs potentially associated with improvements in fear such as Chronic Pain Acceptance Questionnaire (McCracken, Vowles, and Eccleston 2004) were not included. It is recognised that the power for the between-group comparisons of the quantitative data was limited by the sample size, however it is emphasised that the mixed-method component served a triangulation function in this primarily qualitative, exploratory study.

Purposive sampling aimed to capture a diverse range of experiences of pain-related fear rather than a representative sample. We did not collect data on how many invitations were handed out and to whom and can only speculate on how the participants may have differed from the population from which they came. It is possible for example, that this sample had a higher level of health literacy than those who did not contact the researchers. Higher health literacy may have meant that the participants were able to seek, understand and utilise back pain information better (Briggs et al. 2010), making them more likely to experience an improvement in pain-related fear.

Despite these design constraints, this study provides a preliminary evidence-base to inform the next generation of FAM research. It suggests that to increase the clinical utility of the FAM, future iterations may need to consider the heterogenous beliefs underlying pain-related fear and the multiple pathways leading to fear-reduction that may be enhanced by assisting individuals to gain control over the pain experience.

Discussion of chapter findings

By providing a deeper understanding of how and why pain-related fear can change over time, this study has gained insight into the factors that may be important for HCPs to target on the pathways to fear-reduction. These factors include the predictability, controllability and intensity of pain, an individuals' understanding of their LBP, locus of control beliefs, hope, and pain acceptance. These factors are not explicitly described in the current FAM.

This study has also highlighted that multiple pathways to fear-reduction may exist and suggested that interventions may be tailored to target different factors dependent on an individuals beliefs underlying pain-related fear.

In Chapter eight, we will explore how these findings may be incorporated into the next generation of the FAM that can direct HCPs to deliver targeted fearreduction interventions.

Chapter 8. Making sense of pain-related fear

The FAM describes a well-validated model outlining the vicious cycle of pain-related fear, fear avoidance behaviour and disability in CNSLBP. Whilst these fundamental tenants of the model are undisputed, calls have been made for the next generation of FAM research to extend the clinical utility of the model. This research employed a predominantly qualitative methodology to provide novel insights into the lived experience of pain-related fear that could inform future iterations of the FAM. The specific aims of the study were to explore the beliefs underlying pain-related fear, factors associated with beliefs underlying fear and factors associated with improvement in pain-related fear over time.

This body of work commenced with a metasynthesis of the qualitative literature exploring the lived experience of CNSLBP, presented in Chapter three. The metasynthesis highlighted the salience of biomedical beliefs about LBP amongst study participants with CNSLBP. The CNSLBP experience was conceptualised as biographical suspension, in which one's 'wellness', 'self' and 'future' were placed on hold during the search for a diagnosis and 'cure' for LBP. However, no studies specifically explored pain-related fear in individuals with high fear, and therefore limited insights could be gained to inform the study aims.

The baseline findings from interviews with 36 participants with CNSLBP scoring highly on the TSK were presented in Chapter five. Heterogenous beliefs underlying pain-related fear were identified. Some individuals reported damage beliefs, where others denied these beliefs and reported suffering and functional loss beliefs. A few reported both. This suggests that the TSK may not be simply a measure of 'fear of movement and physical activity that is wrongfully assumed to cause (re)injury'. An itemised analysis of TSK scores supported the construct validity of a subscale of the TSK associated with damage beliefs. However it failed to support the construct validity of a second subscale associated with suffering/functional loss beliefs, perhaps due to ambiguously worded items.

In Chapter six, the factors associated with damage, suffering and functional loss beliefs underlying pain-related fear at baseline were explored to gain insight into the factors that contribute to these beliefs. All participants described an inability to make sense of their unpredictable, uncontrollable and/or intense pain experience. Participants with different beliefs underlying fear described different attempts to make sense of their pain. Participants with damage beliefs underlying fear drew on past personal experiences of back pain, societal beliefs, and sought diagnostic certainty; but encountered diagnostic uncertainty, or diagnoses of an underlying pathology that couldn't be fixed. This reinforced damage beliefs and left them confused about how to 'fix' the damage. Participants with suffering/functional beliefs underlying fear drew on past personal experiences of back pain and sought help from clinicians to control their pain; but failed treatments and the repeated failure to achieve functional goals reinforced suffering/functional loss beliefs and left them unable to make 'sensible' decisions of what to do about a pain. The salient roles of pain unpredictability, uncontrollability and intensity in the experience of painrelated fear identified amongst the participants is not captured in the current FAM, which ascribes a limited role to the somatic aspects of the pain experience. Further, the findings raise the novel suggestion that sense-making may play a role in future iterations of a FAM.

The follow-up findings exploring the factors associated with an improvement in pain-related fear were presented in Chapter seven. Participants who were able to gain control over the pain experience reported an improvement in pain-related fear. This appeared to occur through a diverse range of interventions. 'Improvers' described gaining control over the pain experience through an improvement in pain predictability, controllability and/or intensity; some described gaining a conceptual understanding of pain that made sense coupled with targeted management; and others described reduced goal conflict. The pathways to achieving these differed between individuals, and appeared to be influenced by the beliefs underlying their pain-related fear. In particular, gaining a conceptual understanding of pain linked with a targeted management plan that strengthened internal or external locus of control appeared important on the pathways to improvement in fear amongst people with damage beliefs at

baseline. While the FAM describes an alternative model for LBP where painrelated fear can be avoided by confronting pain leading to recovery, it currently does not provide a conceptual model for explaining the process of fearreduction that can guide targeted intervention/management in people with CNSLBP.

These insights into the lived experience of pain-related fear have not been explored previously in the FAM literature. The findings of this research suggest that future iterations of the FAM may be strengthened by:

- 1. Accounting for heterogenous beliefs underlying pain-related fear
- 2. Acknowledging the role of somatic aspects of the pain experience, particularly pain predictability, controllability and intensity, in addition to sense-making processes that may trigger the cycle of pain-related fear
- 3. Accounting for different pathways to fear reduction

In order to extend the FAM in this way, it may be useful to draw on other cognitive behavioural models in the broader health literature to explore if/how these might be integrated into the future iterations of the FAM.

In the health behaviour literature, six models of health behaviour have generated substantial bodies of research and are the most widely cited (Glanz, Lewis, and Rimer 1997). These include The Common Sense Model (Leventhal 1980); The Health Beliefs Model (Janz and Becker 1984, Rosenstock, Strecher, and Becker 1988); Protection Motivation Theory (Rogers 1983); Social Cognitive Theory (Bandura 1977); The Stages of Change model or Transtheoretical Model of Behaviour (Prochaska and DiClemente 1983); and The Theory of Planned Behaviour (Azjen and Madden 1986). Evidence supports the validity of all six models in predicting health behaviours in a variety of different health contexts.

The Common Sense Model of Self-Regulation (also known as the Common Sense Model) describes a process that begins when one encounters a health problem. The process involves three stages occurring at a cognitive and emotional level in parallel: 1. The formation of health representations comprised of five dimensions: identity, cause, consequences, time-line and cure/controllability of

the condition. 2. The implementation of coping responses 3. The appraisal of the response which feeds back into the health representation. A continuous interaction between cognitive, behavioural and contextual factors influences ongoing behaviour (Leventhal, Meyer, and Nerenz 1980).

The Health Beliefs Model attempts to predict health behaviour from the beliefs and attitudes of individuals. These beliefs and attitudes include: 1. Perceived vulnerability to the health threat, 2. Perceived severity of the health threat, 3. Perceived benefits of a health behaviour, 4. Perceived barriers and negative consequences of executing a health behaviour and 5. Self-efficacy to perform the health behaviour (Rosenstock, Strecher, and Becker 1988).

The Protection Motivation Theory describes how four cognitive beliefs influence motivations to protect oneself from danger: 1. The severity of the threat 2. How vulnerable the individual believes they are to the threat, 3. How effective they believe the coping response is in removing the threat 4. Self-efficacy beliefs that they can perform the behaviour necessary to remove the threat. In addition, the model accounts for the influence that the emotional state of fear has on beliefs about the severity of threat (Rogers 1983).

The Social Cognitive Theory describes how self-efficacy and outcome expectancies influence behaviour and are strengthened or weakened through four sources of information: 1. Personal mastery experiences, 2. Vicarious experience, 3. Verbal persuasion and 4. Physiological feedback. A continuous interaction between cognitive, behavioural and contextual factors influences ongoing behaviour (Bandura 1977).

The Stages of Change Model describes five dynamic, non-linear stages of behavioural change: 1. The precontemplation stage, in which individuals are not thinking about change, 2. The contemplation stage in which individuals begin to consider the possibility of behavioural change; 3. The preparation stage, in which individuals prepare to change; 4. The action stage, in which individuals adopt behavioural change; 5. The maintenance stage, in which behavioural change in sustained over time. The model also considers how the costs and benefits of a health behaviour are weighed up and suggests that these will be

weighed up differently depending on the individuals' stage of change (Prochaska and DiClemente 1983).

The Theory of Planned Behaviour attempts to predict behavioural intentions through: 1. The individuals' attitude toward a behaviour including their belief that the behaviour will lead to a certain outcome, and their evaluations of the outcome. 2. The individuals' beliefs about what others think about a behaviour and 3. The degree to which an individual believes they have control over their behaviour (Azjen and Madden 1986).

It is likely that certain theories may be more appropriate for certain health contexts than others (Biddle and Nigg 2000). Following a review of behaviour change interventions for musculoskeletal conditions, Knittle et al. (2012) suggest that a health behaviour model in the context of musculoskeletal conditions should include the following constructs:

- 1. Outcome expectancies. Decisions are influenced by perceived advantages and disadvantages of certain actions
- 2. Self-efficacy. Decisions are influenced by one's perceived ability to perform an action
- 3. Goals. Decisions may be influenced by competing or conflicting goals
- 4. Socio-structural factors. Decisions are influenced by environmental facilitators and impediments such as beliefs and attitudes of HCPs, family and friends, and access to care
- 5. Emotional or stress constructs. Behaviour may be a consequence of stress regulation
- 6. Symptom-related control. Behaviour is influenced by the signs and symptoms of the condition

Table 8.1 summarises the constructs represented by these six health behaviour models, compared side-by-side with the FAM.

Table 8.1. Constructs represented by Health Behaviour Models

Theories of health			Constructs	S		
behaviour	Outcome expectations	Self efficacy	Goals	Symptom related constructs	Sociostructural factors	Emotional or stress constructs
Fear avoidance model	Catastrophising	•	Reduce threat of harm			Fear
Common Sense Model	Consequences, curability/control, timeline, treatment expectancies	Perceived behavioural control	Reduce threat, restore emotional equilibrium	Physiological feedback	Identity, societal beliefs, cues to action	Emotional illness representation
Health belief model	Perceived vulnerability, severity, benefits vs barriers, cues to action	Efficacy expectations		Cues to action	Cues to action	
Protection motivation theory	Coping appraisal and threat appraisal	Self efficacy in coping appraisal	1	ı		Fear
Social cognitive theory	Outcome expectancies	Self efficacy, behavioural capability	Distal and proximal goals	Physiological feedback	Environmental facilitators and impediments	
Stages of Change model	Costs and benefits	Self efficacy	Intention	•	Normative beliefs, cues to action	ı
Theory of planned behaviour	Intention, Subjective norm	Perceived behavioural control	Intention	1	-	
- Concept is not sp	- Concept is not specifically represented in the theory	ry				

As can be seen in the Table 8.1, the FAM includes constructs related to outcome expectations, goals and emotion, but does not include constructs related to self-efficacy, symptom related constructs or sociocultural factors. Similar to the FAM, a limitation of the Protection Motivation Theory and Theory of Planned Behaviour is their failure to consider the role that the present, the immediate personal and environment context has on whether or not individuals act on intentions. Whilst the Health Belief Model, Social Cognitive Theory and Stages of Change Model theorise a dynamic interplay between person, behaviour and environment, they do not propose an explicit role for stress or emotion.

In contrast, the Common Sense Model includes all the constructs identified as important in the context of musculoskeletal conditions. The Common Sense Model was therefore explored in more detail to determine whether it may provide a useful framework to extend and improve the clinical utility of the FAM, based on the findings of this study.

The Common Sense Model

The Common Sense Model is grounded in the health psychology literature which proposes that the way individuals interpret or *represent* an illness experience is associated with the extent to which they adopt behaviours to cope with it (Leventhal, Meyer, and Nerenz 1980). According to the Common Sense Model, when an individual experiences pain, they will attempt to make sense of their symptoms by using pre-existing knowledge (schemas) in order to create a representation of the pain. This representation gives rise to behavioural responses, actions. Once the action has been performed, they will assess whether the gap between their current situation and their target goal has changed. The Common Sense Model can be adapted to provide an understanding of the both the development of pain-related fear, as well as the reduction of pain-related fear. See Figure 8.1.

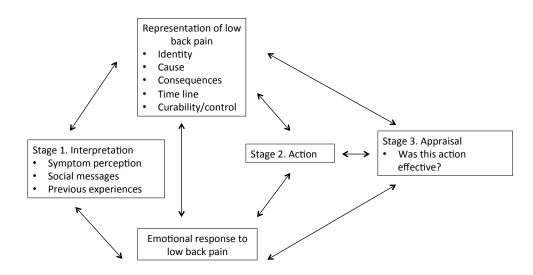


Figure 8.1. Common Sense Model adapted from Leventhal (1980)

Stage 1. Interpretation phase: creating a representation of LBP

When an individual experiences LBP they will attempt to make sense of their symptoms, 'interpret' their symptoms, using their pre-existing knowledge (schemas) about LBP. These schemas are influenced by the individuals' previous experiences of LBP both direct and vicarious, and are constantly and continually updated with new information from sources such as the media, HCPs and by the perception of actual sensations (Leventhal, Diefenbach, and Leventhal 1992). The result of this interpretation will be a 'representation' of their LBP experience. The representation will consist of beliefs associated with 1. The 'diagnostic labels' used to describe the symptoms, 2. The 'causes' of pain, including what triggered the painful episode and flare-ups in pain, 3. The time course of pain (acute, cyclical or chronic) and whether it is stable, recovering or deteriorating, 4. The consequences of pain, such as damage, suffering and functional loss, 5. The control they have over pain including external locus of

control beliefs related to treatment expectations and internal locus of control beliefs related to pain-self efficacy.

Representations are therefore 'lay' representations, embedded in the context of broader personal experience (Coutu et al. 2007). While representations of LBP will vary greatly between individuals, the *process* of 'making sense' of LBP will be similar for all people (Petrie, Jago, and Devcich 2007).

Stage 2. Developing an action plan

Based on the representation, individuals will set goals and develop an action plan to guide their behaviour (problem based coping). In parallel, the representation of LBP may elicit an emotional reaction, in which case individuals may take action towards preserving emotional equilibrium (emotion-directed coping) (Leventhal 1980). In particular, beliefs that an illness has severe consequences, is unpredictable in nature, and out of one's control are thought to strongly affect negative emotional responses to illness (Moss-Morris et al. 2002).

Stage 3. Appraisal of action: Assessing the gap between the current situation and target goal

A self-regulatory process follows, in which individuals appraise the outcome of the behaviour and this appraisal feeds back into the representation of LBP. If the outcome is expected and in the direction of the target goal, the usefulness of the representation in making sense of LBP, the *coherence*, is high and the behaviour will be maintained. If the outcome is unexpected and distances the individual from their target goal, the LBP representation is *incoherent* and the individual lacks clues as to how they should readjust behaviour (Leventhal et al. 2008).

The Common Sense Model and behavioural change

According to the Common Sense Model, behavioural change will result from changes in how individuals represent their LBP or in their available responses to manage the threat or emotions related to threat (Eccles et al. 2013).

Drawing on the findings of this study, how the Common Sense Model may inform future iterations of the FAM by enhancing our understanding of the processes involved in the development of pain-related fear and the processes involved in fear reduction is explored in detail below.

How can the Common Sense Model inform future iterations of the FAM?

Understanding pathways into pain-related fear

The Common Sense Model provides a framework for understanding how people develop pain-related fear. The Common Sense Model suggests that fear and avoidance may be viewed in some individuals as a 'common sense' problem-solving response based on their representation of LBP. If one believes that performing a painful activity could cause their spine to 'break' or 'crumble', it is 'common sense' to avoid the painful activity. If one experiences 'stabbing' pain in their back every time they bend forward, it is 'common sense' to avoid bending forward. As long as the outcome of avoidance is expected (e.g. no further 'damage' and / or no pain 'flare-up' by avoiding the painful activity), the 'representation' is deemed to be 'useful' i.e. coherence is high, and avoidance behaviour will be maintained.

The Common Sense Model raises a further possibility that pain-related fear may be generated and/or perpetuated by a lack of a coherent representation in order to make sense of the LBP experience. At baseline, all the individuals in this study were unable to make sense of their LBP experience. Some participants described uncertain diagnoses and prognoses. Most described unpredictable flare-ups, and all held beliefs in the damaging or suffering/functional consequences of pain and low perceptions of control over their pain. All participants described a discrepancy between the expected and experienced outcomes of the actions they took to seek a diagnosis, control pain and/or avoid its consequences. When this discrepancy was repeated through time, the representation was recognised as ineffective in guiding problem-solving behaviour.

According to the Common Sense Model, in the absence of a useful cognitive representation to make sense of pain, behaviour will be driven by the emotional

response. In the case of 'threatening pain' i.e. where pain has severe consequences, is unpredictable and / or uncontrollable, this emotional response is likely to be fear (Moss Morris 2002). As proposed by the current FAM, fear avoidance behaviour preserves emotional equilibrium by reducing fear in the short term. However it may reinforce incoherency regarding the identity, causes, consequences, time-line and/or the curability/control of the symptoms by preventing opportunities for positive exposure in the long term. A vicious cycle is then implicated in which fear avoidance behaviour reinforces an incoherent LBP representation that in turn reinforces pain-related fear.

It is possible that for some individuals, particularly in the acute stages of LBP associated with tissue injury, fear avoidance behaviour may be a 'common sense' solution to avoiding the consequences of further injury allowing for tissue healing to occur. For other individuals where pain is not related to an injury or where it persists beyond tissue healing time, fear avoidance behaviour may be an 'emotional' response to an incoherent LBP representation.

By incorporating a Common Sense Model perspective, the FAM may therefore be extended to consider the multiple factors including the somatic pain experience and heterogenous beliefs that may trigger the vicious cycle of pain-related fear and avoidance. Further, it conceives a potential role for sense-making processes in the development and persistence of pain-related fear that have not been identified previously in the FAM literature.

Understanding pathways out of pain-related fear

The Common Sense Model may also be a useful framework for understanding fear-reduction. The follow-up findings of this research suggest that participants who had created coherent representations of LBP experienced an improvement in fear. According to the Common Sense Model a coherent LBP representation may be defined as the combination of diagnostic certainty (identity dimension) that is able to explain symptoms (cause dimension) and prescribe procedures for controlling/resolving the symptoms (timeline, control dimension). This is combined with the experience of having control over the symptoms, a reduction in pain intensity and reduced goal conflict (consequences, control dimension). A

coherent LBP representation guides effective problem-solving behaviour that reduces the threat of LBP and therefore fear.

Incorporating a Common Sense Model perspective may also extend the FAM by acknowledging the multiple pathways that may lead to improvements in pain-related fear and the potential role for sense-making processes in fear-reduction.

Support from literature for including a CSM perspective in the FAM

Whilst to date the Common Sense Model has not been used as a framework for understanding pain-related fear in CNSLBP, there is evidence in the literature to support the incorporation of a Common Sense Model perspective of pain-related fear in future iterations of the FAM.

There is some literature to support the suggestion that an inability to make sense of pain may be associated with pain-related fear. Individuals with chronic widespread pain (van Wilgen et al. 2008) and chronic musculoskeletal pain (Albert, Coutu, and Durand 2013) who could not make sense of their symptoms were found to be more likely to catastrophise about them. In a qualitative longitudinal study involving people off work with chronic musculoskeletal pain following injury, O'Hagan et al. (2013) found that uncertain injury representations were interpreted by participants as threatening because they were unable to predict the outcomes of their actions.

In people with chronic pain, there is some evidence that improvements in coherency may occur through the course of a chronic pain management program and result in more adaptive coping (Hobro, Weinman, and Hankins 2004) and improved mental health (Moss-Morris et al. 2007). O'Hagan et al. (2013) explored how coherency is developed amongst people off work with chronic musculoskeletal pain following injury participating in a multidisciplinary occupational rehabilitation program. They found that participants who returned to work described altered injury representations that were linked to self-management strategies. These altered representations enabled them to predict the course of symptom exacerbations and the outcome of coping actions, providing a sense of control and reducing threat.

Clinical implications of including a Common Sense Model perspective in the FAM

Including a Common Sense Model perspective of pain-related fear in the FAM may provide the opportunity to explore new assessment tools and include alternative intervention strategies that have not been considered in the FAM literature to date.

Assessment of pain-related fear

Existing measures of pain-related fear have been criticised for lacking theoretical framework and construct validity (Lundberg et al. 2011). Whilst the TSK is commonly used as an assessment tool to identify candidates for fear reduction interventions based on the FAM, in Chapter five we found that the TSK lacks construct validity and is unable to discriminate between different beliefs underlying pain-related fear. This may limit the potential of the TSK to guide targeted intervention.

It is possible that the Illness Perceptions Questionnaire Revised (IPQ-R) (Moss-Morris et al. 2002) may be an alternative tool to assess pain-related fear in people with CNSLBP. Unlike the TSK which predated the FAM, the IPQ-R is based on the Common Sense Model and was developed as a quantitative measure of illness perceptions, addressing the psychometric limitations of earlier versions (Weinman et al. 1996).

The IPQ-R was developed using data from people with asthma, diabetes, arthritis, chronic pain, acute pain, multiple sclerosis, HIV and myocardial infarction (Moss-Morris et al. 2002). It is comprised of three sections: i) Illness identity, ii) Time-line, Time-line cyclical, Consequences, Cure/Controllability, Coherency and Emotional Response and iii) Causal dimensions. In the first section, 'illness identity', individuals are asked to select from a list of 14 symptoms, which symptoms they see as part of their LBP. In the second section, individuals rate their agreement with statements on a five-point likert scale with 'strongly agree' at one end, to 'strongly disagree' at the other. In the third section, individuals select from a list of 18 possible causes for their LBP, which they causes they attribute their LBP to. The causes include: psychological attribution, risk factors, immunity and accident/chance. In addition, individuals

are asked to write in rank-order, the three most important factors they believe caused their LBP (using items from the items provided or based on their own ideas). In total, the IPQ-R has 80 items. High scores on the identity, timelines, consequences and time-line cyclical dimensions indicate strong beliefs about the number of symptoms an individuals attributes to their condition, the chronicity, negative consequences and cyclical nature of the condition, respectively. High scores on the control and coherence dimensions represent positive beliefs about controllability and how much their condition makes sense to them.

The authors encourage researchers to adjust the items on the IPQ-R to each illness context, for example by replacing the word 'condition' with 'LBP' and inserting items relevant to the identity and causes of the condition (Moss-Morris et al. 2002). A copy of the IPQ-R that could be adapted for use in the LBP context is presented in Appendix 1. Example items can be seen in Table 8.2.

Table 8.2. Example items from the IPQ-R

Construct	Item			
Identity	I have experienced this symptom since my LBP (indicate by circling			
	e.g. sleep difficulties, fatigue, loss of strength, pain			
Time-line	My LBP is likely to be permanent rather than temporary			
Time-line cyclical	My LBP is very unpredictable			
Consequences	My LBP is a serious condition			
Cure/controllability	There is a lot which I can do to control my LBP			
Coherency	My LBP doesn't make any sense to me			
Emotional response	My LBP makes me feel afraid			
Cause	My own behaviour may have caused my LBP			

To date only one study has tested the factor structure of the IPQ-R in individuals presented with LBP to primary care (Nicholls, Hill, and Foster 2013). The study failed to replicate the seven-factor model structure previously suggested by Moss Morris et al. (2002), potentially because of a heterogenous sample of individuals with acute and chronic LBP of varying severity, for whom the items related to beliefs about 'cause' were not specific enough. The authors concluded that future research is required to fully explore patient's LBP representations in order to develop a modified version of the IPQ-R for use in these populations (Nicholls, Hill, and Foster 2013). The findings from this body of work may inform future versions of the IPQ-R for use in this population by providing a description of what people with CNSLBP and high pain-related fear believe about their LBP.

To make the IPQ-R more acceptable to individuals with reduced health literacy and participants in studies involving repeated measures, an abbreviated version of the IPQ-R has also been described in the literature (Broadbent et al. 2006). The Brief IPQ has been shown to be a valid and reliable measure of illness perceptions in patients with non-musculoskeletal chronic conditions including diabetes and asthma (Broadbent et al. 2006). To date it has not been validated in people with LBP. The Brief IPQ comprises of nine items, one for each of the following illness perception dimensions: identity, causes, time-line, consequences, personal control and treatment control. emotional

representation, illness concern (considered to be a combination of emotional and cognitive representations) and coherence. Individuals are asked to rate their degree of agreement with each item on a scale of 0-10. A total score may be computed by reverse-scoring items 3, 4 and 7, and adding them to the remaining six items. The total score reflects the degree to which the condition is perceived to be threatening (high total score) or benign (low total score). A copy of the Brief IPQ is presented in Appendix 2.

In summary, both the IPQ-R and Brief IPQ have been shown to be valid and reliable measures of illness perceptions in people with chronic conditions. With strong theoretical foundations based in the Common Sense Model, the IPQ-R and Brief IPQ may have utility in the assessment of pain-related fear by helping direct HCPs to the underlying factors associated with pain-related fear. Both questionnaires include an item related to fearful responses to LBP. Both questionnaires capture perceptions related to the unpredictability and uncontrollability of LBP that were found to be associated with threat in this study. Both include a measure of how much LBP 'makes sense' which was found to play a role in baseline fear and change in fear in this study. Whilst neither include items specifically related to beliefs about the damaging, suffering/functional consequences of pain, researchers are encouraged to adapt the items on the IPQ-R to be condition-specific (Moss-Morris et al. 2002, Nicholls, Hill, and Foster 2013) and therefore this could be incorporated into future versions of the questionnaire adapted for LBP. Further research is needed to validate the IPQ-R and Brief IPQ for use in the LBP population and in the assessment of pain-related fear.

Treatment of pain-related fear

Including a Common Sense Model perspective of pain-related fear in future iterations of the FAM could provide the opportunity to imbed a representational approach to learning within fear-reduction interventions.

A representational approach to learning has been described in the literature and shown to be effective in improving self-management behaviour and disease-related distress in patients with non-musculoskeletal chronic diseases (Donovan et al. 2007). There are early suggestions that a representational approach may also improve short-term engagement in physical activities in people with CNSLBP (Siemonsma et al. 2013).

The approach involves five key elements that may be approached in a non-linear rather than step-wise way: 1. Encouraging the patient to describe their health problem along the five dimensions of the representation. The HCP attempts to identify gaps, confusions and misconceptions in the representation that should be addressed. 2. Prompting the patient to think about experiences that led to beliefs that are misconceptions and to evaluate the importance of those beliefs. 3. A discussion between the patient and HCP about how the gaps, confusion and misconceptions in the representation impact on behaviour. 4. The presentation of new information to fill in gaps, clarify confusion and replace misconceptions. 5. A summary of the new representation and discussion about how it is expected to impact on behaviour. This approach could be incorporated into interventions based on future iterations of the FAM for people with CNSLBP, and is outlined below.

- 1. Getting the patient to describe their LBP experience along the five dimensions of the representation. Healthcare professionals can explore unhelpful beliefs informing an individuals' LBP representation by asking them about what diagnostic labels they may associate with their LBP, what they believe is causing their LBP, how long they believe their LBP will last and what they believe are the consequences of their LBP. In particular, exploring underlying damage, suffering/functional loss beliefs, how controllable their LBP is and what they believe it will take to better manage their LBP is central to this process. It may also be important to ask individuals how they respond to pain and their appraisal of the outcomes of this action. The HCP should aim to identify gaps, confusions, discrepancies and misconceptions in the representation in order to raise awareness of how these impact on the LBP experience and how they may be reshaped and replaced in order to make sense of their pain (Donovan et al. 2007).
- 2. Encouraging the patient to think about experiences that led to beliefs that are misconceptions and to evaluate the importance of those beliefs. Based on the

findings of this research, it may be useful for HCPs to prompt the patient to reveal the results of any scans/ imaging they have had on their back and how they interpret the meaning of the results. Healthcare professionals should consider how patients link words to concepts that activate representations (Leventhal, Leventhal, and Breland 2011). This may be done by asking individuals' how they interpret any diagnostic labels they may have been provided with. For example, in this study the word 'degeneration' appeared to elicit a representation of LBP as incurable with consequences for future function (i.e. a wheelchair). Similar problematic interpretations of diagnostic labels for LBP have been documented in Aboriginal Australians (Lin et al. 2013) and non-patient populations (Barker, Reid, and Minns Lowe 2009). Other factors that may influence misconceptions include observing the experiences of others, previous direct experiences of LBP, and encounters with HCP.

Leventhal et al. (2011) highlight that some individuals may not be able to articulate or be fully aware of their own beliefs and concerns about their pain and the experiences that led to these beliefs. They emphasise that a strong therapeutic rapport plays a key role in the assessment of a pain-representation by enabling deeper insight into the patients' illness representations, their 'lived environment' and the influence of these on the pain experience. It is likely that for some people, these beliefs may be implicit and only become apparent through behavioural experimentation. This might include exposure, as well as modification of behavioural responses, to threatening activities, in which underlying beliefs can be reflected on in real-time.

- 3. A discussion between the patient and HCP about how the gaps, confusion and misconceptions in the representation impact on behaviour. Encouraging individuals to think and talk about experiences that led to confusions and misconceptions can enable HCPs to understand the strength of the beliefs i.e. how committed the individual is to them.
- 4. The presentation of new information to fill in gaps, clarify confusion and replace misconceptions. The findings from this research suggest that people with CNSLBP seek care in search of a diagnosis and/or to find a way of controlling or resolving their symptoms. It may be that rather than providing individuals with

a diagnostic label, such as 'disc bulge' or 'non-specific LBP', they can be provided with a 'diagnostic explanation' that addresses all five dimensions of the representation. For example, rather than diagnosing an individual with disc degeneration based on imaging findings, it could be explained to them that they have 'sensitisation' of the spinal structures (identity) linked to, protective behaviours (cause), that are sustaining pain (consequence), and that strategies to address these mechanisms such as movement control/body relaxation (controllability) will enhance their functional capacity with pain control within a specific amount of time (time-line).

In order to challenge associations between pain and damage in people with high pain-related fear the findings of this research suggest that it may be useful to couple a 'diagnostic explanation' grounded in biopsychosocial principles with behavioural experimentation. The 'lived experience' of moving without flaring up pain and causing damage is likely to facilitate the adoption of the new understanding and build internal locus of control beliefs.

However it must be noted that two subjects in the follow-up study reported a different pathway to fear reduction underpinned by a 'diagnostic explanation' grounded in biomedical principles that also facilitated reductions in fear. For example, being told that one had age-related (cause) changes in the disc (identity) that left untreated could cause further damage (consequences), but undergoing a surgical intervention or regenerative injections (controllability) could be address the damage within a specified amount of time (time-line). In this way, the external locus of control beliefs are strengthened as individuals believe they have a way of redressing underlying damage. However, failure of this approach has been proposed to lead to a further escalation of pain, fear and distress, reinforcing a reliance on passive therapies to 'fix' the problem (Deyo 2013).

5. Bringing about behavioural change through increasing coherency of the representation. Providing individuals with new information to inform their representation of LBP needs to give rise to adaptive behaviours that can break the cycle of pain-related fear. In addition to providing information, individuals need to be equipped with effective strategies to control pain and prevent flare-

ups in pain intensity so that fear-avoidance behaviour is reduced. Matching these strategies to the new representation is important so that the individuals can problem solve the best course of action in any given context. When the selected action successfully brings the individual towards their target goal, this experience increases the coherency of the representation. When repeated over time, coherency is established, the LBP experience makes sense, leading to improvements in pain-related fear.

In this study it must be acknowledged that the follow-up period was relatively short and it is unknown if the coherency described by 'improvers' at follow-up was maintained over time. However it would seem more likely that coherency is more likely to be sustained over time in individuals who develop an internal locus of control and rely on their own actions to consistently bring them towards their target goals. This is in contrast to individuals who rely on others (i.e. passive or interventional therapies) to consistently bring them towards their target goals (Oliveira et al. 2009).

A representational approach to patient learning suggests that the causal relationship between belief change and behaviour change may be dynamic, reflexive and bidirectional. Individuals can be offered new information and then encouraged to gather their own information through behavioural experimentation, the results of which become the basis of belief change.

The act of encouraging people to discover new information rather than just giving it to them, is consistent with the Socratic method applied in Cognitive Behavioural Therapy (Padesky 1993). A dynamic, reflexive relationship between belief change and behaviour change is similar to the principle underlying Exposure in vivo and Cognitive Functional Therapy, both of which have been shown to be moderately effective in reducing fear in people with high pain-related fear (see Chapter two). Future research may explore whether improvements in pain-related fear associated with these interventions are mediated by improvements in the coherency of an individuals' LBP representation.

However, in addition to coherency as a mediator of fear-reduction, the Common Sense Model suggests an alternative mechanism of fear-reduction in people with CNSLBP through which behavioural change is facilitated. This is by changing an individuals' available behavioural responses to manage the threat or emotions related to threat (Eccles et al. 2013).

Incorporating a Common Sense Model perspective into the FAM would suggest that in some cases, it may be useful to reduce the impact of an incoherent representation by helping individuals learn to accept uncertainty and unpredictability. This is consistent with Acceptance and Commitment Therapy and mindfulness-based approaches that target behaviour change without focusing on belief change, although it is conceded that belief change happens along the way (McCracken and Vowles 2014). The effectiveness of these approaches in reducing fear amongst individuals with CNSLBP and high pain-related fear has not been explored in the literature. However several participants in this study who experienced an improvement in fear described having developed a mindful acceptance of pain at follow-up.

To investigate the relative importance of establishing coherency versus learning to accept an incoherent representation, Gillanders et al. (2013) conducted a study involving a heterogenous group of individuals with chronic pain. They found that the perception of low controllability, long time-line and serious negative consequences were associated with lower acceptance and higher catastrophising. They tentatively suggested that acceptance appears to be important in helping to maintain the pursuit of valued activities; whilst at the same time, a degree of prediction of the impact of doing so (what the consequences will be, how long the consequences will last and their control over the consequences) seems to be important. Mediation analysis from an RCT involving a heterogenous chronic pain sample comparing Acceptance and Commitment Therapy to Cognitive Behavioural Therapy found that increased perceived pain controllability, rather than increased acceptance of pain, mediated improvements across both interventions (Wetherell et al. 2011). It may be that equipping some individuals with mindfulness strategies enables them to control their worry about the consequences of their actions sufficiently

for them to engage in valued life activities. The achievement of desired outcomes means the behavioural strategy is appraised as effective. This appraisal is fed-back into the representation and reinforces coherency.

Encouraging adherence to treatment

According to the Common Sense Model, an individual is likely to select and adhere to a treatment if there is a match between the treatment and representation (Leventhal, Leventhal, and Breland 2011). A 'match' assumes that the procedure targets the identity (symptoms and underlying cause), its efficacy (control) in a given time-frame with its specific consequences. When there is a poor match between an individuals' representation and the treatment recommendation adherence problems may arise (Petrie and Weinman 2012). Dima et al. (2013) conducted qualitative focus groups to explore patients' beliefs about a diverse range of LBP treatments and identified four core dimensions underpinning treatment beliefs: 1. The treatment should have a credible mechanism of action and be delivered by a credible HCP, 2. Have proven to be effective, 3. Should prompt few concerns about safety and accessibility, 4. Should match the individuals' representation and make sense. Consistent with this, in this study a credible HCP delivering a targeted intervention that proved to be effective in controlling their pain, was found to facilitate fear-reduction at follow-up. Participants who reported dropping out of an intervention during the study period cited a lack of targeted intervention and/or no improvement in symptoms as reasons for drop-out.

Methodological reflections

The conclusions that may be drawn from this study must be considered in light of the design constraints and scientific and ethical issues associated with the methodological approach.

The main design constraints and how they may impact on the findings have been discussed in each of the manuscripts presented in Chapters 4-7 are summarised briefly below.

Whilst the Interpretive Description framework emphasises the importance of the 'informed researcher', it is recognised that the researchers' *a priori* knowledge and beliefs have the potential to "unintentionally occlude subjective meanings" (Snelgrove 2014, p.22). A salient example of this is the *a priori* selection of self-report questionnaires used in the mixed-method analysis. To ensure that pre-existing knowledge and suppositions were not imposed on the data such that it occluded subjective meaning, steps were taken as described in detail in Chapter four. These included the presentation of raw data, cross-coding by members of the supervisory team, member-validation at follow-up interviews, and blinding to the self-report questionnaire scores until qualitative data analysis had been completed.

With these measures in place, the Interpretive Description is a significant strength of this study. The *a priori* knowledge and beliefs of the researchers enabled access to a wider range of qualitative and quantitative data. Interpreting the participants' experiences through an 'expert' lens, enabled us to answer the research questions in a way in which we could extend existing theory and inform clinical practice.

The self-report questionnaires were selected based on the existing literature with consideration to participant burden, and therefore potentially relevant questionnaires may have been missed. A key construct identified in the qualitative findings that was not included in the self-report questionnaires was 'acceptance'. Future research exploring the factors associated with fear-reduction may consider including the Chronic Pain Acceptance Questionnaire (McCracken, Vowles, and Eccleston 2004) which has been validated in the chronic pain population (McCracken and Eccleston 2006).

The sampling strategies employed may limit the generalisability of these findings, however attempts were made to capture a range of experiences of pain-related fear rather than a representative sample. Whilst the use of a validated assessment tool was needed to operationalize levels of pain-related fear in this study, it is acknowledged that limitations exist in any self-report tool and it is possible that individuals who were recognised as highly fearful by their HCP, scored below the cut-off for high pain-related fear and were therefore not

eligible for inclusion. Larger scale research in diverse populations with high pain-related fear (such as different socio-demographic and cultural settings) may test the hypothesis that somatic aspects of the pain experience and sensemaking may play a role in the development of pain-related fear and improvements in fear.

It is recognised that the reduction of qualitative data into dichotomous variables means some of the richness of the participants' experiences was lost and interpretive bias may have been introduced. Whilst beliefs are acknowledged to exist on a continuum, the categorisation of beliefs was performed to facilitate comparisons with the existing literature. The 'quantitization' of qualitative data may be a useful method for future studies exploring the construct validity of self-report questionnaires.

The reliance of memory recall at a single time point at baseline and again at follow-up is likely to have introduced some bias in the study findings, such that participants' emphasised the most recent or salient experiences during the interviews. Future research should include repeated measures and/or interviews at multiple time-points to reduce the reliance on memory recall and gain insight into the sequence of changes that may be involved in fear-reduction.

An additional design consideration not discussed in Chapters 4-7 is the interaction between the researcher and the participant and how this may have impacted on the study findings, particularly at follow-up.

In this study, the physiotherapy doctoral candidate sought out individuals with CNSLBP for participation. This differs from the non-research setting, where the individual with CNSLBP seeks out the help of a HCP. However, it is possible that individuals may have in part consented to participate in this study in order to seek the advice of an 'expert', even though all potential participants were made aware of the purpose of study in the study explanatory sheet.

The potential for the research interview to morph into a therapeutic interview is a known phenomenon in health research and may give rise to scientific and ethical considerations for the researcher (Coutu et al. 2010, Kvale and Brinkmann 2009). In this study, whilst the doctoral candidate attempted to

retain her 'researcher role' rather than 'physiotherapist role' during the course of the interviews, situations that raised scientific and ethical considerations were encountered. For example at baseline several participants became emotional when they described how imaging scans had failed to diagnose the source of pain. It was challenging for the candidate to refrain from reassuring participants that it was possible and indeed common to experience pain in the absence of imaging findings. From an ethical perspective, not providing this information to participants who may have been more or less consciously seeking the advice of an 'informed expert' when they consented to participate raised a dilemma. From a scientific perspective, a consequence of providing this information may have been a radical change to the participants' understanding of their situation that could have affected the study findings at baseline and follow-up.

With consultation by the PhD supervisors, it was decided that the best course of action was to retain the 'researcher role' and refrain from sharing 'expert' information with the participants at baseline in order to maintain the scientific integrity of the findings. It was agreed that such information could be shared with the participants after the follow-up interview if the participant asked for advice. The researchers acknowledge that this may have prolonged suffering until the time of the follow-up interview. However, it was considered that refraining from providing knowledge would not have prolonged suffering any longer than would have been the case if the individual had not participated in the study. Participants were made aware that the study was designed with a referral system in place to back to their General Practitioner or to the psychology clinic at the university, so they could access follow-up psychological support if they wished.

However, it is acknowledged that non-specific treatment effects have been shown to influence clinical outcomes in people with CNSLBP (Ferreira et al. 2013) and it is possible that the empathy displayed by the candidate towards the participants during the interviews elicited a therapeutic effect. Indeed, several participants themselves identified the therapeutic value of sharing their 'pain story' in a non-judgemental context. Whilst this may have influenced the

trajectories of some participants through this study, it is unlikely that it would have influenced the key findings at follow-up i.e. the participants' ability to 'gain control' over their pain experience.

Indeed, the role of the candidate as interviewer is also significant strength in this study. The participants may have been more willing to disclose information with a 'physiotherapist' who could understand their experience. Most interviews were conducted in the participants' home and this is likely to have assisted the participants' to feel at ease to share their experiences in a safe and familiar environment.

In the context of these design limitations and strengths, this research endeavoured to offer a "believable, confident representation of the participants experiences, supported by meaningful data and well-qualified themes" (Snelgrove 2014, p.25). In doing so, it is hoped that these findings provide 'valid' insights to inform clinical practice and future research.

Future research

It is important to acknowledge that pain-related fear is only one mediating factor of CNSLBP disability (Smeets et al. 2006). Ultimately, future research is needed to test how the lives of people with CNSLBP can be improved through equipping HCPs with a deeper understanding of the lived experience of pain-related fear, through better identification of the factors driving pain-related fear and by directing more targeted fear-reduction interventions.

Future research may explore the validity and clinical utility of incorporating a Common Sense Model perspective into the FAM. Prospective studies may explore the potential relationship between LBP representations and pain-related fear. Given limitations in the current assessment tools for pain-related fear due to their lack theoretical framework and construct validity, the IPQ-R and the Brief IPQ adapted to LBP may be investigated as potentially useful tools in the assessment of pain-related fear. The Common Sense Model suggests that all people have a schema of LBP and therefore the capacity of representations to predict pain-related fear and associated CNSLBP disability amongst the

general population as well as patients with acute LBP and/or patients with low pain-related fear at baseline may be explored.

Future qualitative studies are needed to identify the LBP diagnostic jargon commonly used in the clinical encounter that may activate problematic representations of LBP. Future studies may explore the effectiveness of replacing 'problematic' diagnostic jargon with a 'diagnostic explanation' based on the representational approach to learning.

Future intervention studies involving participants with CNSLBP and high painrelated fear could explore the role that sense-making processes may play in fear-reduction. Such studies will require repeated measures throughout the intervention period to better understand the mechanisms involved in sensemaking. Including qualitative interviews would enhance an understanding as to how these mechanisms may differ between individuals.

Finally, future intervention studies could explore the efficacy of incorporating a 'representational approach', aimed at establishing coherency through a dynamic reflexive and bidirectional relationship between belief change and behavioural change, into fear-reduction interventions. Randomised controlled trials may compare such an approach to Acceptance and Commitment Therapy and mindfulness-based approaches to better understand the relative importance of establishing coherency versus learning to accept an incoherent representation, in facilitating fear-reduction in people with CNSLBP.

Chapter 9. Conclusions

Since 2000, the FAM has proved to be a valuable framework to understand the vicious cycle of pain-related fear and disability in people with CNSLBP. This series of papers adds an important contribution to support and extend the FAM. By exploring the lived experience of pain-related fear in people with CNSLBP, novel insights are provided into the beliefs underlying pain-related fear, how these beliefs evolve and the pathways to fear reduction.

At baseline, a range of beliefs underlying pain-related fear were identified including damage beliefs and beliefs in the suffering/functional consequences of pain. The participants were unable to make sense of a threatening pain experience, which they described as unpredictable, uncontrollable and/or intense. Attempts to make sense of pain differed depending on beliefs underlying fear, but all participants described repeated failed attempts that appeared to reinforce pain-related fear. At follow-up, individuals who reported an improvement in pain-related fear described gaining control over their pain experience through a range of pathways. These involved improvements in the somatic aspects of the pain experience, an understanding of pain linked to the strengthening of locus of control beliefs.

This thesis suggests that the lived experience of pain-related fear may be understood through the lens of the Common Sense Model. With a strong evidence-base in the health behaviour literature, the Common Sense Model proposes that the experience of LBP elicits a 'representation' comprised of an individuals' unique beliefs about the identity (label), cause, consequences, timeline and controllability of LBP. The representation guides behavioural responses, the outcome of which is assessed to determine whether the distance to the target goal has changed, and self-regulatory processes feed this information back into the representation. Therefore, whilst the content of the representation differs between individuals, the processes involved in making sense of pain will be the same. By providing a framework to understand both the cycle into fear

and out of fear, the Common Sense Model presents a valid, clinically useful framework that may be incorporated into future iterations of the FAM.

Incorporating a Common Sense Model perspective into the FAM would account for a range of beliefs underlying fear including damage beliefs and beliefs in the suffering/functional consequences of pain. It would also ascribe a role for the somatic aspects of the pain experience by including self-regulatory processes in the pathways to pain-related fear. In this way, the Common Sense Model may extend the FAM beyond the current phobia-based conceptualisation of pain-related fear, suggesting that fear may also be conceptualised as a common sense response to a threatening representation of LBP and an inability of individuals to make sense of pain.

Incorporating a Common Sense Model perspective into the FAM would also account for different pathways to fear-reduction. A Common Sense Model perspective would suggest that there is no one ingredient necessary for fear-reduction, rather that fear-reduction requires the integration of a coherent LBP representation that makes sense. As coherency may be considered a 'non-specific' treatment effect that is not specific to any one intervention, this would explain how diverse interventions may result in fear-reduction.

Incorporating a Common Sense Model perspective into the FAM presents novel opportunities for the assessment of pain-related fear and the identification of individuals at risk of developing pain-related fear, using existing tools that may be adapted for use in the CNSLBP population. It presents novel opportunities for the management of pain-related fear by directing targeted, individualised treatment to the beliefs underlying pain-related fear with the assumption of a dynamic, reflexive and bidirectional relationship between belief change and behaviour change.

The representativeness of this sample from the greater population of people with CNSLBP is unknown. It is acknowledged that these findings are hypothesis-generating and future research is needed to explore these hypotheses in larger and more diverse populations of people with CNSLBP. However, this study has deepened our understanding of the subjective

experience of pain-related fear from the perspective of the individual experiencing pain. The novel insights into pain-related fear provided are an important addition to the FAM literature that can inform the next generation of FAM research.

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Appendix 1. The Illness Perception Questionnaire-Revised

YOUR VIEWS ABOUT YOUR LBP

Listed below are a number of symptoms that you may or may not have experienced since your LBP. Please indicate by circling *Yes* or *No*, whether you have experienced any of these symptoms since your LBP, and whether you believe that these symptoms are related to your LBP.

	I have experi symptom sin		This symptom is related to my LBP		
Pain	Yes	No	Yes	No	
Sore Throat	Yes	No	Yes	No	
Nausea	Yes	No	Yes	No	
Breathlessness	Yes	No	Yes	No	
Weight Loss	Yes	No	Yes	No	
Fatigue	Yes	No	Yes	No	
Stiff Joints	Yes	No	Yes	No	
Sore Eyes	Yes	No	Yes	No	
Wheeziness	Yes	No	Yes	No	
Headaches	Yes	No	Yes	No	
Upset Stomach	Yes	No	Yes	No	
Sleep Difficulties	Yes	No	Yes	No	
Dizziness	Yes	No	Yes	No	
Loss of Strength	Yes	No	Yes	No	

We are interested in your own personal views of how you now see your current LBP.

Please indicate how much you agree or disagree with the following statements about your LBP by ticking the appropriate box.

	VIEWS ABOUT YOUR LBP	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP1*	My LBP will last a short time					
IP2	My LBP is likely to be permanent rather than temporary					
IP3	My LBP will last for a long time					
IP4*	This LBP will pass quickly					

	VIEWS ABOUT YOUR LBP	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
IP5*	I expect to have this LBP for the rest of my life					
IP6	My LBP is a serious condition					
IP7	My LBP has major consequences on my life					
IP8*	My LBP does not have much effect on my life					
IP9	My LBP strongly affects the way others see me					
IP10	My LBP has serious financial consequences					
IP11	My LBP causes difficulties for those who are close to me					
IP12	There is a lot which I can do to control my symptoms					
IP13	What I do can determine whether my LBP gets better or worse					
IP14	The course of my LBP depends on me					
IP15*	Nothing I do will affect my LBP					
IP16	I have the power to influence my LBP					
IP17*	My actions will have no affect on the outcome of my LBP					
IP18*	My LBP will improve in time					
IP19*	There is very little that can be done to improve my LBP					
IP20	My treatment will be effective in curing my LBP					
IP21	The negative effects of my LBP can be prevented (avoided) by my treatment					
IP22	My treatment can control my LBP					
IP23*	There is nothing which can help my condition					
IP24	The symptoms of my condition are puzzling to me					
IP25	My LBP is a mystery to me					
IP26	I don=t understand my LBP					
IP27	My LBP doesn=t make any sense to me					
IP28*	I have a clear picture or understanding of my condition					
IP29	The symptoms of my LBP change a great deal					

from day to day

	from day to day			
IP30	My symptoms come and go in cycles			
IP31	My LBP is very unpredictable			
IP32	I go through cycles in which my LBP gets better and worse.			
IP33	I get depressed when I think about my LBP			
IP34	When I think about my LBP I get upset			
IP35	My LBP makes me feel angry			
IP36*	My LBP does not worry me			
IP37	Having this LBP makes me feel anxious			
IP38	My LBP makes me feel afraid			

CAUSES OF MY LBP

We are interested in what <u>you</u> consider may have been the cause of your LBP. As people are very different, there is no correct answer for this question. We are most interested in your own views about the factors that caused your LBP rather than what others including doctors or family may have suggested to you. Below is a list of possible causes for your LBP. Please indicate how much you agree or disagree that they were causes for you by ticking the appropriate box.

	POSSIBLE CAUSES	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
C1	Stress or worry					
C2	Hereditary - it runs in my family					
С3	A Germ or virus					
C4	Diet or eating habits					
C5	Chance or bad luck					
С6	Poor medical care in my past					
С7	Pollution in the environment					
C8	My own behaviour					
C9	My mental attitude e.g. thinking about life negatively					
C10	Family problems or worries					
C11*	Overwork					
C12*	My emotional state e.g. feeling down, lonely, anxious, empty					
C13*	Ageing					
C14*	Alcohol					
C15*	Smoking					
C16*	Accident or injury					
C17*	My personality					
C18*	Altered immunity					

In the table below, please list in rank-order the three most important factors that you now believe caused <u>YOUR LBP</u>. You may use any of the items from the box above, or you may have additional ideas of your own.

The most important causes for me:-					
1.					
2					
3.					

Appendix 2. The Brief Illness Perceptions Questionnaire

Consent to reproduce this questionnaire was provided by Elizabeth Broadbent (PhD) on 16.07.2015.

The Brief Illness Perception Questionnaire

For the following questions, please circle the number that best corresponds to your views:

How much	does	your		affec	t your l	ife?				
0 no affect at all	1	2	3	4	5	6	7	8	9	10 severely affects my life
How long o	lo you	think	your		will c	ontinue	?			
0 a very short time	1	2	3	4	5	6	7	8	9	10 forever
How much	contr	ol do y	ou feel	you ha	ave ove	r your		?		
0 absolutely no control	I	2	3	4	5	6	7	8	9	10 extreme amount of control
How much	do yo	u thin	k your t	reatme	nt can	help yo	our	7)	
0 on of all	1	2	3	4	5	6	7	8	9	10 extremely helpful
How much	do yo	u exp	erience	sympto	oms fro	m you	r	?		
0 no symptom at all	l ns	2	3	4	5	6	7	8	9	10 many severe symptoms
How conce	rned	are yo	u about	your		?				
0 not at all concerned	1	2	3	4	5	6	7	8	9	10 extremely concerned
How well d	o you	feel y	ou unde	erstand	your		?			
0 don't unders	l stand	2	3	4	5	6	7	8	9	10 understand very clearly
How much upset or de				affec	t you e	motion	ally? (e	g. doe	s it ma	ke you angry, sca
0 not at all affected emotionally	1	2	3	4			7		9	10 extremely affected emotionally ve caused your
<u>The m</u> ost in	mport	ant ca	uses fo	r me:-		ortant i	aciois	iliai yo	u Delle	ve causeu <u>your</u>
1 2										
3.										

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Watkins, Anne Smith, et al

Publication: Clinical Journal of Pain, The **Publisher:** Wolters Kluwer Health, Inc.

Date: Jan 1, 2013

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Author: Bunzli, Samantha; Smith, Anne;

Watkins, Rochelle; Schutze, Robert; O'Sullivan, Peter

Publication: Clinical Journal of Pain, The **Publisher:** Wolters Kluwer Health, Inc.

Date: Jan 1, 2015

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Title:

Beliefs underlying pain-related fear and how they evolve: a qualitative investigation in people with chronic back pain and high pain-related fear

Author: Samantha Bunzli, Anne Smith, Robert Schütze, Peter O'Sullivan

Publication: BMJ Open

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From: Anne Smith <Anne.Smith@exchange.curtin.edu.au>

Subject: Authorship statement Date: 10 July 2015 3:37:29 PM AEST

To: "Samantha. Bunzli" <Samantha.Bunzli@postgrad.curtin.edu.au>

I declare that the doctoral candidate, Samantha Bunzli, met the criteria for first authorship on the publications I co-authored that appear in this

Anne Smith
Associate Professor and Principal Research Fellow School of Physiotherapy & Exercise Science Curtin University

From: Rob Schütze <r.schutze@curtin.edu.au>@

Subject: Authorship

Date: 10 July 2015 3:33:32 PM AEST

To: Samantha Bunzli <samantha.bunzli@postgrad.curtin.edu.au>

1 Attachment, 2 KB

To Whom It May Concern,

I declare that the doctoral candidate, Samantha Bunzli, met the criteria for first authorship on the publications I co-authored that appear in this thesis.

Kind Regards

Rob Schütze
BA, BJourn, GradDipPsych, BSc(Psych)Hons, MPsych(Clinical)
Adjunct Lecturer | Clinical Psychologist | PhD Candidate

School of Psychology & Speech Pathology

Curtin University
Email | r.schutze@curtin.edu.au
Web | www.curtin.edu.au

From: Peter O'Sullivan <P.OSullivan@curtin.edu.au> \mathscr{Q}

Subject: Re: statement for thesis submission
Date: 11 July 2015 1:57:14 PM AEST

To: Samantha Bunzli <samantha.bunzli@postgrad.curtin.edu.au>

1 Attachment, 5 KB

"I declare that the doctoral candidate, Samantha Bunzli, met the criteria for first authorship on the publications I co-authored that appear in this thesis"

Peter

Professor Peter O'Sullivan

Specialist Musculoskeletal Physiotherapist (as awarded by the Australian College of Physiotherapists 2005), PhD Physiotherapy School Health Sciences Division www.pain-ed.com

Curtin University Tel I +61 8 9266 3629 Fax I +61 8 9266 3699

From: Peter O'Sullivan <P.OSullivan@curtin.edu.au>@ Subject: Re Dr Rochelle Watkins and author confirmation

Date: 29 July 2015 9:48:43 PM AEST

To: Samantha Bunzli <samantha.bunzli@postgrad.curtin.edu.au>

1 Attachment, 5 KB

This email supports that Dr Rochelle Watkins is not currently able to sign and attest that Samantha Bunzli met the criteria for first author in the two publications that are included in her PhD thesis.

Dr Watkins is currently very unwell and has been on sick leave for the past 12 months and is currently uncontactable.

Sincerely

Peter

(Primary Supervisor)

Professor Peter O'Sullivan

Specialist Musculoskeletal Physiotherapist (as awarded by the Australian College of Physiotherapists 2005), PhD Physiotherapy School Health Sciences Division www.pain-ed.com

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Appendix 5. Curtin University Human Research Ethics Committee Approval



Memorandum

To	Professor Peter O'Sullivan, Physiotherapy
From	Professor Stephan Millett, Chair, Human Research Ethics Committee
Subject	Protocol Approval HR 65/2011
Date	9 February 2012
Сору	Mrs Samantha Bunzli, School of Physiotherapy Dr Anne Smith, School of Physiotherapy Mr Rob Schutze, School of Psychology and Speech Pathology, Graduate Studies Officer, Faculty of Health Sciences

Office of Research and Development Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "An exploration of pain related fear in people with chronic low back pain". Your application has been reviewed by the HREC and is approved.

CONDITIONS

- 1. Future use of data
 - 1.1. The statement in the Participant Information Sheet regarding future use requires revision. The participants must be informed as to what their data may be used for in future research.
 - 1.2. The HREC must be advised who the Data Custodian of dataset as the data will be collected originally as part of a doctoral degree.
 - 1.3. Any projects seeking to use the use of the data for research must have ethics clearance (Chapter 3.2 National Statement on Ethical Conduct in Human Research).
- 2. Participant Information Sheet and Consent Form
 - 2.1. Removal of the term 'battery' and replace with 'series of tests';
 - 2.2. Amend Point 6 of Consent form '... at risk of depression, I will pass on the details ...".
 - 2.3. Amend Point 7 of Consent form 'principle' to 'principal'.
 - You have ethics clearance to undertake the research as stated in your proposal.
 - The approval number for your project is HR 65/2011. Please quote this number in any future correspondence.
 - Approval of this project is for a period of twelve months 07-02-2012 to 07-02-2013. To renew this
 approval a completed Form B (attached) must be submitted before the expiry date 07-02-2013.
 - If you are a Higher Degree by Research student, data collection must not begin before your Application for Candidacy is approved by your Faculty Graduate Studies Committee.
 - The following standard statement **must be** included in the information sheet to participants:

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 65/2011). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au.

Applicants should note the following:

It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

The attached **FORM B** should be completed and returned to the Secretary, HREC, C/- Office of Research & Development:

When the project has finished, or

- If at any time during the twelve months changes/amendments occur, or
- If a serious or unexpected adverse event occurs, or
- 14 days prior to the expiry date if renewal is required.
- An application for renewal may be made with a Form B three years running, after which a new
 application form (Form A), providing comprehensive details, must be submitted.

Yours sincerely,

Professor Stephan Millett

Chair Human Research Ethics Committee

Curtin University participant information sheet



Faculty of Health Sciences School of Physiotherapy

Telephone +61 8 9266 3618 Facsimile +61 8 9266 3699 Web www.physiotherapy.curtin.edu.au

PARTICIPANT INFORMATION SHEET

Project title: An investigation of pain related fear in people with chronic low back pain

Principal Investigator: Professor Peter O'Sullivan, Professor of Physiotherapy, School of Physiotherapy, Curtin University.

Co-Investigators: Samantha Bunzli, PhD Candidate, School of Physiotherapy, Curtin University. Dr Anne Smith, School of Physiotherapy, Curtin University, Mr Rob Schutze, Wisdom Health, Dr Rochelle Watkins, Telethon Institute for Child Health Research.

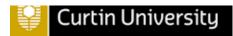
Purpose of research: Low back pain is a common condition which can affect many areas of daily living. People respond to pain in a variety of ways. Many people are afraid of the pain and the affect it has on their life. We are interested in understanding why people with low back pain are afraid of pain and how we can help reduce fear.

Your role:

- 1. In this study we will ask you to participate in two interviews. In the first we will ask you some questions about what you think of your back pain, how you cope with it and how it affects your daily life. We will also ask you what other people may have told you about back pain and how you respond to other situations in your life. In the second interview four months later we will ask you similar questions and see if and how your back pain experience may have changed. There are no right or wrong answers, we are only interested in your thoughts and experiences. The interviews may take around 60-90 minutes and will be tape recorded so that we can write down your responses afterwards. If you do not wish to be recorded please inform Samantha Bunzli before the interview commences.
- 2. Immediately before the interviews we will ask you to fill in a series of questionnaires which physiotherapists commonly use in their assessment of people with back pain. The questionnaires will take about 30 minutes to complete.
- 3. Your role in the study will end after the completion of the second interview. If you wish to receive a copy of the study findings, these can be provided once the final study manuscript has been written by contacting Samantha Bunzli: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3646; email: Samantha.bunzli@postgrad.student.curtin.edu.au

Risks and discomforts: There are no risks associated with this project. We understand that talking about how back pain affects your life may evoke some emotional feelings. We would like to remind you that you may stop or end the interview at any time you wish. The interviewer is also able to organize a referral to psychological services at Curtin University if you feel it is important or necessary to talk about these feelings with a professional psychologist.

Benefits: If you are still receiving treatment at the completion of your participation in the study, with your consent, the findings of your assessment may be discussed with your practitioner to provide more detailed information about your situation and assist your practitioner in managing your back pain. The results of this



research may assist health professionals to better understand and manage pain and disability in other people with back pain.

Confidentiality: All of the information we gain from your assessment will be given a code so that your name does not appear on any of the information. Only Samantha Bunzli will have access to a secure file with the data we record from you. The research team are the only people who will hear your recorded interview, read your interview transcript and see your questionnaire answers. All this information will be stored in a locked cabinet in a locked office at Curtin University and will be destroyed after 7 years. No personally identifiable information will appear on any research report. Research findings may be presented in scientific journals and at conferences.

Refusal or withdrawal: You have the right to refuse to participate in this study without providing any explanation and without incurring any prejudice from the research team or your treating practitioner. You also have the right to withdraw from the study at any time before, during or after the interview sessions without providing any explanation and without incurring any prejudice from the research team or your treating practitioner.

Further information: If you would like to discuss this project in more detail please contact the principle investigator Professor Peter O'Sullivan: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3629; email: P.Osullivan@curtin.edu.au or Samantha Bunzli: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3646; email: Samantha.bunzli@postgrad.student.curtin.edu.au

Ethics approval: This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR 65/2011). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. Its main role is to protect participants. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University of Technology, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing hrec@curtin.edu.au

Curtin University participant consent form



Faculty of Health Sciences School of Physiotherapy

Facsimile +61 8 9266 3699 Web www.physiotherapy.curtin.edu.au

CONSENT SHEET An investigation of pain related fear in people with chronic low back pain

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number: HR65/2011).

- 1. I have been provided with an information sheet, have been given the opportunity to ask questions and fully understand what the purpose of this study is and what my involvement
- 2. If I am concerned about any aspect of this study or have any complaints I can contact the Secretary of the Curtin University Human Ethics Committee c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845; by phoning 9266 2784 or by emailing hrec@curtin.edu.au.
- 3. I understand that if I wish I am free to withdraw from this project at any time without any explanation and will not receive any repercussion as a result from the research team or my treating practitioner.
- 4. I understand that all the information I freely give to the researcher in the interview, the tape recording of my voice and my answers on the questionnaires will be de-identified and seen/heard only by the research team. I will not be identifiable in any research publication. All information will be treated confidentially and securely stored for seven years at Curtin University. After seven years all information will be destroyed.
- 5. By ticking this box here $\ \square$ I agree to my non-identifiable responses being included in future studies conducted by these researchers.
- 6. I give consent to pass on the details of my GP to Samantha Bunzli for a referral letter if I score highly on the questionnaire for depressive symptoms.
- 7. I understand that Professor Peter O'Sullivan is the principal investigator of this research study. I understand that Samantha Bunzli will interview me. If I would like to discuss this project in more detail Professor Peter O'Sullivan's contact details are: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3629; email: P.Osullivan@curtin.edu.au. Samantha Bunzli's contact details are: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3646; email:
 - Samantha.bunzli@postgrad.student.curtin.edu.au
- 8. I give consent for Samantha Bunzli to discuss the findings of her assessment of me with my treating practitioner. I understand this may enhance my quality of care by providing my practitioner with more detailed information of my situation.
- 9. I understand that the findings from this research study may be presented at scientific conferences attended to by health professionals and published in scientific journals to be read by health professionals. This will assist health professionals working with people like me to provide better care and to help reduce pain and disability in other people with back pain.
- 10. I agree to voluntarily participate in this research study as outlined to me

Signature	Date
Witness Signature	Date

Appendix 6. South Metropolitan Area Health Service Human Research Ethics Committee Approval



Human Research Ethics Committee

wk 15 December 2011

Ms Samantha Bunzli School of Physiotherapy Curtin University Bentley WA 6102

Dear Samantha,

Re: A Prospective, Qualitative Investigation of Pain Related Fear in People With Chronic Low Back Pain.

Thank you for your correspondence dated 20 September 2011 submitting a research application and relevant documents relating to the above study, seeking approval from the South Metropolitan Area Health Service (SMAHS) Human Research Ethics Committee (HREC) to recruit participants from the Pain Medicine Unit at Fremantle Hospital. I understand that Dr Stephanie Davies is happy to assist in identifying suitable participants.

The documentation has been considered by a sub-group of the SMAHS HREC and the group agree that the project be recommended for approval. I have, therefore, recommended to the Chief Executive that the study be approved as a low risk project. I can confirm that the Chief Executive's delegate, on 14 December 2011 and under delegated authority from the Minister for Health, endorsed my recommendation to approve the study. You may, therefore, commence recruiting participants from Fremantle Hospital.

Please note that HREC approval is for a three year period from the date of final approval and the research should be commenced and completed within that period. If the study period is longer than three years, you are required to seek an extension to the approval before the end of this period. In the event that the study does not commence within 12 months from the date of final approval the study must be resubmitted to the HREC for approval.

The HREC is bound by NHMRC Guidelines to monitor the progress of all approved projects until completion, to ensure they continue to conform to approved ethical standards. In accordance with the *National Statement Chapter 5.5.3*, researchers also have a significant responsibility in monitoring their research activity and must submit the following to the HREC (if relevant), in relation to this study:

- Annual reports on the progress (including compliance with any conditions of approval and maintenance and security of records).
- Final report on completion (including a copy of the results and any publications).

Human Research Ethics Committee c/- Fremantle Hospital and Health Service Alma Street Fremantle Western Australia 6160 Postal Address: PO Box 480 Fremantle Western Australia 6959 Telephone (08) 9431 2929 Fax (08) 9431 3930

- Reports of adverse/serious adverse events, according to the Committee's SAE Reporting Guidelines and advise the Committee if the event has resulted in an amendment to the protocol and/or to the informed consent document.
- *Protocol amendments, or changes to informed consent documents.
- Any significant deviation from, or violation of, the study protocol.
- If the study is withdrawn, terminated or suspended before the expected date of completion (providing reasons for this).

*When submitting a protocol amendment to the Committee, you should provide, in a covering letter, a statement outlining to the Committee the significance of the change/s, whether they are procedural and/or whether they are likely to have an impact on the study.

An annual report on this study is due in December 2012.

A reference number for this study will be forwarded to you by the HREC Office following the next SMAHS HREC meeting (7 February), which you will be required to quote on future correspondence with the Committee.

Yours sincerely

DR DAVID BLYTHE

CHAIRMAN

HUMAN RESEARCH ETHICS COMMITTEE

cc: Dr Stephanie Davies, Head of Department, Pain Management Unit, FH

South Metropolitan Area Health Service participant information sheet





Participant Information Sheet

Exploring pain related fear in people with long standing low back pain

You are invited to participate in a study on low back pain. This study is being conducted by Curtin University as part of a doctoral thesis and has been approved by the South Metropolitan Area Health Service Human Research Ethics Committee.

Please take time to read the following information carefully and to discuss it with your family, friends and general practitioner if you so wish. If any part of the information is not clear to you, or if you would like more information do not hesitate to ask us to explain it more fully.

Who is conducting this study?

Principal Investigator: Professor Peter O'Sullivan, Professor of Physiotherapy, School of Physiotherapy, Curtin University.

Co-Investigators: Samantha Bunzli, PhD Candidate, School of Physiotherapy, Curtin University. Dr Anne Smith, School of Physiotherapy, Curtin University, Mr Rob Schutze, Wisdom Health, Dr Rochelle Watkins, Telethon Institute for Child Health Research.

Who is funding this study?

Samantha Bunzli has received an Australian Postgraduate Award as a PhD student.

Decision to Participate:

Your decision to participate in this study is voluntary, that is, you may decide to be in this study or not take part in it at all. If do you decide to participate, you are able to change your mind at any time during the study. However, before you make any decision, it is important that you understand why this study is being done and what it will involve, including your rights and responsibilities. You will also be given a copy of this Participant Information Sheet and Consent Form to keep for your personal record.

Any decision you make will not affect your regular medical care or any benefit to which you would otherwise be entitled.

What is the purpose of this study?

Low back pain is a common condition which can affect many areas of daily living. People respond to pain in a variety of ways. Many people are afraid of the pain and the affect it has on their life. We are interested in understanding why people with low back pain are afraid of pain and how we can help reduce fear.

Why is this study suitable to me?

You have been invited to participate in this study as you have been identified as having long standing (>6 months) low back pain and have scored within our range on the fear of pain questionnaire.

How long will I be in this study?

If you agree to participate in this study, you will be contacted to arrange a baseline interview at a time and place convenient to you. You will then be contacted again 4 months later to arrange a follow-up interview. Each interview session is expected to last approximately 1 hour. Following the second interview, your participation in the study will be finished.

What will happen if I decide to be in this study?

In this study we will ask you to participate in 2 interviews. In the first we will ask you some questions about what you think of your back pain, how you cope with it and how it affects your daily life. We will also ask you what other people may have told you about back pain and how you respond to other situations in your life. In the second interview 4 months later, we will ask you similar questions and see if and how your experience of back pain may have changed. There are no right or wrong answers, we are only interested in your thoughts and experiences. The interviews will take around 1 hour and will be tape recorded so that we can write down your responses afterwards. If you do not wish to be recorded please inform Samantha Bunzli before the interview commences.

A week before the interviews we send a questionnaire pack to your home. These are questionnaires which physiotherapists commonly use in their assessment of people with back pain. The questionnaires will take about 30-40 minutes to complete depending on your personal circumstances. We will ask you to complete these in your own time and hand the completed pack to the researcher at the time of the interview.

Your role in the study will end after the completion of the second interview.

What will happen if I wish to withdraw from the study?

If at any time you wish to withdraw from the study, for whatever reason, you are able to do so without any consequences to your medical management.

Are there any reasons I should not be in this study?

There are no risks associated with this project. We understand that talking about how back pain affects your life may evoke some emotional feelings. We will remind you that you may stop or end the interview at any time you wish. As part of the screening process prior to participation, we will administer a questionnaire which screens for depressive symptoms. This questionnaire will be interpreted by the lead researcher, a qualified physiotherapist, in consultation with the clinical psychologist co-supervisor. If you score in or above the range of moderate depressive symptoms, we will send a letter to your GP informing them of our findings and recommending further assessment by them.

What are the costs to me?

Interviews will be conducted at Woodside Hospital, 18 Dalgety St, East Fremantle. You are able to choose a time convenient to you for the interview. You will not receive any payment or reimbursement for participating in this study.

What are the possible benefits of taking part, to me and to the wider community?

If you are still receiving treatment at the completion of your participation in the study, with your consent, the findings of your assessment may be discussed with your practitioner to provide more detailed information about your situation and assist your practitioner in managing your back pain. The results of this research aim to assist health professionals to better understand and manage pain and disability in other people with back pain.

Will my taking part in this study be kept confidential?

All of the data we gain from your assessment will be given a code so that your name does not appear anywhere. Data we gain from your assessment will include the audio recording of your voice and the questionnaires that you have filled out. Only Samantha Bunzli will have access to a secure file with the data we record from you. The research team are the only people who will hear your recorded interview, read your interview transcript and see your questionnaire answers. All this information will be stored in a locked cabinet in a locked office at Curtin University and will be destroyed after 7 years. No personally identifiable information will appear on any research report. By taking part in this study you are agreeing not to restrict the use of any data even if you withdraw. However, your rights under any applicable data protection laws are not affected. Research findings may be presented in scientific journals and at conferences attended to by health professionals.

We would like to use the information gained in this study for future studies. With your consent, your non-identifiable responses may be included in future studies conducted by these researchers.

How can I find out the results of this study?

If you wish to receive a copy of the study findings, these can be provided once the final study manuscript has been written by contacting Samantha Bunzli: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +618 9266 3646; email: Samantha.bunzli@.postgrad.curtin.edu.au

Who has reviewed this study?

The South Metropolitan Area Health Service Human Research Ethics Committee (Approval Number 12/11) and the Curtin University Ethics Committee (Approval Number HR 65/2011) have reviewed this study and have given their approval for the conduct of this research study. In doing so, this research conforms to the principles set out by the National Statement on Ethical Conduct in Human Research and abides by the Good Clinical Practice Guidelines.

Contact persons:

If you have any questions or concerns about the study you can contact: Professor Peter O'Sullivan: Phone No. 9266 3629 Samantha Bunzli: Phone No. 9266 3646

If you have any complaints or concerns about the way in which the study is being conducted, you may contact the Chairman of the South Metropolitan Area Health Service Human Research Ethics Committee on 9431 2929.

South Metropolitan Area Health Service participant consent form



Researcher Signature



CONSENT SHEET

An investigation of pain related fear in people with chronic low back pain

Participant's Name:		Da	ate of Birth:
1.		ack pain" conducted by Cu	study "An investigation of pain related fear in people urtin University as part of a doctoral study. I am 18
2.	I have been provid	led with an information she	eet, have been given the opportunity to ask pose of this study is and what my involvement will
3.	Chairman of the S 9431 2929. Altern Committee c/- Offi	outh Metropolitan Area He atively you may contact t	tudy or have any complaints I can contact the ealth Service Human Research Ethics Committee on the Secretary of the Curtin University Human Ethics lopment, Curtin University, GPO Box U1987, Perth
4.	I understand that i	f I wish I am free to withdra ill not receive any repercu	aw from this project at any time without any ssion as a result from the research team or my
	recording of my vo seen/heard only b information will be After seven years	oice and my answers on the y the research team. I will treated confidentially and all information will be dest	
6.		ere II agree to my non- ed by these researchers.	-identifiable responses being included in future
	If I score highly or the details of my C	the screening measure for SP to Samantha Bunzli for	or depressive symptoms, I give consent to pass on a referral letter.
8.	understand that S detail Professor P	amantha Bunzli will intervi eter O'Sullivan's contact d	is the principle investigator of this research study. I ew me. If I would like to discuss this project in more letails are: School of Physiotherapy, Curtin
	Samantha Bunzli's U1987, Perth; pho	s contact details are: Scho ne: +61 8 9266 3646; ema	+61 8 9266 3629; email: P.Osullivan@curtin.edu.au. ol of Physiotherapy, Curtin University, GPO Box ail: Samantha.bunzli@postgrad.curtin.edu.au
9.	treating practitions		ss the findings of her assessment of me with my enhance my quality of care by providing my f my situation.
	. I understand tha conferences atten by health profession provide better care	the findings from this resided to by health professionals. This will assist health and to help reduce pain a	earch study may be presented at scientific nals and published in scientific journals to be read th professionals working with people like me to and disability in other people with back pain. earch study as outlined to me
	Participant Signa	ture	Date

Date

Appendix 7. Sir Charles Gairdner Hospital Human Research Ethics Committee Approval





1 December 2011

Professor Roger Goucke
Pain Management
G Block Lower Ground Floor
Sir Charles Gairdner Hospital
Hospital Ave
NEDLANDS WA 6009

Professor Peter Sullivan School of Physiotherapy Curtin University NEDLANDS WA 6009

Dear Professor Goucke

APPLICATION TO CONDUCT HUMAN RESEARCH AT SCGH:

TRIAL No: 2011-087

TRIAL TITLE: A prospective, qualitative investigation of pain related fear in people with chronic low back pain

On behalf of the Sir Charles Gairdner Group Executive I give approval to conduct your research project at Sir Charles Gairdner Hospital based on the favourable reviews provided to me by Research Governance and the Sir Charles Gairdner Group Human Research Ethics Committee. This approval is granted until 1 December 2015, and on the basis of compliance with all requirements laid out in your application and with the provision of reports as required by the Research Governance and the approving HREC in giving their favourable opinion (attached).

The responsibility for the conduct of this study remains with you as the Principal Site Investigator. You must notify the HREC Office of any relevant issues arising during the conduct of the study that may affect continued favourable opinions by the hospital or by an HREC

Please quote Study number 2011-087 on all correspondence associated with this study.

Yours sincerely

Men

Dr Robyn Lawrence EXECUTIVE DIRECTOR SIR CHARLES GAIRDNER GROUP

cc: HoD

Sir Charles Gairdner Group Human Research Ethics Committee, Level 2 A Block, Hospital Ave, Nedlands, WA 6009
Telephone (08) 9346 2999 Fax (08) 9346 3307 ABN: 13 993 250 709
email HREC.SCGH@health.wa.gov.au Website www.scgh.health.wa.gov.au

Sir Charles Gairdner Hospital participant information sheet





Faculty of Health Sciences School of Physiotherapy

Telephone +61 8 9266 3618 Facsimile +61 8 9266 3699 Web www.physiotherapy.curtin.edu.au

PARTICIPANT INFORMATION SHEET

Project title: An investigation of pain related fear in people with chronic low back pain

Principal Investigator: Professor Peter O'Sullivan, Professor of Physiotherapy, School of Physiotherapy, Curtin University.

Co-Investigators: Samantha Bunzli, PhD Candidate, School of Physiotherapy, Curtin University. Dr Anne Smith, School of Physiotherapy, Curtin University, Mr Rob Schutze, Wisdom Health, Dr Rochelle Watkins, Telethon Institute for Child Health Research.

Purpose of research: Low back pain is a common condition which can affect many areas of daily living. People respond to pain in a variety of ways. Many people are afraid of the pain and the affect it has on their life. We are interested in understanding why people with low back pain are afraid of pain and how we can help reduce fear.

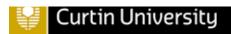
Your role:

In this study we will ask you to participate in two interview sessions which will take around 1 $\frac{1}{2}$ to 2 $\frac{1}{2}$ hours each.

- 1. At the start each session, we will ask you to fill in a series of questionnaires which physiotherapists commonly use in their assessment of people with back pain. These 9 separate questionnaires will take about 30-40 minutes to complete depending on your personal circumstances. Whilst it may seem like a lot of questions, answering these questionnaires is important as we want to see which one best reflects what you tell us in the interview. Other people in your situation may benefit in the future by spending less time in pain clinics.
- 2. After you have filled these in, we would like to talk to you about what you think of your back pain, how you cope with it and how it affects your daily life. We will also ask you what other people may have told you about back pain and how you respond to other situations in your life. We ask similar questions in the first and second interview four months later as we are interested in seeing if and how your back pain experience may have changed with time. There are no right or wrong answers, we are only interested in your thoughts and experiences. The interviews may take around 60-90 minutes and will be tape recorded so that we can write down your responses afterwards. If you do not wish to be recorded please inform Samantha Bunzli before the interview commences.
- 3. Your role in the study will end after the completion of the second interview. If you wish to receive a copy of the study findings, these can be provided once the final study manuscript has been written by contacting Samantha Bunzli: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3646; email: Samantha.bunzli@postgrad.curtin.edu.au

Risks and discomforts: There are no risks associated with this project. We understand that talking about how back pain affects your life may evoke some emotional feelings. We would like to remind you that you may stop or end the interview at any time you wish.

As part of the screening process prior to participation, we will administer a questionnaire which screens for depressive symptoms. This questionnaire will be interpreted by the lead researcher, a qualified



physiotherapist, in consultation with the clinical psychologist co-supervisor. If you score in or above the range of moderate depressive symptoms, we will send a letter to your GP informing them of our findings and recommending further assessment by them.

Costs: You will not receive any payment or reimbursement for participating in this study. You are able to choose a time and location convenient to you for the interview. Examples may include (but are not limited to) your home or a private office within the School of Physiotherapy at Curtin University. The interviewer can travel to you to eliminate your travel costs. As each session may take up to 2 ½ hours, this may present you with a time inconvenience. By allowing you to choose the time and location of the interview, we aim to keep this inconvenience to a minimum.

Benefits: If you are still receiving treatment at the completion of your participation in the study, with your consent, the findings of your assessment may be discussed with your practitioner to provide more detailed information about your situation and assist your practitioner in managing your back pain. The results of this research may assist health professionals to better understand and manage pain and disability in other people with back pain.

Confidentiality: All of the information we gain from your assessment will be given a code so that your name does not appear on any of the information. Only Samantha Bunzli will have access to a secure file with the data we record from you. The research team are the only people who will hear your recorded interview, read your interview transcript and see your questionnaire answers. All this information will be stored in a locked cabinet in a locked office at Curtin University and will be destroyed after 7 years. No personally identifiable information will appear on any research report. Research findings may be presented in scientific journals and at conferences.

We would like to use the information gained in this study for future studies. This would mean using the answers you give us in the interview or the scores you gained on the questionnaires **without any link to your name** as part of a larger study which includes more people. With your consent, your non-identifiable responses may be included in future studies conducted by these researchers.

Refusal or withdrawal: You have the right to refuse to participate in this study without providing any explanation and without incurring any prejudice from the research team or your treating practitioner. You also have the right to withdraw from the study at any time before, during or after the interview sessions without providing any explanation and without incurring any prejudice from the research team or your treating practitioner.

Further information: If you would like to discuss this project in more detail please contact the principle investigator Professor Peter O'Sullivan: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3629; email: P.Osullivan@curtin.edu.au or Samantha Bunzli: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3646; email: Samantha.bunzli@postgrad.curtin.edu.au

Ethics approval: This study has been approved by the Sir Charles Gairdner Group Human Ethics Committee (Approval Number 2011-087) and Curtin University Human Research Ethics Committee (Approval Number HR 65/2011). In approving this study, this research conforms to the principles set out by the National Statement on Ethical Conduct in Human Research and abides by the Good Clinical Practice Guidelines. If further information is required or in the event of any complaints please contact the Sir Charles Gairdner Group Human Ethics Committee, Department of Research, Sir Charles Gairdner Hospital, Hospital Ave, NEDLANDS WA 6009 or by telephoning +61 8 9346 2999

Sir Charles Gairdner Hospital participant consent form





Faculty of Health Sciences School of Physiotherapy

Telephone +61 8 9266 3618 Facsimile +61 8 9266 3699 Web www.physiotherapy.curtin.edu.au

CONSENT SHEET An investigation of pain related fear in people with chronic low back pain

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number: HR65/2011).

- I have been provided with an information sheet, have been given the opportunity to ask
 questions and fully understand what the purpose of this study is and what my involvement
 will be.
- If I am concerned about any aspect of this study or have any complaints I can contact the Secretary of the Curtin University Human Ethics Committee c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845; by phoning 9266 2784 or by emailing hrec@curtin.edu.au.
- 3. I understand that if I wish I am free to withdraw from this project at any time without any explanation and will not receive any repercussion as a result from the research team or my treating practitioner.
- 4. I understand that all the information I freely give to the researcher in the interview, the tape recording of my voice and my answers on the questionnaires will be de-identified and seen/heard only by the research team. I will not be identifiable in any research publication. All information will be treated confidentially and securely stored for seven years at Curtin University. After seven years all information will be destroyed.
- 5. By ticking this box here 🔞 I agree to my non-identifiable responses being included in future studies conducted by these researchers.
- 6. I give consent to pass on the details of my GP to Samantha Bunzli for a referral letter if I score highly on the questionnaire for depressive symptoms.
- 7. I understand that Professor Peter O'Sullivan is the principal investigator of this research study. I understand that Samantha Bunzli will interview me. If I would like to discuss this project in more detail Professor Peter O'Sullivan's contact details are: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3629; email: P.Osullivan@curtin.edu.au. Samantha Bunzli's contact details are: School of Physiotherapy, Curtin University, GPO Box U1987, Perth; phone: +61 8 9266 3646; email: Samantha.bunzli@postgrad.student.curtin.edu.au
- 8. I give consent for Samantha Bunzli to discuss the findings of her assessment of me with my treating practitioner. I understand this may enhance my quality of care by providing my practitioner with more detailed information of my situation.
- 9. I understand that the findings from this research study may be presented at scientific conferences attended to by health professionals and published in scientific journals to be read by health professionals. This will assist health professionals working with people like me to provide better care and to help reduce pain and disability in other people with back pain.
- 10. I agree to voluntarily participate in this research study as outlined to me

Signature	Date	
Witness Signature	Date	