Cognitive Functional Therapy for Persistent Low Back Pain: A Mixed Methods Feasibility Study

Thesis submitted to the University of Nottingham for the degree of Doctor of Philosophy

by

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Abstract

Background

Low back pain (LBP) is the most disabling and costly health condition globally, causing persistent pain and disability for more than ten million people in the United Kingdom (UK). Persistent LBP is characterised by a complex interplay of biopsychosocial factors that results in variable and fluctuating levels of pain and disability for each person. However, the contemporary management of persistent LBP has failed to integrate the multidimensional complexity of the disorder or target treatment towards individuals' needs. A plethora of physical, behavioural, combined (physical and behavioural) and psychologically informed physiotherapy interventions have all resulted in modest reductions in pain and disability when compared to minimal treatment or care as usual, with no one type of intervention demonstrating superiority over another.

Cognitive Functional Therapy (CFT) is an individually tailored, psychologically informed physiotherapist-led intervention, specifically developed to target the biopsychosocial complexity of persistent LBP. CFT has demonstrated encouraging results in two randomised controlled trials (RCT), in Norway and Ireland, with superior and sustained clinically important outcomes in comparison to guideline recommended care. However, CFT has not previously been evaluated in the UK National Health Service (NHS). Before the clinical and cost-effectiveness of CFT can be measured in a suitably powered RCT the feasibility of completing such a trial, in the UK health setting, needed to be established. This PhD thesis examines the feasibility of completing a future definitive RCT that would evaluate the clinical and cost-effectiveness of CFT in comparison to usual physiotherapy care (UPC) for patients with persistent LBP in the UK NHS.

Method

The feasibility of applying CFT in the UK NHS was investigated using a mixed methods approach over three studies. Study one (Chapter two), established the barriers and facilitators to implementing CFT within the NHS from the perspectives of physiotherapists (n=10) and a purposive sample of patient participants (n=8) using semi-structured interviews and framework method. Study two (Chapter three), was a pragmatic two-arm parallel feasibility RCT that compared CFT with UPC for 60 patient participants with persistent LBP. The criteria to progress to a definitive RCT were established *a priori*. In study three (Chapter four), a qualitative process

evaluation of the feasibility RCT explored the acceptability of the research processes and the experiences of the interventions from the perspectives of patient participants and their treating physiotherapists. Eight semi-structured interviews (patient participants) and two focus groups (the first focus group included the four physiotherapists who delivered CFT and the second focus group comprised of the six physiotherapists who provided UPC within the trial) were conducted and analysed thematically.

Results

Study one

Ten NHS physiotherapists who completed a three-day CFT training programme learnt a new biopsychosocial understanding of LBP and additional skills that they could apply to their clinical practice. Ongoing peer support and mentorship following CFT training was suggested to sustain changes to their clinical practice. Barriers to implementing CFT included concerns from physiotherapists about extending their scope of practice in addressing psychological factors with patients and the difficulty of letting go of biomedical treatments. Patient participants (n=8) recognised the difference between CFT and UPC when interviewed. They welcomed the CFT approach as beneficial and it enabled self-management of their LBP. Healthcare system barriers included lack of appointment time and limited availability of follow-up appointments. Key findings were incorporated into study two. For example, the CFT training programme was expanded to include six months of practice-based learning with mentorship sessions provided by a CFT educator, initial appointment times were increased to one hour and follow-up appointments were reserved in clinician's diaries.

Study two

In total, 60 patient participants (n=30 CFT and n=30 UPC) were recruited to the feasibility RCT with >70% retained at six-month follow-up. CFT was delivered to fidelity, relevant and clinically important outcome data were rigorously collected and CFT was tolerated by patients with no safety concerns. Intention to treat analysis indicated a signal of effect in favour of CFT with moderate and large between group effect sizes observed for a range of outcome measures at three and six-month follow-up. The Roland Morris disability questionnaire was the most suitable primary outcome measure and sample size calculations were completed for a future definitive RCT.

Study three

The embedded process evaluation confirmed that the feasibility RCT procedures were acceptable to patients and the CFT training programme provided the physiotherapists with the necessary knowledge, skills and confidence to deliver CFT as intended. The UPC training programme was also acceptable to the physiotherapists but the intervention was not always delivered to fidelity and evidence suggested that there was the potential for contamination of UPC with aspects of the CFT intervention. The Common Sense Model of Illness Representations was used to interpret and understand the perceived mechanisms of effect of CFT and differentiate the two interventions.

Conclusion

This PhD thesis confirms it is feasible to conduct a randomised study of CFT in comparison to UPC for NHS patients with persistent LBP and indicates a future, fully powered RCT to determine the clinical and cost effectiveness could be completed. Novel insights into the barriers, facilitators, feasibility, acceptability and the perceived mechanisms of effect of CFT in the context of the UK NHS have been provided. CFT also appeared to result in improved treatment outcomes in comparison to UPC, further supporting the need for a definitive RCT to be completed. Due to the potential contamination observed, a multi-centre cluster RCT design is recommended for the future study.

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Outputs

Publications

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Conference presentations

Shanghai International Rehabilitation Conference. 22nd August 2020. Invited Speaker: Cognitive Functional Therapy in the NHS? Results of a mixed methods feasibility study.

Society for Rehabilitation in Research Conference. 5th February 2019. Oral presentation: The barriers and facilitators to Cognitive Functional Therapy in the NHS: A qualitative study of the perspectives of people with low back pain and physiotherapists'.

North East Musculoskeletal Society: Annual conference, 15th September 2018. Invited speaker. Bridging the gap? Cognitive Functional Therapy for persistent low back pain.

Primary Care and Public Health Conference 17th May 2018. Invited speaker. Cognitive Functional Therapy for persistent low back pain in the NHS?

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Abbreviations

AE	Adverse event
CFT	Cognitive Functional Therapy
CI	Confidence interval
CSM	Common Sense Model of Self-Regulation
CONSORT	Consolidated Standards of Reporting Trials
COREQ	COnsolidated criteria for REporting Qualitative research
DASS-21	Depression, Anxiety and Stress Scale (short form)
DNA	Did not attend
DoH	Department of Health
EQ-5D-5L	Euro-QoL
EQ- VAS	Euro-QoL Visual Analogue Scale
ES	Effect size
FABQ	Fear Avoidance Beliefs Questionnaire
FAM	Fear Avoidance Model of chronic pain
GRC	Global Rating of Change Scale
IQR	Interquartile range
LBP	Low back pain
MCID	Minimum clinically important difference
MD	Mean difference
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NPRS	Numeric pain rating scale
ODI	Oswestry Disability Index
PCS	Pain Catastrophising Scale
PPI	Patient and public involvement
PROM	Patient Reported Outcome Measure
PSEQ	Pain Self-Efficacy Questionnaire
PT	Physiotherapist
RCT	Randomised Controlled Trial
RMDQ	Roland Morris Disability Questionnaire
SAE	Serious Adverse Event

SD	Standard Deviation
SMD	Standardised Mean Difference
SF-ÖMPQ	Short-form Örebro Musculoskeletal Pain Screening Questionnaire
SPIRIT	Standard Protocol Items: Recommnedations for Interventional Trials
STarT Back	Subgroups for Targeted Treatment screening tool
TiDieR	Template for Intervention Description and Replication
UHL	University Hospitals of Leicester NHS Trust
UK	United Kingdom
UPC	Usual Physiotherapy Care
WATOCI	Working Alliance Theory of Change Inventory

Chapter One - Introduction

1.1 Introduction

This chapter provides a state of the art review of the scientific literature of the global burden, diagnosis, multidimensional complexity and the management of persistent low back pain. The development of Cognitive Functional Therapy as an approach to managing persistent low back pain is discussed and the justification for evaluation, using mixed methods research, in the United Kingdom National Health Service is made. The chapter is summarised and the aims and objectives of this PhD thesis are described.

1.2 Low back pain: A global health problem

Low back pain (LBP) affects people of all ages and genders with similar prevalence rates reported in low, middle and high income countries [1]. It has been estimated that up to 84% of the general population will experience an episode of LBP within their lifetime and approximately 23% of people will report pain within the last month [2, 3]. In 2015, the Global Burden of Diseases study reported more than half a billion people were living with LBP worldwide [4]. Although LBP becomes persistent and disabling for a small proportion of these people (5-12%) [5], its high prevalence means it is the leading cause of disability globally [4, 6].

In the United Kingdom (UK), more than 10 million people are estimated to be living with persistent LBP [7]. It is the second leading cause of work absenteeism, after minor illness (e.g. the common cold), with many people becoming incapacitated from their work in the longer term [8].

Persistent LBP is the primary cause of disability in the UK, causing significant economic burden. In 2013, annual direct costs of LBP were reported to be £2.8 billion [9]. Prior to this, indirect costs were estimated to be £10.7 billion due to incapacity benefit payments and work productivity loss [10]. There are no recent UK cost of illness studies but the financial burden is likely to be much higher due to an increasing and ageing population since this time. Indeed, during the last 30 years LBP disability has grown by more than 50% globally [6] with economic impacts comparable to that of diabetes mellitus, cardiovascular disease, mental health disorders and cancer [1]. Escalating levels of disability and costs suggest that current interventions to manage persistent LBP are inadequate [11, 12] and that different strategies are required to lessen the burden of this ubiquitous public health problem [6, 13-15].

1.3 Low back pain diagnosis

Historically, clinical guidelines have recommended using a triage system to categorise LBP into serious, specific or non-specific causes [16-18]. Serious causes of LBP include malignancy, infection, fracture, cauda equina syndrome and inflammatory disorders, accounting for less than 1% of all LBP presenting to primary care clinicians [19]. When suspected urgent medical investigation and management is required [20]. A further 5-10% of cases are defined as specific causes of LBP that are characterised by radicular pain, commonly known as sciatica, with or without neurological deficits (sensory changes in the distribution of a specific dermatome, stretch reflex inhibition and muscle weakness correlated to a specific nerve root level) [20]. Specific causes of LBP include disc herniation, spinal stenosis and high grade

spondylolisthesis (greater than grade two) and are diagnosed through clinical history [21]. Medical imaging is only indicated in the presence of trauma or progressive neurological deficits [22].

The majority (approximately 90%) of LBP is considered to be ‘non-specific’ in origin meaning there is no identifiable pathology [1, 23]. In this instance, a generic diagnosis of ‘non-specific LBP’ is used and is experienced as symptoms of pain, muscle tension and/or stiffness in the lower back [18, 21, 24]. It is this group of patients who are included in this thesis as they are the most frequent users of healthcare services for LBP in the UK [7] and account for the majority of direct National Health Service (NHS) costs (appointments, imaging and interventions) [9, 10].

While diagnostic triage is useful for excluding serious and specific causes of LBP, it has not been helpful in directing management for those diagnosed with non-specific LBP. Firstly, there has been an exponential rise in radiological tests that attempt to identify structural causes of non-specific LBP [25, 26], despite this going against the consistent recommendations of clinical guidelines to not use them in this population [17, 18, 27-29]. This has largely been driven by clinician and patients beliefs that pain is caused by tissue damage or an injury and that structural or pathological sources of non-specific LBP can be identified through imaging [30]. However, there is a weak correlation between pain and pathology [31]. Structural changes, such as disc degeneration, disc bulges, disc protrusions and facet joint arthritis are commonly seen on radiological images of people without non-specific LBP and when present do not correlate well with pain intensity and disability

levels [32-34]. Furthermore, they do not predict who will develop LBP in the future [35]. Without careful explanation, these so called ‘abnormal’ changes can be interpreted by patients as a sign of damage or permanent injury. This can lead to maladaptive beliefs, thoughts (e.g. catastrophising), protective and avoidant behaviours [36, 37], as described in the fear and avoidance model of persistent pain [38]. In this way, diagnostic imaging has been associated with escalation to treatments that carry little clinical benefit and risk of harm, such as opioid prescriptions and surgery [25, 39]. Poor outcomes for patients including prolonged disability and work absenteeism have been observed [28, 40, 41]. For these reasons, non-specific LBP has been considered to be an iatrogenic disorder in which biomedical practices have contributed to the increasing global disability levels and spiralling costs [1, 14, 42].

Non-specific LBP has also been differentiated by symptom duration. Acute non-specific LBP has been used to describe LBP that has been present for less than three months and chronic non-specific LBP for symptoms lasting longer than this [27, 43]. However, a temporal approach to diagnosis of non-specific LBP may not be accurate or helpful to direct management. Acute non-specific LBP was previously thought to be a self-limiting condition with the majority of people recovering within six weeks [44]. A number of prospective longitudinal observational studies have challenged this view [5, 45-49], with as many as 60-80% of people reporting persistent symptoms one year later [5, 47, 50]. One UK study identified four distinct non-specific LBP clusters amongst 342 patients consulting in primary care [45]. These were, ‘persistent mild’ (35.7%), ‘recovering’ (30.4%), ‘fluctuating’ (13.1%) and

‘severe chronic’ (20.8%) LBP. The research participants remained in the same cluster at one and seven year follow-up [45, 46]. Furthermore, similar clusters and trajectories have been identified in separate cohorts [49] and in different countries [48], providing validity of their existence. Each study also seems to have demonstrated similar profiles and characteristics as being representative of these groups. For example, people in the ‘severe chronic’ cluster reported high pain intensity, held negative LBP beliefs, demonstrated passive coping behaviours and were of a lower socioeconomic status [49].

Taken together these studies highlight the refractory nature of non-specific LBP, question the clinical utility of diagnosis based time and suggest that the identified trajectories are generalisable across different populations. Furthermore, the findings emphasise the multidimensional nature of non-specific LBP across the biopsychosocial spectrum [43].

Non-specific LBP as a diagnostic term has also been criticised for being illogical and unacceptable to clinicians and patients [51]. Such a diagnosis can lead to unsatisfactory communication, uncertainty and undermine patients’ confidence in healthcare practitioner’s ability to identify a legitimate reason for their pain [20, 52], which may contribute to negative outcomes [53, 54]. For the reasons described in this section, persistent LBP will be adopted as the preferred term throughout this thesis.

In summary, it is paradoxical that while persistent LBP has no known biomedical cause, it has historically been considered through a pathological model of tissue injury and disease. This has led to an exponential increase in imaging and ineffective treatments that have resulted in worse outcomes for

patients (increasing disability levels and costs). Instead, longitudinal research has identified LBP to be a persistent long-term condition that is associated with multiple factors that span the biopsychosocial spectrum. Therefore, for interventions to be effective a comprehensive understanding of persistent LBP from a multidimensional perspective is required. The next section considers the multidimensional nature of persistent LBP.

1.4 Multidimensional complexity of persistent low back pain

Current understanding is clear in that persistent LBP is a heterogeneous and complex biopsychosocial disorder [15, 55, 56] made up of a collection of physical (e.g. postural and movement behaviours, loading demands), psychological (e.g. negative LBP beliefs, catastrophising thoughts, fear, anxiety, depression), social (e.g. low socioeconomic status, family relationships, social support, work), lifestyle (e.g. activity levels, poor sleep, smoking, obesity), genetic and comorbid health (e.g. diabetes, mental health conditions) factors. Different combinations of these factors manifest uniquely in each person, at different life stages and can interact to mediate changes in the structure and function of the neurological, immune and endocrine systems [55, 57, 58]. Figure 1, published by O'Sullivan et al. (2016) provides an illustrated view of the complex nature of LBP [59].

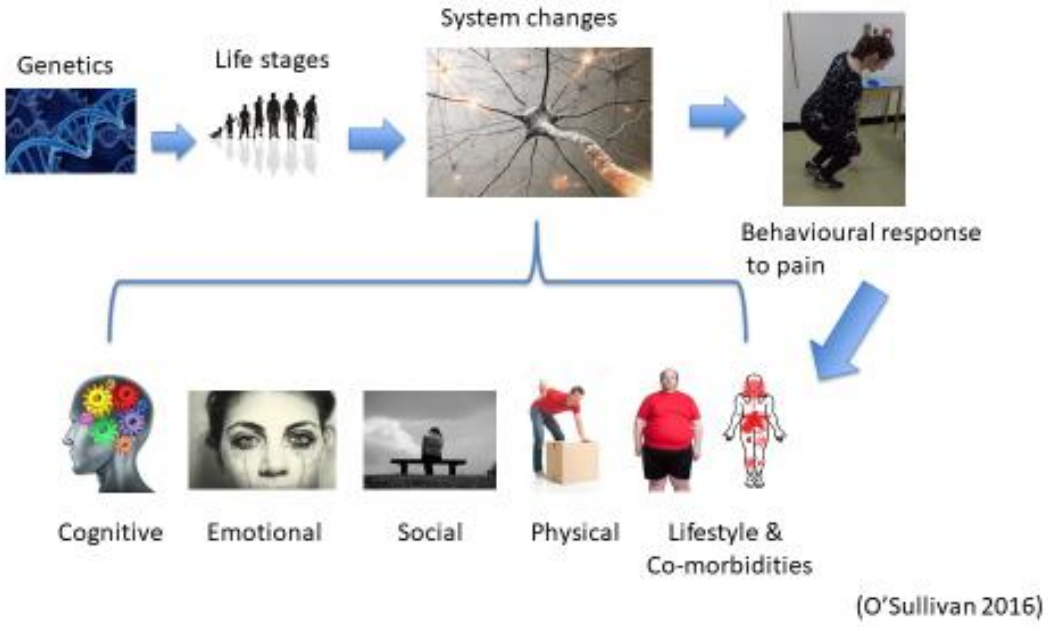

Figure 1: Multidimensional complexity of persistent LBP.

Neuro-immune-endocrine changes in the presence of persistent LBP include reduced grey matter density in cortico-limbic brain regions [60-64], inhibition of descending modulation of pain within the spinal cord [65, 66], activation of glial cells causing a neuroinflammatory response [67], elevation of circulating pro-inflammatory cytokines and chemokines [68, 69] and dysregulation of the hypothalamo-pituitary-adrenocortical axis (HPA) [57, 70].

Persistent LBP also invokes a motor system response regarded as a protective mechanism to actual or perceived threat of pain, injury or damage [71]. These behavioural responses are commonly observed through sympathetic nervous system arousal (e.g. apical breathing, muscle tension) and the presence of safety behaviours (e.g. avoidance of movements and activities and guarding responses such as off-loading a painful limb or propping with hands during sitting to standing movements) within the clinic

[72]. The factors underlying the multidimensional complexity of LBP are now discussed and their contribution to persistent LBP is described.

1.4.1 Physical factors

Physical factors such as sitting, standing, bending and lifting have long been believed to be the cause of LBP among the general public [73, 74], people with LBP [75, 76] and the healthcare community [30, 77-79]. These beliefs may have been propagated by early biomechanical studies implicating the intervertebral disc as a cause of LBP when subject to repetitive loading (83, 84) and sustained postures [80, 81] and later reinforced by the high prevalence of LBP reported in manual occupations [82-84].

However, the high prevalence of morphological changes seen in the intervertebral discs of people without LBP (e.g. disc degeneration 52%, disc bulges 40% and disc herniation 31% at the age of 30) [34] and their strong association with genetics, rather than physical work, challenge this view [85]. Cross sectional and prospective studies have found conflicting evidence regarding relationships between physical factors and the onset of LBP. For example, no association was identified between forward bending time and the development of LBP in manual [86, 87], construction, healthcare workers (nurses) [88] and elite endurance athletes exposed to repetitive spinal loading and bending in comparison to the general population [89]. In contrast, repetitive low load lifting tasks were associated with the development of LBP in 1196 manual and office workers (odds ratio 2.06, 95% confidence interval (CI) 1.32.-3.2) [90]. Trunk flexion (Relative Risk (RR) = 1.5, 95% CI 1-2.1), rotation (RR 1.3, 95% CI 0.9-1.9) and lifting > 25

kilograms (RR 1.6, 95% CI 11.-2.3) were also observed to be risk factors for developing LBP in another prospective study of manual and office workers (n=861) also at three year follow-up [91]. However, the similar LBP prevalence rates reported in sedentary (e.g. office workers) and manual workers and that as many as one in three people are unable to identify a physical trigger for the onset of their LBP [92, 93] challenges the view that physical factors are a significant cause of LBP.

Systematic reviews have also found conflicting evidence regarding associations between LBP and physical factors. Heavy lifting, bending and twisting were associated with LBP onset in one systematic review [94] and repeated exposure to lifting more than 25 kilograms daily was associated with an increased incidence of LBP by 4.32% in another study [95]. Other systematic reviews have failed to identify a dose response relationship between lifting, bending, twisting, and sustained postures during work [96-98]. The conflicting findings between systematic reviews may be explained by the heterogeneity of methods used to measure physical parameters (e.g. radiological measures, video observation and wearable devices) in the included studies. In addition, reliance on questionnaires to document previous experiences of LBP rather than directly quantifying exposure to physical factors in some studies suggests that recall bias could have also been a factor [99].

While demonstrating variable associations, systematic reviews have concluded that there is insufficient evidence to identify causal relationships between a number of physical exposures and LBP [100, 101]. These include

sitting [102], standing [103], walking [103], bending [97], twisting [97], carrying [104], pushing or pulling [105], lifting [96], awkward postures [106], manual or material handling [107] and spinal curvatures [108].

Although causal relationships between the development of LBP and physical factors are not consistently supported by evidence from cross-sectional studies and systematic reviews, physical behavioural responses following the onset of LBP have been observed. People with LBP generally move more slowly, with less range of motion and increased muscle activity of the trunk in comparison to people without LBP [109, 110]. These motor behaviours have been proposed to represent a psychophysiological response to the actual or perceived threat of pain [72].

Geisser et al. (2004) demonstrated in 76 people with persistent LBP that pain-related fear was associated with reduced lumbar flexion, increased trunk muscle activity and lack of flexion relaxation response during forward bending [111]. Furthermore, summation of pain during a repeated lifting task was associated with pain catastrophising, fear and low mood [112]. One systematic review identified that fear, catastrophising, self-efficacy, anxiety and low mood were associated with reduced spinal range of motion and increased trunk muscle activity in LBP patients [113]. The findings of these studies highlight the close mind-body relationship between physical and psychological factors in LBP [111, 114].

In the presence of acute LBP, the changes observed in movement and muscle activity may signify a normal protective and adaptive behavioural response to LBP. However, when protective behaviours continue beyond

normal tissue healing times they may represent an unhelpful, maladaptive and provocative response and can be the reason symptoms persist [115]. Maladaptive movement behaviours in the presence of persistent LBP are not stereotypical. While aberrant kinematics, motor patterns and proprioceptive deficits have been observed, they present in a variety of postures, movement planes [116-118] and during different functional activities [119, 120]. For example, an individual may be sensitised to flexion activities (e.g. sitting, bending, tying shoe laces and lifting) by bracing through their trunk muscles and limiting flexion movement. Alternatively, an individuals' LBP may be sensitised to extension by bracing the lower back into lordosis during the same activities [115]. Safety behaviours such as breath holding and propping with the hands are commonly observed during these functional activities. More distressed patients may also present with signs of sympathetic nervous system arousal (high levels of muscle tension, sweating and apical breathing) [72]. These maladaptive behaviours and their close association with psychological factors may be modifiable and represent targets for management [115].

1.4.2 Psychological factors

Psychological aspects of LBP have been extensively studied with strong evidence of associations between cognitive and emotional factors in the development and maintenance of symptoms [121-123]. Cognitive factors include the thoughts and beliefs that an individual may have about the identity, cause, consequences, management and prognosis of their LBP [124]. One prospective study of 488 patients with LBP in the UK identified

negative LBP beliefs were associated with future pain and disability at five year follow-up (relative risk = 1.06, 95% CI = 1.03-1.09) [125].

The most pervasive beliefs are that LBP is caused by structural, anatomical or biomechanical abnormalities. In this way, an individual may perceive their lower back to be vulnerable, in need of protection and that provocative activities should be avoided to prevent further pain or damage [75]. Maladaptive beliefs such as these often originate from or are reinforced by encounters with healthcare professionals [36, 42, 126] and can cause patients to catastrophise [127]. Pain catastrophising is characterised by hypervigilance through rumination and magnification of the threat of pain and can lead to feelings of helplessness [55, 121]. High levels of catastrophising at baseline have shown to be a risk factor for the development of persistent LBP [128]. Pain catastrophising has also been associated with fear of pain, depression, anxiety [121, 123], reduced endogenous pain modulation, increased pain sensitivity and disability in people with persistent LBP [66, 122, 129].

Negative LBP beliefs have also been linked to low levels of self-efficacy. Pain self-efficacy is the perceived control of and the confidence an individual has to engage in activities despite the presence of pain [130]. Lower pain self-efficacy has been associated with higher pain intensity and disabling LBP [121]. Self-efficacy has consistently been identified as a mediator of pain intensity and disability [131-133] and also a mediator of depression in patients with persistent LBP [134].

Maladaptive cognitions and negative emotional responses to pain appear to be interrelated. Emotions such as fear, anxiety, stress, depression, anger and injustice are commonly observed following the onset of LBP [55, 127]. However, pre-existing emotional factors due to contextual social stressors or co-morbid mental health conditions have also been associated with persistent LBP [135], which suggests a bi-directional relationship exists between them [121].

As a protective response to perceived threat or danger, pain related fear is a common emotion associated with the onset of and the transition to persistent LBP [38, 128, 136]. Described in the fear-avoidance model of persistent pain, negative beliefs and catastrophising thoughts are antecedents to pain-related fear and avoidant behaviours which in turn can lead to physical deconditioning, disability and depression (Figure 2) [38]. Pain-related fear has been associated with increased pain intensity, prolonged disability and work absenteeism [137, 138] and has been identified as a moderator of outcome following LBP [139].

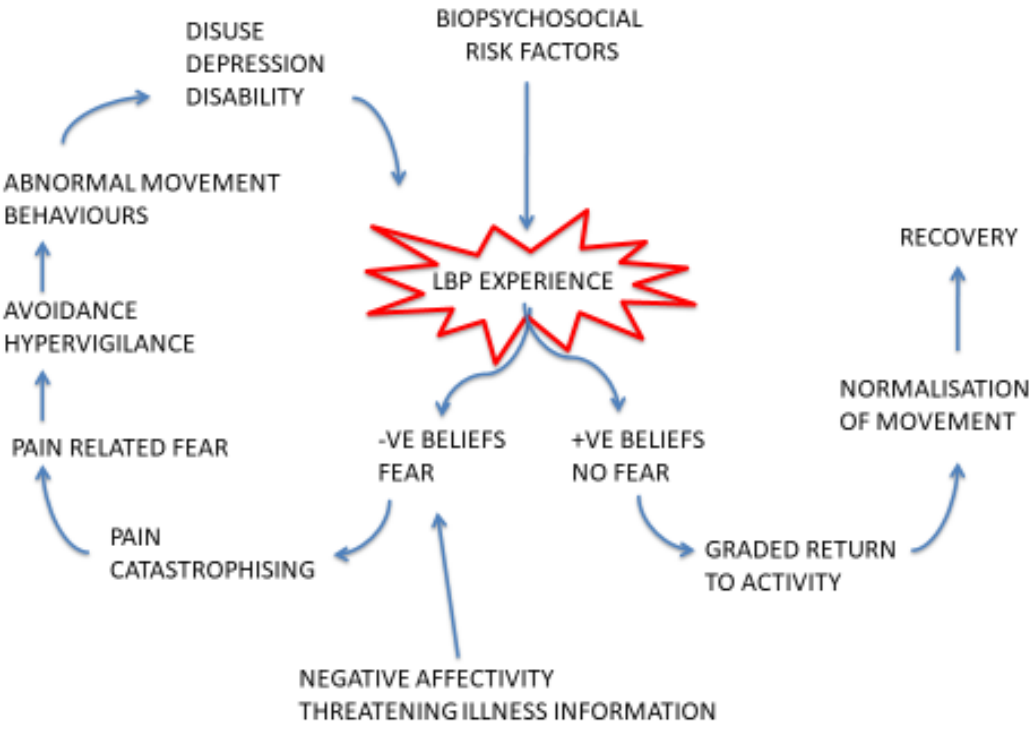

Figure 2: The fear-avoidance model of persistent pain, modified from Vlaeyen and Linton (2000).

As described in the fear-avoidance model, depression is a common sequelae of pain persistence but it can also be a pre-existing health comorbidity [121]. For example, LBP was associated with an increased risk of depression and anxiety in a longitudinal twin study [140] but a prospective cohort study identified that patients with depression at baseline were 2.3 time more likely to develop LBP at three year follow-up [35]. An important finding of this study was that depression rather than lumbar spine imaging findings (degenerative disc disease, disc bulges, annular tears and facet joint arthrosis) was a stronger predictor of future LBP [35]. Depression, coupled with anxiety and distress, (negative affectivity) is not only a strong predictor of developing persistent LBP [122, 141] but has also been associated with unhelpful behaviours such as taking extended periods of rest, low levels of physical

activity and physical deconditioning [142]. This may be because anxiety and fear are interrelated constructs that activate the stress response [57]. Patients who are anxious may also magnify the threat of pain and avoid activities, as described in the fear-avoidance model (Figure 2) [38]. Perceptions of injustice and anger have also been associated with fear, anxiety, depression and delayed recovery in people with persistent pain [143].

While some people are fearful and avoidant others will show an endurance coping response which is characterised by continual activity and persistence with tasks in the presence of pain [144, 145]. However, some people will present with a combination of coping responses, evidenced by a boom and bust pattern of pain persistence and avoidance [72].

It is important to highlight that the psychological factors described above should be considered to be normal responses to pain [146]. Beliefs (e.g. pain is a sign of damage), emotional responses (e.g. distress regarding diagnosis or scan findings, fear of causing harm or damage, low mood due to an inability to engage in valued activities) and coping strategies (e.g. inability to control pain and avoidance behaviours) may be modifiable and are considered separate to serious mental health disorders [146, 147]. Conditions such as severe clinical depression, personality disorder, post-traumatic stress disorder and stated suicidal intent may not be modifiable and require specialised care [148].

In summary, psychological factors are important predictors for the development of persistent LBP, they appear to be interrelated, occur

concurrently and act as a cause of effect of persistent LBP [127]. Many of these factors may be modifiable and represent targets for treatment.

1.4.3 Social factors

A criticism of the biopsychosocial model has been the failure to adequately integrate and address social factors within the framework [149]. Many social factors such as socioeconomic status, deprivation, educational attainment, health literacy and traumatic or stressful life events have been linked to negative LBP outcomes and may not be modifiable [121, 150]. This may explain why some social factors have received little research attention and that clinicians feel they have limited capacity to influence them [149].

Previous traumatic life events were associated with the development of LBP in a cross-sectional survey of more than 38000 people from 14 countries. A history of one traumatic life event (e.g. death of a loved one, physical or sexual abuse) was associated with being 1.7 times more likely to experience back and neck pain in the future which increased with an increasing number of traumatic life events (odds ratio = 3.0, 95% CI 2.6-3.5) [135]. People with low socioeconomic position are three times more likely to experience persistent pain than people in higher social classes [151] and the development of persistent and disabling LBP has also been associated with low educational attainment and low health literacy [150].

Dissatisfaction with work, inadequate social support of colleagues and negative work relationships were associated with an increased risk of developing LBP in one systematic review [152]. Similar findings were identified in another systematic review, 14 years later, showing that job

dissatisfaction, limited control over work, and negative relationships with colleagues were also associated with the onset of LBP [153].

Relationships with family members, partners and significant others (solicitous or negative responses) have also been associated with LBP disability and pain intensity [154]. Social isolation, particularly in older age has also been associated with increased odds of experiencing LBP [155]. Furthermore, avoidant behaviours and pain interference can be a barrier to social obligations and engagement [156]. Sociocultural perceptions may also influence LBP beliefs, coping strategies, activity levels and care seeking behaviours [42, 157, 158].

1.4.4 Lifestyle factors

A number of lifestyle factors including physical activity levels, sleep, smoking and obesity have demonstrated relationships with LBP. Participation in sport and engaging in physical activity has been associated with a lower risk of developing persistent LBP in comparison to sedentary individuals [159]. However, another systematic review reported that physical activity levels (exercise and time spent in sport) were not associated with or were predictors of levels of pain or disability after the onset of LBP [160]. Heneweer et al. (2009) identified that both sedentary behaviours and higher levels of physical activity were associated with increased risk of persistent LBP, describing a u-shaped relationship between sedentary behaviours, physical activity and LBP [93]. Despite these contrasting findings exercise seems to be a beneficial intervention for both the prevention of [161, 162]

and the treatment of LBP [163], although the type of exercise undertaken seems to be less important [164].

A reciprocal relationship exists between sleep and LBP [165], with insufficient sleep being associated with the development of persistent LBP [166] and that persistent LBP is a predictor of poor sleep [167]. Irrespective of the direction of association, insufficient sleep has been associated with a number of LBP co-morbidities (depression, type 2 diabetes mellitus, and obesity) [165] and higher levels of systemic inflammation (interleukin-6) in people with persistent LBP, suggesting a role of sleep in pain sensitivity [168].

Dario et al. (2015) [169] identified a relationship between obesity and LBP and a higher body mass index was associated with LBP at 32 year follow-up in a British birth cohort study [170]. Elevated levels of inflammatory markers (C-reactive protein) in adipose tissue has been proposed as a potential explanatory mechanism between obesity and LBP [171]. Smoking has also been linked to LBP but the exact mechanism is yet to be fully understood [172]. A systematic review based on twin samples identified both smoking and obesity to be independent risk factors for developing LBP [173]. A sedentary lifestyle, smoking, poor sleep quality and obesity have all been associated with LBP and higher levels of circulating inflammatory cytokines [168, 171] which may suggest a common mechanism of pain sensitivity and why the anti-inflammatory effects of exercise and an active lifestyle may be beneficial [69].

1.4.5 Co-morbid health, life stages and genetic factors

Persistent LBP is commonly associated with other persistent pain, musculoskeletal and chronic health conditions, with as many as 62% of people reporting a least one comorbidity [174]. Common comorbid pain complaints with persistent LBP include osteoarthritis, fibromyalgia, headache, migraine, abdominal and neck pain [173-176], with researchers suggesting a shared mechanism of central sensitisation and reduced endogenous pain inhibition [177]. Indeed, one large prospective study (n=7523) showed that recovery from persistent LBP was inversely related to widespread pain with ≥4 pain sites associated with a lower chance of recovery at 11 year follow-up [178]. A higher number of pain co-morbidities has also been associated with high levels of disability, work absenteeism and health care utilisation [179]. In addition to mental health comorbidities (described in section 1.4.2), poorer self-reported general health and physical function [180] as well as cardiovascular and respiratory disease have been associated with persistent LBP [175].

LBP also appears to be more prevalent at different life stages and has been associated with genetic and environmental risk factors. For example, LBP is uncommon in younger children but lifetime prevalence increases sharply during adolescence with up to 40% of teenagers affected [181]. In one study, approximately one third of 1249 teenagers reported ongoing or increasing LBP into young adulthood [182]. By the age of 18, prevalence rates of LBP are equivalent to those observed in adult populations [183]. Pain persistence in teenagers has been associated with female gender, adverse life events, pain comorbidities (neck pain, abdominal pain and headaches), low mood

and adiposity [182, 184-187], underscoring the complexity of the problem. However, physical factors such as carrying school bags, spinal posture, endurance of spinal muscles and hypermobile joints were not strong predictors of future LBP [188].

LBP is more prevalent in females than males, occurs commonly during pregnancy and has been associated with widespread pain during menopause [3, 189]. The peak incidence of LBP occurs in the middle ages of life [13] with limitations in daily activities more frequently observed in elderly populations [190]. A recent prospective study showed that 57% of older adults did not recover from a new onset of LBP over a five year period [191]. With a growing population and increased life expectancy, LBP morbidity and disability is predicted to increase amongst people of older age [192].

A systematic review of 27 twin studies identified that disabling and severe LBP was associated with genetic heritability as well as a number of environmental (smoking) and comorbid factors (obesity, asthma, diabetes mellitus and osteoarthritis) [173]. The associations between LBP and a range of comorbidities, at different life stages and genetic factors further underscores the complexity of the disorder.

1.4.6 Pain profiles

Based on contemporary understanding, persistent LBP has been re-defined as a protective mechanism and idiosyncratic output, produced by the neurological, immune, endocrine and motor systems in response to perceived threat, danger or disruption to homeostasis [57, 59, 193]. The unique interplay between multiple biopsychosocial factors (described above)

and the neuro-immune-endocrine systems means that varying and fluctuating levels of pain, tissue sensitivity, distress and disability are observed for each person [57, 59, 194].

For some people pain is localised to the lower back and is provoked by specific movements, postures or loading activities [115]. This may represent a peripherally mediated nociceptive pain profile with a clearly defined stimulus-response relationship [195]. Other people may present with pain that is less well defined, more widespread and disproportionately provoked by mechanical stimuli (postures, movements and loading activities) [115, 194]. This clinical profile may represent amplification of nociception by the central nervous [196] and is also associated with increasing presence of psychological and social factors as well as sensitivity to pressure and cold stimuli [194]. A further pain profile is characterised by pain that is spontaneous or paroxysmal and is not reproducible through the clinical examination, representing a dominance of central mechanisms [195]. However, not all people will present with clearly defined symptoms that can be neatly categorised in this way. A combination of peripheral and central pain mechanisms (mixed pain profile) may be observed for many people, reflecting the complexity and contribution of different underlying factors [72]

Summary

The existing literature clearly identifies LBP to be a complex, heterogeneous and multifactorial disorder associated with persistent pain and disability for many people. Many of the factors underlying persistent LBP are interrelated, modifiable and may represent targets for treatment. Therefore, for

interventions to be effective a comprehensive approach is required that considers and integrates all of the dimensions underlying persistent LBP [72]. However, previous research has by and large neglected this complexity in the design and evaluation of interventions for LBP. The next section will discuss and appraise existing interventions and contemporary models of care for persistent LBP.

1.5 Contemporary LBP management

The heterogeneity and variation in clinical presentations of persistent LBP means it is a complex condition, requiring assessment and management across multiple interacting domains [59]. For interventions to be effective they will need to reflect this complexity, be flexible in their delivery and tailored to each person's unique presentation [11, 197]. However, incorporating this complexity into the design, evaluation and implementation of interventions for persistent LBP has proven to be challenging for researchers and clinicians [192, 198]. The increasing burden (disability levels and costs) globally suggest that current management of persistent LBP is inadequate [1]. This section considers the contemporary management of persistent LBP, recommendations of clinical guidelines and the development of clinical pathways to support evidenced-based care.

1.5.1 Biomedical approaches

Persistent LBP has historically been treated by clinicians using a biomedical approach with interventions targeting proposed structural, anatomical or biomechanical causes of LBP [26]. There are more than sixty published Cochrane systematic reviews evaluating an abundance of pharmaceutical,

interventional (injection therapies and surgical procedures) and conservative biomedical treatments for LBP [199].

Pharmaceutical preparations for persistent LBP including non-steroidal anti-inflammatories [200], opioid analgesics [201], anti-depressants [202] and anti-convulsants [203] have all shown minimal effects in reducing pain and improving function in comparison to placebo for persistent LBP. Studies reporting the effectiveness of paracetamol [204] and muscle relaxants [205] are limited to acute LBP only.

There is also insufficient evidence to support the use of interventional procedures for improving pain and function for various types of injection therapies (prolotherapy, epidural, intra-articular steroid and trigger point injections) [206], radiofrequency denervation [207] and surgery for persistent LBP [208-210]. Furthermore, many of these treatments have been associated with increased risk of harms and high costs which means they should be considered to be of low value [6, 211].

Conservative treatments for persistent LBP have included acupuncture, manual therapy, education and different forms of exercise. Acupuncture performs no better than sham treatment or usual care and does not result in clinically meaningful improvements in pain [212]. Manual therapy, manipulation and massage all appear to have modest short term effects but no long-term improvements in pain or function have been reported [213-215].

There is also limited evidence to support the effectiveness of individual education (e.g. in person or educational booklets) [216] or the use of back schools [217]. However, exercise and education may be useful in preventing

LBP [162]. Exercise has shown a small magnitude of effect for reducing pain and improving disability at long-term follow-up [163], but the type of exercise does not appear to be important with similar effect sizes reported for Pilates [218], Yoga [219] and motor control exercise [220]. Indeed, the analgesic effects of a range of conservative treatments appear to be small [221], irrespective of the intervention provided [12].

1.5.2 Behavioural interventions

Behavioural treatments for persistent LBP include cognitive and behavioural therapies such as Acceptance and Commitment Therapy and Mindfulness-Based Stress Reduction and have also shown small effect sizes for reducing pain and disability at short and long-term follow-up [222, 223]. Similar to exercise, no one type of behavioural intervention appears to be superior to another for managing persistent LBP [222].

Many physical and psychological interventions have been delivered in isolation but even when they have been combined there does not appear to be any additional benefit gained [59]. For example, one systematic review that compared physical, psychological and combined (physical and psychological) interventions for persistent spinal pain reported that only small reductions in pain and disability were sustained across all between-group comparisons [224]. This may be because combined interventions do not adequately integrate multiple biopsychosocial factors underlying persistent LBP or tailor treatment to individual needs. It may however simply be that persistent LBP is highly resistant to change.

1.5.3 Subgrouping and targeted treatment

The disappointing outcomes reported in clinical trials of physical and psychological treatments has been the catalyst for developing interventions that target treatment towards specific subgroups of persistent LBP [225-227]. By identifying specific subgroups of people with persistent LBP, who display similar characteristics and tailoring interventions to these unique individual features, it is reasonable to assume that treatment outcomes may be enhanced [198]. There have been more than 80 LBP subgrouping systems developed [228], many with overlapping philosophies [229]. The most commonly researched and used approaches in clinical practice have been based on modifying symptoms through postural and movement behaviours [230, 231], directing different treatments towards a constellation of clinical features [232] or stratifying care based on individuals' psychosocial risk profile [233].

The modification of symptoms through changing movement or altering mechanical load on peripherally sensitised tissues within the lumbar spine is the goal of movement-based subgrouping systems, popularised by McKenzie and Sahrmann [230, 231]. An alternative subgrouping method attempts to match an individual to one of four treatments (manipulation, stabilisation exercise, specific exercise or mechanical traction) on the basis of their clinical presentation and the physical examination [232, 234-236]. However, irrespective of the subgrouping method used, comparative effectiveness studies suggest no long-term differences in pain, disability or psychosocial function when these subgrouping systems have been compared to conventional physiotherapy approaches in persistent LBP populations [237-

239]. These subgrouping approaches appear to reduce the complexity of persistent LBP to specific physical features only and do not account for the broader psychosocial context of persistent LBP. Additionally, they do not consider different pain profiles in people with persistent LBP (described in section 1.4.6) beyond nociception.

One subgrouping method has attempted to identify specific populations of persistent LBP based on neurophysiological pain mechanisms [195]. The different pain profiles described by Smart et al. (2010) (nociceptive, peripheral neuropathic and central sensitisation) were constructed on the basis of expert opinion using Delphi methods, rather than validated procedures, such as quantitative sensory testing [195]. Furthermore, previous work has highlighted the presence of mixed pain presentations in persistent LBP [194] which suggests that the subgroups proposed may not be distinct entities, limiting the clinical application of this type of approach.

A contrasting advancement in physiotherapy, is the ‘Subgroups for Targeted Treatment’ approach (STarT Back) [233]. Based on evidenced-based prognostic indicators (psychosocial factors, pain characteristics and functional ability), the STarT Back approach employs a screening questionnaire prior to consultation that stratifies people with LBP into low, medium and high risk of poor outcome and subsequently targets management by matching treatment to the predetermined risk profile of each individual [240]. The STarT Back approach was compared to ‘best practice’ physiotherapy in a randomised controlled trial (RCT) of 851 patients with LBP. Although functional disability and pain intensity significantly improved,

the between group differences at 12 months were reported to be non-significant. However, there were significant reductions in work absenteeism and a notable improvement in quality of life in favour of the STarT Back approach, giving a cost saving of £34.39 per patient [233].

In summary, a multitude of treatments that just target physical or psychological aspects of persistent LBP have shown consistently modest reductions in pain and disability in both the short and long-term [12, 163, 213, 222]. The majority of existing treatments are broadly applied to treat singular structural, anatomical or biomechanical dimensions of persistent LBP and at best only appear to palliate symptoms in the short-term. Psychological or combined physical and psychological interventions do not appear to confer any additional benefit. Subgrouping systems developed so far also appear be reductionist and have mainly focused on physical factors. The coverage of pain profiles, psychological, social and lifestyle factors do not appear to be given priority within existing subgrouping systems and this is evidenced by the lack of improvement in the outcomes reported in systematic reviews of clinical trials utilising subgrouping methods when compared to usual care [239, 244-249].

1.5.4 Clinical guidelines

Clinical guidelines serve to synthesise the best available evidence and make recommendations that inform clinical and policy decision making about healthcare interventions. The aim of clinical guidelines is to promote evidence-based interventions, reduce variations in care and potential harms so that improved patient outcomes and healthcare system efficiencies are

made [29]. A systematic review identified 15 published clinical guidelines for LBP between 2008 and 2017, of which nine included the assessment and management of persistent LBP [28]. The guidelines recommend self-directed care including education about the favourable nature of recovery from an episode of LBP and advice to remain active. Physical activity and exercise is universally recommended across guidelines, irrespective of LBP duration, but specific advice about the optimal type, dosage and intensity of exercise is unclear [28]. In line with the evidence-base, reviewed in section 1.5.1, interventional procedures such as injections and surgery for LBP are not recommended apart from in exceptional circumstances such as being part of a clinical trial [27].

There are inconsistencies regarding pharmacological management of LBP with some guidelines recommending analgesic (e.g. paracetamol and opioids) and anti-depressant medication, despite limited evidence of their effectiveness [202, 250]. However, most guidelines now concur that the potential harms of opioid and anticonvulsant medications (dependency, increased risk of falls and death) outweigh the clinical benefits [39]. In the UK, non-steroidal anti-inflammatory medications are preferred where there are no risks or contra-indications to their use (e.g. respiratory, cardiovascular and gastro-intestinal) [27].

Unequivocal evidence indicates that psychological factors are strong predictors of outcome after the onset of LBP (described in section 1.4.2) [122] but clinicians are seldom able to identify them [251]. However, only four out of 15 recent clinical guidelines recommend using validated screening

questionnaires, such as the STarT Back tool or Örebro Musculoskeletal Pain Screening Questionnaire, in order to identify psychological factors and guide treatment [28].

The UK National Institute for Health and Care Excellence (NICE) guidelines do recommend using psychosocial risk screening tools [27]. In this clinical guideline, recommendations for those identified as low risk of persistent LBP, and to prevent over-treatment, include providing education about the favourable nature of LBP and self-management strategies such as continuing with normal activities and exercise. In addition to this, higher risk patients are recommended a core package of care inclusive of manual therapy, exercise and low intensity cognitive behavioural approaches. Where self-management strategies and core treatments have been ineffective or there are significant psychosocial obstacles to recovery, combined physical and psychological rehabilitation programmes are recommended [27].

Combined physical and psychological rehabilitation programmes are based on cognitive behavioural principles and methods of physical rehabilitation, sharing the same philosophy of pain management programmes [252, 253]. They aim to promote pain self-management but they do not specifically seek pain reduction [243, 252, 253].

Despite the increasingly consistent recommendations of clinical guidelines, one systematic review reported that clinicians do not appear to adhere to them [254]. A number of possible barriers to engagement have been identified, including lack of awareness and knowledge about guidelines, conflicts with guideline recommendations and real world practice constraints

such as appointment times and access to recommended services [255]. While implementation plans have been provided in some guidelines, it has been argued that healthcare systems (both public and privately funded) are not designed to support the recommended shift away from biomedical treatments towards physical and psychological rehabilitation [256].

A series of papers published in the Lancet in 2018, recommended that health care systems need to adapt to manage the global burden of LBP more effectively [14]. This includes the redesign of clinical pathways to replace established low value practices (e.g. imaging, opioid prescriptions, injections and surgery) with promising evidenced-based and cost-effective alternatives, the removal system barriers to clinical guideline implementation (e.g. short consultation times, clinician education) and public health campaigns [14].

1.5.5 Clinical pathways

In the UK, LBP clinical pathways vary considerably [257]. Indeed, many patients experience a ‘revolving door’ between services and providers for little clinical benefit at increased cost [243]. In 2013, NHS England identified LBP as a priority area for clinical pathway redesign [243]. The National Low Back and Radicular Pain Pathway (NLBRPP), published in 2014, was designed to lessen the burden of LBP by restricting access to low value procedures and interventions and replace them with lower risk and higher value alternatives. A key feature of the pathway was to improve access to and provide effective care for people with persistent LBP [243]. While, the pathway provides a blueprint for commissioners to follow and is endorsed by NICE, NHS RightCare and The Getting It Right First Time (GIRFT) National

speciality report on spinal services, it has only been implemented by 15% (20 out of 135) of clinical commissioning groups in England [243]. This may be one reason why the GIRFT report for England in 2019, highlighted that low value procedures, such as repeated facet joint injections for people with persistent LBP prevail despite evidence to indicate they are not effective, with annual costs exceeding £10 million to the NHS in 2018 [257].

In line with the NLBRPP, the GIRFT report also recommends the decommissioning of low value interventions and to re-invest cost savings in the workforce to provide the right skills to deliver guideline recommended interventions [257]. Central to the functioning of the NLBRPP is the provision of combined physical and psychological rehabilitation programmes for people with persistent LBP who have failed to respond to guideline recommended care [243].

The recommended combined physical and psychological programme is multidisciplinary (delivered by a pain specialist, nurse, physiotherapist, psychologist, occupational therapist and dietician), is of high intensity (residential, 100 hours over three weeks) and therefore expensive to deliver which may explain why this component of the pathway has not been as widely commissioned in England [243]. Indeed, the Department of Health Spinal Taskforce in the UK previously identified the absence of combined physical and psychological programmes as the biggest gap in service provision for persistent LBP patients [309], a group who cost the NHS and society a significant proportion of resources [7].

Combined physical and psychological programmes are often delivered in groups and the content typically includes pain education, cognitive behavioural approaches such as graded exposure to exercise, pacing and relaxation techniques [243, 258]. Preliminary evaluation of the combined physical and psychological rehabilitation programme in the north east of England reported short-term improvements in mood, general health and pain but not disability. Long-term outcomes have not been reported [258]. Similar findings have been reported for a lower intensity (12 hour) multidisciplinary combined physical and psychological rehabilitation programme delivered in Birmingham, UK, but at more than two year follow-up [259]. The findings of these two studies align with a Cochrane systematic review that reported small effect sizes for reductions in pain and disability at long-term follow-up following multidisciplinary biopsychosocial treatment for persistent LBP when compared to usual care and physical interventions [260]. However, the studies by Green et al. 2017 [258] and Rogers et al. 2018 [259] were service evaluations and not subject to robust methodology, such as an RCT. Importantly, the results of these two studies highlight that the intensity of the programme (12 or 100 hours) does not appear to affect patient outcomes.

Despite modest outcomes, combined physical and psychological rehabilitation programmes continue to be recommended by a number of contemporary clinical guidelines [27, 261, 262]. However, there does not appear to be a standardised approach to delivery with heterogeneity in the type, content, frequency, duration and intensity of existing programmes. In addition, the associated high costs of multidisciplinary care [263] and the disappointing clinical outcomes observed in studies so far makes delivery by

a single professional an attractive alternative and provides an opportunity for further research.

1.6 Psychologically informed physiotherapy

The management of LBP by UK Physiotherapists has not been quantified since 2000 when clinical practice was grounded in a structural-biomechanical model of LBP [264]. Since this time, there has been a rapid growth in pain research, the development of pain theories (e.g. fear avoidance model) and new treatments delivered by physiotherapists (e.g. pain neuroscience education) to patients with persistent LBP [71]. To this end, there is growing interest in psychologically informed physiotherapy as a lower intensity alternative to multidisciplinary combined physical and psychological rehabilitation programmes [263].

Psychologically informed physiotherapy augments traditional physiotherapy interventions for LBP, such as manual therapy and exercise, with cognitive behavioural principles including education, mindfulness, graded activity, graded exposure, relaxation techniques and goal setting [265]. Like multidisciplinary pain management and combined physical and psychological programmes, psychologically informed physiotherapy does not seek to control pain but rather focuses on thoughts, beliefs, behaviours and engaging in valued activities in the presence of pain [266-268]. For example, physiotherapy incorporating Acceptance and Commitment Therapy employs mindfulness strategies to develop acceptance of thoughts and feelings and psychological flexibility so that valued life activities can be achieved, despite the presence of pain [269, 270].

A number of psychologically informed physiotherapy approaches for persistent LBP have been developed and evaluated in clinical trials in the UK [233, 268, 271-274]. However, the outcomes observed in these studies are consistent with a systematic review and meta-analysis that did not identify long-term improvements in pain (mean difference (MD) = -0.25), disability (standardised mean difference (SMD) = -0.06) or psychological function (self-efficacy, catastrophising, fear of movement, anxiety and depression) when psychologically informed physiotherapy was compared to usual physiotherapy care [277].

The barriers to implementing psychologically informed physiotherapy interventions for people with persistent LBP are well established and may explain these findings [278]. Physiotherapist personal factors such as concerns regarding practice boundaries and confidence to manage the complexity of LBP across the biopsychosocial spectrum after training have all been identified as threats to implementation [279], particularly in the NHS [278, 280-282]. Contextual barriers such as inefficient care pathways including long waits for treatment and short consultation times appear to be universal [279].

In light of these barriers and in keeping with another systematic review [224], it was suggested by Guerrero et al. (2018) that psychologically informed physiotherapy interventions may not adequately integrate cognitive, behavioural and physical aspects of LBP and individually tailor management [277].

Cognitive Functional Therapy (CFT), the intervention studied within this thesis, was noted as an outlier in this systematic review with large effect sizes reported for reducing pain (MD=-1.50) and disability (SMD=-0.91) as well as large mean improvements in fear of movement, anxiety and depression at twelve-month follow-up [277]. A key difference between cognitive behavioural approaches and CFT, is that CFT explicitly integrates cognitive, behavioural and physical aspects of LBP and specifically targets pain control [72].

In summary, clinical guidelines and pathways recommend the restriction of low value procedures and interventions for persistent LBP and to replace them with higher value alternatives. In the UK, combined physical and psychological programmes are recommended to meet this need. Combined physical and psychological programmes are usually multidisciplinary and can be expensive to deliver with significant heterogeneity between the programmes reported so far. Psychologically informed physiotherapy was presented as a lower intensity alternative to multidisciplinary combined physical and psychological programmes. A review of the existing evidence highlights that multidisciplinary combined physical and psychological programmes and psychologically informed physiotherapy do not appear to have improved outcomes for persistent LBP patients, with effect sizes for pain and disability similar in magnitude to the approaches described in section 1.5.

A commonality between the approaches is that they do not appear to specifically target pain control but focus on reducing disability and distress

with the implication that persistent pain is not responsive to treatment. This is notwithstanding a systematic review of 17 Cochrane reviews that identified pain intensity to be more responsive to treatment than disability in LBP trials [283]. For LBP interventions to be effective, a comprehensive clinical reasoning framework is required that identifies and targets treatment towards the multidimensional nature of LBP, including specifically targeting pain control [72].

1.7 Cognitive Functional Therapy

Considering the existing evidence-base and the limited effectiveness of existing models of care, an intervention called Cognitive Functional Therapy (CFT) has been specifically developed to target the biopsychosocial complexity of persistent LBP [72, 115, 284, 285]. CFT has shown sustained long-term effects for a range of clinical outcomes including reduced pain intensity, improved disability and psychological function in a number of uncontrolled [286-291] and controlled studies [292-294]. These studies will be fully reviewed in section 1.7.4, first CFT is described.

1.7.1 Definition and development of CFT

CFT is an individualised physiotherapist-led psychologically informed intervention that targets modifiable physical, cognitive, emotional and lifestyle factors of persistent LBP [72]. As described in section 1.4 many of these factors are not mutually exclusive and interact to influence an individuals' pain experience, levels of distress, tissue sensitivity and disability [57, 59, 63].

Originating from a combination of physical rehabilitation [115], behavioural [38, 295, 296] and pain neurophysiological perspectives [297, 298], CFT is a flexible model of care that has evolved from predominantly a movement based system to incorporate a clinical reasoning framework that integrates multiple biopsychosocial dimensions of persistent LBP (Appendix A) [285]. The multidimensional clinical reasoning framework enables the clinician to identify modifiable and non-modifiable biopsychosocial factors underlying an individual's persistent LBP.

The inherent complexity of CFT means that it is not underpinned by one particular philosophy or theoretical model but rather aligns to numerous theoretical constructs of human behaviour, health and learning, including the fear avoidance model, inhibitory learning theory and the theory of self-efficacy [136, 299-302].

1.7.2 CFT training

CFT training teaches physiotherapists to use the multidimensional clinical reasoning framework which is achieved through a combination of methods. Firstly, a three-day clinical workshop outlines the multidimensional nature of persistent LBP and key components of the CFT intervention, which is reinforced through live masterclass demonstrations by a CFT tutor with persistent LBP patients. Secondly, a CFT training manual provides operational definitions of the intervention and multidimensional clinical reasoning framework. Access to publications and web-based resources (www.pain-ed.com) supports this process. A previous clinical trial reported approximately 100 hours of training was required, including experiential

learning and clinical supervision, for physiotherapists to deliver CFT to fidelity [292].

1.7.3 CFT delivery

Based on a comprehensive interview (incorporating psychosocial risk screening [303]) and physical examination the physiotherapist identifies the dominance, weighting and interplay between multidimensional factors (e.g. pain related cognitions, emotional responses, functional postural and movement behaviours, sleep and physical activity levels) that contribute to an individuals' pain experience. The physiotherapist is then able to design a management plan that is tailored towards an individuals' unique clinical presentation and reflects their preferences, valued activities and goals [72]. CFT targets these factors by helping the patient understand their pain from a biopsychosocial perspective, develop confidence to engage in movement and activity and adopt positive lifestyle behaviours [72]. The three overlapping components of the intervention are briefly discussed.

Making sense of pain is a reflective process that allows a person to understand pain from a biopsychosocial perspective. The unique multidimensional contributors to pain and disability, identified though the patient interview, combined with experiential learning during guided behavioural experiments are used to disconfirm unhelpful beliefs (e.g. pain is a sign of structural damage) and change maladaptive responses to pain (e.g. protective guarding) to form a new understanding of LBP.

Exposure with control is an experiential learning process whereby a series of behavioural experiments are used to gradually expose an individual to

their feared, avoided and/or painful movements and functional tasks in order to facilitate behaviour change. This is achieved through controlling sympathetic nervous system responses (e.g. controlled breathing and bodily relaxation) and safety behaviours (e.g. normalising postures and movement behaviours) during these nominated provocative, feared or avoided tasks. Gaining control violates expectations of pain and or damage consequences and these new strategies are immediately integrated into everyday functional activities to build self-efficacy.

Lifestyle change: Unhelpful lifestyle behaviours are modified through increasing physical activity levels and social participation (based on preference), sleep hygiene, stress management (relaxation strategies, mindfulness) and dietary advice where relevant.

To facilitate behaviour change and develop therapeutic alliance, motivational interviewing and empathetic communication underpins this process [72, 304, 305]. An individualised self-management program is provided, monitored and evolved that includes progressive functional exercises and lifestyle modifications, where indicated without the need for specialised equipment. The dosage and intensity of the exercise programme is tailored towards an individual's valued activities, goals, preferences and levels of physical conditioning.The overall aim of CFT is to coach a person towards sustained self-management [72].

The initial consultation lasts for one hour and follow-up appointments for 30 minutes. Individuals are initially seen weekly for two to three sessions with 5

to 10 individual treatment sessions typically required over a three month period to achieve self-management [286, 287, 290, 292, 294, 306].

1.7.4 Current evidence of CFT to treat LBP

To date, the published literature evaluating CFT has used a variety of methods including a single case-experimental design [288], five cohort studies [286, 287, 289-291], and two RCT's have been completed [292, 294]. Each of the eight studies are now reviewed in detail with critical analysis at the end of the section.

1.7.4.1 Single case experimental and cohort studies

A single case experimental design, completed in Australia, included four participants with persistent LBP and high pain related fear (measured using the Tampa Scale of Kinesophobia (TKS)). Immediately after starting CFT, reduced pain intensity and decreased fear of movement occurred concomitantly with improvements in disability [288]. While the reductions in disability and fear surpassed clinically important thresholds (>2.5 points for the Roland Morris disability questionnaire (RMDQ) and > 8 points for the TKS) the small number of participants and short duration of follow-up (3-months) restricts the generalisability of this study. However, this study provided a preliminary indication that reduced fear and pain intensity may be important mediators of disability following CFT.

Five different cohort studies of CFT have been completed in various countries and health care settings including the UK [286], Ireland [287], Denmark [289, 290] and Belgium [291]. The cohort study in Ireland, recruited 26 participants with persistent LBP from pain management and

rheumatology clinics [287]. An A-B-A design was used which included a three-month of period no treatment (phase A1), phase B where CFT was provided over a mean of 7.7 sessions over 12 weeks and was followed by phase A2 where no treatment was provided over 12 months. The primary outcomes were disability (measured using the Oswestry Disability Index (ODI) on a scale of 0-100, where 0 represents no disability and 100 maximal disability) and pain intensity (measured using the numeric pain rating scale (NPRS) on a 0-10 scale where 0 equals no pain and 10 the worst possible pain). Outcomes were collected a six week intervals during phase A1, at the end of the intervention in phase B and at three, six and 12 months during phase A2.

Data were analysed for 21 participants retained in the study at 12-month follow-up. Statistically significant and clinically important effect sizes were reported with a reduction in disability (ODI) by 24 points ($p<0.001$, Cohen's $d = 0.85$) and reduced pain intensity (NPRS) by 1.7 points ($p<0.001$, Cohen's $d = 0.65$). However, the absence of a control group, blinded assessor and the small sample size were significant limitations of this study.

A further A-B-A case-control study was used to evaluate the effect of CFT on work absenteeism, pain and disability in 33 nurses with persistent LBP in Belgium [291]. In comparison to previous studies of CFT, baseline pain intensity (NPRS 2.6) and disability levels (ODI 11.3%) were very low. Work absenteeism (measured as the total number of days absent from work) was significantly reduced from 167 days in the first year before starting CFT reducing to 6, 15, 17 and 28 days respectively in each calendar year that

followed. However, caution should be exercised in the interpretation of these results as only 33% of the sample (n=10) reported work absenteeism because of LBP throughout the study.

Another cohort study, that included a highly disabled group of participants with persistent LBP (mean baseline disability score of 33.3, measured using the Pain Disability Index on a scale of 0-50 where zero indicates no disability) compared CFT (n=47) to a multidisciplinary combined physical and psychological rehabilitation programme (n=99) within a specialist pain centre in Denmark [290]. Statistically significant and clinically important reductions in pain related disability (SMD=0.52; 95% CI 0.15-0.97 p<0.01), health related quality of life (Euro-Qol 5D, scale 0-100) (SMD=0.60, 95% CI 0.23-0.97, p<0.01) and a 93% cost saving (€3,688) was reported in favour of CFT at six-month follow-up [290]. However, there were no differences in pain intensity (NPRS) (SMD=0.21, 95% CI -0.15 to 0.66, p=0.45) and analgesia consumption between the groups (SMD=0.09, 95% CI-0.52 to 0.08, p=0.84). While CFT was compared to a control group in this study, it was matched retrospectively to an existing data set meaning the lack of randomisation was a significant limitation of this study.

In a further cohort study, also completed in Denmark, identical methods to Vaegter et al. (2019) [290] were used to compare CFT (n=37) to a retrospectively matched cohort of participants who received usual care (n=185) [289]. Usual care consisted of several treatment pathways including discharge with advice only, attendance to twelve sessions of an exercise class for LBP or manual therapy and exercise delivered by a physiotherapist

or Chiropractor. Participants receiving CFT attended a mean of 5.7 sessions over 12 weeks. Statistically significant and clinically important within group reductions in the primary outcome (disability, measured using the RMDQ) were recorded at three, six and 12 month follow-up following CFT. Between group changes were statistically and clinically important in favour of CFT at three and six months but not 12-month follow-up (RMDQ –8.1, 95% CI –17.4 to 1.2, p=0.086). However, purposeful sampling of the CFT participants and a 49% loss to follow-up at 12 months were significant limitations of this study.

There has been only one study of CFT, delivered by physiotherapists without extensive CFT training, in the UK NHS. This cohort study explored the effectiveness of introducing CFT into an NHS physiotherapy service in 48 participants with high levels of LBP related functional disability (mean ODI = 36% at baseline) [286]. Clinically important reductions in pain (defined as >2 point reduction in the NPRS) and disability (defined as >10 point reduction in the ODI) were observed at two-year follow-up. High participant satisfaction ratings were also recorded with 96% of respondents being either satisfied or very satisfied with the care received at long-term follow-up [286]. This study indicates that CFT can be implemented with success in the UK in one acute hospital, but it does not indicate whether the participants were any better or worse than patients who received routine treatments. The lack of blinding to treatment allocation, blinded assessments and a control group limits the generalisability of the findings of Newton et al. (2014) [286].

While all of these cohort studies have all signalled an indication of positive effect following CFT, especially for reduced pain related disability, such

research designs are not without their limitations [356]. The small sample sizes, absence of control groups [286-288, 291] and that the researcher was often involved in participant recruitment, delivery of the intervention, data collection and analysis introduces numerous sources of bias and threats to validity [92]. Hence why such studies are considered to be of lower quality in the hierarchy of evidence [356, 357].

1.7.4.2 Randomised controlled trials

There have been two published RCT's of CFT [292, 294]. The first was completed in Bergen, Norway and compared CFT to manual therapy and exercise in 121 people with persistent LBP. The primary outcomes were pain intensity (measured using the NPRS) and disability (measured using the ODI). Statistically significant and clinically important reductions in pain (defined as >1.5 reduction in NPRS) (mean NPRS = 3.2, 95% CI 2.5-3.9, $p<0.001$) and disability (defined as a >10 point reduction in the ODI) (mean ODI = 13.7, 95% CI 11.4-16.1, $p<0.001$) were reported in favour of CFT at six month follow-up [292]. Improvements in disability were maintained up to three years later (mean ODI = 6.6%, 95% CI -10.1 to -3.1, $p<0.001$, Cohen's d =0.70) however, data was only available for 52.1% (n=63) of participants at three years which threatens the validity of the findings [293].

Although this study had positive results and was published in a peer reviewed journal, some caution needs to be taken when generalising to other populations. The participants in this study were a self-selecting group recruited in response to newspaper advertisements and from private physiotherapy practices, who reported low to moderate baseline levels of

functional disability (mean ODI 22.7%, 0-100 scale) [292]. In comparison, baseline disability levels of the participants in the cohort study by Newton et al. (2014) and the case controlled studies by O'Sullivan et al. (2015) and Vaetger et al. (2019) were reported to be much higher than this with ODI scores of 36.2%, 41% and 45% respectively [286, 287, 290]. This indicates that the sample differs from LBP populations typically seen in other settings, geographical locations and healthcare systems and the results may not be generalisable. Furthermore, blind to allocation assessments and intention to treat analyses were not performed at all follow-up times which introduced the potential for bias and over-estimation of the treatment effect [356]. In addition, although the original sample size was n=121 participants, 27 participants (22%) were lost to follow-up at 12 months. This means that the study may have been affected by attrition bias and could have been underpowered to detect between group differences for the primary outcomes of disability and pain intensity.

The second published RCT compared CFT with a biopsychosocial pain education and exercise class in 206 people with persistent LBP in Ireland [294]. Statistically significant and greater improvements in disability (measured using the ODI) were reported in favour of CFT (mean between group difference ODI = 7.02; 95% CI 2.24-11.08, p=0.004, Cohen's *d* =0.55) but not pain intensity (measured using NPRS) (mean between group difference 0.65; 95% CI-0.20-1.50, p=0.134, Cohen's *d* = 0.31) at 12-month follow-up [294]. It is unclear why reductions in pain intensity were not observed in this trial compared to the first RCT of CFT. The higher baseline disability levels (mean ODI of 22% versus 32%), lower dosage of treatment

(mean of 7.7 versus 5 sessions of CFT) and a high number of pain comorbidities reported by participants in the Irish trial could explain this finding.

It must also be noted that only 63% of participants who were randomised started or completed their assigned intervention and only 69% of these participants completed 12-month follow-up. However, in comparison to the first RCT of CFT [292], this study was analysed by estimating the between group differences of the primary outcomes using intention to treat principles which was a key strength. A further limitation was that the interventions in both arms of this study were delivered by the same three clinicians. While assessment of treatment fidelity was described in the study protocol [421], the results of which were not reported in the full trial publication [294]. It is therefore unknown if the interventions were delivered as intended and/or were free from the effects of contamination.

It is also important to highlight, in all of the previous studies [287-294], except the study conducted in the NHS [286], that CFT has been delivered by experienced clinicians, with post-graduate qualifications in musculoskeletal physiotherapy and that they received more than 100 hours of training and mentorship in the intervention. None of these previous studies of CFT [287-294] have included physiotherapists novice to the approach which limits the generalisability of the findings to environments with less experienced staff. In addition, none of the studies explored how CFT should be implementation into general physiotherapy practice, such as NHS physiotherapy clinics.

In conclusion, and given the limitations of CFT described, it is clear that further clinical trials are required that are of high quality and low risk of bias. It is also important that future RCT's of CFT are completed in different geographical locations and healthcare systems as there is evidence that the success of complex LBP interventions might be influenced by different environments, contexts and settings [27, 41]. To date, the clinical and cost effectiveness of CFT has not been evaluated in an RCT in the UK NHS or compared to usual physiotherapy care. Despite the research completed so far, it remains unknown if CFT is feasible in the UK NHS, if CFT can be delivered by UK NHS physiotherapists and if it is an acceptable intervention to patients and clinicians. However, this preliminary research has provided an indication of effect and the next stage is to test the feasibility of CFT within the NHS.

1.7.5 Comparison with other studies of psychologically informed physiotherapy for persistent LBP in the UK NHS

As described in section 1.6 (page 33) there has been a proliferation of research evaluating psychologically informed physiotherapy as an emerging intervention for managing persistent LBP [233, 267, 268, 271-274]. Within the UK, several differing psychologically informed physiotherapy approaches for persistent LBP have been developed and evaluated in large-scale clinical trials in the NHS [233, 267, 268, 271-274]. This section considers three of the most recent studies, namely the Subgroups for Targeted Treatment (STarT Back) approach [233], The Back Skills Training Programme (BeST) [267] and Physiotherapy informed by Acceptance and Commitment Therapy (PACT) [268].

The STarT Back approach is a notable advancement in the management of LBP, developed and evaluated in Primary Care in the UK [198]. A short nine-item screening questionnaire, derived from evidenced-based prognostic indicators of LBP (psychosocial factors, pain characteristics and functional ability), is used to classify people into low, medium and high risk of poor outcome. Treatment is subsequently matched to the predetermined risk profile of each individual [240]. Patients identified as low risk are advised about activity levels, exercise and return to work, which is reinforced through educational resources (the back book [275] and a 15-minute educational video called ‘Get back active’). The same advice and resources plus the addition of physiotherapy, inclusive of manual therapy and exercise, is provided to those stratified as medium risk. For those identified as high risk of persistent pain and disability, a psychologically informed physiotherapy intervention based on the principles of Cognitive Behavioural Therapy is used to target rehabilitation towards physical function and valued activities [233, 266].

The STarT Back approach was compared to usual physiotherapy care in 851 participants with LBP, recruited from 10 Primary Care practices. The primary outcome was disability, measured using the RMDQ (scale 0-24, where lower scores indicate less disability) and all data were analysed by intention to treat. Overall, the STarT Back approach was more effective than usual physiotherapy care at 12-month follow-up (mean between group difference RMDQ = 1.06, 95% CI 0.25 to 1.86 p=0.0095) saving £34.39 per participant

but the effect size was small (Cohen's *d* = 0.19) [233]. Similar findings were also reported for a range of secondary outcome measures including pain intensity, psychological factors (fear avoidance, catastrophising and anxiety), general health, quality of life, days missed from work, global perceived effect and satisfaction with treatment.

An important finding of the STarT Back trial was that low risk participants who received the minimal advice and education intervention in one treatment session responded just as well as those who were randomised to usual physiotherapy care and attended a mean of 5.1 treatment sessions. This finding supports data to suggest that many people with LBP are over-treated in Primary Care [25] and may explain the majority of the cost savings observed in the trial [233]. This research emphasises the importance of economic evaluation in clinical trials, absent so far from RCT's of CFT.

Of the 851 participants enrolled in the study, 236 (28%) were classified as 'high risk' with 157 participants allocated to psychologically informed physiotherapy and 79 to usual physiotherapy care. At 12 months follow-up, the between group differences favoured the psychologically informed physiotherapy intervention but they were not statistically or clinically significant (mean between group difference RMDQ = 1·22, 95% CI –0·47 to 2·91, Cohen's *d* = 0·27, p=0·1547) [233]. However, it must be noted that the within group differences for both interventions surpassed the minimum clinically important threshold of > 2.5 points for the RMDQ, defined *a priori*, which suggests that both interventions were effective.

A limitation of the trial was that 23.7% (n=202) of participants were lost to follow-up at 12 months but data for all participants who were randomised were included in the intention to treat analysis. Indeed, a notable strength of the STarT Back trial was the large sample size which was powered to allow sub-group analysis and adjusted to permit up to 25% loss to follow-up. This means the trial was sufficiently powered to allow for the drop-outs observed and therefore provided reliable estimates of the treatment effect for each of the stratified care sub-groups (low, medium and high risk). Furthermore, randomisation was completed remotely, all outcome assessments and data analyses were completed by blinded assessors adding validity to the findings [233]. The strengths of the STarT Back trial are also reflected by the inclusion of the approach in a national clinical pathway in England [243] and the recommendation by NICE to consider psychosocial risk stratification and matched treatments as part of comprehensive LBP management in the updated guidelines [27].

The STarT Back trial was completed in one Primary Care setting in 10 GP practices within the UK, which may restrict the generalisability to other care settings and regions. To address this concern, the IMplementaion to improve Patient Care through Targeted treatment (IMPaCT) study evaluated implementation of the STarT Back approach in Primary Care in the UK. A pre and post-implementation design was used to determine the clinical and cost effectiveness of the STarT Back approach and the effect on processes of care including numbers referred to physiotherapy, diagnostic imaging requests, medication prescriptions, sickness certifications and re-

consultation rates for LBP [455]. Five Primary Care practices that consisted of a range of rural, semi-urban and urban settings hosted the study.

In phase one 364 participants were recruited to receive usual care. After phase one, training and support to embed the STarT Back approach in Primary Care was provided to 64 General Practitioners and 14 physiotherapists over three months. In phase three, a new cohort of participants (n=554) were recruited and the impact of the STarT Back approach was evaluated at six month follow-up.

Process of care outcomes showed that after the quality improvement package of training to support implementation that more participants were referred appropriately to physiotherapy in the medium and high-risk groups (40% during phase one and 72% during phase three, odds ratio 2.36, 95% CI 1.80-3.10, $p<0.001$). There were also reductions in non-opiate and opiate analgesia prescriptions but no change in re-consultation rates or imaging requests for LBP. Disability also improved (RMDQ = 0.71, 95% CI 0.06 to 1.36, $p=0.03$) in favour of the STarT Back approach and an overall cost saving of £34 per patient was calculated for the STarT Back pathway. Notably, high risk participants who received stratified care (psychologically informed physiotherapy) fared better with a 2.5 point between group reduction in the RMDQ when compared to usual care ($p=0.004$). However, a limitation was that General Practitioners followed the risk stratification and matched treatment pathway for 393 (71%) of participants [455].

The implementation of the STarT Back approach has also been evaluated in a large cluster RCT, completed in six Primary Care clinics in the United

States of America (n=1701) [328]. Within this study, significant threats to implementation were identified including poor utilisation of the STarT Back tool (used <50% of the time) and clinicians did not always refer participants to the matched treatment pathways. Resultantly, no differences were observed in the primary outcome (RMDQ) between usual care and the STarT Back approach at six-month follow-up (mean between group difference RMDQ = 0.5, 95% CI -0.55 to 1.55, p=0.349) [328]. Despite the success of the STarT Back approach in England [233, 455] this study identifies the difficulties when implementing complex interventions for LBP into different healthcare systems, environments and countries.

An alternative approach to managing LBP within Primary Care is the Back Skills Training Programme (BeST). The BeST trial was large scale multi-centre RCT completed in 56 Primary Care practices in seven regions of the UK. Seven hundred and one participants with sub-acute or persistent LBP received an intervention based on best practice (one consultation lasting 15 minutes that included advice to remain active, to avoid rest and advice regarding pharmacological management for LBP that was supplemented with an educational booklet, the Back Book [275]). Enrolled participants were then randomised to receive no further intervention (control group) or one additional individual session (lasting 1.5 hours) plus up to six sessions (9 hours) of a group cognitive behavioural approach. The cognitive behavioural approach was based on graded activity, pacing, goal setting and targeted negative LBP beliefs and behaviours about activity avoidance and physical activity [267]. Training was provided to clinicians over 15 hours (two days). Treatment fidelity was monitored through audio recording of 35 treatment

sessions and competency assessed against pre-determined criteria for Cognitive Behavioural Therapy. The primary outcomes were disability and pain intensity measured using the RMDQ and Von Korff scale (0-100% scale with lower scores indicating less disability and pain) at three, six and 12-month follow-up. Group allocation was concealed, blinded assessors completed all of the outcome assessments, statisticians were also masked during data analysis and intention to treat analysis was completed for all randomised participants at 12 months.

At 12-month follow-up mean reductions in disability (RMDQ) were 1.1 points (95% CI 0.39 to 1.72) for the control group (advice and education) and 2.4 points (95% CI 1.89 to 2.84) for the group cognitive behavioural approach. The mean RMDQ between group difference was statistically significant (SMD=1.3 points, 95% CI 0.56 to 2.06, p=0.008, Cohen's *d* = 0.3) but this did not reach the pre-defined clinically important threshold set at 1.4 points [267]. Economic data was provided by 70% (n=490) of participants and showed that the mean cost of the cognitive behavioural intervention was £187.00 compared to £16.38 for the control group.

Assessment of treatment fidelity identified that 86% of the group sessions were delivered as intended. Although physiotherapists were the main providers of the BeST approach (81% in the trial), a significant strength is that a range of primary health care professionals can be trained to deliver the intervention to fidelity (nurses, occupational therapists and psychologists). Importantly this is achieved following just two days of training [267]. Furthermore, the group format means that higher numbers of patients can be

treated which is also an important consideration when scaling up interventions in healthcare systems such as the NHS where patients can face long waiting times for treatment. Other strengths of the BeST trial were the large sample size recruited with broad inclusion criteria, sufficient power to detect between group differences in the primary outcomes, the low loss to follow-up at 12 months (14.7%, n=103) and the pragmatic multi-centre design (participants were recruited from range of rural, urban, affluent and deprived areas). All of these factors enhance the external validity of the BeST trial.

The BeST intervention has also been evaluated in an implementation study in the UK [456]. The study was completed in two parts. In stage one physiotherapists, nurses, occupational therapists and psychologists were recruited from NHS Trusts and they received 10 hours of online BeST. In stage two, the outcomes of patients treated by the trained clinicians were evaluated at three and 12-month follow-up. Primary patient reported outcomes were pain intensity (NPRS) and disability (measured using the Patient Specific Functional Scale).

In total, 586 (44%) out of 1324 (56%) clinicians who enrolled, completed the training. Forty-nine clinicians (31.1%), who were all physiotherapists, went on to implement the BeST programme in 21 NHS Trusts. Only 50% of patient participants (n=364) provided follow-up data at 12-months. Mean change in pain (NPRS) was 0.84 (95% CI, -1.1 to -0.58, Cohen's *d*=0.34) and disability (Patient Specific Functional Scale, 0-10 scale where 0=no disability and 10=maximal disability) mean change of 1.55 points (95% CI, 1.25, 1.86,

Cohen's *d*=0.56) in favour of the BeST approach. Limitations of this study included the large number of clinicians who enrolled but did not complete the training, absence of fidelity assessments of the clinicians who implemented BeST and the large number of patients (50%) who did not complete follow-up assessments. Furthermore, unlike the IMPaCT study [455], economic evaluation was not performed and to date the BeST intervention has not been evaluated in other countries or contexts.

Physiotherapy informed by Acceptance and Commitment Therapy (PACT) is another psychologically informed approach that was compared to usual physiotherapy care in a multicentre RCT (completed in four secondary care NHS physiotherapy services) and recruited 248 people with persistent LBP. The intervention combines physiotherapy with Acceptance and Commitment Therapy (a cognitive behavioural approach) that focuses on psychological flexibility and improving function through pain acceptance, mindfulness and valued goals rather than explicitly seeking pain reduction [268]. The PACT training programme was manualised and a two-day course was provided with monthly supervision sessions from a clinical psychologist for the enrolled physiotherapists (n=8). Two independent expert assessors evaluated a random sample (20%) of audio recoded PACT treatment sessions in order to determined treatment fidelity. The RMDQ was the primary outcome collected at three and 12-months post randomisation. The Euro-Qol questionnaire (EQ-5D-5L) was used to determine the cost-effectiveness of PACT.

Two hundred and four participants (83%) provided follow-up data at three months and 181 (73%) at 12 months. Although PACT participants reported better outcomes than usual physiotherapy care at three months (RMDQ mean difference = 1.07, 95% CI -2.08 to -0.07, p=0.037, Cohen's *d*=0.2) this was not sustained at 12 months (RMDQ mean difference = -0.38, 95% CI -1.54 to 0.78, p=0.53, Cohen's *d*=0.1). No statistically or clinically significant between group differences were identified for a number of secondary clinical outcomes measuring pain intensity (NPRS), psychological (depression, anxiety) and physical function (Patient Specific Functional Scale). Although high levels of treatment fidelity were recorded (88% of PACT sessions were delivered as intended) the authors suggested that a diluted version of Acceptance and Commitment Therapy was delivered in this study which may explain the outcomes observed [268]. Indeed, only three individual sessions (approximately 2.5 hours) of PACT were provided to participants which is at odds to the 100 hours of psychological support recommended by NICE LBP guidelines when this study was registered [18]. The low number of sessions provided may also be a reason why PACT (£220.50) was £26.22 cheaper per participant than usual physiotherapy care (£193.88). To date no implementation studies of PACT have been completed.

In comparison to the two RCT's of CFT [292,294], it could be argued that these three studies of psychologically informed physiotherapy [233, 267, 268] were of higher quality as they included larger sample sizes, masking to outcome collection and all statisticians were blinded to group allocation during data analysis which was completed according intention to treat principles. Only one RCT of CFT followed the same principles [294].

Furthermore, an advantage of the three clinical trials of psychologically informed physiotherapy reported in this section is the lower dose of training required for clinicians to deliver the intervention than described in CFT publications (>100 hours) [72]. For example, in the BeST trial 15 hours of training was provided, training for the high-risk intervention in the STarT Back trial totalled 67 hours and the PACT training was delivered over 15 hours. A lower dose of training may mean that implementation of these interventions at scale would be less time and resource intensive than the training required for CFT.

In summary of this section, three high quality clinical and cost effectiveness RCT's of psychologically informed physiotherapy have recently been completed for patients with LBP within the UK NHS [233, 267, 268]. Implementation research has also been completed for the STarT Back and BeST approaches with encouraging results [455, 456]. In contrast, the two clinical trials of CFT published so far did not include economic evaluation and no implementation research has been completed. In the UK, this is an important consideration as such research is valuable in assisting the recommendations of clinical guidelines.

Given the enormous social and economic consequences and the lack of evidence of effectiveness for a broad range of interventions for persistent LBP [1], establishing the value of novel and promising interventions is a priority of future LBP research [192, 307]. At a time of financial difficulty for the NHS and society, such a study is important with NHS Physiotherapy providers tasked to deliver better clinical outcomes for people with long-term

conditions, such as persistent LBP, but with fewer resources [308, 309]. As a first step, and to meet this need, a feasibility RCT of CFT in comparison to usual physiotherapy care (UPC) in the UK NHS was proposed.

1.8 Summary

A state of the art review of the literature has highlighted the biopsychosocial complexity of LBP and challenges faced by clinicians, researchers and the healthcare system in managing this costly and recalcitrant condition. Burgeoning LBP disability levels have been attributed to inadequate management leading to urgent calls to evaluate novel therapies and treatments in well designed research studies [192, 307]. A number of models of care and methods of treating persistent LBP have been developed and numerous clinical guidelines have been written, but there only a few interventions that have been shown in rigorous clinical trials to be clinically and cost effective. CFT has been introduced as an integrated model of care that manages the multidimensional complexity of persistent LBP across the biopsychosocial spectrum, showing positive results in previous studies. However, to date the efficacy of CFT has not been established in the UK NHS.

1.9 Aim and Objectives of the Thesis

The studies in this PhD thesis aimed to explore the feasibility of carrying out a future full-scale RCT that would evaluate the clinical and cost effectiveness of CFT in comparison to UPC for people with persistent LBP within the UK NHS.

The objectives were to determine;

1) The feasibility of implementing CFT in the UK NHS.

2) The feasibility of recruitment to a clinical trial and the willingness of patient participants to be randomised to either intervention.

3) The retention rates of enrolled patient participants to the feasibility RCT and the factors contributing to this.

4) The feasibility of collecting patient reported outcome data within the feasibility RCT.

5) If the interventions can be delivered to fidelity during the feasibility RCT.

6) Adherence rates to the interventions during the feasibility RCT.

7) The type and frequency of adverse events.

8) The most suitable primary outcome measure and calculate the sample size for a definitive RCT.

9) The acceptability of the research processes and interventions to patient participants and physiotherapists.

10) To explore any indication of effectiveness of CFT.

CFT is considered to be a complex intervention due to the multiple interacting biopsychosocial dimensions underlying persistent LBP that requires careful evaluation and a broad clinical skillset to flexibly tailor care towards each person's unique presentation [72, 197]. Therefore, the Medical Research Council framework for developing and evaluating complex

interventions [197] was followed and three separate but overlapping studies, using a mixed method approach, were designed to meet the aims and objectives of this thesis.

The first study of this thesis explores the barriers and facilitators to implementing CFT within the NHS from the perspectives of physiotherapist and patient participants, using qualitative methods.

The second study was a pragmatic two-arm parallel feasibility RCT that compared CFT with UPC for 60 people with persistent LBP. Data on study processes, resources, management and patient reported outcome measures were collected at baseline, three and six-month follow-up, analysed and evaluated against pre-specified indicators in order to establish feasibility.

The third study was a qualitative process evaluation, embedded within the feasibility RCT that explored the acceptability of the research processes and the experiences of the interventions from the perspectives of patient participants and their treating physiotherapists.

Chapter Two – The barriers and facilitators to implementing Cognitive Functional Therapy in the NHS

In Chapter one, CFT was introduced as a novel intervention designed to target the biopsychosocial complexity of persistent LBP at an individual level. The chapter highlighted that CFT has not yet been evaluated within the NHS. However, before a definitive trial is completed it is necessary to identify the factors that might influence the implementation of CFT within the NHS. This chapter reports a qualitative study that aimed to determine the barriers and facilitators to CFT from the perspectives of NHS patients and physiotherapists in preparation for a future RCT.

2.1 Introduction

Clinical practice guidelines consistently recommend clinicians should adopt a biopsychosocial approach in the management of patients with persistent LBP [17, 27-29, 310]. To meet this requirement, psychologically informed physiotherapy has become an area of growing interest, evidenced by the development and evaluation of a number of interventions over the last two decades [148, 233, 265, 267, 268, 271-274, 311, 312]. Despite this progress, enhanced clinical outcomes for patients receiving psychologically informed interventions have not been observed [277, 313].

One explanation may be that while physiotherapists recognise the need to address the multidimensional nature of persistent LBP [314-316], they report feeling unprepared by their prior training [282, 317, 318] and lack the requisite knowledge, skills and confidence to effectively do so [314-316, 319].

In response, a variety of psychologically informed physiotherapy training programmes have been developed. These training programmes typically include theory based lectures, role play, patient demonstrations, the provision of supporting materials, such as intervention manuals, and in some cases post-training mentorship with a clinical tutor is provided [78, 280, 320-322]. However, after intensive training, challenges to implementing psychologically informed approaches remain. Personal and professional barriers have been described and include the lack of confidence to explore psychological factors, anxieties about working outside the traditional role of a physiotherapist and managing patient expectations of physiotherapy, such as the desire for 'hands-on' treatment [279, 281, 320, 323-325].

Psychologically informed physiotherapy training programmes also vary considerably in their delivery (e.g. online versus face to face training), content (e.g. cognitive behavioural, acceptance and exposure principles) and duration, with total training time reported to be between 10 and 150 hours [320, 326]. The variation in training time may explain the modest outcomes observed in recent clinical trials. To date, studies of psychologically informed physiotherapy have mainly focused on physiotherapists' perceptions of the training they have received and patient experiences of the interventions.

The perspectives of physiotherapists in Australia, Ireland and the UK following CFT training have been explored [281, 327] and collectively they described the acquisition of new skills, a broadened biopsychosocial scope of practice and increased confidence and competence following training as important facilitators to delivering CFT [281, 327]. These findings suggest

that CFT training overcomes the barriers reported by physiotherapists who have undertaken training for other psychologically informed interventions [279, 281, 320, 324, 325]. The biggest difference was in the confidence the CFT physiotherapists gained in their ability and skillset to manage persistent LBP across the biopsychosocial spectrum. However, insights into the barriers and facilitators of CFT within the context of the NHS have yet to be explored in depth. The existing studies have only reported time constraints as one factor [72, 281, 323] and few studies of psychologically informed physiotherapy have specifically considered contextual and organisational barriers and facilitators to implementation [280], despite MRC recommendations to identify them in the development and evaluation stages [197].

While CFT has shown positive effects for reducing pain and disability in clinical trials in Norway and Ireland [292-294], factors that may facilitate or inhibit clinical translation in different healthcare systems and geographical locations need further consideration. This is important as LBP interventions that have shown evidence of effectiveness in one healthcare system have not in others [328]. Variations in clinical pathways, funding arrangements and the demands of the healthcare system in different geographical locations may restrict the delivery of interventions to fidelity [263]. Plus, due to the demand and financial pressure on healthcare providers it is essential that only evidence based interventions are provided [308, 329]. Increased waiting lists for physiotherapy, rationing of initial appointment length and follow-up treatments have been observed within the NHS [330] which may threaten the

implementation of complex interventions for LBP [331], such as CFT, providing further justification for a robust evaluation of CFT.

To date, no study has evaluated the barriers and facilitators from the perspectives of patients with persistent LBP and physiotherapists to implementing CFT within the UK NHS. Consultation of stakeholders has been recommended when designing, evaluating and implementing complex interventions [197]. In the case of CFT, the patients experiencing the intervention and the clinicians delivering it are the key stakeholders to be considered in this process of feasibility testing. Understanding the key components of complex interventions and the context in which they are delivered is necessary to refine and improve their delivery in order to reduce threats to completing a future trial [332, 333].

Therefore, the aim of this study was to explore the barriers and facilitators of CFT within the UK NHS through the experiences of people with persistent LBP and physiotherapists. In doing so, this study aimed to inform the design of a future feasibility RCT that will compare CFT to UPC for people with persistent LBP in the NHS as well as provide insights for clinicians, educators and service providers about the sustainability of implementation of CFT more widely in clinical practice.

2.2 Method

2.2.1 Study design

One to one semi-structured interviews were used to collect data from physiotherapists who had previously attended a three-day CFT clinical workshop and people with persistent LBP who had received a CFT intervention at University Hospitals of Leicester NHS Trust (UHL) between 2014 and 2017. Data were reported in accordance with the COnsolidated criteria for REporting Qualitative research (COREQ) [334]. Ethical approval was granted by Greater Manchester South Research Ethics Committee, reference number 14/NW/0189 (Appendix B).

The study was situated within an interpretative description framework which was specifically developed to understand the clinical phenomenon of human health and the context in which healthcare occurs [335, 336]. Interpretive description permits *a priori* theoretical and clinical knowledge which is refined and challenged through the iterative research process [335].

2.2.2 Participants

Purposive sampling was used to identify and recruit potential patient participants who had completed a CFT intervention for persistent LBP, within the last six months, at UHL, using an electronic patient record system (Tiara 9™). To gather a range of patient experiences following CFT, the Oswestry Disability Index (ODI) was used to identify patient responders and non-responders to the intervention. A responder was defined as a person achieving more than a 30% positive change in the ODI at the end of

treatment, indicating that their persistent LBP had improved by an amount considered to be clinically important [337]. The Örebro Musculoskeletal Pain Screening Questionnaire (short form) (SF-ÖMPQ) was used to gather data about patient participants psychosocial risk profile [303].

The eligibility criteria were based on previous studies of psychologically informed physiotherapy for LBP [37, 38, 312, 373, 421] and/or determined through expert recommendations of the supervisory team. Patient participants were eligible for inclusion if they reported LBP lasting more than three months, had LBP that was not attributable to a pathological (e.g. cancer, infection, fracture, inflammatory spondyloarthritis or cauda equina syndrome) or specific cause (e.g. disc prolapse, spinal stenosis or >grade II spondylolisthesis with concordant lower limb radicular pain or radiculopathy), scored greater than 14% on the ODI [37, 38, 421], reported more than 3/10 on the numerical pain rating scale (NPRS) for the last week [37, 312, 373], were older than 18 years of age and were fluent in English language.

Physiotherapist participants were identified from a register of attendance at a CFT workshop. Delegates who voluntarily provided an email address within the course material for the purpose of future networking and research were contacted.

Physiotherapists met the criteria for inclusion if they had attended at least one three-day CFT clinical workshop in the UK, were employed as an NHS musculoskeletal physiotherapist with a minimum of 3 years post qualifying experience and were currently working in a musculoskeletal physiotherapy outpatient setting.

Twenty-four people (11 people with persistent LBP and 13 physiotherapists) meeting the inclusion criteria were sent a study invitation and participant information sheet via post or email. Eighteen people indicated they were willing to participate (8 people with LBP and 10 physiotherapists). Three people with LBP and one physiotherapist declined to participate. Two physiotherapists were non-contactable.

2.2.3 Data collection

Two male senior physiotherapists (Mr Christopher Newton (CN) and Mr Gurpreet Singh (GS)), with more than ten years of musculoskeletal physiotherapy practice and prior experience of qualitative research [158], conducted the one to one semi-structured qualitative interviews face to face. A mutually convenient date, time and venue was arranged for the interview to be completed in the Physiotherapy Department or the patients' own home.

The interviewers (CN and GS) had previously attended a CFT workshop to gain familiarity with the intervention but had no prior involvement in CFT training of the physiotherapists or treatment of the patient participants enrolled in the study. The background and aims of the study were explained and only then written consent was obtained.

The following demographic data was collected from patient participants; age (years), gender (male/female), duration of LBP (months) and employment status. For physiotherapists, the length of time employed as a musculoskeletal physiotherapist, post-graduate qualifications and number of previous CFT workshops attended was recorded.

Interview guides (Appendix C) for both groups of participants (patients and physiotherapists), were designed by CN with reference to previous LBP literature and *a priori* theories generated from previous qualitative research of CFT [327, 338]. Interviews were audio-recorded using a digital recording device.

2.2.4 Data analysis

Descriptive statistics including mean and range were used to describe the characteristics of the participants (patients and physiotherapists). Interview data were analysed using framework method [339]. Framework method shares the same analytical principles as thematic analysis but employs a systematic and visible approach to enhance methodological rigor [340]. Framework method offers a hybrid approach by combining deductive *a priori* concepts from existing literature with inductive themes arising from the experiences of the research participants to form new understanding [340, 341].

An iterative approach to data analysis was taken. Each interview was played back several times and listened to by the principal investigator (CN) in order to gain familiarity. Reflexive field notes were made after each interview by CN and GS (Appendix D). The interviews were transcribed verbatim (CN) which afforded the opportunity to listen, reflect and re-examine the interviews to gain deeper understanding [342]. Notes were made within the margins of each transcript where common or divergent opinions emerged. Next, a coding framework was developed for four transcripts (two physiotherapist participants and two CFT patient participants) by three members of the

research team independently (CN, Dr Booth (VB) and Dr O'Neill (SO)). CN coded four transcripts blind to VB and SO, who completed two blinded but different transcripts each (one physiotherapist participant and one CFT patient participant). Blind coding was completed to reduce any risk of researcher bias and to improve the trustworthiness of the findings [343].

Coding was based on emerging themes and the *a priori* theories. Each member of the team highlighted segments of text to reflect patterns, similarities, discrepancies and relationships that emerged through interpretation of the data. Comments were made in the right hand margin using the track changes feature of Microsoft Word to generate an initial set of codes [341] (Appendix E). Codes were compared across the four transcripts for coherence and pooled to form an analytic framework [340, 341] (Appendix F).

The agreed analytic framework was indexed against the remaining 14 transcripts by CN. A further meeting was used (CN, VB and SO) to gain consensus on the analytic framework and to identify themes that emerged. It was agreed that data saturation had occurred. Data was pooled and charted by case and code into the framework matrix using Microsoft Excel (Appendix G).

Themes were generated using the framework matrix by CN. Cross comparison of codes within and between participants (patients and physiotherapists) were matched against the aims and objectives of the research and a final set of themes generated. Each theme was discussed

with the research team at a final meeting to confirm representation of the data.

2.3 Results

2.3.1 Description of the sample

The sample consisted of 18 participants; eight patient participants who had previously completed a CFT intervention for persistent LBP and ten physiotherapist participants. There were five female patient participants, with a mean age of 48 years, mean duration of LBP of 169.5 months (14 years) and four were in paid employment at the time of the study (Table 1). Patient participants reported a mean pain rating of 5.3/10 (NPRS), disability of 33% (ODI) and psychosocial risk screening 53/100 (SF-ÖMPQ). There were five patient participants who were recorded as responders and three who were classified as non-responders to the intervention (Table 2).

Participant code	Age	Gender	LBP duration (months)	Employment status
Patient participant 1	44	F	120	Working
Patient participant 2	56	M	192	Working
Patient participant 3	33	F	7	Working
Patient participant 4	34	M	5	Sick listed
Patient participant 5	25	F	72	Working
Patient participant 6	76	F	552	Retired
Patient participant 7	66	M	168	Sick listed
Patient participant 8	50	F	240	Sick listed
Mean	48		169.5	

F, female; M, male; LBP, low back pain

Table 1: Demographic data of patient participants.

Participant code	Baseline			Post CFT			Responder (>30% change in ODI)
	SF-ÖMPQ	ODI	NPRS	SF-ÖMPQ	ODI	NPRS	(Yes/No)
Patient participant 1	39	26	5	20	2	0	Yes
Patient participant 2	47	20	3	27	0	2	Yes
Patient participant 3	49	16	4	26	12	0	No
Patient participant 4	42	20	4	37	2	0	Yes
Patient participant 5	78	56	8	34	24	6	Yes
Patient participant 6	33	26	3	31	6	0	Yes
Patient participant 7	65	52	7	61	46	7	No
Patient participant 8	71	48	8	57	38	5	No
Mean	53	33	5.3	36.6	16.3	2.5	

SF-ÖMPQ; Short-form Örebro Musculoskeletal Pain Screening Questionnaire, ODI; Oswestry Disability Index, NPRS; Numerical Pain Rating Scale, CFT; Cognitive Functional Therapy

Table 2: Patient participants psychosocial risk profile, disability and pain before and after Cognitive Functional Therapy.

The physiotherapist participants reported a mean of 13.6 years experience of musculoskeletal physiotherapy and had attended between 1 and 5 CFT workshops previously. None had post-graduate qualifications further than a post-graduate diploma (Table 3). Interviews (for both cohorts) ranged from 33 to 80 minutes in duration.

Participant	Years Qualified	Qualifications	Number of CFT workshops attended
Physio 1	16	PG Dip	1
Physio 2	18	-	5
Physio 3	11	PG Dip	1
Physio 4	9	-	1
Physio 5	13	-	1
Physio 6	33	-	1
Physio 7	5	-	1
Physio 8	14	PG Dip	4
Physio 9	7	PG Dip	2
Physio 10	10	-	2
Mean	13.6		1.9

CFT; Cognitive Functional Therapy, Physio; Physiotherapist; PG DIP; Post-graduate diploma in musculoskeletal physiotherapy.

Table 3: Physiotherapist participants' demographic details.

Charting of the indexed interviews into the framework matrix generated four main themes and 15 subthemes.

The themes were;

1) Training experiences of the physiotherapists.

2) Physiotherapists experiences of implementing Cognitive Functional Therapy in the NHS.

3) Patient participants experiences of Cognitive Functional Therapy.

4) The healthcare system.

Each theme is presented, with quotes. The themes and subthemes are summarised in Table 4.

Themes	Subthemes
1. Training experiences of the physiotherapists.	Prior knowledge and skills; Unfulfilling clinical experiences.
	‘In search of something different’.
	‘This makes sense but I’m only putting my toe in the water’.
2. Physiotherapists experiences of implementing Cognitive Functional Therapy in the NHS.	A new understanding of low back pain through experiential learning.
	Communication skills.
	Scope of practice: ‘I’m so used to examining things physically’.
	Clinical effectiveness.
	‘This is harder than I thought’.
	‘I’ve still got my ‘L’ plates on, support me’.
3. Patient participants’ experiences of Cognitive Functional Therapy.	New understanding of low back pain through ‘concrete’ experiences.
	Communication and therapeutic alliance: ‘It wasn’t like anything I’ve had before’.
	Self-management and effectiveness; ‘A new lease of life’.
4. The healthcare system.	‘You’ve got to give more time to the people’.
	Perceptions of CFT: ‘Too good to be true?’
	‘Stuck in the system’.

Table 4: Identified themes and subthemes.

2.3.2 Theme 1: Training experiences of the physiotherapists

2.3.2.1 'Prior knowledge and skills; unfulfilling clinical experiences'

All of the physiotherapist participants reported that prior to attending a CFT workshop that their training, both at undergraduate and post graduate levels, did not provide them with the necessary skills to be able to effectively address the biopsychosocial complexity of LBP with their patients. The physiotherapist participants reported that their knowledge and ability to clinically reason was confined within a biomedical framework. Five physiotherapist participants reported that psychological and social factors were acknowledged during their prior training but they lacked communication skills to confidently address them in clinical practice.

> *'I actually found it very hard. I'd been taught it. I'd been told that there were these things such as yellow flags. That's how they were taught at uni…we needed to go through the ABCDEF…and yes I asked the questions, and then what to do with the answers, well I didn't really know'.* (Physio 9).

Treatment was described as being generic, not tailored to the individual and outcomes were described as being *'hit and miss'* (Physio 3). This caused the physiotherapist participants to question their clinical abilities, in some cases patients were viewed as *'heart sink patients*' (Physio 4) or '*stigmatised'* (Physio 3) when they did not respond to treatment. This resulted in the physiotherapist participants reporting low satisfaction in their work and they felt that patients would remain in the healthcare system.

'In hindsight I feel that I did the best I could with the knowledge that I had at that point in time. The result was sometimes frustrating, but I had no other tools at my disposal'. (Physio 6).

2.3.2.2. 'In search of something different'

Due to the inadequacies of their prior training and unfulfilling clinical experiences, the physiotherapist participants described searching for alternative ways to manage LBP, which led them to attend a CFT workshop.

'I was searching for something that made sense, so I was very open to it'. (Physio 7).

Seven of the physiotherapist participants identified the positive attitudes of their colleagues towards CFT as a reason for enrolling in the workshop. Observing colleagues assess and treat patients and the positive clinical effects that followed created further interest in CFT training.

'You could see the enthusiasm and also the change in their patients, seeing them treat patients in a completely different way from the biomechanical way, really changed the way I looked at my own practice and then I obviously went on the CFT course'. (Physio 4).

2.3.2.3 'This makes sense but I'm only putting my toe in the water'

All of the physiotherapist participants described the content of the CFT workshop (lectures covering the biopsychosocial nature of LBP, CFT intervention and live patient demonstrations) and the supporting materials (pre-course reading, workbook and clinical reasoning framework) as important components of the training. One physiotherapist participant

reported feeling '*overwhelmed'* (Physio 9) by the volume of information covered on the first day but that the workbook and accompanying research papers helped to consolidate learning after the workshop. All physiotherapist participants reported increased knowledge regarding the biopsychosocial nature of LBP after attending the workshop.

Observing live patient assessments and treatment by a CFT tutor was described as a *'vitally important'* (Physio 6) component of the training that '*bridged the gap'* (Physio 3) between theory and clinical practice. Doubts about the validity of live patient assessments, seen by one physiotherapist participant as, *'a bit Derren Brown'* (Physio 5), were lessened by the provision of evidenced based lectures underpinning LBP and the CFT intervention.

> *'I think part of what I liked about the course was the fact that the early part of it is entrenched in all of the evidence base and presenting a story. And then of course he backs it up with patient demonstrations, doesn't he?'* (Physio 10).

Following live patient demonstrations the physiotherapist participants described using the CFT clinical reasoning framework, alongside the CFT tutor, to evaluate the biopsychosocial profile of each clinical presentation and to consolidate their learning during the workshop.

> *'You've got to see it to recognise all the layers, for communication, interaction, manual therapy skills, handling, explanation, seeing the complexity of it, the patient changing symptoms, moving forwards*

and then going on to a big plan and the patient being engaged in the process'. (Physio 3).

However, during this process four of the physiotherapist participants described difficultly in understanding the different movement patterns described within the CFT framework.

'I was getting really het up like really trying to work out exactly, is she an active extender or a passive extender? One minute I thought she was sort of sitting in one classification, the next I wasn't so sure and I couldn't quite get to grips with it'. (Physio 7).

Unanimously, the physiotherapist participants suggested that attending one workshop only provided an introduction to CFT. One physiotherapist participant felt that they were only *'putting their toe in the water'* (Physio 2). Four physiotherapist participants suggested that '*top-up training',* within three to six months following completion of the workshop, would allow them to reflect on their learning and also to consolidate knowledge and skills through clinical experience.

Others felt the workshop was '*too big'* and *'intimidating'* to ask questions (Physio 1) and would have preferred a seminar style approach to learning (Physio 5).

2.3.3 Theme 2: Physiotherapists experiences of implementing Cognitive Functional Therapy in the NHS

2.3.3.1 A new understanding of low back pain through experiential learning

Immediately following the workshop the physiotherapist participants recognised that CFT woul*d 'take a big skillset to deliver well'* (Physio 9) and that time and practice was required to hone the skills learnt during the workshop.

> *'It is an evolution in practice rather than being very technical based in terms of, 'there's a technique go and do it'.* (Physio 6).

A new understanding (gained during the workshop) of the interplay between cognitive, emotional, physical and lifestyle factors and their influence on an individuals' movement behaviours and pain experience was reinforced through experiential learning.

> *'I think from what I've realised in practice is that the psychosocial elements of pain play a massive part in the physical presentation of the patient'.* (Physio 4).

The physiotherapist participants reported employing new methods of physical assessment that allowed them to evaluate behavioural responses to pain and movement such as protective muscle guarding and hypervigilance.

> *'You're looking at different things. You're not just looking that it's their full movement there; you're looking at how they move, looking*

at what they're doing as they move, looking at how they feel, what they think is going on'. (Physio 7).

2.3.3.2 Communication skills

The physiotherapist participants described a number of new communication skills that were acquired through the workshop and developed through experiential learning. Self-reported changes to physiotherapist participants' communication included adopting a flexible interview style that incorporated open ended questions and altered language to reduce the threat and fear of pain and movement. Two physiotherapist participants described *'slowing their communication down'* (Physio 1) to be able to actively listen.

> *'Yeah I mean like trying to like take a step back thinking about like your subjective history, you know, making the questions much more open, reflecting and really actively listening'*. (Physio 8).

Enhanced communication skills were seen as essential to developing positive therapeutic relationships with patients.

2.3.3.3 Scope of practice: 'I'm so used to examining things physically'

Despite a broader biopsychosocial understanding of LBP and enhanced communication skills not all of the physiotherapist participants felt comfortable addressing psychological factors with their patients. Some described feeling *'awkward'* (Physio 4) and working outside of the traditional role of a physiotherapist as *'daunting'* (Physio 8).

> *'Frightening in terms of, I'm so used to examining things physically - muscle length, muscle strength, joint movement, joint stability - to*

examine the mind a little bit, that was very different and something I'm still not totally comfortable with'. (Physio 6*).*

In contrast, others felt that dealing with psychological factors should be within a physiotherapists' scope of practice.

'In order to do your job sufficiently you've got to address the other side of things to get the full result. You're losing so much information by not sort of going down that road'. (Physio 7).

Despite the difference in opinions of the physiotherapists, focusing on psychological factors was important to patient participants, absent from previous healthcare encounters.

'I suppose in my view when you're assisting someone with a physical ailment, you have to be thinking of not just their physical pain, but how they feel mentally. I didn't feel that that was there actually with any of the other professionals I saw apart from 'Steve' (CFT trained physiotherapist)'. (Patient participant 1)*.*

2.3.3.4 Clinical effectiveness

In practice, the physiotherapist participants described being more clinically effective, identifying improvements in their patients *'straight away'* (Physio 2). One physiotherapist participant said they no longer had *'that sinking feeling'* (Physio 4) when treating patients and they were more satisfied in their work.

'It's absolutely inspired me…the fun I get from work and the interest I have in work, it's just been revolutionary…it's so obviously effective that it makes coming to work worthwhile'. (Physio 9)*.*

Self-management was recognised as a key target of CFT by the physiotherapists which was in contrast to their previous experiences.

> *'This approach does empower the patient, puts them in control, whereas the other approaches are more passive and they (patients) can become reliant on that'*. (Physio 4).

2.3.3.5 'This is harder than I thought'

However, it wasn't all plain sailing. All of the physiotherapist participants described CFT as being much harder to implement than they first thought. Even though the physiotherapist participants described feeling equipped following CFT training to communicate and manage the complexity of persistent LBP more effectively, they still reported difficulties in changing the beliefs of patients.

> *'So there have still been cases where I've had patients come in and they are so stuck in their structural belief, and I still find that they are the most challenging ones'.* (Physio 4).

One physiotherapist participant described losing confidence in the approach when patients did not respond.

> *'The first couple of patients I tried didn't do that well, and I thought that was a reflection on me and my approach. So I lost a little bit of confidence at that point'.* (Physio 6).

'L*etting go'* (Physio 5) of biomedical beliefs and old methods of practice following exposure to the principles of CFT was '*difficult'* and *'conflicting'* for some (Physio 4).

'We're so schooled to do things in a certain pattern starting with our body chart and our history of presenting condition and our past medical history and everything else. And again that's quite hard to leave aside. You do feel yourself getting dragged back into a medical model sometimes'. (Physio 10).

2.3.3.6 'I've still got my 'L' plates on, support me'

All of the physiotherapist participants recognised the need for ongoing peer support and mentorship following attendance at a CFT workshop to prevent them from *'slipping back'* (Physio 10) into traditional methods of physiotherapy practice.

'I think you need teaching and peer support to be able to go through those patients and understand it. I think you have to keep at it, you can't just do the course and then that's it, you know'. (Physio 7).

Some of the physiotherapist participants described setting up peer support groups and training sessions to support implementation of CFT into their own clinical environments (Physios 4, 6, 7, 8 and 9).

2.3.4 Theme 3: Patient participants' experiences of Cognitive Functional Therapy

2.3.4.1 New understanding of low back pain through 'concrete' experiences

Gaining control of pain through relaxed body postures and movements was viewed as a '*concrete experience'* by patient participants that facilitated a biopsychosocial understanding of LBP and engagement with CFT.

'Well I suppose if you can feel a difference you start to think, 'right OK, there's something tangible there', it really made sense to me'. (Patient participant 1).

Experimentation with different postures and ways of moving while performing functional tasks were an important step in understanding their physical responses to thoughts and emotions, such as fear.

'I knew I was kind of sitting weirdly, but I didn't realise I was tensing up all the time, even when I was walking my core muscles were always tensed up. I was doing that because I was so scared that I was going to hurt my back more'. (Patient participant 3).

These 'concrete' experiences appeared to be important in changing patient participants LBP beliefs about causation and future management.

'What's an MRI going to tell you? It's going to tell you that you've got problems with your back and it's going to reinforce the message with you that you've got a problem with your back. Actually what I was doing by keeping myself stiff was actually reinforcing the message that my back was a problem and if I wanted to get better I actually needed to move differently and to think differently'. (Patient participant 2).

2.3.4.2 Communication and therapeutic alliance: 'It wasn't like anything I've had before'

Prior to receiving CFT, the experiences of patient participants reflected that of the physiotherapist participants. Unfulfilling healthcare interactions and

ineffective treatments were described. In some cases they felt stigmatised when they did not respond to treatments.

> *'By the end of that treatment (physiotherapy) he told me that he thought my pain was psychosomatic. Which was quite upsetting to hear because then you start to question your own sanity about, you know, is it really a physical pain or is it something I'm just making up?'* (Patient participant 1).

However, following CFT all patient participants reported developing positive therapeutic relationships with their physiotherapists. Being listened to was an important first step and for some patient participants this was a novel experience.

> *'It's sort of odd because I'd been to all these NHS professionals before and I wouldn't say that any of them was a bad person or a bad physiotherapist because that's not the case, but actually I feel a great sense of comradeship with 'Paul' because he's the one that taught me to think differently about this'.* (Patient participant 2).

Displays of empathy by the physiotherapists gave patient participants a sense of being cared for, which built confidence and trust in the working relationship.

> *'He was different as in he spent time to listen to you and he instilled confidence in me. He made me feel like I was able to change things myself'.* (Patient participant 5).

One physiotherapist participants' experience reflected this.

'He was quite a young guy that wanted a lot of answers, I think I might have panicked a bit prior to that. But actually I felt really confident with him and I think he fed off that'. (Physio 7).

2.3.4.3 Self-management and effectiveness: 'A new lease of life'

Following CFT, most patient participants described being in control and able to manage their condition independently.

'For me it was a very different experience because it wasn't something being done to me by somebody else; it was something being given to me that I could help myself with and I could control and I could then use myself'. (Patient participant 1).

Patient participants reported gaining confidence to re-engage in previously avoided activities such as work, sports and hobbies and there was a sense of returning back to normality.

'Well, I dug a pond. I would never have attempted that before. I feel like somebody that actually can just do stuff normally. I feel this is a new lease of life'. (Patient participant 2).

However, this was not the case for all of the patient participants. Two patient participants retained biomedical beliefs about the cause of their LBP, such as, '*discs compressing nerves'* (Patient participants 5 and 6) and another remained uncertain about the cause of their LBP and future management.

'Nobody has ever sent me for an x-ray or a scan to see what it actually is, if you don't know what it is, you can't treat me'. (Patient participant 7).

2.3.5 Theme 4: The healthcare system

2.3.5.1 'You've got to give more time with the people'

While the patient participants' and the physiotherapist participants' perceptions and experiences of CFT were generally positive, there was an overriding feeling that the UK healthcare system was a significant barrier to the implementation of CFT. Short physiotherapy appointment duration was seen by all of the physiotherapist participants as a barrier to effective communication, to delivering CFT as intended and completing documentation. Time and pressure to deliver to NHS targets was also recognised by one patient participant as a barrier to communication.

> *'I think it's quite an interesting problem with the NHS...I don't think enough time is spent listening to patients because of the pressure to deliver to targets and to deliver to time slots'.* (Patient participant 2).

One physiotherapist participant suggested that available time dictated whether a standard physiotherapy assessment or an assessment based on the multidimensional components of CFT was completed (Physio 1). Others stated that parts of the CFT intervention may be *'bypassed'* (Physio 7) due to lack of time.

> *'I remember then about a week later thinking, 'oh this is harder than I thought it was going to be', because around you you've still got the time pressures and then getting the full CFT package of proper questioning and interviewing done. So something often was getting very compromised'.* (Physio 5).

Access to follow-up appointments was also viewed as problematic from both the physiotherapists and patient participants' perspectives.

> *'To break off after 45 minutes and then you don't see them for another 3 weeks 'cos they can't get into your diary, err… the momentum has definitely been lost.* (Physio 1).

Providing more time and earlier follow-up appointment availability was one solution offered by the physiotherapist participants and one patient participant.

> *'Giving half an hour every 2 to 3 weeks is not enough. I know you're queued up with people this that and the other needing it but they've got to look at some way of giving you more time with the people'.* (Patient participant 7).

2.3.5.2 Perceptions of Cognitive Functional Therapy: 'Too good to be true?'

Negative perceptions of physiotherapy colleagues were also seen as a barrier to engagement with CFT. The physiotherapist participants felt that CFT was viewed by their colleagues as, *'a fad'* and that the profession did not need *'another classification system for LBP'* (Physio 8).

> *'There's definitely a group in the Trust that are negative towards it. Very dismissive of it and saying we do it anyway in our practice… People are quite resistant to change, there's more to do with trying to get the therapists on board with it'.* (Physio 8).

Other colleagues were sceptical and that clinical outcomes were *'too good to be true'*.

> *'ah yes, but it seems a little bit 'five breads two fish situation'.*
> (Physio 3).

One physiotherapist participant thought that CFT was not appropriate for all LBP patients, only for *'people who have been around the mill'* and the *'hopeless cases that nobody else wants'* (Physio 1).

2.3.5.3 'Stuck in the system'

Prior to CFT, seven out the eight patient participants described being stuck in the healthcare system, receiving conflicting diagnoses and a plethora of treatments by multiple health care providers which offered little benefit.

> *'I had so many different treatments, different people saying different things to me, it's like, you know, nobody knows, I don't know and everybody else is sort of, not guessing, but don't really know exactly what's going on'.* (Patient participant 8).

There was a feeling that access to CFT was at the wrong point in the care pathway. Four patient participants suggested earlier access to CFT may have prevented them from becoming *'stuck in the system'* (Patient participant 3).

> 'I am pretty sure that if I hadn't come and had that treatment I would still be in the system of a bad back. I'm pretty sure I would be'.
> (Patient participant 1).

The barriers and facilitators to CFT are summarised in Table 5.

Barriers	Facilitators
Physiotherapists prior to CFT training • Biomedical focused knowledge and skills • Structured clinical assessment • Ineffective clinical reasoning • Ineffective communication • Biomedical treatment • Negative clinical outcomes • Psychological impact – low confidence and work satisfaction	CFT training – Physiotherapist participants • CFT workshop content • Biopsychosocial understanding of LBP • Observation of live patient assessments • Broadened skillset (communication, functional behavioural approach) • Therapeutic alliance • Clinical effectiveness • Satisfaction and increased confidence
Post CFT training • Physiotherapist confidence • Lack of peer support and mentorship • Concerns over scope of practice	CFT experience – Patient participants • Biopsychosocial understanding of LBP • Body awareness and pain control • Effective communication • Therapeutic alliance • Self-management • Effectiveness
Healthcare system • Lack of time • Appointment length and availability • Negative perceptions of CFT	

CFT; Cognitive Functional Therapy; LBP; low back pain

Table 5. Summary of the identified barriers and facilitators to Cognitive Functional Therapy in the NHS.

2.4 Discussion

2.4.1 Summary of the main findings

This study aimed to understand the barriers and facilitators to integrating CFT within the NHS. The key findings were that UK NHS physiotherapists can be trained to deliver CFT. They valued the training, considered the intervention to be effective and generally felt confident to deliver CFT successfully to patients in UK NHS physiotherapy departments but with certain caveats. Patient participants welcomed CFT as they felt it was beneficial and enabled them to self-manage their LBP and they could recognise the difference between CFT and usual care. The barriers, mainly related to the healthcare system, included short appointment times and poor availability of follow-up appointments. The physiotherapist participants reported a broadened biopsychosocial understanding of LBP and learnt new skills that they could apply to their clinical practice following the workshop. Live patient demonstrations by a CFT tutor were considered fundamental to linking theory with practice. However, ongoing peer support and mentorship following training from an experienced CFT practitioner was deemed necessary for the physiotherapists to sustain changes to their clinical practice.

The physiotherapist participants also described concerns over extending their scope of practice in addressing psychological factors and negative perceptions of colleagues as barriers to engagement with CFT.

2.4.2 Comparison with other studies

Prior to CFT training, the physiotherapist participants felt that their undergraduate and post-graduate training did not equip them with adequate knowledge and skills to address psychosocial barriers to recovery, communicate effectively, develop positive therapeutic relationships with patients and to clinically reason wider than a biomedical framework. This finding is consistent with previous qualitative research that highlights that while physiotherapists acknowledge the importance of psychosocial factors in LBP, their prior training does not provide the requisite skills to address them in clinical practice [251, 282, 315-317, 344].

These findings were also reflected in the experiences of the patient participants in this study. Prior to CFT, patient participants reported unfulfilling clinical experiences, ineffective treatments for LBP and in some cases experienced stigmatisation when they failed to respond to treatment. This finding further underscores the inadequacies of current interventions to effectively manage LBP across the biopsychosocial spectrum [11, 345] and highlights the pressing need to evaluate emerging biopsychosocial models of care in future research [347].

After attending a CFT workshop, the physiotherapists reported a broader understanding of the multidimensional nature of LBP and enhanced communication skills that enabled them to explore the relevance of cognitive, emotional, physical and lifestyle factors with LBP patients. This is in keeping with previous research that identified physiotherapists beliefs become more biopsychosocially orientated following CFT workshops and structured

training [78, 281]. The acquisition of new skills in communication, such as active listening and conducting a flexible patient interview, using reflective and open ended questions, and addressing functional movement behaviours were also described by physiotherapist participants. These factors have previously been identified as important components of CFT but were only demonstrated after intensive training in CFT [327].

The physiotherapists in the study by Synnott et al. (2016) had attended, on average, more than nine CFT workshops and had received a minimum of 4 supervision sessions in implementation, guided by a CFT tutor [327]. The findings of the present study suggest that less intensive training over a three-day workshop may be adequate to facilitate clinical translation into the NHS. However, the physiotherapists enrolled in this study were not formally assessed for competence so this inference must be interpreted with caution.

Similar to Cowell et al. (2018) [281], the results also suggest that the live patient demonstrations completed by a CFT tutor were a key factor in the clinical translation of new knowledge and skills. Live patient demonstrations appear to be unique to CFT training, not reported in other psychologically informed physiotherapy training intervention protocols [148], and should be a key component of future CFT training programmes.

However, following training some physiotherapists still lacked confidence to provide CFT because of the complexity of the intervention, the challenge of relinquishing old biomedical practices and reported concerns of working outside the traditional role boundaries of a physiotherapist. This finding is consistent with several other studies of psychologically informed

physiotherapy interventions for musculoskeletal pain conditions [280, 281, 320]. Recommendations to resolve these barriers have included the provision of individualised mentorship that is facilitated by an experienced clinician and regular assessment of treatment fidelity [279, 348].

Indeed, mentorship in physiotherapy has been associated with improved clinical skills, ability to manage complexity and physiotherapist confidence [349]. The need for ongoing peer support and mentorship, recognised by the physiotherapist participants in this study, has also been highlighted as an important mechanism to sustain implementation beyond training in other research of psychologically informed approaches to LBP [280, 350]. Therefore, to address the barriers of low confidence and concerns regarding scope of practice, future CFT training programmes should provide post training mentorship with an experienced CFT practitioner.

Successful training and delivery of CFT by physiotherapist participants appeared to be reflected in the experiences of people with LBP. A new multidimensional understanding of LBP, improved body awareness and pain control led to re-engagement with valued life activities and effective self-care. These findings match the themes identified by Bunzli et al. (2016) in their of study 14 people with persistent LBP following CFT [338]. Importantly, the experiences described by the patient participants in this study correspond to the fundamental components of the CFT intervention [72], offering validity to the approach and targets for future training of physiotherapists in CFT prior to the feasibility RCT.

Following CFT, patient participants reported positive therapeutic relationships that were developed through effective communication. A recent systematic review highlighted that communication skills (e.g. listening, empathy and therapist confidence), physiotherapist practical skills, individualised care and environmental factors (e.g. time and access to appointments) all influence patient-therapist alliance [304]. Therapeutic alliance between patients and physiotherapists improves satisfaction and clinical outcomes for people with LBP [54, 351, 352]. These factors appeared to be barriers to effective care for both patient and physiotherapist participants that were overcome following CFT. This novel finding suggests that CFT training equips physiotherapists with the necessary skills to overcome some of the challenges imposed by the healthcare system to effectively manage persistent LBP.

However, short appointment duration, lack of availability of follow-up appointments were significant organisational barriers to implementing CFT in the NHS from both the patient and physiotherapist participants' perspectives. Time is a barrier commonly reported in qualitative studies evaluating psychologically informed physiotherapy [281, 324, 325, 353] that is difficult to overcome in public healthcare systems such as the NHS. Organisational factors such as these have been cited as barriers to forming effective patient-therapist relationships [304] and embedding psychosocial interventions within clinical practice [317, 331]. A novel and unexpected finding was the ambivalence of colleagues towards CFT. Only one previous study has identified negative attitudes towards psychologically informed interventions for persistent musculoskeletal pain [353].

2.4.3 Strengths and limitations

This is the first study that has explored the barriers and facilitators of CFT within the context of the UK NHS through the experiences of both patient and physiotherapist participants. NHS band six and seven musculoskeletal physiotherapists were recruited as they represent the workforce who typically treat LBP patients within the NHS. The interview schedule was based on a literature review, the data was checked by two researchers and the findings were reviewed by four researchers.

A number of methodological limitations and sources of bias must be recognised. Participants were enrolled in this study following attendance at a CFT workshop (physiotherapist participants) or CFT intervention (patient participants) therefore they were all already interested in CFT and maybe were biased towards the intervention. However, the researchers were not part of the clinical team or training team and explained to all participants that they could provide honest answers, without it affecting their employment or treatment.

The fact that some physiotherapist participants reported not feeling confident to deliver CFT after the training provides some evidence that the participants were giving honest accounts. Another limitation was that only one interview with each participant was completed. The author recognises that a series of interviews conducted before, during and following CFT exposure would have strengthened the results. Recall bias of patient and physiotherapist participants and social desirability may have influenced the results obtained. The inclusion of responders and non-responders to the CFT intervention was

used in an attempt to balance these effects [343]. Member checking was not used in this study. On the basis of these findings a number of recommendations are made for future training.

2.5 Recommendations:

1) CFT training can be delivered over a three-day clinical workshop and must include live patient demonstrations by a CFT tutor.
2) To address the barriers of low confidence and concerns regarding scope of practice, post training mentorship with a CFT practitioner should be provided where possible.
3) Following the workshop, up to six months of experiential learning should be completed by the physiotherapist and supported by the clinical mentor.
4) Intervention fidelity should be measured regularly during the experiential learning period.
5) Where practical and as recommended by CFT tutors [72], the initial CFT consultation time should be one hour and follow-up appointments for 30 minutes.
6) Appointments should be maintained, where possible, with the same physiotherapist for continuity of care.
7) Implementation research should be completed to evaluate whether the recommendations above can be sustained in the NHS.

2.6 Conclusion

This is the first study to establish the barriers and facilitators to CFT as an intervention for persistent LBP within the NHS through the experiences of

both patient and physiotherapist participants. The findings show that CFT training is acceptable to NHS employed physiotherapists and once trained most physiotherapists are happy to deliver the intervention in a routine NHS setting. Following a CFT workshop, physiotherapists described increased knowledge of persistent LBP and that the live patient demonstrations bridged the gap between theory and practice. However, one workshop was not enough for the physiotherapist participants to confidently deliver CFT in practice. Peer support and mentorship was recognised as essential to successful implementation of CFT in the NHS setting, while concerns regarding the role boundaries of physiotherapist participants was a significant barrier.

Patient participants were happy to be treated by CFT trained physiotherapists and they reported benefits after the intervention. Following CFT, patient participants described a 'different' experience of healthcare. A new understanding of LBP, improved body awareness and pain control led to effective self-care. Successful communication, improved therapeutic alliance and self-efficacy to engage in valued activities underpinned this transition. However, not all patient participants experienced this change. Some patient participants retained biomedical beliefs about causation. Short duration of appointment time and availability of follow-up appointments was a consistent healthcare system barrier to CFT described by both patient and physiotherapist participants. In the correct environment and with adequate resources, CFT could be evaluated in a clinical trial.

Chapter Three – Feasibility Randomised Controlled Trial

In Chapter two, the barriers and facilitators to delivering CFT in the NHS were identified using qualitative methods of inquiry. Building on these findings, this chapter reports and discusses the rationale, methods and outcomes of an RCT that assessed the feasibility of completing a future large scale clinical and cost effectiveness trial of CFT in the NHS. Data concerning the study processes, resources, management and patient reported outcome measures (PROM's) were collected at baseline, three and six-month follow-up, analysed and evaluated against pre-specified indicators in order to establish feasibility. The study protocol has been accepted for publication [354].

3.1 Introduction

To date, the clinical and cost effectiveness of CFT has not previously been evaluated in an RCT in the UK NHS setting or compared to UPC. This is important as evidence suggests complex LBP interventions might not be as effective in different countries and settings [233, 328].

CFT is a complex intervention, targeting a multifactorial health problem, LBP, and therefore indicates evaluation in a pragmatic randomised controlled trial (RCT) [197]. RCT's are widely accepted as the most rigorous method for evaluating the effectiveness of healthcare interventions [355]. Random allocation of study participants to an intervention or a suitably defined control group within an RCT minimises the effects of selection bias [99]. In this way, observed participant characteristics (e.g. age, gender, LBP duration, health comorbidities) and other unknown confounding variables (e.g. natural history,

regression to the mean, placebo effect) are balanced between the groups, thereby attributing any differences in the outcome to the intervention under scrutiny [356-358]. Concealing group allocation to researchers during recruitment and randomisation limits the effects of selection bias further [359]. Blinding participants and clinicians to group allocation is notoriously difficult in physiotherapy RCT's, but alongside blinded outcome assessments, can limit the effects of performance and detection bias respectively [99] which can over-estimate the magnitude of treatment effects by 17% [360]. Well conducted RCT's are placed at the top level of the hierarchy of evidence, due to their low risk of bias [355, 356, 358], and are used to support clinical practice guidelines designed for clinicians, patients, commissioners and policymakers [361].

RCT's do, however, have several limitations. While pragmatic RCT's are more likely to reflect delivery of healthcare in the real world, where interventions are often tailored to meet individual needs, they are difficult to standardise and replicate than more tightly controlled studies [362]. In addition, an RCT can only tell us about the average effect of an intervention at the population level and do not explain how an intervention may or may not work for an individual [363]. Alternative methods, such as case control studies, single case experimental designs and N of 1 studies may be more suited to meet these needs and have been used to explore the mechanisms of effect and refine the delivery of CFT in preparation for future RCT's [287-290, 306].

Furthermore, RCTs are expensive, time consuming and labour intensive to design, set up and conduct [364]. Therefore, funding bodies will require assurances that a large scale trial represents a secure return on investment [197]. According to the Physiotherapy Evidence Database (PEDro) only 38% of 35,000 indexed physiotherapy RCT's were rated as being of moderate to high quality in 2020 meaning that more than 21,000 trials were inadequately designed, executed or underpowered to detect between group differences [355].

These limitations make determining feasibility a critical precursor to completing a future definitive RCT of CFT and justify the mixed methods approach used within this PhD as recommended by the Medical Research Council framework for developing and evaluating complex interventions [197]. Importantly, a feasibility study asks 'if this study can be done' by evaluating the parameters required to design, enact and complete such a study [365, 366]. Therefore, before the clinical and cost-effectiveness of CFT can be measured in a suitably powered RCT in the UK NHS, it is essential to determine if such a trial can be completed [365].

The primary aim of this study was to establish the feasibility of completing a future definitive fully powered RCT that will evaluate the clinical and cost effectiveness of CFT in comparison to UPC for people with persistent LBP within the NHS. A pragmatic two-arm parallel feasibility RCT comparing CFT with UPC for people with persistent LBP was completed.

Considering the concerns reported by physiotherapists regarding their ability to deliver psychologically informed physiotherapy safely and effectively [279,

282, 314-319], the willingness of some patients to engage in such programmes [338, 367] and the challenges inherent in completing RCTs, a nested qualitative process evaluation will also be conducted. The aim of which is to evaluate the acceptability of the interventions and research processes to patient participants with persistent LBP and their treating physiotherapists. This study is reported separately in Chapter four.

The objectives of this feasibility RCT were to determine:

1. The number of eligible patient participants and actual recruitment rate.
2. Retention rates of enrolled patient participants.
3. Adherence rates to the interventions through attendance to scheduled physiotherapy appointments and a self-completed exercise diary.
4. The acceptability, return and completion rates of the PROM's.
5. The type and frequency of adverse events.
6. Treatment fidelity.
7. The most suitable primary outcome measure and calculate the sample size for a definitive RCT.
8. The acceptability of the intervention and the research process as experienced by patient participants with persistent LBP and their treating physiotherapists.
9. To explore any indication of effectiveness of CFT.

3.2 Methods

3.2.1 Study design and setting

A pragmatic two-arm parallel single centre assessor blinded feasibility RCT completed in a UK NHS hospital-based physiotherapy service.

The study followed the guidelines of The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [368] (Appendix H). The trial protocol was registered with the international Standard Randomised Controlled Trial Network on 10th May 2019 (ISRCTN12965286, https://doi.org/10.1186/ISRCTN12965286) and has been accepted for publication [354] (Appendix H). Reporting followed the Consolidated Standards of Reporting of Trials (CONSORT) for pilot and feasibility studies guidelines [369]. Ethical approval for this study was granted, by East Midlands Nottingham 1 Research Ethics Committee on the 1st February 2019, reference number 18/EM/0415 and was sponsored by UHL (Appendix I).

3.2.2 Patient and public involvement

Three patient advisers, who previously attended the host physiotherapy service with persistent LBP, informed the development of this research protocol. They assessed the suitability and practicality of PROM's, which have informed the choice for the proposed study.

3.2.3 Recruitment and consent

3.2.3.1 Patient participant recruitment and consent

Patient participants were recruited from a physiotherapy outpatient service waiting list at UHL between April 2019 and October 2019. Referrals were screened against the eligibility criteria and confirmed during a telephone triage consultation by the clinical team. Those patients meeting the eligibility criteria were provided brief information about the study and those expressing interest were asked if they consented to being contacted by the research team. For those consenting, the research team provided further information about the study over the telephone, established a postal or email address to forward the study covering letter and participant information sheet and arranged a study screening appointment. This was more than one week after the telephone call to ensure the participant had sufficient time to consider the study information and requirements of taking part.

Potential participants were given the option of taking part in the study or receiving physiotherapy care as usual. The participant information sheet stated that two active interventions were being studied, that it was unknown if one intervention was superior to the other but that both were used in routine physiotherapy services (Appendix J). After consideration of the study information, people who attended the screening appointment and indicated that they were willing to participate were asked to provide written informed consent.

3.2.3.2 Eligibility criteria

The study eligibility criteria are reported in Table 6 below.

Eligibility criteria for patient participants with low back pain

Inclusion criteria	Exclusion criteria
• Aged 18 or older at the time of recruitment. • Reported low back pain lasting longer than the previous three months. • Reported limitations in daily activities and function due to their low back pain. • Reported an average pain intensity score ≥3/10 over the preceding week measured by the Numeric Pain Rating Scale (NPRS) [370]. • Were independently mobile to be capable of participating in a rehabilitation programme, as assessed by the clinician.	• Reported leg pain as the primary problem. • Had received at least one interventional procedure for their low back pain in the preceding three months (e.g. facet joint denervation or caudal epidural injection). • Were less than six months after lumbar spine, lower limb or abdominal surgery. • Were pregnant or less than six months postpartum. • Had a medically diagnosed psychiatric disorder that prevented engagement in a self-management intervention • Had a diagnosed rheumatological disease (e.g. rheumatoid arthritis, ankylosing spondylitis or psoriatic arthritis). • Had a progressive neurological condition (e.g. multiple sclerosis, Parkinson's disease). • Had a diagnosed unstable cardiac condition that prevented participation in exercise. • Had a suspected serious cause for their low back pain that required urgent medical intervention (e.g. malignancy, spinal fracture, spinal infection or cauda equina syndrome), as assessed by the clinical team.

Table 6: Eligibility criteria for patient participants with low back pain.

3.2.3.3 Sample size

As the primary aim of this study was to determine the feasibility of conducting a full-scale pragmatic RCT of CFT versus UPC, a formal sample size calculation was not performed [371]. Sample sizes of 40 to 60 participants have been recommended for feasibility studies [365]. For this study, an upper limit of 60 participants was chosen to ensure adequate data was available, including the standard deviation (SD), confidence intervals (CI) and effect sizes, to enable a sample size calculation for a future definitive RCT to be performed, while allowing for attrition.

3.2.3.4 Physiotherapist participant recruitment and consent

Ten senior physiotherapists working at UHL (NHS band 6 and band 7 clinicians) were invited to participate as treating clinicians in the study. Attempts were made to match age, level of experience and job grade of physiotherapists between the two study arms (n=5 CFT and n=5 UPC).

The physiotherapist participants were approached about the study at a clinical meeting, provided with verbal and written information about the study, a participant information sheet and consent form (Appendix J). Those who were willing to participate provided written informed consent.

3.2.4 Baseline assessments

Patient participants provided the following demographic data: age, gender, duration of LBP (years) and employment (working, unemployed, retired) status and completed baseline outcome measures prior to randomisation to reduce allocation bias. A full description of the measures are provided later in this chapter.

3.2.5 Randomisation and blinding

Consenting patient participants were randomly allocated to receive CFT or UPC. The randomisation order was generated using online software (www.randomization.com; accessed on 21st March 2019) and included blocks of variable size (block sizes 2, 4, 6, and 8). Group allocation was concealed via sequentially numbered opaque envelopes, issued to the patient participants following baseline measurements and consent. The researcher (CN) who completed baseline and follow-up assessments with patient participants was blinded to treatment allocation. It was not possible to blind the physiotherapists who delivered the interventions to group allocation. The intervention started within two weeks of randomisation.

3.2.6 Interventions

The intervention in both arms was delivered by the recruited physiotherapist participants. Five physiotherapists were trained to deliver the CFT intervention and to control for contamination between the study arms, five different physiotherapists provided physiotherapy care as usual.

The CFT (described in Chapter one, and summarised later in this chapter) and UPC (described in this chapter) interventions are reported in line with the Template for Intervention Description and Replication (TIDieR) checklist [372].

3.2.6.1 CFT overview and delivery

Patients participants allocated to the CFT group received the intervention from physiotherapists who had undertaken the CFT training. They were assessed in line with the CFT multidimensional clinical reasoning framework

(Appendix A) and provided with a management plan that was individually tailored based on the findings of the interview and clinical examination [72].

CFT was provided face to face over three months with the number of sessions (up to 10 individual sessions) determined by the participant's confidence to effectively self-manage their condition, through shared decision making with the physiotherapist [287-290, 292, 294]. The initial appointment was for one hour and subsequent appointments for 30 minutes.

3.2.6.2 CFT physiotherapist participant training

CFT training followed a standardised programme based on the core components of the multidimensional clinical reasoning framework and intervention [72]. Firstly, each physiotherapist attended a three-day workshop (22.5 hours), delivered by a CFT tutor (Professor Peter O'Sullivan (PO)), where evidence regarding the multidimensional nature of LBP and an introduction to the multidimensional clinical reasoning framework underpinning the intervention was provided. Demonstration of the key components of the intervention was exemplified during live observation of four patients with persistent LBP, during a masterclass by a CFT tutor (PO).

Secondly, access to web-based resources (www.pain-ed.com) and two electronic training manuals with embedded videos and operationalised definitions of the multidimensional clinical reasoning framework underpinning CFT and its management were provided to support six months of experiential learning following the workshop. During this time each physiotherapist completed two video-recorded new patient assessments to evaluate their progress in delivering CFT. Each video was reviewed by all five CFT

physiotherapists against a predefined competency checklist, utilised in a large trial of CFT in Australia (Appendix K) [373], during monthly meetings. Group discussion were used to facilitate learning and self-reflection and individual feedback was provided by a clinical mentor (CN) to summarise key points. Peer support included further clinical observations and case discussions between the physiotherapists and mentor during this period.

The training programme culminated with an assessment of competency, in CFT. Each physiotherapist was observed by CN and PO while assessing and treating one new patient with persistent LBP within the physiotherapy department at UHL. The same pre-defined checklist was used to determine physiotherapist competency [373].

3.2.6.3 CFT intervention

The initial patient assessment lasted for up to one hour and included the completion of the interview, psychosocial risk screening using the SF-ÖMPQ [303] and a functional examination covering the broad biopsychosocial components of the CFT multidimensional clinical reasoning framework (Appendix A) [72].

Interview: The participant was invited to ‘tell their story’. This allowed the participant to communicate how they made sense of their LBP to the physiotherapist. The CFT physiotherapists were taught to use a sensitive, non-judgemental interviewing style to facilitate disclosure and to allow the consideration of the following CFT multidimensional clinical reasoning framework components [72].

1) Pain history and contextual factors (e.g. physical, cognitive, emotional, social, lifestyle and general health) at the time of onset to differentiate traumatic and non-traumatic causes.
2) Mechanical and non-mechanical pain characteristics to determine stimulus-response relationships to postures, movements, activities and rest.
3) Cognitive (e.g. beliefs regarding cause, future consequences, pain controllability) and emotional (e.g. fear, low mood, anxiety) responses to pain.
4) Painful, feared and/or valued functional activities including unhelpful behavioural responses to pain such as movement and activity avoidance.
5) Social (e.g. work and home relationships, socioeconomic factors) and cultural obstacles to adopting positive lifestyle and health behaviours.
6) Lifestyle factors, such as physical activity levels, sleep hygiene, stress levels, diet and smoking.
7) Personally relevant short and long-term goals.
8) Past medical history (general health, vitality and co-morbidities and their relationship to pain).

Functional behavioural assessment: The specific functional tasks (spinal movements, postures and activities), identified during the interview, as provocative, feared and/or avoided are evaluated for signs of safety behaviours (e.g. movement avoidance, abdominal bracing, breath holding, propping with hands) and sympathetic arousal (e.g. rapid apical breathing

and body tension). Palpation is used to identify levels of tissue sensitivity, trunk muscle activation and respiratory patterns. A series of behavioural experiments, guided from these observations, are used to evaluate an individuals' response to reducing sympathetic arousal and diminishing safety behaviours. This is achieved through training relaxed diaphragmatic breathing, body relaxation, awareness of movement (i.e. mirror feedback) during graded exposure to identified feared, avoided and provocative postures, movements and functional activities. Discrepancies between expected and actual pain responses are highlighted to reinforce that engagement in relaxed confident movement is safe. This provides an opportunity for education about the resilience of the spine, that pain does not equal harm and a clear direction for management aligned to each participant's preferences and valued goals.

Management plan: Based on the interview, SF-ÖMPQ and functional behavioural assessment, an individualised self-management plan was provided for each participant to enable them to:

1) Make sense of their pain from a biopsychosocial perspective using their own narrative and personal experience.
2) Achieve pain control, where possible, through graduated exposure to feared, avoided and/or painful movements and valued activities.
3) Adopt healthy lifestyle behaviours (e.g. increase physical activity levels, improved sleep, healthy diet and stress management) [72].

To facilitate behaviour change and develop therapeutic alliance, motivational interviewing and empathetic communication underpinned this process [305].

A video-recorded, self-management program (using the patient participants own smartphone device) was provided to each patient participant which included functional exercises and lifestyle modifications, where they were indicated [72]. The dosage and intensity of the exercise programme was tailored towards an individuals' valued activities, goals, preferences and levels of physical conditioning. The exercises were monitored and progressed at each appointment. A personalised handout that outlined an individual's vicious cycle of pain and web-based educational resources (www.pain-ed.com) that address common misconceptions about LBP, physical activity, sleep hygiene and the role of imaging were provided. In between sessions patient participants were advised to carry on with their self-management programme and record the frequency and duration of their exercise programme in the provided exercise diary (Appendix L). At the end of the intervention patient participants were provided with a pain exacerbation plan to guide self-management in the event of an increase in LBP.

3.2.6.4 UPC overview and delivery

The UPC intervention was provided by physiotherapists who had received training and information to enable to them to deliver treatments reflective of current practice, clinical guidelines and decision-making within the UK NHS [27, 264]. UPC was delivered face-to-face, with the initial appointment lasting up to one hour and follow-up appointments 30 minutes. There was no limit on the number of treatments provided during the three-month intervention period.

3.2.6.5 UPC physiotherapist participant training

To reinforce existing knowledge and skills each physiotherapist attended a three-hour teaching session which comprised of lectures and practical demonstrations covering the contemporary physiotherapy assessment and management of LBP, aligned to UK clinical guidelines (self-management advice, manual therapy and exercise as a package of care) [27]. The teaching session was delivered by a member of the research team (SO), who was an Associate Professor of Musculoskeletal Physiotherapy and had not received any formal training in CFT. No formal assessment of competency was undertaken as it was assumed as qualified physiotherapists that they would be competent to deliver care as usual.

3.2.6.6 UPC intervention

Interview: The UPC physiotherapists used a structured interview format to collect information from the patient participant involving the history of the presenting complaint, past medical, medication and social history. Regarding the presenting complaint, information was collected about the onset and duration of symptoms, pain location and quality, behaviour of pain related to physical aggravating and easing factors, diurnal variation of symptoms and psychosocial factors identified using the SF-ÖMPQ [303].

Physical examination: The examination included observation of spinal posture, active and passive physiological spinal motion testing (including repeated movements, combined movements and over-pressure), tests of muscle length and strength, as well as neurological and special tests, where indicated.

Treatment: UPC physiotherapists provided education (e.g. imaging findings, pain neurophysiology), manual therapy and exercise (stretching, strengthening, and cardiovascular) as well as optional referral to a LBP rehabilitation class. The LBP class was timetabled weekly for one-hour and included general group exercise and education about the spine and pain physiology, which could be attended for a maximum of six sessions. Patient participants were provided written information on how to perform the prescribed exercises and were asked to record the frequency and duration of their completed exercises in the adherence diary (Appendix L). Treatment was ended through shared decision making between the patient participant and physiotherapist. Patient participants were encouraged to continue with their home exercise programme as part of self-management.

3.2.7 Feasibility outcomes

3.2.7.1 Eligibility, recruitment and retention rates

To determine the eligibility rate, the number of 'potentially eligible' referrals was recorded and divided by the number of actual referrals meeting the inclusion criteria after face-to-face screening and expressed as a percentage. To calculate the recruitment rate each month, the number of people meeting the eligibility criteria was recorded and divided by the number of people providing consent to participate. Based on a sample size of 60 and a 12-month recruitment period, the minimum feasible recruitment rate was set at five participants per month.

Study retention was determined by the number of participants who withdrew or who did not return their postal questionnaires at three and six-month

follow-up and was expressed as a percentage of the total sample. Patient participants could withdraw from treatment but could still complete and return their PROM's.

3.2.7.2 Adherence rates

Intervention adherence in both groups was measured through attendance to scheduled intervention appointments and a paper-based diary where patient participants recorded the frequency they completed their prescribed home exercise programme (Appendix L).

3.2.7.3 Feasibility of Patient Reported Outcome Measures

Feasibility of the PROM's (described in section 3.2.9) were evaluated by calculating the total time to complete the questionnaire booklet at baseline and the number of missing items (expressed as a percentage) for each measure at baseline, three and six-month follow-up.

3.2.7.4 Adverse events

Adverse events (AE's) and serious adverse events (SAE's) were documented by type and frequency and were reported to the sponsor (UHL) in line with standard operating procedures and the appropriate action taken.

3.2.7.5 Assessment of competency and treatment fidelity

Competency in CFT after the training programme was reported in section 3.2.6.2. Treatment fidelity was monitored and evaluated during the intervention period in three ways, consistent with the behavioural change fidelity framework guidelines for treatment delivery recommended by Borelli et al (2005) [374]. Firstly, by auditing the physiotherapists' clinical notes, for all patient participants, against a predefined fidelity checklist (separate

checklist for each intervention, see Appendix K and M). Secondly, by videoing a random sample of approximately 20% of the physiotherapists delivering CFT and UPC and checking against the same predefined fidelity checklists. These videos were analysed by CN (CFT) and SO (UPC) to ensure competency was maintained and that the interventions were delivered in accordance with the study protocol. Fidelity of treatment delivery was confirmed if >80% of the intervention components were delivered as intended, for both the clinical notes and video recordings [64]. Thirdly, during the process evaluation (Chapter four) where patient participants and physiotherapists reported their experiences qualitatively.

3.2.8 Feasibility criteria

The feasibility criteria were defined *a priori* and thresholds set to confirm progression to a definitive RCT or if modifications to the protocol were required before such a trial could be completed (Table 7). The criteria and threshold were based on similar musculoskeletal feasibility RCT's [375, 376].

Criteria	Description	Feasibility Threshold
Eligibility	Number of screened referrals meeting eligibility criteria	>50%
Recruitment	Recruitment rate (participants per month)	>5
	Consent rate	>50%
Retention	Study retention at 3 & 6-month follow-up.	≥ 70%
Intervention adherence	Attendance to allocated appointments	>80%
	Completion and return of exercise adherence diary	>70%
Patient reported outcome measures	Mean PROM completion time	<20 minutes
	Number of missing PROM items	<20%
Participant safety	Reported adverse events	<5%
Intervention training	Competence to deliver CFT after training	100%
Treatment fidelity	Interventions were delivered as intended	≥ 80%

Table 7: Feasibility criteria and thresholds to proceed to a definitive clinical trial.

3.2.9 Patient Reported Outcome Measures

Patient participants were asked to complete a number of self-reported PROMs at baseline (face to face) and via postal follow-up at three and six months post randomisation.

The chosen PROM's have been used widely in previous LBP RCT's, based on their strong psychometric profile and capacity to capture clinically important change, as recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials [276]. The PROM's were also selected according to the multiple theoretical constructs on which

CFT is based (Chapter one, section 1.4) and the changes observed across multiple biopsychosocial domains in previous CFT studies [287-290, 292, 294]. The PROM's were also deemed to involve an acceptable burden by the PPI group (see section 3.2.2). The PROM completion schedule is reported in the SPIRIT figure (Appendix H) and a description for each PROM, including psychometric properties, is provided in Table 8 below.

Domain	Name	Description
Disability	1. Roland Morris Disability Questionnaire	The Roland Morris Disability Questionnaire (RMDQ) was used to measure disability. The RMDQ consists of 24 statements related to disability and activities of daily living. Respondents tick each statement that applies to them at the time of completion, giving a score between 0 (no disability) and 24 (maximum disability). It has been reported to take less than ten minutes to complete [377]. The RMDQ has shown to be valid, reliable, with good internal consistency (Cronbach's α 0.84-0.93) and is responsive to change in persistent LBP populations [378]. A reduction by 30% has been identified as the minimum clinically important difference (MCID) in one UK LBP population at six-month follow-up [379] and agreed internationally [337].
Pain intensity	2. Numeric Pain Rating Scale	The Numeric Pain Rating Scale (NPRS) asks a person to rate their pain intensity, on average over the previous week, on a scale of 0-10 (11 possible responses), where 0 implies 'no pain at all' and 10 is equal to 'pain as bad as you can imagine'. The NPRS takes less than one minute to complete, is valid and reliable for use in persistent LBP with a two point change accepted as the MCID [337, 370].
Fear avoidance	3. Fear Avoidance Beliefs Questionnaire	The Fear Avoidance Beliefs Questionnaire (FABQ) was chosen as it was specifically developed to assess an individuals' LBP beliefs regarding physical activity and work [380]. The FABQ consists of two subscales with five physical activity and 11 work-related questions. Responses to each question range from 'completely disagree' to 'completely agree', on a seven-point Likert scale, giving a total score of 96 with higher scores representing higher fear-avoidance beliefs [75]. The FABQ has good-test-retest reliability and correlation to measures of LBP disability [380]. The minimal detectable change has been reported as 5.4 for the physical activity and 6.8 for the work subscales respectively [381].

Prognosis	4. Subgroups for Targeted Treatment screening tool	To gather prognostic information about future outcome, the Subgroups for Targeted Treatment (STarT Back) screening tool was used. The STarT Back tool is a short self-completed questionnaire that contains nine items related to physical function, disability and psychosocial obstacles to recovery [240]. The STarT Back tool stratifies people with LBP into low, medium and high risk of persistent pain and disability. The STarT back tool has strong psychometric properties, is sensitive to change and has been used in secondary care settings [382-384].
Self-efficacy	5. Pain Self-Efficacy Questionnaire	The Pain Self-Efficacy Questionnaire (PSEQ) has been developed for use in persistent LBP populations and contains 10 items that evaluates an individuals' confidence to complete a range of activities in the presence of pain. Scores range from 0-60, with lower scores indicating less confidence to perform activities whilst in pain. The PSEQ has good psychometric properties and has shown to be responsive to change in people with persistent LBP with the minimal important change reported to be 5.5 points [385].
Pain catastrophising	6. Pain Catastrophising Scale	Pain catastrophising was assessed using the Pain Catastrophising Scale (PCS). Thirteen statements related to pain catastrophising (rumination, magnification and helplessness) are provided which ask individuals to reflect on previous painful experiences, such as, 'I worry all the time about whether the pain will end' with five possible responses to each statement (0 – 'not at all' to 4 'all the time'). The PCS is reported to take less than five minutes to complete, gives at total score of 52, with higher scores indicating more catastrophising thoughts [386]. The PCS is valid and reliable for use in LBP populations [387] and a 9 point change is considered to be the minimal detectable change [381]
Depression, anxiety and stress	7. Depression, anxiety and stress scale (short form)	Three emotional states of depression, anxiety and stress were measured using the 21 item Depression, Anxiety and Stress Scale (DASS-21). Questions for each subscale (depression, anxiety and stress) range from 0-4 with higher scores indicating more distress. The DASS-21 is valid and reliable for use in a UK non-clinical population [388] and in people with

		persistent LBP in two previous studies of CFT [287] but there is no data on the instruments responsiveness.
General health	8. Euro-Qol	General health status was captured using the Euro-Qol (EQ-5D-5L) [389]. Respondents check one of five possible statements that best describes their general health over five domains; mobility, self-care, usual activities, pain/discomfort and anxiety/depression [389]. Respondents were also asked to rate their general health on a scale of 0 to 100, where 100 represents the best health possible (EQ VAS). The EQ-5D-5L data is converted into an index summary for use in economic evaluation.
Participant satisfaction	9. Participant satisfaction	Participant satisfaction with their allocated intervention was measured at three and six-month follow up using a simple satisfaction questionnaire containing four responses to the question "how satisfied were you with the care you received for your low back pain? 'Very unsatisfied', 'unsatisfied', 'satisfied' and 'very satisfied' [292].
Participant global rating of change	10. Global Rating of Change Scale	Magnitude of deterioration or improvement post intervention was measured using the 11 point Global Rating of Change scale (GRC), with responses ranging from -5 (very much worse) to +5 (very much better) [390]. The 11 point GRC has good clinimetric properties including excellent test-retest reliability (intraclass correlation coefficient = 0.90) and responsiveness with the MCID reported as 2 points [391]
Therapeutic alliance	11. Working Alliance Theory of Change Inventory	Therapeutic alliance was measured using the 16 item Working Alliance Theory of Change Inventory (WATOCI). With scores ranging from 16 to 112, the WATOCI has shown to be responsive in persistent LBP populations, with higher scores representing stronger therapeutic alliance between patients and physiotherapists [352]. The WATOCI was collected at three-month follow-up only.

Table 8: Patient reported outcome measures.

3.2.10 Data analysis

Descriptive statistics summarised participant demographic data using mean (SD), median (interquartile range) and proportions (percentage) as appropriate. Feasibility outcomes are described descriptively using numbers or percentages as appropriate for each feasibility criteria. Continuous data were assessed for skewness by visual inspection of plots and Shapiro-Wilk and Kolmogorov-Smirnov tests of normality. Analysis of the continuous outcome variables (Table 8) were undertaken using linear mixed models, with treatment group, time and treatment by time included as fixed effects and within-person correlation modelled as a random effect using an unstructured covariance structure. Intention-to-treat analyses used all available data at baseline, three and six months. Data were analysed using SPSS Statistics Version 27.0 (Armonk, NY: IBM Corp.). Mean between group differences, including calculation of 95% CI's and p-values were reported at three and six months. A positive mean difference indicated better outcome values for CFT. Effect sizes (Cohen's *d*) were calculated as the mean difference relative to the pooled standard deviation of baseline scores. An effect size of 0.2 was considered to be small, 0.5 a moderate effect and 0.8 to be a large effect [392].

The analysed data was used to assist selection of the PROM's to be included in a future study, to complete sample size calculations for a future definitive RCT and to provide an signal of the estimated treatment effects.

3.2.11 Monitoring

The dignity, rights, safety and well-being of patient participants and staff were monitored and safeguarded in accordance with the sponsor's standard

operating procedures. The health of patient participants was monitored through attendance to physiotherapy and the study was overseen by the PhD supervisory team at University of Nottingham.

3.3 Results

3.3.1 Patient participants

3.3.1.1 Eligibility and recruitment

Referrals were received from General Practitioners, hospital Consultants, physiotherapists working in first point of contact roles and via patient self-referral. During the recruitment period, 135 referrals were screened by the clinical team with 79 (59%) potentially eligible patient participants identified and invited to a study screening appointment. A further ten people failed to meet the inclusion criteria during this appointment. Reasons included being under investigation for inflammatory spine disease (n=2), diagnosed spinal stenosis (n=2), a recent cancer diagnosis (n=1), awaiting interventional procedures for LBP (n=1), low levels of functional disability (n=1), LBP of less than three months duration (n=1), not being independently mobile (n=1) and less than six months post-partum (n=1). Of the 135 screened referrals, 69 (51%) satisfied the criteria for inclusion, meeting the a priori defined threshold (>50%) for eligibility. Nine people who fulfilled the eligibility criteria declined to participate for the following reasons; eight people wanted to attend routine physiotherapy and one person declined pending the results of an MRI scan.

Out of the 69 people meeting the eligibility criteria after face to face screening, sixty (87%) provided consent and were recruited to the study between 17th April 2019 and 10th October 2019 with 30 randomly allocated to each group. Figure 3 reports the flow of patient participants through the study. The predefined feasibility criteria for consent (>50%) was achieved.

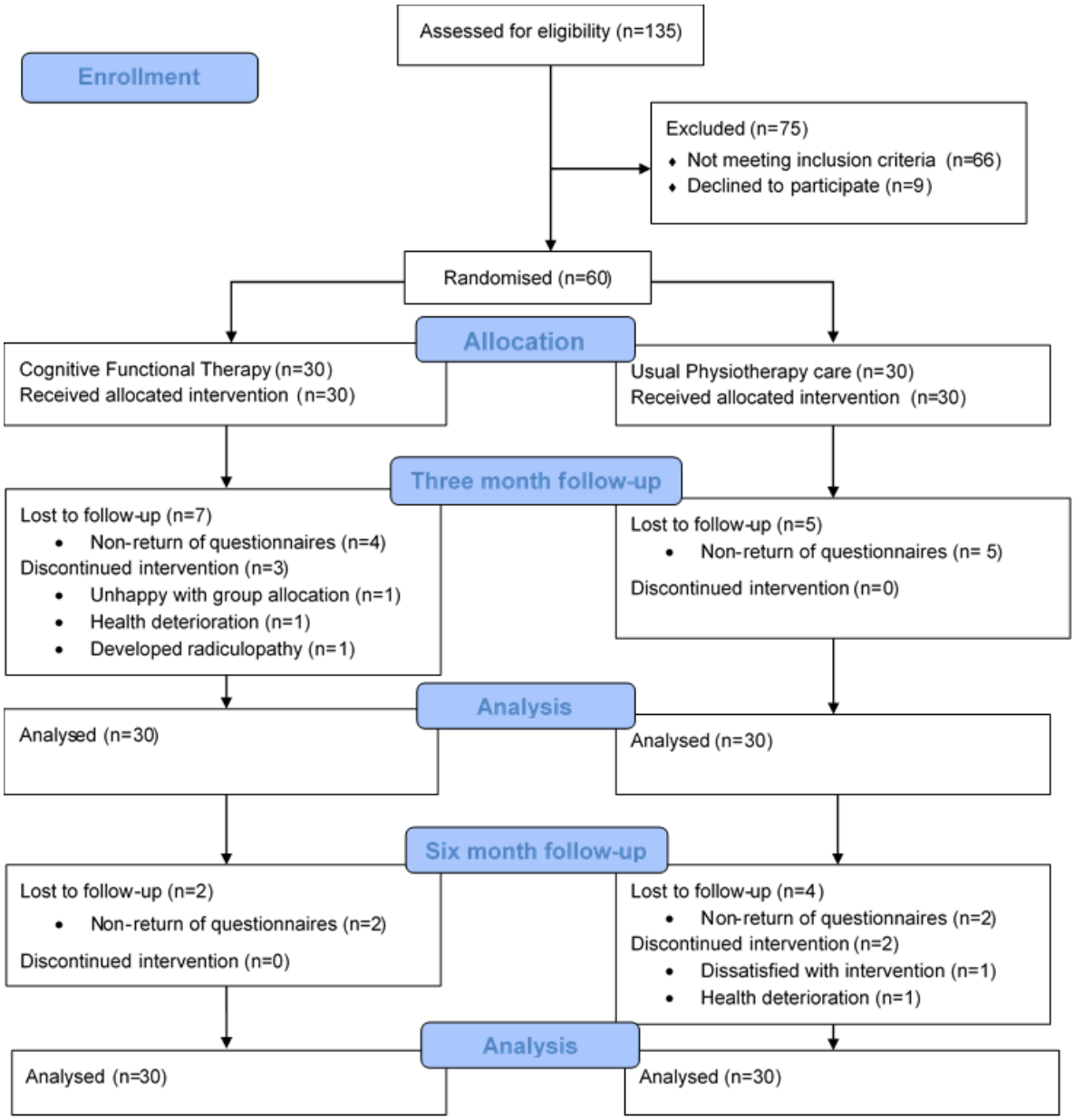

Figure 3: Consort flow diagram.

The recruitment rate was 10 patient participants per month which surpassed the minimum feasible (five per month) recruitment rate set *a priori* (Figure 4), meaning that the study was closed to recruitment six months earlier than anticipated.

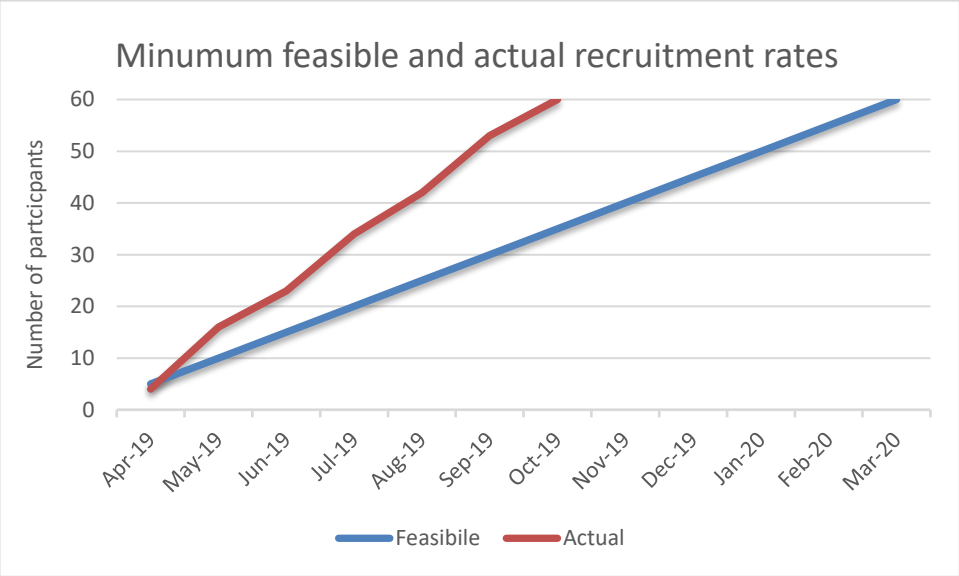

Figure 4: Minimum feasible and actual recruitment rates.

3.3.1.2 Randomisation and blinding

The randomisation procedures were delivered according to the study protocol [354] (Appendix H) with 30 patient participants allocated to CFT and 30 to UPC respectively. The randomisation order was concealed to the researcher during recruitment.

3.3.1.3 Baseline characteristics

The groups were well matched for age, LBP duration, employment status, pain intensity, pain self-efficacy, pain catastrophising, and self-reported general health at baseline (Table 9). In the CFT group, there was a larger proportion of patient participants identified as high risk of persistent pain and disability (50% versus 33.3%), as measured by the STarT back tool [240],

more female than male participants (17 versus 11) and higher baseline levels of disability, fear avoidance beliefs, depression, anxiety and stress than in the UPC group. The baseline characteristics of the study patient participants are reported by group allocation in Table 9.

Characteristic	CFT	N	UPC	N
Age (years)	45 (14.2)	30	46.7 (12.8)	30
Gender		30		30
Male (%)	43.3	13	63.3	19
Female (%)	56.6	17	36.6	11
Duration of LBP (years)*	5.5 (9.8)	30	5.5 (8.3)	30
Work status		30		30
Working (%)	73.3	22	73.3	22
Not working due to LBP (%)	16.7	5	20.0	6
Retired (%)	10.0	3	6.7	2
Disability (RMDQ)	13 (4.7)	30	11.5 (4.7)	30
Pain intensity last week (NPRS)	6.5 (1.8)	30	7.0 (1.6)	30
Fear avoidance beliefs (FABQ)	44.8 (20.7)	30	38.6 (18.0)	28
Physical activity subscale	16.6 (6.2)	30	14.7 (5.9)	30
Work subscale	19.0 (10.9)	30	17.3 (10.9)	28
Prognostic risk (STarT Back)*	5.7 (3.3)	30	5.3 (3.3)	30
High (%)	50.0	15	33.3	10
Medium (%)	36.7	11	43.3	13
Low (%)	13.3	4	23.3	7
PSEQ	29.5 (13.7)	30	31.8 (13.1)	30
PCS	26.5 (13.5)	30	26.3 (12.8)	30
DASS 21*	41.0 (32.6)	30	31.4 (31.4)	30
Depression subscale*	11.0 (20.0)	30	6.0 (11.5)	30
Anxiety subscale*	5.0 (16.5)	30	3.0 (10.5)	30
Stress subscale*	18.0 (19.0)	30	10.0 (16.0)	30
Health status (EQ-5D-5L)*	0.47 (0.36)	30	0.49 (0.28)	30
Self-rated health (EQ VAS) (%)	59.7 (24.1)	30	62.8 (14.8)	30

CFT; Cognitive Functional Therapy, UPC; Usual Physiotherapy Care, RMDQ; Roland Morris Disability Questionnaire, NPRS; Numeric Pain Rating Scale, FABQ; Fear Avoidance Beliefs Questionnaire, STarT Back; Sub-groups for Targeted Treatment Screening Tool, PSEQ; Pain Self-Efficacy Questionnaire, PCS; Pain Catastrophising Scale, DASS 21; Depression, Anxiety and Stress Scale, EQ-5D-5L; EuroQol five dimensions, EQ VAS; EuroQol Visual Analogue Scale.
* denotes median (interquartile range).

Table 9: Baseline characteristics of patient participants by group. Values are mean (SD) unless otherwise stated.

3.3.1.4 Retention rates

The feasibility criteria of >70% participant retention at three and six-month follow-up was met. Of the sixty randomised patient participants, three withdrew (all in the CFT intervention group) prior to three-month follow-up (one participant was dissatisfied with their group allocation, one discontinued due to a mental health deterioration and one participant was withdrawn as they developed radicular pain and underwent a nerve root block injection). Four patient participants in the CFT group and five patient participants in the UPC group did not return their PROM booklets and were lost to follow-up at three months (Figure 3). The retention rates were 76.6% (n=23) for CFT and 83.3% (n=25) for UPC at three months, resulting in an overall retention rate of 80% (n=48) at three-month follow-up.

At six-month follow-up, another two patient participants withdrew (both from the UPC intervention). One patient participant was dissatisfied with their allocated intervention and one underwent urgent surgery for an unrelated health complaint; both requested withdrawal. At six-month follow-up an additional four patient participants did not return their PROM booklets (two in the CFT group and two in the UPC group). The retention rates were 73.3 % (n=22) for CFT and 70% (n=21) for UPC giving an overall retention rate of 71.6% (n=43) at six-month follow-up.

3.3.1.5 Patient reported outcome measures

At baseline fifty-eight out of 60 (96.6%) PROM booklets were completed in full. Two patient participants did not complete the ‘work’ subscale of the FABQ (22 missing items, 2.3%) as they were not working at the time of

enrolment (one retired, one not working due to LBP). All other measures were completed in full, meaning that there were only 0.39% missing items in total. The mean duration of the PROM booklet completion was 13 minutes, below the twenty-minute feasibility threshold set.

At three-month follow-up, allowing for withdrawal, 48 out of 58 (82.6%) PROM booklets were returned. Of the returned questionnaires, the FABQ was incomplete for nine patient participants with 83 missing items (10.8%). The PCS was incomplete for two respondents missing 21 items in total (3.4%). The DASS21 was returned incomplete for one participant missing all 21 items (2.1%), as was the GRC scale which was missing 1 item (2%). Six WATOCI's were returned incomplete with a total of 67 missing items (8.7%). Overall, at three-month follow-up there were 213 (3.7%) missing items out of possible 5808 responses.

At six-month follow-up, allowing for withdrawals, 43 out of 56 (76.8%) PROM booklets were returned. One participant who did not return the three-month questionnaires did so at six-month follow-up. Of the 43 returned PROM booklets, the FABQ was returned incomplete by three patient participants, missing 28 (4%) items in total. One DASS-21 was missing all 21 (2.3%) items. All the other PROM's were completed and returned in full, resulting in 49 (0.94%) missing items of the returned questionnaires at six months. Overall, missing data at baseline (0.39%), three-month (3.7%) and six-month follow-up (0.94%) fell well below the predefined level set (<20%) for feasibility (Appendix N summarises the missing data).

3.3.2 Physiotherapist participants

3.3.2.1 Physiotherapist characteristics

In total, 11 physiotherapist participants were recruited into the study; five in the CFT intervention group and six in the UPC group. The characteristics of the physiotherapist participants who were recruited and trained are reported by group in Table 10. One CFT trained physiotherapist withdrew from the study before patient participant recruitment commenced due to change of role (not included in the table). Due to staff rotations that occurred during the recruitment period an additional physiotherapist received training in the UPC intervention and treated three trial participants, denoted as PT 6 UPC (Table 10).

3.3.2.2 Training

Five physiotherapists attended CFT training between September 2018 and April 2019 and four achieved competency. Following written and verbal feedback and further experiential learning over two months, a second assessment of competency was completed for the remaining physiotherapist who was then deemed competent. The predetermined threshold indicating that it is feasible to train UK NHS physiotherapists to deliver CFT was met. An example of a completed CFT competency checklist is provided (Appendix K). Six separate physiotherapists attended and completed UPC training.

	Gender	NHS Band	Post graduate qualifications	Years qualified	Years working in MSK
PT 1 UPC	M	Band 6	None	2	2
PT 2 UPC	M	Band 6	None	8	8
PT 3 UPC	F	Band 7	None	14	12
PT 4 UPC	F	Band 6	None	4	4
PT 5 UPC	F	Band 6	None	4	4
PT 6 UPC	F	Band 6	None	4	4
Mean (SD)				6 0 (4.8)	5.7 (4)
PT 7 CFT	M	Band 7	MRES	12	10
PT 8 CFT	M	Band 6	None	3	3
PT 9 CFT	M	Band 7	None	13	11
PT 10 CFT	M	Band 7	None	11	11
Mean (SD)				9.8 (4.6)	8.8 (3.9)

PT: Physiotherapist, UPC; Usual Physiotherapy Care, CFT; Cognitive Functional Therapy, M; Male, F; Female, MSK; Musculoskeletal, MRES; Masters Degree in Research.

Table 10: Characteristics of the physiotherapists.

3.3.3. Adherence

The attendance rate to all scheduled appointments was 93.4% (n=128) in the CFT group and 86% (n=105) in the UPC group respectively. The overall appointment attendance rate was 90% (n=214), meaning the adherence feasibility criteria of > 80% attendance to scheduled appointments was met. Very few appointments were not attended without prior notice of cancellation with 6.6% (n=9) appointments in the CFT group and 11.4% (n=13) in the UCP group missed respectively. The mean number of appointments attended was 4 (SD 3) in the UPC group and 4.6 (SD 2.1) in the CFT group. The number of patient participants who completed their allocated intervention within the pre-specified intervention period of three months was 13 (46.4%) in the CFT group and 11 (39.3%) in the UPC group. Only six patient participants (10%) returned the self-completed exercise diaries, three in each group, which did not meet the criteria for feasibility.

3.3.4 Treatment fidelity

Four video recorded CFT sessions and one CFT session that was observed in real-time (due to lack of participant consent for video recording) were evaluated against the CFT fidelity checklists by CN. Five UPC treatment sessions were video recorded and evaluated against the checklist by a different rater (SO). For the notes audit, 28 participant records in the CFT group and 20 participant records in the UPC group were evaluated against the predefined checklists respectively, by CN. Twelve sets of notes were unable to be retrieved and audited because of restricted access to the physiotherapy records store on one study site during the COVID-19

pandemic. The results of the assessments of treatment fidelity are summarised in Appendix O.

In total, 93% of the observed sessions and 88.4% of the audited clinical notes reported that CFT was delivered as intended, exceeding the pre-defined level set for treatment fidelity (>80%). In contrast, only 68.8% of the video recorded sessions and 62.2% of the audited clinical notes reported that UPC was delivered to fidelity.

Reasons for the low levels of treatment fidelity in the UPC group included the absence of the use of a psychosocial screening tool (0%), the identification of psychosocial factors by the physiotherapists (<50%) and agreement of patient centred goals (<50%) during the subjective assessment. Treatments described in the study protocol, specifically manual therapy and the low back rehabilitation class, were seldom included by the UPC physiotherapists. Furthermore, video analysis and the notes audit provided evidence of potential contamination with CFT in the UPC arm of the study. Additional interventions observed and identified, that overlapped with CFT, included breathing control during functional tasks (bending and lifting), addressing safety behaviours, graded exposure to feared and/or avoided movements, motivational interviewing and recommending CFT educational resources to patient participants (e.g. www.pain-ed.com). The frequency of these additional interventions delivered to UPC participants is reported in Appendix O.

3.3.5 Adverse events

There were no adverse or serious adverse events reported during the study period. However, one participant in the UPC group disclosed feeling suicidal to their treating physiotherapist during a follow-up appointment. Following discussion with the physiotherapist, the participant, sponsor and supervision team, it was decided this event was not related to the intervention. The patient participants GP was informed who arranged a clinical review. The event was documented in the physiotherapy records and case report form in the site master file.

3.3.6 Feasibility thresholds

To summarise, all measures that determined feasibility of the study processes (eligibility, recruitment, retention, PROM completion), participant safety, physiotherapist training and treatment fidelity were within the *a priori* thresholds except for UPC treatment delivery and completion of the exercise adherence diaries. The feasibility outcomes are summarised in Table 11.

Criteria	Description	Feasibility threshold	Outcome	Feasible
Eligibility	Percentage of screened referrals meeting eligibility criteria	>50%	51%	✓
Recruitment	Recruitment rate (participants per month)	>5	10	✓
	Consent rate	>50%	87%	✓
Retention	Study retention			
	3 months	≥70%	80%	✓
	6 months	≥70%	71.6%	✓
Intervention adherence	Attendance to allocated appointments	>80%	90%	✓
	Completion and return of exercise adherence diary	>70%	10%	✗
PROM's	Mean completion time (minutes)	<20	13	✓
	Number of missing items per PROM			
	Baseline	<20%	0.39%	✓
	3 months	<20%	3.7%	✓
	6-month	<20%	0.94%	✓
Participant safety	Reported adverse events	<5%	0%	✓
Intervention training	CFT competence	100%	100%	✓
Treatment fidelity	CFT treatment fidelity	≥80%	93%	✓
	UPC treatment fidelity	≥80%	68.8%	✗

PROM's; Patient Reported Outcome Measures, CFT; Cognitive Functional Therapy, UPC; Usual Physiotherapy Care

Table 11: Feasibility criteria and decisions to proceed to a full clinical trial.

3.3.7 Clinical outcomes

Greater reductions in disability (RMDQ) were reported in favour of CFT at three (mean difference 3.39, CI 0.98-5.8, *d* = 0.72) and six-month follow-up (mean difference 2.75, CI 0.13-5.37, *d* = 0.58). Greater improvements were also demonstrated for all of the other PROM's including pain intensity (NPRS), fear (FABQ), risk of persistent LBP (STarT Back tool), pain self-efficacy (PSEQ), pain catastrophising (PCS), depression, stress and anxiety (DASS-21), general health (EQ-5D-5L and EQ VAS), global rating of change (GRC) and therapeutic alliance (WATOCI) in favour of the CFT intervention at both three and six-month follow-up.

The estimated marginal means are reported in Table 12 with 95% CI's. The mean differences between the groups (UPC - CFT), with 95% CI's and effect sizes (Cohen's *d*) are given in Table 13. The WATOCI was only collected at one time point (3 months), therefore independent t-tests were completed and the results added to Table 13.

The changes in disability (RMDQ) and pain intensity (NPRS) relative to baseline for each follow-up time are depicted in Figures 5 and 6. A larger proportion of participants were satisfied with their treatment at 3 and 6 months in the CFT group than the usual care group (Figure 7 and Figure 8).

PROM	Group	Baseline	3 Months	6 Months	Time X Group	Time
RMDQ	UPC	11.50 (9.78, 13.22)	7.32 (5.64, 9.01)	5.47 (3.62, 7.33)	0.004	<0.001
	CFT	13.00 (11.28, 14.72)	3.93 (2.21, 5.66)	2.72 (0.87, 4.57)		
NPRS	UPC	7.00 (6.39, 7.61)	4.93 (4.13, 5.73)	4.70 (3.72, 5.68)	0.173	<0.001
	CFT	6.47 (5.85, 7.08)	3.90 (3.07, 4.73)	3.33 (2.37, 4.3)		
FABQ	UPC	38.63 (31.54 , 45.73)	28.66 (21.27 , 36.05)	27.25 (19.46 , 35.03)	0.001	<0.001
	CFT	44.8 (37.71 , 51.89)	16.28 (9.04 , 23.52)	13.4 (5.9 , 20.9)		
STarT Back	UPC	5.3 (4.56 , 6.04)	3.17 (2.26 , 4.08)	2.62 (1.69 , 3.55)	0.067	<0.001
	CFT	5.73 (5 , 6.47)	1.92 (0.98 , 2.86)	1.38 (0.45 , 2.31)		
PSEQ	UPC	31.83 (26.93 , 36.73)	40.61 (35.99 , 45.23)	41.66 (36.82 , 46.49)	0.183	<0.001
	CFT	29.47 (24.57 , 34.37)	44.26 (39.54 , 48.99)	46.74 (41.93 , 51.55)		
PCS	UPC	26.27 (21.45 , 31.09)	18.08 (13.33 , 22.84)	11.84 (7.09 , 16.59)	0.045	<0.001
	CFT	26.53 (21.71 , 31.35)	9.86 (5.06 , 14.66)	8.79 (4.1 , 13.49)		
DASS-21	UPC	31.4 (19.7 , 43.1)	23.46 (13.91 , 33.02)	16.28 (7.97 , 24.6)	0.436	<0.001
	CFT	40.6 (28.9 , 52.3)	21.79 (12.13 , 31.44)	14.23 (6.15 , 22.3)		
EQ-5D-5L	UPC	0.49 (0.4 , 0.57)	0.63 (0.55 , 0.72)	0.7 (0.62 , 0.78)	0.305	<0.001
	CFT	0.47 (0.39 , 0.55)	0.72 (0.63 , 0.8)	0.74 (0.67 , 0.82)		
EQ-VAS	UPC	62.77 (55.46 , 70.08)	70.58 (63.13 , 78.03)	72.98 (65.92 , 80.04)	0.595	<0.001
	CFT	59.73 (52.42 , 67.04)	72.78 (65.15 , 80.4)	77.82 (70.84 , 84.8)		
GRC	UPC	-	1.81 (1.16 , 2.47)	1.89 (1.19 , 2.6)	0.071	0.596
	CFT	-	2.82 (2.16 , 3.48)	2.95 (2.25 , 3.65)		

PROM; Patient Reported Outcome Measure, CFT; Cognitive Functional Therapy, UPC; Usual Physiotherapy Care, RMDQ; Roland Morris Disability Questionnaire, NPRS; Numeric Pain Rating Scale, FABQ; Fear Avoidance Beliefs Questionnaire, STarT Back; Sub-groups for Targeted Treatment Screening Tool, PSEQ; Pain Self-Efficacy Questionnaire, PCS; Pain Catastrophising Scale, DASS 21; Depression, Anxiety and Stress Scale, EQ-5D-5L; EuroQol five dimensions, EQ-VAS; EuroQol Visual Analogue Scale, GRC; Global Rating of Change Scale.

Table 12: Estimated marginal means (95% CI) of the secondary outcomes linear mixed model analysis including all time points.

PROM	Three Months	p-value	Effect size (*d)*	Six months	p-value	Effect size (*d)*
RMDQ	3.39 (0.98, 5.80)	0.007	0.72	2.75 (0.13, 5.37)	0.040	0.58
NPRS	1.03 (-0.12, 2.18	0.079	0.61	1.37 (-0.01, 2.74)	0.051	0.82
FABQ	12.38 (2.03, 22.73)	0.020	0.64	13.85 (3.04, 24.65)	0.013	0.71
STarT Back	1.25 (-0.06, 2.56)	0.060	0.62	1.24 (-0.07, 2.55)	0.063	0.62
PSEQ	-3.65 (-10.26, 2.95)	0.272	0.27	-5.09 (-11.91, 1.73)	0.140	0.38
PCS	8.23 (1.47, 14.98)	0.018	0.62	3.05 (-3.63, 9.73)	0.364	0.23
DASS-21	1.68 (-11.91, 15.27)	0.805	0.05	2.06 (-9.53, 13.65)	0.723	0.06
EQ-5D-5L	-0.08 (-0.2, 0.03)	0.156	-0.35	-0.04 (-0.15, 0.07)	0.444	-0.17
EQ-VAS	-2.19 (-12.86, 8.47)	0.681	-0.11	-4.84 (-14.77, 5.09)	0.331	-0.24
GRC	-1.01 (-1.94, -0.08)	0.034	0.62	-1.06 (-2.05, -0.06)	0.038	0.58
WATOCI*	9.2 (-16.6, -1.8)	0.016	0.78	-	-	-

PROM; Patient Reported Outcome Measure, RMDQ; Roland Morris Disability Questionnaire, NPRS; Numeric Pain Rating Scale, FABQ; Fear Avoidance Beliefs Questionnaire, STarT Back; Sub-groups for Targeted Treatment Screening Tool, PSEQ; Pain Self-Efficacy Questionnaire, PCS; Pain Catastrophising Scale, DASS 21; Depression, Anxiety and Stress Scale, EQ-5D-5L; EuroQol five dimensions, EQ-VAS; EuroQol Visual Analogue Scale, GRC; Global Rating of Change Scale, WATOCI; Working Alliance Theory of Change Inventory. (*d);* Cohen's *d* effect size.

Table 13: Intention to treat analysis for all of the collected patient reported outcome measures.
Mean difference (95% CI) for linear mixed model analysis including all time points.
*WATOCI collected at one time point only, therefore independent t-tests were completed on the unadjusted means (n=42).

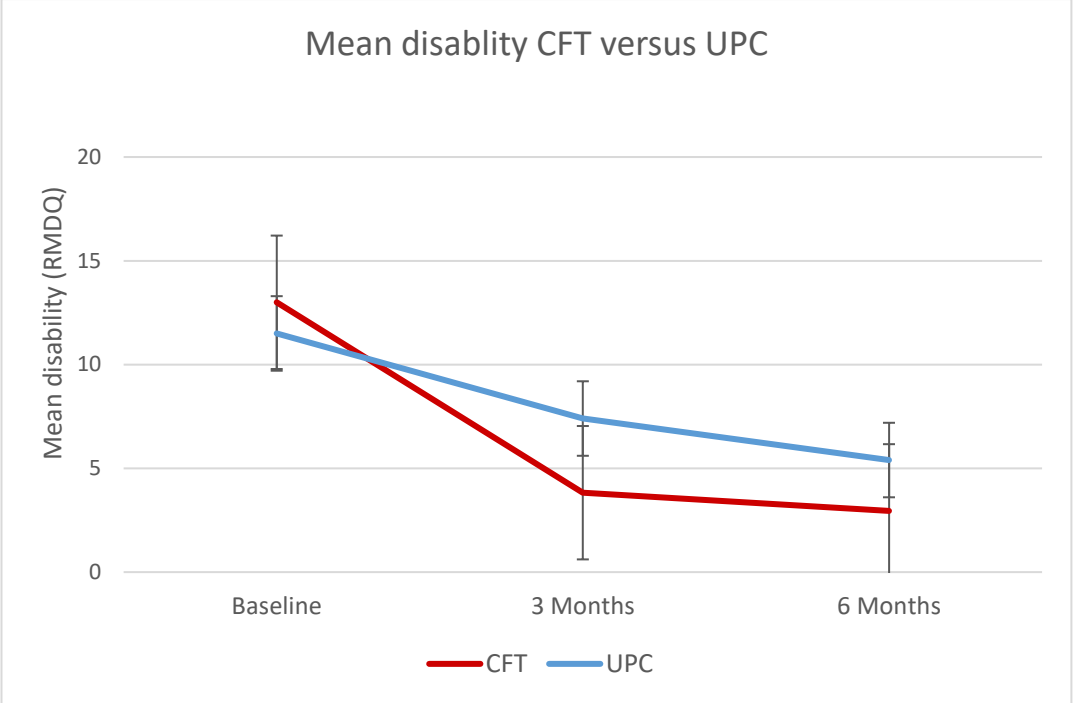

Figure 5: Mean disability (RMDQ) for CFT versus UPC at baseline, three and six-months post intervention.

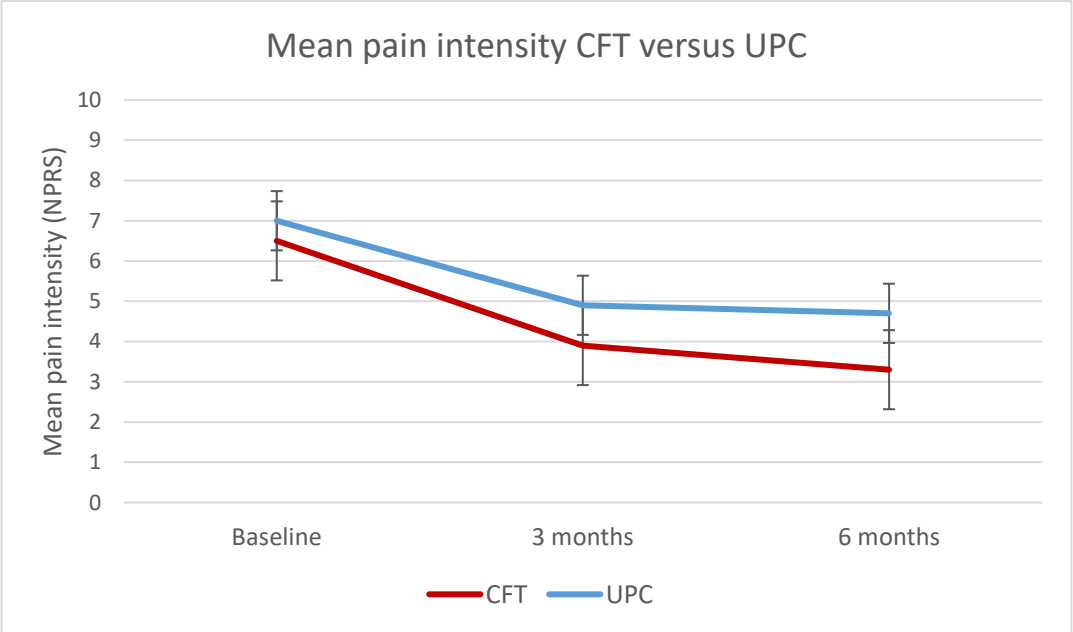

Figure 6: Mean pain intensity (NPRS) for CFT versus UPC at baseline and three and six-months post intervention.

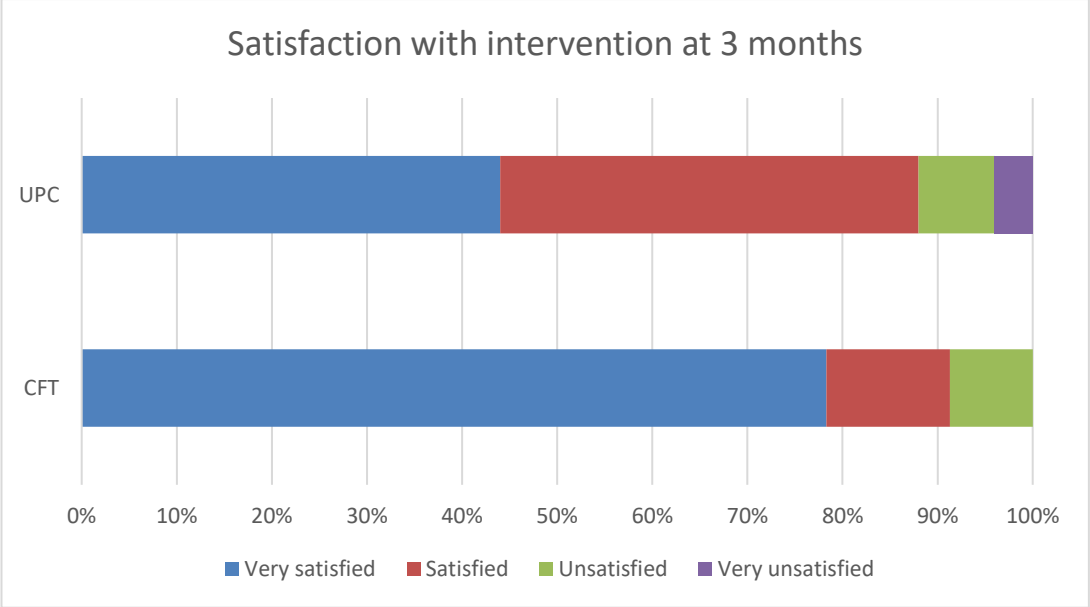

Figure 7: Participant satisfaction with treatment at three-month follow-up.

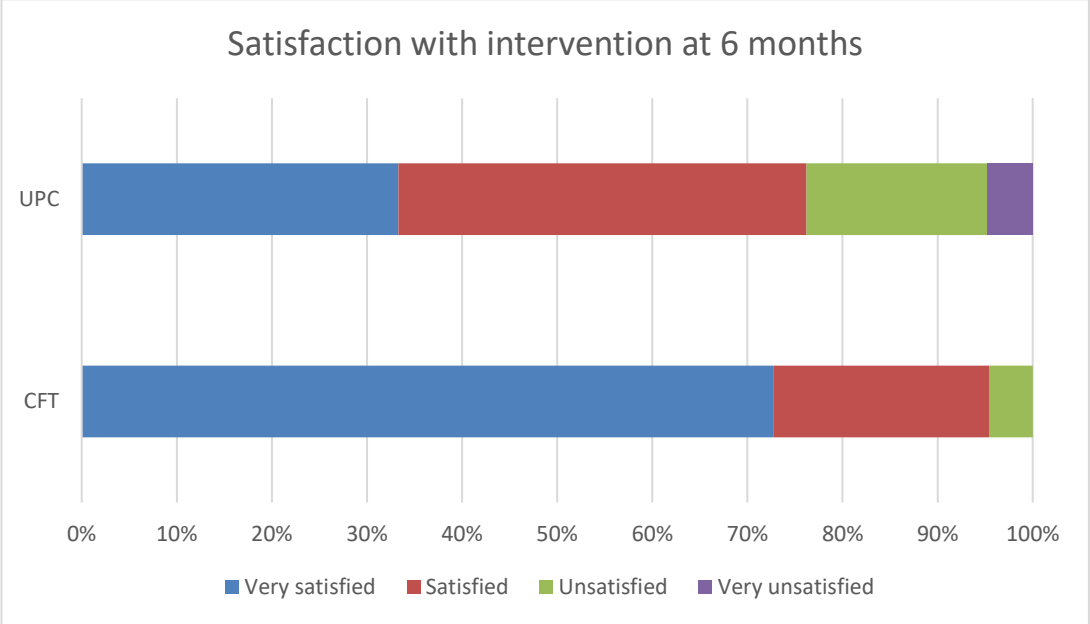

Figure 8: Participant satisfaction with treatment at six-month follow-up.

3.3.8 Sample size calculations

Given the good utility observed (high return and completion rates) within this study, the RMDQ would be a suitable primary outcome for a definitive future RCT. Dr Helen Purtill, Lecturer in statistics, Department of Mathematics and Statistics, University of Limerick, Ireland, calculated a range of sample sizes for a future RCT using nQuery statistical software. The sample size calculations were based on the moderate effect size observed at six months in the feasibility RCT for the RMDQ (*d*=0.58) and used the methods and formulae described by Hemming et al. (2011) [393].

For a parallel, two group RCT, based on a moderate effect size *(d=0.5)*, a sample size calculation estimates 64 participants per group (128 total sample size) will have 90% power to detect a three point mean difference (0-24 scale) in disability (RMDQ) between CFT and UPC, assuming a common SD of 6 (RMDQ) and a two-sided level of significance of $p<0.05$.

However, due to the potential for contamination in a parallel RCT, as reported in section 3.3.4, a cluster RCT may be an appropriate design for a definitive trial. Based on different constraints (number of available sites and number of participants per cluster) and a conservative intra-cluster correlation of 0.7, two sample size estimates are provided:

1) A cluster RCT with 9 clusters of 30 participants in each arm of the 2-armed trial is estimated to have 90% power of detecting a mean difference of 3 points on the RMDQ with a SD of 6 at the 5% level of significance (two-tailed test). The total sample size required would be 540, with 270 allocated to each group.

2) A cluster RCT with 8 clusters per arm requires 41 participants in each cluster of the 2-armed trial to have 90% power of detecting a mean difference of 3 points on the RMDQ with a SD of 6 at the 5% level of significance (two-tailed test). The total sample size required would be 654 with 328 allocated to each group. Appendix P provides further details on the sample size calculations for different constraints.

3.4 Discussion

This study indicates that it is feasible to deliver CFT in the UK's NHS with fidelity, that relevant and clinically important outcome data can be rigorously collected and that CFT can be tolerated by patients with indications that the intervention is effective with no safety issues. All but two of the pre-determined feasibility criteria were met which suggests that it is feasible to plan, conduct and complete a definitive RCT in the UK that will trial the clinical and cost effectiveness of CFT in comparison to UPC for people with persistent LBP.

3.4.1 Study processes

Recruitment to the trial was completed quickly with 2.5 patient participants enrolled per week which was twice the pre-trial minimum feasibility recruitment rate. One reason for the excellent recruitment was thought to be the use of the telephone triage system. Telephone triage was very effective for study screening as the patients were not treated but were able to provide sufficient details to allow comparison against the eligibility criteria. Rapid and adequate identification and recruitment of potentially eligible patient participants also suggests that the inclusion and exclusion criteria were appropriate, that study information was acceptable to patients and the process of screening for the study was satisfactory for the triaging physiotherapists.

The retention rates were higher in this study compared to other NHS-based musculoskeletal feasibility RCT's with similar sample sizes and follow-up times [394, 395]. The low attrition rate at three months may have been

because more than 50% of patient participants were still receiving the intervention. At six-month follow-up the attrition rate slightly increased but remained within the *a priori* defined feasibility criteria of ≥ 70%. The loss to follow-up is comparable to two other LBP RCT's [268, 294] but generally higher than larger scale trials evaluating LBP interventions in the NHS [233, 267, 273], which usually factor in a 20% attrition rate as the limit for validity [396]. The limited resources for the PhD meant that retention strategies such as text message or telephone call reminders, the administration of PROM's by telephone or electronically and the introduction of incentives were unable to be evaluated for feasibility. Retention strategies such as these have been used effectively in a feasibility study of a psychological intervention for LBP [395] and a large scale RCT that reported >85% retention at long-term follow-up in people with sciatica when the primary outcome was administered by text messaging [397]. A definitive study should employ similar methods to maximise retention in a future study.

An additional and alternative explanation for the increased attrition at six-months could be attributed to questionnaire burden. Eleven different PROM's were evaluated for their acceptability and feasibility within the RCT. Removal of repetitive and/or overlapping questions will reduce responder burden in a definitive trial. Another reason for non-returned PROM's at six months follow-up may be due to the closure and relocation of the physiotherapy department during the COVID-19 pandemic during March and April 2020. Redirection of post was delayed four weeks during the move.

Despite these complications, the high level of completion of the PROMs, with very few missing items, indicates that the study was relevant and interesting for the patient participants. Only the FABQ proved difficult for some participants to complete. This may have been because the work subscale of the FABQ has not been validated for use in people who are not working [380] which is evidenced by omission of this subscale in the analysis in a recent LBP RCT [294]. Future research should perhaps ascertain the feasibility and acceptability of other measures of fear and avoidance, such as the Tampa Scale of Kinesiophobia [398], in preparation for a future trial.

There were no observed or reported difficulties in the completion of the RMDQ. The RMDQ is an internationally validated questionnaire with recognised MCID's [276] and has been used as the primary outcome in numerous large scale LBP RCT's in the UK [233, 267, 268, 273]. The RMDQ would be a suitable choice as the primary outcome measure for a definitive trial.

3.4.2 Physiotherapist training

The training of the physiotherapists was successful, with only one out of the five physiotherapists requiring additional training to achieve competency in CFT. The training programme in this study, although similar in content, was of a lower intensity (approximately 50 hours) to that in other CFT studies (approximately 100 hours) [281, 289, 291, 292, 294] which suggests a lower dose of training may be practical for delivery within the NHS for some physiotherapists to achieve competency. This is discussed further in the process evaluation (Chapter four).

In contrast, the UPC intervention was intended to reflect contemporary physiotherapy practice, delivered pragmatically and aligned to NICE guidelines [27]. Therefore, the physiotherapists did not receive an extensive training programme which may have influenced the results obtained and the enthusiasm of the physiotherapists towards the study.

3.4.3 Adherence

Intervention adherence was good with few patient participants not completing their allocated treatment. However, less than 50% of patient participants in both groups achieved this within the specified three month period which could be due to the local context, such as long waiting lists and full physiotherapists appointment diaries. In this study, the ‘Did Not Attend’ rates were lower than the national average (9.45%) [399] for the CFT group with 6.6 % of appointments being missed without prior notice of cancellation. The DNA rate in UPC was slightly higher at 11.4%. Satisfactory levels of adherence in this study are similar to other reported NHS feasibility studies [395, 400]. This may be attributed to the patients being participants in a trial, but also indicates that the intervention being evaluated is acceptable to people with LBP. Indeed, the high levels of reported satisfaction with the CFT intervention support this proposition.

It is unclear why only six patient participants returned their exercise diaries. It could be due to practical reasons (such as having to post paper diaries) or personal preference (such as not completing them and or that patient participants did not like to admit they were not doing the programme at home). The original protocol described the use of a smartphone application

that measures intervention adherence through an accelerometer and self-reporting of completed exercise programmes. Unfortunately, funds were not released by the sponsors' finance department to secure licences for use by the time the study had commenced recruitment. To overcome this problem, a future study should address the best way to collect exercise adherence data and once again consider the smartphone application as an alternative method. This would need addressing before a large study is commenced.

3.4.4 Treatment fidelity

The notes audit and video assessments for the CFT group surpassed the expected threshold of 80% for treatment fidelity, meaning CFT was delivered to high fidelity. However, two elements of the CFT intervention were not always consistently delivered, specifically by one physiotherapist. These were exploring beliefs, emotions and pain responses before, during and after exposure and identifying discrepancies between expectation and experience to feared and/or avoided activities during behavioural experiments. In addition, directing patient participants to key supporting resources (e.g. www.pain-ed.com), the provision of a flare up plan and the dosage of the home programme was not always consistently documented in the physiotherapy records. This finding highlights key components of CFT treatment delivery that require monitoring during implementation.

In contrast, the UPC intervention was not always delivered as intended and described in the protocol. Key elements of the intervention, that are recommended by UK LBP clinical guidelines [27], were seldom observed during the video analysis and notes audit. This included identifying

psychosocial factors and patient centred goals during the subjective assessment and the low utilisation of manual therapy and the back rehabilitation class as core treatments. This finding is consistent with a systematic review that suggested physiotherapists do not always adhere to the recommendations of LBP clinical guidelines [254]. Alternative interventions delivered suggested there may have been contamination with CFT during the trial. There was evidence of motivational interviewing, graded exposure to feared and avoided movements and patient participants were directed towards CFT educational resources (e.g. www.pain-ed.com). The process evaluation in chapter four should explore these findings further.

3.4.5 Clinical outcomes

The findings of this study are consistent with previous RCT's and case controlled studies that have reported similar effect sizes for reductions in disability following CFT [287, 292, 294]. Also in keeping with other CFT studies are the similar positive effects observed for several of the other PROM's including pain intensity, fear, self-efficacy, catastrophising, therapeutic alliance and participant satisfaction. This is important as self-efficacy, fear, catastrophising and enhanced therapeutic alliance have been identified as mediators of pain and disability in persistent LBP populations [133, 134, 139], offering an insight into the mechanisms of effect of CFT. Indeed, a recent mediation analysis of an RCT of CFT in Ireland reported that self-efficacy was a mediator of disability [294].

Another important finding is that both groups showed improvements that surpassed the MCID for disability (RMDQ > 30% reduction), pain (NPRS > 2

point change), fear avoidance beliefs (physical activity), pain self-efficacy and pain catastrophising relative to baseline at six month follow-up [337, 370, 379] but the magnitude of effect was larger in the CFT group (Table 13). This suggests that UPC was an adequate intervention and control. The improvements observed could also reflect the natural history of the condition, regression to the mean or the nonspecific effects of treatment [54]. However, the long duration of LBP at baseline (median 5.5 years) and accompanying high levels of baseline disability and pain suggest that natural recovery was less likely. The addition of a no treatment control group would have allowed more certain conclusions in this regard but this may be not be acceptable to patient participants [401].

There were large within group reductions in disability (10.3 versus 6 point change, Table 12) in favour of CFT at six months which is an interesting finding worthy of further discussion. Other RCT's employing psychologically informed physiotherapy interventions for LBP in the NHS that used the RMDQ as the primary outcome have not reported similar outcomes. Mean changes in these studies ranged between a two and five point change in the RMDQ [233, 267, 268, 273].

The higher intensity of training and treatment monitoring completed in this study may explain this discrepancy. For example, the Physiotherapy informed by Acceptance and Commitment Therapy (PACT) study reported that few elements of the intervention were delivered to fidelity after two days of training in Acceptance and Commitment Therapy [268]. Factors such as these may explain the modest reductions in LBP disability (SMD=-0.06, 95%

CI -0.22-0.11) following psychologically informed physiotherapy in comparison to UPC at long-term follow-up [277].

An alternative explanation for this finding may be that CFT explicitly integrates cognitive, behavioural and physical aspects of LBP and provides a bespoke management plan, rather than simply supplementing psychological approaches to traditional physiotherapy interventions, as the definition of psychological informed physiotherapy implies [265]. Overall, the outcomes observed in this study further justify evaluating CFT in comparison to UPC in a fully powered RCT in the NHS.

3.4.6 Strengths and limitations

A strength of this study was that it was a pragmatic, assessor-blinded, parallel feasibility RCT designed, conducted and reported in accordance with CONSORT [369], SPIRIT [368] and TiDieR [372] statements. However, this was a single centre study, completed in an NHS secondary care physiotherapy service which may limit the generalisability of the findings. Fidelity checks illustrated that even in one centre, the UPC intervention was not always delivered to protocol. The UPC physiotherapists received additional training to standardise the intervention, however, this may have led to UPC not being delivered as would be observed in routine practice within the NHS. A limitation of using an RCT design is the reliance on quantitative data to measure treatment fidelity, and indeed to determine feasibility, rather than exploring these issues with those involved in the study [402].

The fast recruitment of patient participants through a telephone triage system, concealed allocation, comparable baseline demographic data, single blinded assessments and overall retention of patient participants in the study are other notable strengths. The duration of LBP, high levels of baseline disability and pain suggest the eligibility criteria were adequate to identify the target population.

The CFT training programme was delivered successfully as evidenced by 100% of trained physiotherapists achieving competency and the high levels of treatment fidelity observed within the RCT.

Although a clinically relevant guideline recommended approach to LBP was used as the comparator in the control arm, the intervention was not always delivered as described in the protocol. The treatments observed may represent the normal variation in physiotherapy practice. This should be explored further in the process evaluation (Chapter four) and perhaps identifies the need to examine contemporary physiotherapy practice across the NHS.

The use of a notes audit to assess treatment fidelity was a limitation of the study. The outcome of the notes audit was dependent on the physiotherapists documenting every aspect of the intervention they delivered which may not always be possible in a busy NHS outpatient department. This may explain the lower fidelity score for the notes audit of both interventions in comparison to the video analysis and illustrates that further exploration of the physiotherapist's views is required.

A wide range of PROM's were used within the study, however, physical activity was not objectively measured, despite both interventions explicitly targeting physical activity through exercise and lifestyle change. Nonetheless, the high completion rates and few missing items indicated the outcome measures were relevant to patient participants and allowed point estimates and their precision to be evaluated. The small sample size allowed the research team to contact patient participants who did not return their outcome measures, potentially providing a false-positive completion rate.

There were several deviations from the registered protocol (Appendix H). Statistical analysis for between group differences were conducted and reported within this chapter but not described in the protocol (Appendix H). It is acknowledged that the study was not powered to detect between group differences and that a small sample size can lead to over estimation of treatment effects through type II error [356]. Secondly, more than 50% of patient participants were still receiving their allocated intervention at three month-follow up which may have biased the results. Reasons for this were uncertain but may be due to the complex health needs of patient participants, physiotherapist decision making or lack of appointment availability within the physiotherapists diaries.

3.5 Conclusion

The findings of this feasibility RCT indicate that the study processes were adequate and acceptable to participants (patients and physiotherapists), that CFT is deliverable by physiotherapists to high fidelity to people with persistent LBP and that clinically important data can be collected with

indications of clinical effectiveness and participant safety. While an RCT design provides a quantitative assessment of feasibility further exploration of patient and physiotherapist participants' opinions about the acceptability of study processes are required prior to a larger scale RCT.

Chapter Four – Process evaluation of the feasibility RCT

This chapter presents the qualitative process evaluation, which was embedded within the feasibility RCT (Chapter three). It aimed to understand the research processes, treatment fidelity and how the interventions brought about change from the perspectives of patient participants and their treating physiotherapists. This chapter builds on the identified barriers and facilitators to the implementation of CFT in the context of the NHS, presented in Chapter two.

4.1 Introduction

In chapter two, the barriers and facilitators to the implementation of CFT within the context of the NHS were explored from the perspectives of physiotherapists and patient participants. Contextual factors that included, short appointment duration and limited availability of follow-up appointments were seen as barriers to implementing CFT. In addition, although training in CFT through attendance at a three-day clinical workshop provided an introduction to the intervention, the physiotherapists described the need for ongoing clinical mentorship and peer support to develop, maintain and embed newly acquired skills with confidence into clinical practice. These qualitative findings were incorporated into the planning, design and conduct of the feasibility RCT (Chapter three) and are detailed in the study protocol [354] (Appendix H). For example, initial and follow-up appointment times were increased and the CFT training programme included clinical mentorship with a CFT educator and bespoke feedback following observed live patient assessments.

The feasibility RCT, reported in chapter three, aimed to determine if a future definitive RCT comparing CFT with UPC could be delivered in the NHS. While an RCT design is a suitable method to answer such a feasibility question, it can only provide a quantitative estimate of the study parameters, which are evaluated against *a priori* thresholds to give a dichotomous indication of feasibility [403, 404]. Common objectives of feasibility studies that include, determining recruitment and retention rates, outcome measure response and completion rates, recording the frequency of adverse events, measuring treatment fidelity and adherence and calculating the sample size for a future definitive study may be well suited to quantitative methods [197, 365, 404]. However, an RCT design may not elucidate understanding of how the different components of the trial and the intervention may or may not work [402, 405, 406]. Instead of asking if a trial works, as demonstrated through descriptive statistics, statistical or clinical significance, crucially, process evaluation attempts to explain how or why the intervention did or did not work in the context in which it was delivered [197, 407]. Oakley et al. offer the following definition of process evaluation,

> *'Process evaluations within trials explore the implementation, receipt, and setting of an intervention and help in the interpretation of the outcome results'* [408].

The updated Medical Research Council guidelines reinforce this position and recommend integrating process evaluation within RCT's in order to understand how an intervention was implemented, determine causal mechanisms of action of the intervention(s) and to evaluate how contextual

factors may explain the observed effects within a trial [197]. Integrating qualitative with quantitative methods within an RCT is viewed as essential to achieving these aims [403, 405, 406]. By doing so at the feasibility stage, modifications and improvements may be made to optimise the research design and intervention ahead of a definitive study [405]. To illustrate, the quantification of PROM completion rates may not provide sufficient detail regarding their acceptability to patient participants. Factors such as questionnaire relevance, appropriately worded questions and the overall burden of questionnaires may influence the responses received and therefore requires deeper understanding before deciding which measures are to be used in a definitive trial [409].

In addition to evaluating the research processes, qualitative methods may also provide valuable insights into how complex interventions were delivered and experienced by patients and their clinicians within an RCT [407]. To support the notes audit and video analysis used to assess treatment fidelity in the feasibility RCT, qualitative methods may also differentiate the content of the interventions and treatment integrity further.

The aim of CFT is to reduce pain and disability by targeting multiple biopsychosocial factors through an individualised multi-component intervention consisting of biopsychosocial pain education, graded movement exposure and lifestyle modification [72]. Therefore, the mechanisms that bring about changes in pain and disability following CFT may be specific to the individual and multifactorial. It is important these mechanisms are explored in an early, feasibility phase; a process evaluation allows this

alongside determining clinical outcomes and treatment effects in RCT's [407].

Several recent studies have investigated the mediators of change following CFT [288, 306, 338, 410]. Although clinically important reductions in disability appear to be consistent between studies [287, 288, 292-294], it is important to note that the reported mediators of disability vary. For example, self-efficacy mediated disability in one RCT in Ireland [410] and pain intensity, pain controllability and fear mediated disability in another study in Australia [288]. Furthermore, sustained reductions in pain intensity also appear to differ between studies completed in different locations [287, 292-294]. The similarities and variations in outcomes following CFT in these reported studies highlight the requirement to understand how CFT may exert its effects in different geographical locations and healthcare systems. Indeed, a novel aspect of this PhD aims to understand how CFT may be implemented within the context of the UK NHS.

The findings of the feasibility RCT study (Chapter three) indicated larger mean reductions following CFT for measures of disability, pain intensity, fear, pain catastrophising, global rating of change and therapeutic alliance at three and six-month follow-up in comparison to UPC, with medium to large effect sizes reported. These findings are broadly consistent with previous CFT studies [287, 288, 292-294]. It is important therefore to understand how CFT may exert its effects within the context of the NHS.

By evaluating trial processes, treatment fidelity and proposed mechanisms of change within a qualitative framework the planning, design and delivery of

the intervention may be enhanced in preparation of definitive future RCT of CFT in the NHS, and provide insights into wider implementation [405, 407]. This process evaluation aimed to;

1) Explore the views of patients with LBP about the acceptability of the trial design and research processes (e.g. recruitment, randomisation, appointment processes, data collection methods and suitability of the outcome measures).

2) Explore the views of physiotherapists on the training they received in preparation for the feasibility RCT.

3) Evaluate the content, delivery and identify the perceptions of causal mechanisms of action of the interventions through the experiences of patients with LBP and their treating physiotherapists.

4.2 Methods

4.2.1 Study design

A qualitative process evaluation embedded within a feasibility RCT (Chapter three) explored the acceptability of the research procedures (e.g. recruitment, randomisation and outcome measures) and the experiences of the intervention from the perspectives of patient participants and their treating physiotherapists.

Due to the heterogeneous nature of persistent LBP and the individualised approach to management adopted within the study, semi-structured interviews were employed to gather data from patient participants. The physiotherapists were a more homogenous group, known to each other,

working in the same clinical environment and had attended group training prior to delivering the interventions in the feasibility RCT. Therefore, semi-structured interviews for patient participants and focus groups for the physiotherapists were deemed the most appropriate and feasible methods to draw on a range of views regarding the trial design and conduct, perceptions of the training programme and experiences of the intervention within the feasibility RCT [405].

A priori categories regarding research processes were generated from published guidelines [405] by CN, therefore an initial deductive approach was taken. However, to understand the intervention experiences of patient participants and the physiotherapists an inductive approach would also be required.

The study has been reported in accordance with COREQ checklist for qualitative research [334]. Ethical approval was obtained from East Midlands Nottingham 1 Research Ethics Committee on the 1st February 2019, reference number 18/EM/0415 (Appendix I).

4.2.2 Participants

Patient participants were purposively recruited from a sample of 60 patients who were enrolled in the feasibility RCT (Chapter three). Sample sizes for qualitative research in feasibility RCT's are typically small, between five and 20 participants [405]. For this study, an initial sample size of eight to ten patient participants was chosen. This was based on previous qualitative studies, embedded within physiotherapy musculoskeletal feasibility RCT's in the UK, that had similar aims and objectives and had reported data

saturation [411, 412]. However, recruitment continued until data saturation had been observed [413].

Following completion of their assigned intervention, patient participants who consented to be contacted about this study during recruitment to the feasibility RCT were sent a participant information sheet and consent form (Appendix Q). This was followed by a telephone call one week later to discuss the purpose and requirements of the study. For those expressing an interest to participate, a convenient date and time was arranged for consent to be obtained and the interview completed.

For the purposes of variability and to limit selection bias a sample of patient participants stratified by intervention received, age, gender, LBP duration, loss to follow-up and responders and non-responders to the interventions (defined by a minimum clinically important change threshold of ≤ 30% change in pain (NPRS)) were invited to participate [276].

All ten physiotherapists who delivered the interventions during the feasibility RCT were invited to participate in one of two focus groups. The four physiotherapists who delivered CFT were invited to take part in the first focus group and the six physiotherapists who delivered UPC were invited to participate in the second focus group. There was an imbalance in the number of physiotherapists who delivered UPC in comparison to CFT due to local service requirements (band 6 rotations), which was out of control of the researcher (CN). The proposed sample size for the focus groups was considered adequate to achieve the study aims and similar to previous qualitative studies embedded within RCT's [280, 411]. Attempts were made

at the recruitment phase of the feasibility RCT to recruit a diverse sample of physiotherapists by age, gender and clinical experience.

The physiotherapists were provided with a participant information sheet and consent form at a clinical meeting and invited to take part (Appendix Q). All ten physiotherapists indicated that they were willing to take part and a date and time was arranged, during normal physiotherapy working hours, for consent to be obtained and the focus group to be completed.

4.2.3 Data collection

The semi-structured interviews (patient participants) were completed by the chief investigator (CN), a male physiotherapist with 17 years musculoskeletal physiotherapy experience. All patient participants were made aware that the lead researcher (CN) was a physiotherapist with a clinical and research interest in persistent LBP. CN had received three days of formal training in qualitative research methods, data collection and analysis and had prior experience of qualitative research in people with persistent LBP [158].

The focus groups were facilitated by CN and a PPI adviser (Mrs Karen McMullan (KM)). KM was a member of the research team and has prior experience of physiotherapy for persistent LBP. KM received training in focus group methodology and qualitative data collection and analysis, at University of Nottingham, over two days in 2018. The interviews and focus groups were completed in a quiet seminar room, at UHL.

Separate interview guides for the patient and the physiotherapist participants were developed by CN on the basis of the study aims and *a priori* theories related to processes [405] (Appendix R).

Interview topics for patient participants broadly covered the trial processes (e.g. recruitment, retention, participation and acceptability), outcome measures (e.g. selection, content and completion) and the experience of the intervention (e.g. content, mechanisms of action and acceptability). For the physiotherapist participants, focus group topics included the trial design and conduct (e.g. participation in the trial, acceptability of the trial in practice and contextual factors surrounding trial delivery), the perceptions of the training programme (e.g. content, training methods and assessment of competency) and the experiences of delivering the interventions within the feasibility RCT (e.g. content, delivery and mechanisms of action) [405].

The topic guides were reviewed and agreed by CN and VB and were piloted with a PPI member and physiotherapist not involved in the study. No changes were made to the topic guides after the piloting stage.

The semi-structured interviews were completed after patient participants had finished their treatment but before six-month follow-up to allow sufficient time for participants to self-manage their LBP and reflect upon their experiences. The focus groups were convened approximately three months after recruitment to the feasibility RCT was completed (December 2019) to allow the physiotherapists sufficient time to deliver the interventions and to limit any influence over future treatment delivery. The interviews and focus groups were audio recorded using a digital dictaphone and data was transferred to a password protected personal computer.

4.2.4 Data analysis

Based on the agreed *a priori* categories that informed the interview guides, a deductive approach to data analysis was employed to understand the research processes. However, an inductive approach was required to gain an understanding of how patient and physiotherapist participants conceptualised the interventions. Framework method was considered to be a suitable method of data analysis for these purposes [340, 341, 414]. Framework method permits in depth exploration of the data by incorporating thematic analysis [415] while simultaneously providing a systematic, visible approach with a clear audit trail [340]. It may be for these reasons that framework method is increasingly used in musculoskeletal physiotherapy research [320, 411, 412, 416-418]. The seven steps of framework method as used in this study are described as follows [341].

Firstly, the data was anonymised and transcribed verbatim by CN. Secondly, each interview was listened to and each transcript read several times to gain familiarity with the data. Thirdly, the first three interviews and the two focus group transcripts were coded independently by four researchers (CN, VB, KM and Miss Joanna Simkins (JS)) in an attempt to minimise researcher bias. VB is a clinical academic physiotherapist and JS a physiotherapy research assistant, both of whom have no prior training or clinical experience of CFT. In the fourth stage, two coding meetings (one for the three patient transcripts and one for the two focus group transcripts) were held with CN, VB, KM and JS to discuss their preliminary reflections and coding. There were no significant coding discrepancies between the researchers and the

working analytic framework was agreed at the end of each meeting. An example of coding is provided in Appendix S.

CN applied the analytic framework to the remaining transcripts. In the sixth stage the data was organised into the framework matrix using Microsoft Excel [341]. A further meeting then discussed the interpretation of the data and agreed the final themes. Following application of the analytic framework to the remaining transcripts, no further themes were identified and data saturation was achieved [413].

Research diaries were recorded before and after each interview by CN and focus group by KM, that contained reflexive notes about initial impressions of the data, non-verbal interactions and group dynamics (focus groups) and were used to support the analysis in the familiarisation and coding stages (Appendix T) [341, 419].

4.3 Results

Ten patient participants were invited to take part in the study, of which eight provided informed consent. One person declined participation without giving a reason and another cancelled the interview on three occasions and could not be contacted to arrange a further appointment. Recruitment commenced in November 2019 but was paused in March 2020 due to the COVID-19 pandemic. All interviews were completed between the three and six-month follow-up period after patient participants had completed their allocated intervention and were discharged from physiotherapy.

Five female and three male patient participants took part in the semi-structured interviews with a mean age of 49 (SD 15.5) years and mean LBP duration of 11.6 (SD 7.7) years. The eight semi-structured patient interviews lasted between 15 and 34 minutes (average of 19 minutes). Three patient participants were classified as ‘non-responders’ and five as ‘responders’ to the interventions. There was an equal distribution of four CFT and four UPC patient participants. The demographic details of the patient participants are provided in Table 14.

Participant	Age	Gender	LBP duration (years)	Intervention received	Responder (Yes/No)
P1	61	M	3.5	UPC	No
P2	48	F	22	CFT	No
P3	35	M	15	CFT	Yes
P4	54	F	20	CFT	Yes
P5	74	F	15	CFT	Yes
P6	25	F	10	UPC	No
P7	54	F	7	UPC	Yes
P8	39	M	0.33	UPC	Yes

LBP; low back pain, M; Male, F; Female, UPC; Usual Physiotherapy Care, CFT; Cognitive Functional Therapy; Responder ≥ 30% change in the Numeric Pain Rating Scale (NPRS).

Table 14: Demographic details of the patient participants.

All ten physiotherapists trained to deliver the interventions within the feasibility RCT gave their consent to participate in the focus groups. Six male and four female senior (band 6 and 7) NHS physiotherapists with a mean of 7.9 (SD 4.7) years experience of musculoskeletal physiotherapy practice participated. The demographic details of the physiotherapist participants are reported in Table 10 (Chapter three, page 134). Focus group one (CFT) was 42 minutes in duration and focus group two (UPC) 35 minutes.

Four main themes were identified; research processes, physiotherapist training, treatment fidelity and perceived mechanisms of change. The themes are structured according to the agreed *a priori* framework related to the research processes, physiotherapist training and treatment fidelity as well as emergent concepts based on the mechanisms of action interpreted from the data. A summary of each theme is provided and supported by verbatim

quotations. Anonymity was preserved by removing identifiable data and assigning all participants (patient and physiotherapist participants') a unique study code (Tables 10 and 14).

4.3.1 Research processes

Information about the research processes was gathered from patient and physiotherapist participants from both study groups and collated into one theme describing enrolment, randomisation, appointments and outcome measure collection.

4.3.1.1 Enrolment

Participation in the RCT was motivated by a few factors including the influence of family members, a sense of helping others in the future and to *'get better'.*

> *'I didn't think anything of it, because I thought if this is helping me, then it's helping other people'.* (P2 CFT).

There was an expectation that *'something would be done*' such as, *'hands on treatment'* (P6 UPC) and self-management strategies would be provided including exercise and '*being less dependent on painkillers'* (P3 CFT), which influenced patient participants to enrol.

The majority (five out of eight) of patient participants had previously experienced ineffective healthcare for their LBP and were '*hesitant'* and '*sceptical'* about participation.

> *'I was under everything. So I thought, what, what are you gonna give me out of this? Is it going to work? That's my initial thought, because*

I've had so much, so many operations, injections and medication, everything. I didn't think, well what else is going to work? If my back's bad, it's bad, because I was always told it was never going to get better'. (P2 CFT).

All patient participants described the study information that they received and the processes prior to enrolment as being straightforward, understandable and acceptable to them. Two patient participants (P2 and P8) made suggestions to reduce the length of the participant information sheet as it was too long.

The physiotherapist participants in both groups described positive feelings towards being invited to participate in the study, such as '*excitement*' and *'enthusiasm'*, and viewed it as an opportunity to learn more about clinical practice and research.

'I was eager to kind of participate, thought I could learn a few things, get some feedback from the trial itself errm and that might help improve in terms of just confidence with patients as well so err yeah, felt motivated coming into the trial'. (PT 3 UPC*).*

4.3.1.2 Randomisation

Seven patient participants reported not having a preference for the treatment they were allocated to. One participant hinted at a preference for CFT.

'I was hoping it would be a bit more, you know, to help with the, you know, sort of, your mental state of things, rather than, you know, just stretching out your muscles and that kind of thing…I was hoping that

I wouldn't just have bog standard physio like I'd had before'. (P3 CFT).

After randomisation, five patient participants stated being unsure of which treatment they had been allocated to. Three patient participants identified their allocated intervention correctly based on their prior experience of physiotherapy for LBP.

'Actually because the physio care that you gave me, [Physio name omitted] dealt with it differently to what most physios would do'. (P2 CFT*).*

'It was no different to just being sent to a physiotherapist'. (P6 UPC).

The physiotherapist participants in the CFT group had a similar perception to blinding of the patient participants.

'Most of the patients that I saw on the trial had been through physio multiple times in the past. This wasn't their first time. So if they've been through this process or through physio multiple times before you'd like to think they'd have an appreciation or an understanding of standard care. Errm so I think on the whole, patients particularly on this arm will have known'. (PT 7 CFT).

4.3.1.3 Appointment processes

All physiotherapist participants reported that the 'ring-fenced' initial and follow-up appointment times were helpful and enabled patient participants to commence their interventions without the usual delays of waiting lists.

Patient participants did not identify any difficulties with the appointment availability.

> *'Generally speaking it was all bang on time'.* (P1 UPC).

Longer initial appointment time was valued by the physiotherapist participants as it relieved some of the *'pressure'* when delivering the interventions and facilitated communication. However, one physiotherapist in the UPC arm of the study felt that 60 minutes was too long and that they were *'filling time'*.

> *'I felt like I was trying to fit more in than I normally would'.* (PT 2 UPC*).*

In contrast, all the CFT trained physiotherapists described using the time available to the fullest and in some cases one hour was not sufficient.

> *'I can pretty much say that every patient lasted at least the 60 minutes. It's not something I spent less time on….And this is definitely an approach, is something that you cannot rush. And allowing patients that time is just imperative'.* (PT 10 CFT).

One physiotherapist recognised that while the longer initial appointment times supported delivery of the intervention in the RCT that this may not be readily available and could be a barrier to wider implementation in the NHS.

> 'So then the use of time has to replicate that of the NHS'. (PT 7 CFT).

The physiotherapist participants experienced variable responses and support of administrative staff when arranging appointments for study participants. Peer support of physiotherapy colleagues involved in the study helped to mitigate this barrier.

> *'Yeah we had a lot of that, like people help organising our diaries, that was never really on us at all and it wasn't a problem, so I think yeah… the peer support and supervisors and stuff was absolutely fine'.* (PT 5 UPC).

4.3.1.4 Outcome measures

4.3.1.4.1 Content

All patient participants described the patient questionnaires as comprehensive, easy to understand and straightforward to complete. However, five patient participants deemed the questionnaires to be repetitive with a suggestion by one participant to remove repeated questions in future studies. Another participant described the work subscale of the FABQ irrelevant to him as he was not working.

Most (six out of eight) patient participants described the questionnaires as being able to capture their experience of LBP but two patient participants in the UPC intervention did not understand why the questionnaires asked about their mental health status when they had a physical problem with their back (P6 UPC and P8 UPC).

'And then asking questions about your mental capability, your mental state, you're like 'why are you asking this?' when it's my back that hurts, it's just like [um] 'odd'. (P6 UPC).

Interestingly, patient participants who had received the CFT intervention were more accepting of the use of a broad range of questionnaires to capture their physical and psychological health. This was not evident in the UPC participants.

'I think this is the thing; I think that it's all a big part of it really. It's not just the physical part of, you know, your back and that pain, it's impacted me across the whole spectrum of my life. I think you guys need to see that it's had an impact on all of that. If you don't ask those questions then you won't know'. (P3 CFT).

4.3.1.4.2 Completion and format

Patient participants reported that the questionnaires were legible and easy to complete. Time to complete the questionnaires was described as acceptable to all patient participants with answers varying between 10 and 30 minutes. Patient participants also reported reduced burden when completing the questionnaires at follow-up as they became more '*familiar'* with them. Those identified as responders (Table 14) to the interventions reported that the questionnaires were easier to complete at follow up as they didn't have to '*think about the answers'* as much due to reduced impact of LBP on their lives.

All of the patient participants described completing the questionnaires in paper format and return by post as acceptable but six patient participants

made suggestions for electronic completion online via a personal computer or smart device application with the implication that it would enhance response rates. This was reinforced by the observations of a physiotherapist (PT 8 CFT).

> *'It was acceptable, but you know what happens is sometimes with the post, you put it to one side and you say, 'I'll look at it in a bit'. Whereas if you've got it on an email, your phone is in your hand 24/7, you get an email or in an app'.* (P2 CFT).

One barrier reported was finding time to complete the questionnaires when in full-time employment and that email completion may be a solution to adapt to participants' lifestyle (P1 UPC). Three patient participants requested the support of research staff via telephone or email contact should any difficulties be encountered and that prompts or reminders to complete them would also be useful (P1 UPC, P5 CFT and P6 UPC).

In summary, the research processes (enrolment, randomisation, appointment processes and outcomes measure) appeared to be acceptable to the patient and physiotherapist participants. Many agreed that they would take part in this study if it were to be completed again in the future.

> *'It's not been any extra work, it's not been any more pressure or, you know, other than what you expect in normal day to day physio. And like Sarah and Joanne (names anonymised) said, it's been positive, and definitely if you asked us again to do it next year I'd be like, 'yeah, I'd be up for it'.* (PT 3 UPC).

4.3.2 Physiotherapist training

The second theme describes the physiotherapists' perceptions of the training programme they received. The content and mechanisms for engaging with the respective training programmes are described and recommendations are made to enhance future training.

4.3.2.1 Content and peer support

All CFT physiotherapist participants described the content of their training to include attendance at a CFT workshop, a period of supported experiential learning and access to online manualised resources detailing the CFT intervention and clinical reasoning framework. They described all these elements as being valuable. However, they did not feel their training followed a formalised programme, as described in previous studies.

> *'When you look at the sort of training package on other trials, I don't think we got that level of formal training. And I think we did quite well to actually get ourselves to what we think we delivered a suitable intervention, pretty much ourselves'.* (PT 9 CFT).

Peer support and mentorship during the period of experiential learning was viewed as an important element of the CFT training programme.

> *'I think once you've got the theory and you've got the basic understanding, then it's about sitting in clinics and trial and error and practicing and feedback and it's how you get that feedback and how you get that mentorship'.* (PT 7 CFT).

How feedback was provided was described in terms of being bespoke and 'individualised' which provided clear strategies for reflection, future development and engendered confidence to deliver the intervention.

> *'By far it's the best CPD I've ever had. One of the things I would say about those two days was that it was bespoke to me as an individual but also I felt that the feedback that he (CFT tutor) gave us as individuals was also quite bespoke as well from that. In addition to gaining more confidence I've got some clear strategies to work from'.* (PT 8 CFT).

The training programme for the physiotherapists delivering UPC was also described as a positive and reassuring experience. Reviewing standard assessment procedures and evaluating the meaning of clinical tests were viewed as the core components of the training package by UPC focus group physiotherapist participants.

> *'I think just generally looking at range of movement, neuro like reflexes, SLR, what they mean and how to kind of like interpret the results, what's positive, what's negative, what if you have someone who's absent. So those kind of things, just to recap'.* (PT 3 UPC).

Peer support was not described in the context of training and intervention delivery by the usual care physiotherapists, but more to support study administrative procedures.

4.3.2.2 Video and competency assessments

Overall, most physiotherapists described the video recorded patient assessments as a constructive learning experience.

> *'As much as it's nerve-wracking, you actually can break down your assessment and think 'okay, I could improve this, I could do it this way'.* (PT 3 UPC).

> *'I think prior to the CFT tutor coming in, when we did the sessions between the 5 of us where we spent some time videoing ourselves that was valuable'.* (PT 10 CFT).

One physiotherapist felt the video recording affected how they would normally deliver UPC.

> *'I think when I was recorded I was quite nervous, I literally lost my trail of thought …I felt all over the place. I definitely felt under pressure to kind of deliver this kind of masterpiece'.* (PT 3 UPC).

In contrast, the CFT trained physiotherapists did not feel the video recording influenced their behaviour. Instead it allowed the opportunity for self-reflection and identified areas of development 'bespoke' to the individual ahead of formal assessment of competency in delivering CFT.

> *'And the other cool thing about that, the video playback was that we had the opportunity to reflect ourselves and then we came together to see if there was some agreement around that'.* (PT 8 CFT).

Despite these positive feelings, the physiotherapists in both groups also conveyed a sense of *'nervousness'* in meeting a level of competency after the training and *'pressure'* to deliver the interventions well.

> *'All the time and the effort that's gone in to my training and support, both on an individual level but also from the rest of you guys… I needed to ensure I didn't let the side down I suppose. Inevitably there was some pressure there'.* (PT 7 CFT).

Nonetheless, all physiotherapists described the training and competency assessment as a unique experience and improved their confidence to deliver the interventions within the study.

4.3.2.3 Future training needs

All of the CFT physiotherapists reported that future CFT training should include video recorded consultations with individualised feedback from a CFT tutor. Peer support and mentorship was unanimously recommended to support future training of physiotherapists in CFT.

> *'I certainly think if this was rolled out on a wider scale then that support has got to be readily available erm, whether that's from a mentorship kind of role or whether it is peer support or observations I think we've got to make sure that's available for those people'.* (PT 7 CFT).

The only training recommendations made by the UPC physiotherapists for a future trial were to include more content on treatment and the provision of a supporting manual detailing what usual care is and how it differs from CFT.

'How do you define like traditional care? Maybe there are things that overlap, so if there's a possibility of, I don't know, if it were more clear cut… differences between the two things, that would help. If you almost had, I know every patient's different, but almost like guidelines for the two different arms of the trial'. (PT 4 UPC).

4.3.3 Treatment fidelity

The third theme explored treatment fidelity though the sub-themes of content of and adherence to treatment, the physiotherapist as a component of the intervention and study contamination.

4.3.3.1 Content

The common perception amongst patient participants receiving UPC and the descriptions of their treating physiotherapists (physiotherapist participants) reported that exercise was the main component of intervention, delivered either individually or as part of a group rehabilitation class. Almost all reported not using manual therapy with any patients. The prescribed exercises were used to modify movement, mobilise the spine and strengthen muscles and appeared to be accompanied with a biomedical explanation.

'They said you might have weak muscles in your back, so you need to build them up. I got told, it's not strong enough for what I do'. (P6 UPC).

One UPC participant described an experimental approach to exercise that was contingent on pain intensity.

'We progressed with the treatment we used different exercises depending on how bad the pain was. We tried different exercises through the, I think it was 3 months, we finally found exercises that really helped'. (P8 UPC).

Three out of four patient participants receiving UPC described their exercises as being effective in reducing pain and improving movement.

One usual care physiotherapist proposed that education about scans, sleep and physical activity was a possible mechanism for improving patient participants' lower back movements. However, this was not recognised by any of the UPC patient participants.

'Like scan results, lots of education around that, what it means, and hopefully how that will change their movements and their beliefs around how they can move'. (PT 5 UPC).

In contrast to UPC, the exercise component of CFT was described as being targeted towards everyday functional activities such as bending, lifting, standing and walking. One participant contrasted his experience of CFT with a previous episode of physiotherapy, which was reinforced by the CFT physiotherapists.

'Rather than just lying there and you know, stretching things out which I would expect from physio normally. This was all more yeah doing like practical movements. Things like getting in and out of a chair or picking things up off the floor….Whereas before, in all my

previous physio, it was almost like everything was geared towards almost avoiding those type of situations'. (P3 CFT).

'One of the liberating things from my perspective has been linking in to peoples values and goals and getting people to engage in stuff that they can't do, they didn't think they could do'. (PT 8 CFT).

However, rather than being '*just exercises'* (P6 UPC) as described by UPC patient participants, all CFT patient participants described a different, more complex understanding of the intervention they received. This included 1) an educational component that enabled patient participants to re-define their LBP understanding to incorporate a broad range of biopsychosocial factors, 2) confidence to engage in movement and activities that were previously reported as painful, feared and/or avoided, 3) sustained self-management and 4) a different experience of communication and therapeutic relationships. These factors are discussed in detail within the mechanisms theme (section 4.3.4).

Patient participants in both arms of the study generally described completing their home exercise programmes. UPC patient participants suggested verbal and written information about how to perform their exercise programme was helpful. However, one UPC participant described lacking guidance on how to complete the home exercise programme and that it was not compatible with her lifestyle.

'The physio didn't actually tell me to do them (exercises), it was just a booklet on lower back pain on things to do in the morning on your

bed but I'm waking up at half six and leaving the house at seven, so with my job I can't get up any earlier'. (P6 UPC).

CFT patient participants reported being given a detailed explanation of the home programme, that their exercises replicated daily functional tasks and that they continued with them, even after they had completed the intervention. In contrast, UPC patient participants described reducing the volume of exercise after discharge.

'So everything that he taught me, he went through it bit by bit with me…I'm still doing them now. I do them every day, in the morning and I do them in the evening and then I do my walking when I'm at work'. (P2 CFT).

All physiotherapist participants suggested that it was difficult to know if patient participants had completed their home exercise programmes and that there were poor completion rates of the exercise diaries.

'Some came back ticking it off and some didn't. And there's no way of kind of knowing if they've done this exercise or you know'. (PT 3 UPC).

Personal factors such as time management, mood and confidence were recognised by CFT physiotherapists as being influential on the consistent delivery of the intervention.

'What do you guys think about us and our mood and how we feel, 'cos I see that as a barrier? I have days where I am super confident, I'm feeling good, everything is going well and I have other days

where I go into clinic and I don't feel the same. I feel that I don't deliver the intervention the same'. (PT 9 CFT).

One CFT physiotherapist (PT 8 CFT) recognised their own time keeping as a barrier to delivering CFT. While this illustrates how the physiotherapist is a component of the intervention (see mechanisms theme section 4.3.4), it also overlaps with previous findings regarding provision of appropriate appointment lengths. Personal factors were not discussed by the UPC physiotherapists.

4.3.3.2 Contamination

One UPC participant described a different experience of physiotherapy that she received in the RCT compared to her prior physiotherapy treatment. The intervention appeared to be cognitively focused which may suggest contamination between the study arms or that cognitive behavioural principles are becoming part of routine physiotherapy practice.

'It was more about me thinking about what I was doing, rather than her telling me what to do. 'Cos I was holding my breath as well, which I hadn't realised that I was doing that. So every time I was doing something like that I was holding my breath and holding in…and she just made me think about letting it out, letting the breath out, and trying to relax'. (P7 UPC).

All UPC physiotherapists agreed that it was difficult not to be influenced by CFT as there was a lot of talk about it within the physiotherapy profession and clinical environment. This concern about contamination was confirmed by P7's (UPC) treating physiotherapist.

'You pick up all these things and you suddenly think 'oh, maybe I shouldn't be doing that because it shouldn't be CFT, but am I doing CFT?' You kind of get yourself a bit muddled and confused. I was definitely worried that there would be contamination from our arm'. (PT 5 CFT).

4.3.4 Perceived mechanisms of change

Despite the concerns over contamination, there were clear differences between the groups in how patient participants understood their LBP, their behavioural response to it, the self-management strategies adopted and communication experienced. These sub-themes make up the final theme that describes the mechanisms of change from the perspectives of patient participants and their physiotherapists (physiotherapist participants).

4.3.4.1 LBP representation

Following UPC, patient participants continued to attribute biomedical explanations to the cause of their LBP. Identity beliefs such as *'wear and tear'*, *'arthritis'*, the *'intervertebral discs'* and *'older age'* were described and accompanied by the potential for negative future consequences.

'To be fair, I think it's a bit of wear and tear, I think that's what it is and I think you have to live with it'. (P7 UPC).

All CFT patient participants described a different understanding of their LBP to incorporate a complex interplay of biopsychosocial factors to make a mind-body connection. Physical (e.g. posture and movement), cognitive (e.g. negative beliefs), emotional (e.g. low mood, perceived stress levels, anxiety),

lifestyle (e.g. sleep deficits and sedentary behaviour) and behavioural responses (e.g. avoidance of movements) to pain or threat were described.

> *''So it's quite clear, if you're not sleeping you're not healing, so you're gonna hurt…because I was getting stressed about it, I could see that there was a lot of muscle tension there. That I was worrying about the pain in my back and because I didn't know how to manage it properly…that was just sort of exacerbating everything'.* (P4 CFT).

4.3.4.2 Behaviour change

CFT patient participants and their treating physiotherapists described behavioural experiments as a central component of the intervention, providing opportunities for novel learning experiences and *'penny drop'* (P3 CFT) moments. This appeared to be fundamental to developing a new understanding, changing beliefs and modifying maladaptive behavioural responses towards their LBP.

> *'So they predict that they are about to do something that's going to 'damage' them and then you expose them to it, you change their safety behaviour, and they don't get the consequence they think they're going to get. So then all of a sudden, 'wow, that's interesting, that's new, that's novel. I've learnt something, it makes a load of sense, and I'm going to go and do that an awful lot more''.* (PT 9 CFT).

> *'I was amazed. I was just absolutely amazed. Because before I, if I did squat down, 'cos obviously I would, I would like, put my hand on something to try and steady myself to get back up. Which really…I*

now realise, that's quite detrimental to you, because you're putting more pressure (on your back), on actually steadying yourself, getting back up. And it's like, trusting yourself and trusting your spine and realising how flexible your spine really is, and how strong it really is. And it's not going to snap'. (P4 CFT).

This new learning enabled CFT patient participants to recalibrate their causal beliefs.

'I thought if I bent down real quickly and get up again, I'd be damaging my back, but that's not the truth. I was always told that you have to be careful with your spine, because your spine is delicate. No, (CFT physiotherapist name omitted) taught me a whole, different, different ball game'. (P2 CFT).

In contrast, none of the UPC physiotherapists reported using strategies to target fear and avoidance behaviours. Despite this, one usual care participant recognised that she had been avoiding functional tasks.

'I had stopped doing a lot of movements with my back which made everything worse I think… I was avoiding, yeah, yeah…even to the point of tying shoelaces, I was bringing my foot up. Rather than bending over to do it'. (P7 UPC).

For the other three UPC patient participants, fear avoidance beliefs and behaviours appeared to have been retained following the intervention.

'It (LBP) slows you down and you are careful when you're lifting and doing things'. (P1 UPC).

4.3.4.3 Self-management

Following exposure to feared and/or avoided movements, CFT patient participants described *'trust'* in their body and *'confidence'* to manage their LBP which appeared to transfer into everyday activities of daily life.

> *'A lot more confidence. A lot more. I… even at work, even the guys at work turn round and said to me, 'you've got more of a spring in your step' and I said 'that's because I can walk properly, I can do things, I'm not scared of doing anything'. So when I lifted a box of paper they go 'oh, I'll lift it for you', 'no, no I can do that now, I can bend down and pick up. I can do those things myself'.* (P2 CFT).

This could be viewed as an internal locus of control with high self-efficacy which appeared to facilitate sustained self-management. CFT patient participants described engaging in valued activities, becoming more physically active and returning to a *'normal'* life. This had positive impacts on their physical and mental health and quality of life.

> *'My mood is definitely 100 times better than what it was. I feel physically stronger and fitter…It's not just a case of, you know, I've got moving and improved the pain. It's been the quality of my whole life, you know, sort of family life, work life, social life, everything has been brought up by this'.* (P3 CFT).

Resultantly, CFT patient participants described breaking a vicious cycle of pain and disability and were optimistic for the future.

What was enlightening is, it's not as harrowing and as dark as you think it is. I was thinking, you know, 'is this it for the rest of my life?' Now, I see…Now I see it's completely different, it's not like that, it's not…it doesn't have to be like that, and there's a way out'. (P4 CFT).

'My future's bright. I've got two lovely grandchildren now. I can pick my grandson up, my son would say to me 'oh don't pick him up, you can't', 'uh-uh, no, I can pick him up now', so I can give him a cuddle, I can play with him, I can run with him, I can get down on the floor. So, my outlook is good'. (P2 CFT).

In contrast, UPC patient participants reported continued avoidance and the use of mainly passive strategies to manage their LBP consisting of rest, taking time off work, medication usage and requiring assistance with functional tasks.

'I know what my body could, like, withstand. I know when it's telling me to stop'. (P6 UPC).

Only two patient participants (P7 and P8 UPC) classified as responders (Table 14) reported exercise as an ongoing self-management strategy. There were contrasting experiences within UPC patient participants with regards with returning to normality. Only one UPC patient participant described being, *'Back to normal with no issues whatsoever'*, (P8 UPC), with positive effects experienced for his mental health. However, three patient participants described persistent LBP and disability. Without effective strategies to manage their LBP, these participants remained pessimistic of a positive outcome and reported dependency on the healthcare system for future care.

This could be viewed as an external locus of control with low self-efficacy to independently manage their LBP.

> *'Cos sort of, if I'm like this at 55, what am I gonna be like when I'm 60?'* (P7 UPC).

> *'I don't see it being very helpful, if in the future I end up carrying a child because that puts pressure on a normal, healthy back. And then having a back like mine, it'll…for less of better words, probably snap….So you feel like you have to go round the houses, back in the system to try and get some treatment again'.* (P6 UPC).

In contrast, CFT patient participants described independence in managing LBP in the future and not being reliant on the healthcare system.

> *'If I have a bad flare up day, I don't get that sort of feeling of, of, impending doom... I think the key was, I got more confident that the pain wasn't anything major…Just crack on with it, 'cos I know that within a day or two I'm gonna be pretty much back to where I should be. Which I didn't have the confidence to do that before, definitely'.* (P3 CFT).

The changes described by CFT patient participants were summarised by one CFT physiotherapist.

> *'I'd say one of the key changes that I saw, just a couple of great examples – fear reduction, definite improvements in disability and then levels of confidence linked to, like self-efficacy. I think they were probably the things that I noticed change'.* (PT 8 CFT).

4.3.4.4 Communication and therapeutic alliance

Effective communication and positive therapeutic alliance appeared to underpin the described mechanistic themes (LBP representation, behaviour change and self-management) for CFT patient participants. Terms such as *'rapport'*, *'empathy'*, *'trust'* and *'confidence in the therapist'* were used by patient participants to describe their interactions.

> *'I think his belief in me. I think, I think the whole thing, the rapport we had with each other, that helped. The trust that we built, that helped. That obviously helped, a lot...He was brilliant, he listened to everything and he was just, he was exceptional really, a really good people person. Like, it's like, I could tell he cared'.* (P4 CFT).

CFT patient participants also recognised an open style of communication that appeared to facilitate self-reflection, particularly noticeable during the guided behavioural experiments.

> *'The communication with [Physio Y] was really, really good. You went in and then he'd ask me questions like, 'How did you feel about that?', 'Why did you think that was good?' 'Did you think you could ever do that?' 'Do you think you could of ever picked that up?'… I thought that was really good because it made you think'.* (P2 CFT).

In contrast to prior experiences of physiotherapy, a different experience of the role of the physiotherapist, seen as a coach was described by one CFT participant.

> *'It's not been anything specific or magical that anyone's done to me, it's just the case of needing almost like, coaching to get back into my normal way of doing things almost…That's how I would describe it really, more rather than actual physio. It was more like being coached'.* (P3 CFT).

In contrast, while patient participants receiving UPC reported positive communication experiences and therapeutic relationships, they did not do so in such depth, using terms such as the physiotherapist was *'nice'* and *'polite'*. In some cases UPC patient participants suggested that their expectations had not been met. One physiotherapist did not feel equipped with the necessary communication skills to effectively address participant's expectations.

> *'I think it was quite difficult to try and break down those barriers'.* (PT 5 UPC).

Table 15 provides a summary of the themes and subthemes.

Theme	Subtheme
Research processes	Enrolment
	Randomisation
	Appointment processes
	Outcome measures
Physiotherapist training	Content and peer support
	Video and competency assessment
	Future training needs
Treatment fidelity	Content
	Contamination
Perceived mechanisms of change	LBP representation
	Behaviour change
	Self-management
	Communication and therapeutic alliance

Table 15: Process evaluation: Themes and subthemes.

4.4 Discussion

4.4.1 Summary of the main findings

The key findings from this study were that NHS physiotherapists and routine NHS patients with LBP are willing and capable of taking part in an RCT, they enjoyed the research process, they completed the interventions, follow-up questionnaires and took part willingly in this process evaluation. This provides additional evidence to Chapter three that a definitive RCT is feasible and should be completed. This discussion will reflect on the detailed findings and highlight areas which need additional study before a larger trial is undertaken.

Each theme is discussed in turn and where there is cross-over, the discussion is merged.

4.4.2 Comparison with other studies

4.4.2.1 Research processes

Most of the research processes were acceptable and feasible so will not be discussed but there were several notable exceptions. Firstly, several of the questionnaires were described as being repetitive. This is possibly because the STarT Back Tool was constructed using questions from the RMDQ and PCS [240] and all three of these PROM's were used in the RCT study.

Secondly, the questionnaires that enquired about a patient participants' mental health status were perceived to be irrelevant by two UPC participants. The rationale for including such questionnaires may not have been provided clearly enough within the participant information sheet. An alternative

explanation is that UPC participants continued to frame their LBP within a biomedical construct post-treatment, using terms such as ‘wear and tear’ and ‘arthritis’ and may not have recognised the broad biopsychosocial nature of LBP. In contrast, findings from this study and another by Bunzli et al. (2016) [338] suggest that patients who respond to CFT become more accepting of psychological factors in their LBP experience and may find such measures more acceptable than patients who retain biomedical beliefs about the identity and cause of their LBP.

Thirdly, the work subscale of the FABQ returned the most missing items at three and six month follow-up (Appendix N) and was considered irrelevant to one patient participant who was unemployed. The FABQ work subscale has not been validated for use in non-working populations [380] which might explain this finding and why recent studies have omitted the FABQ subscale of work from their analysis [294].

4.4.2.2 Physiotherapist training and intervention delivery

The content of training appeared to be acceptable to all UPC and CFT physiotherapists. UPC training content was designed to reflect the recommendations of current UK clinical guidelines and included self-management advice, psychosocial screening, manual therapy and exercise [27]. Reinforcing assessment procedures and treatments during training was described as a positive and reassuring experience for the physiotherapist. However, content analysis suggested that UPC was not always delivered as intended.

Intervention drift is observed when an intervention is not delivered by the clinician in the same way that they were trained to do so [420]. Stretching and strengthening exercises of the lower back and lower limbs were the most commonly prescribed treatments within the feasibility RCT. However, psychosocial screening and manual therapy were infrequently used. Instead, interventions that were not included in the protocol were described by the UPC physiotherapists and included cognitive behavioural approaches such as addressing negative beliefs, motivational interviewing strategies, relaxation training and graded activity.

Basic cognitive behavioural principles have been described as a core skill set of physiotherapists practice [319] which may explain these findings. However, it is difficult to differentiate whether the physiotherapists delivered cognitive behavioural approaches or elements of CFT within this study as there is some cross-over [306]. The usual care physiotherapists themselves eluded to contamination through the influence of social media and talk of CFT within their working environment.

The CFT trained physiotherapists described their training programme as a *'unique'* opportunity and *'profound'* learning experience. While the content of the CFT training was consistent with other studies [281, 289, 292, 327, 373], the intensity of training differed between this study and other clinical trials. In other studies a sustained period of clinical supervision guided by an experienced CFT tutor is typical, with total training contact time averaging more than 100 hours [289, 292, 373, 421]. In the feasibility RCT (Chapter three), a less experienced CFT educator (CN) provided informal supervision

and mentorship sessions with total training time estimated to be 50 hours. This may explain why the physiotherapists did not feel that their training followed a structured or *'formalised'* programme.

The CFT physiotherapists highlighted clinical supervision and mentorship following direct observation as a fundamental component of training that facilitated self-reflection and learning towards achieving competency in the delivery of CFT for the feasibility RCT. Ongoing supervision and mentorship based on direct observation has been described as a key component of training in psychologically informed physiotherapy [320], including CFT [281, 327]. Self-reflection also appears to be a critical component for engagement and development during CFT training [323]. However, an important distinction between CFT training and other psychologically informed physiotherapy approaches is the direct observation of the live clinical encounter followed by bespoke feedback by a clinical mentor, rather than training based on vicarious experience alone [281]. These findings support the notion that bespoke training may be more successful in achieving changes to professional practice behaviour [422].

Overall, the CFT physiotherapists described the training programme gave them the capacity and confidence to deliver CFT within the feasibility RCT. These findings are consistent with two other studies that suggest the content and structure of CFT training improves physiotherapists' self-reported confidence to deliver CFT in practice [281, 327]. This is in contrast to other psychologically informed physiotherapy interventions where, despite intensive training of up to 150 hours, physiotherapists lacked confidence to

explore psychosocial factors and had concerns about their scope of practice [320].

4.4.2.3 CFT mechanisms of effect

The mechanisms of effect described by patient participants and their treating physiotherapists following CFT further supports CFT being delivered as intended within this feasibility RCT. These mechanisms include how patient participants understood and explained their LBP following the interventions. One way to interpret these mechanisms is by using the Common Sense Model of Self-Regulation (CSM) [301].

The CSM proposes that when an individual experiences a health complaint (e.g. LBP), they will cognitively appraise it to form a set of beliefs known as a 'representation' regarding the identity, the cause, the control they have over it, the consequences of it and the duration it is likely to last [301]. This representation guides a behavioural response or 'action' in an attempt resolve the health problem. A positive or negative emotional response results from the cognitive representation and behavioural action. If the problem-solving behaviour is successful, it will be repeated but if it is unsuccessful a new behaviour may be employed. Appraisal of the action will result in a new representation and emotional response [301]. The CSM has been used to explain the process of change following CFT in a LBP patient with high levels of pain-related fear [306] but has not previously been applied to contrast the perceptions of patients following differing interventions for LBP within an RCT.

Following UPC , patients described their LBP using structural terms such as ‘a disc prolapse’ and ‘wear and tear’ (identity beliefs), attributing the onset to causal factors such as ‘lifting’ and ‘age’ (causal beliefs). Patients reported having little control over their LBP with persistent functional limitations for some (consequence beliefs).

In contrast, CFT patients conceptualised their LBP as a multifactorial problem (identity beliefs), influenced by an interplay biopsychosocial factors (causal beliefs) including physical (e.g. guarded postures and movements), cognitive (e.g. negative LBP beliefs such as pain as a sign of damage), emotional (e.g. low mood, fear) and lifestyle factors (e.g. poor sleep and physical activity levels) following treatment.

The contrasting LBP representations following treatment, as explained by the CSM [301], are exemplified in Figure 9 and Figure 10. Figure 9 represents the beliefs of usual care participant 4 (UPC 4) and Figure 10 represent the beliefs of CFT participant 3 (CFT P3).

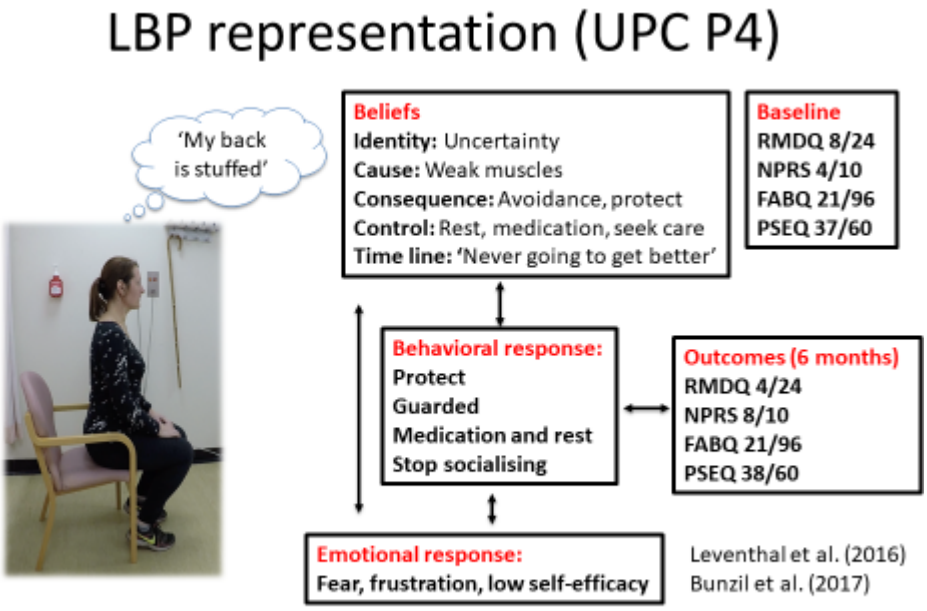

Figure 9: LBP representation of usual physiotherapy care participant 4.

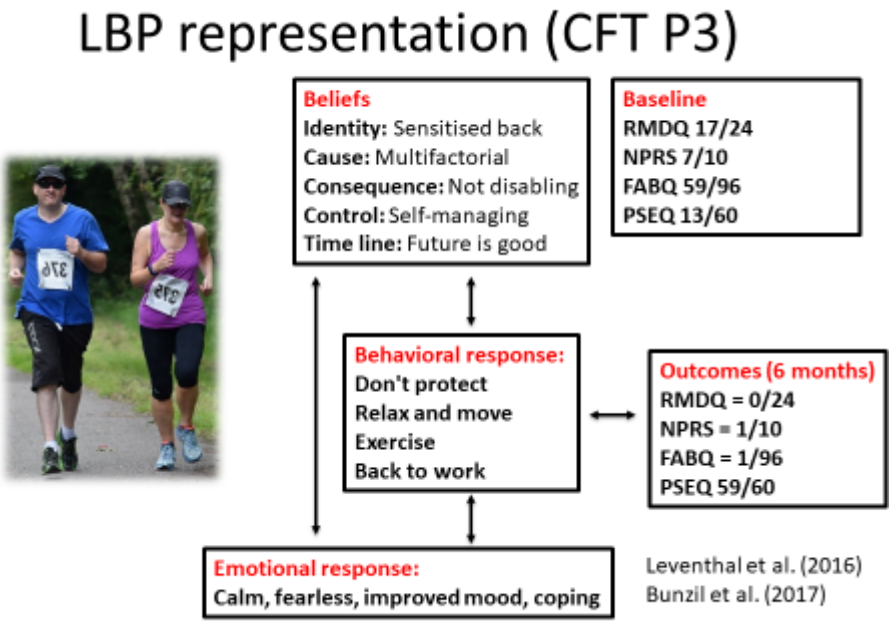

Figure 10: LBP representation of CFT participant 3.

A 'new' representation of LBP appeared to be facilitated through behavioural experiments for CFT patients. CFT specifically uses behavioural experiments to evaluate the validity of an individuals' representation of their LBP by

directly exposing them, with control (by reducing sympathetic arousal and diminishing safety behaviours) to their identified painful and/or feared functional tasks [72, 423]. Behavioural experiments appear to be crucial to changing patients' beliefs about their LBP after CFT [281, 338] with fear reduction a key target due to the moderating effects on pain and disability [133, 139]. Several previous studies have also demonstrated clinically important reductions in pain-related fear following CFT [287, 288, 292]. The qualitative findings of this study underscore the targeting of fear avoidance beliefs and behaviours as a key of mechanism of change following CFT.

In contrast, UPC patients did not provide descriptions of treatments targeting feared and/or avoided movements or activities which allays some of the concerns over contamination held by the usual care physiotherapists. Although, UPC patient participants described an improvement in function, they remained vigilant and in some cases avoidant of specific tasks such as, bending and lifting (consequence beliefs). While self-management strategies did include exercise, patients reported passive coping strategies including rest, taking medication as well as seeking further healthcare for their LBP (control beliefs). The future was viewed with low optimism of a positive outcome (timeline beliefs). In this light, UPC patients displayed a tendency towards an external locus of control with lower self-efficacy to manage their condition.

In healthcare, locus of control is the belief an individual has regarding how much control they have over the outcome of their health. A person with an internal health locus of control believes they can take action to manage their

own health problem. An individual with an external health locus of control believes their health problem is the result of “chance” or “fate” and looks for external solutions to their problem, such as seeing their doctor [424]. Health locus of control appeared to differ between the narratives of CFT and UPC patients. CFT patients described an internal health locus of control and high self-efficacy, evidenced through achieving independent self-management. This was in contrast to UPC patients who described an external locus of control and low self-efficacy evidenced through a reliance on passive strategies and health care professionals.

High self-efficacy coupled with an internal locus of control have been associated with better mental and physical health in people with persistent LBP [425]. Self-efficacy is the belief in one’s ability to enact a specific behaviour or skill [300]. High self-efficacy has been associated with lower disability and pain intensity and higher levels of physical activity in people with persistent LBP [133, 134]. Furthermore, self-efficacy was shown to mediate the relationship between pain and disability following CFT in one RCT [410]. These findings support those observed in the feasibility RCT with a larger mean difference (mean difference 5.1, 95% CI 11.9-1.7, d = 0.38) reported in favour of CFT for improved pain self-efficacy.

CFT patients also emphasised effective communication, including Socratic questioning and motivational interviewing strategies that enabled them to directly reflect on their experiences and challenge their own beliefs further. Strong therapeutic alliance was also reported with patients experiencing empathy and describing *‘trust’* and *‘confidence’* in their physiotherapists who

they viewed as a '*coach'*. This is important as a strong therapeutic alliance has been associated with positive outcomes in patients with persistent LBP [54, 352] and is consistent with physiotherapists' [323, 327] and patients' [338] experiences in other CFT studies. Patient perceptions of therapeutic alliance were supported by the statistically significant and large between group effect sizes for therapeutic alliance (WATOCI) at three months in favour of CFT in the feasibility RCT (mean difference 9.2, 95% CI -16.6—1.8, *d* = 0.78).

The findings from this study converge with Bunzli et al. (2016) [338] who identified that following CFT patients changed their LBP beliefs towards a biopsychosocial understanding and were able to independently self-manage their LBP. Independent self-management was associated with increased self-efficacy, fear reduction, improved problem solving skills and stress coping which was a pathway for returning to normality. These changes in beliefs and behaviours appeared to be facilitated by behavioural experiments and positive therapeutic alliance. However, the generalisability of these findings may be limited by the small sample size of responders (n=6) and that the interventions were delivered by experienced CFT clinical educators in this study [338].

4.4.3 Strengths and limitations

A strength of the study was that all physiotherapists who took part in the RCT also took part in this process evaluation. A limitation was that was that only 8 of the patient participants offered to complete the process evaluation. Although the point of data saturation was reached, the sample size of patient

participants was small (n=8) (four from each intervention group). Gaining the perspectives of a more variable sample of patient participants, including those who consented to participate but left the trial (e.g. those lost to follow-up or withdrew before completing treatment) may have provided additional insights into the study processes and mechanisms of action of the interventions [426]. However, recruitment was limited to a feasible number considering the scope of the study and situation (completed during the COVID-19 pandemic). Nonetheless, a range of responders and non-responders who completed the interventions were recruited in an attempt to mitigate the effects of selection bias [99].

A novel aspect of this study was the involvement of a PPI representative in the collection and analysis of the data. PPI is usually incorporated into the planning, design, monitoring and dissemination of studies with representatives seldom involved as active research partners [427]. One systematic review identified that PPI representative involvement provided deeper insights and wider perspectives towards data collection and interpretation [428]. The perspectives of the PPI representative may have enhanced the credibility and trustworthiness of the findings of this study.

A limitation was that the data was collected on one occasion only, at the end of the intervention, opening the possibility of participant recall bias [429]. Repeated interviews completed at baseline, during and following treatment and focus groups completed before, during and after the physiotherapists training programmes may have reduced any negative effects of recall bias and strengthened the credibility of the findings. Repeated interviews have

been employed in other studies examining training and process outcomes of other psychologically informed interventions for musculoskeletal pain conditions [312, 320] and may highlight problems in trial conduct that were encountered in this study such as intervention drift and contamination. However, funding arrangements and time did not allow for repeated qualitative data collection.

Focus groups were decided as the most appropriate method to collect data from the physiotherapists as they had completed the training programme together and were working within the same clinical environment during the trial. The enthusiastic views of one participant was highlighted in the reflexive diary (Appendix T) which may have influenced the interaction of the other focus group members [405]. Semi-structured interviews may have mitigated this risk but would not have allowed in depth discussion and interactions between the physiotherapists that were observed.

A limitation may also have been that the interviewer was a physiotherapist with previous training in CFT and chief investigator for the study. This may have positively influenced the responses obtained. However, to limit the effects of bias during data analysis, coding was completed by four researchers independent of each other (a PPI representative with prior experience of persistent LBP, a physiotherapy research assistant and HEE/NIHR clinical lecturer both of whom had no prior experience of CFT).

Lastly, the CFT trained physiotherapists were not novices to the approach, having attended at least one CFT workshop prior to formal training in the feasibility RCT. The training requirements may therefore differ between those

with and without prior experience of CFT [281, 292, 323, 373] and should be a consideration in the planning of a future trial. Further research that quantifies the duration and dosage of training required to achieve competency in CFT is also needed, although there is unlikely to be a precise number as individuals may require different levels of training and support [72].

4.5 Conclusion

This process evaluation has confirmed that the research processes, including recruitment, randomisation and the content and administration of the PROM's were acceptable to patients who took part in the feasibility RCT. The CFT training programme provided the physiotherapists with the necessary knowledge, skills and confidence to deliver CFT as intended within the study. Experiential learning that included video recorded assessments with clinical supervision and mentorship were viewed as fundamental components of CFT training. The findings of this process evaluation suggest that the CFT training programme used in this study is feasible for some physiotherapists to achieve competency to deliver CFT in the NHS in a future RCT.

The UPC training programme was also acceptable to the physiotherapists. However, there was evidence that UPC was not consistently delivered as intended within the feasibility RCT. Despite concerns over contamination, the mechanisms of action were differentiated between the two interventions by key stakeholders.

CFT patients described beliefs that demonstrated a broad biopsychosocial representation of their LBP following CFT. Behavioural experiments were described as a central component of the intervention that facilitated independent self-management. An internal health locus of control and high self-efficacy were conceptualised as the mediators of change following CFT. In contrast, UPC participants continued to frame their LBP using biomedical terms, displayed an external health locus of control and reported low self-efficacy to independently manage their LBP.

Chapter Five - Discussion

In this chapter, the findings and implications of each study will be summarised, synthesised and discussed relative to the aims and objectives of the thesis. The strengths and limitations of the study, recommendations for future research, reflections and overall conclusions are provided.

5.1 Summary of the main findings

A step-wise, mixed methods approach, with stakeholder perspectives embedded throughout this thesis has provided novel insights and original findings related to CFT and the clinical management of persistent LBP within the UK NHS. Overall, the findings of the three studies conclude that it is feasible to deliver CFT in a routine NHS setting, that NHS physiotherapists can be trained and can implement CFT and that patients can be recruited on time and to target, with no safety concerns to a RCT. Furthermore, clinically relevant data can be collected using standardised outcome measures and there were positive indicators from these measures that CFT was effective and may be superior to UPC.

In chapter one, a state of the art literature review identified persistent LBP as a multidimensional disorder comprised of a range of physical, psychological, social, lifestyle, comorbid health and non-modifiable (genetic and life stages) factors that interact to produce variable and fluctuating levels of pain and disability that is unique to each person. This contemporary understanding highlighted the shortcomings of current models of care that;

1) Target treatment towards single biomechanical or structural causes of persistent LBP (e.g. facet joint dysfunction with manual therapy or radiofrequency denervation).
2) Adopt, generic ‘one size fits all’ approaches (e.g. pharmacological management, interventional procedures).
3) Utilise subgrouping methods to target specific features of persistent LBP (e.g. modifying symptoms through postural and movement behaviours, stratifying care based on psychosocial risk profiles).
4) Combine physical and psychological interventions (e.g. physiotherapy combined with Acceptance and Commitment Therapy) but do not specifically integrate factors or directly seek to reduce pain intensity.

A review of RCT evidence and Cochrane systematic reviews highlighted that all of these interventions appear to result in similar outcomes. Modest reductions in pain and disability for patients in the long-term are typically reported, with no superiority of one intervention over another. One explanation proposed was that each model of care appears to be reductionist and may not include and/or adequately integrate the complex interplay of biopsychosocial factors evident in persistent LBP.

CFT was introduced as a physiotherapist-led psychologically informed intervention for persistent LBP that explicitly integrates these elements, showing sustained long-term positive effects for reductions in pain, disability and psychological function in a number of uncontrolled and controlled studies. However, the clinical and cost-effectiveness of CFT has not previously been evaluated in the UK NHS. To address this need, this PhD

aimed to establish the feasibility of completing a future full-scale RCT that would evaluate the clinical outcomes and cost effectiveness in the UK NHS.

Three separate but overlapping studies were completed to achieve this aim and included;

1) A qualitative study that established the barriers and facilitators to implementing CFT within the NHS from the perspectives of patient and physiotherapist participants.
2) A pragmatic two-arm parallel feasibility RCT that compared CFT with UPC for 60 people with persistent LBP attending an NHS physiotherapy service.
3) A qualitative process evaluation, embedded within the feasibility RCT that explored the acceptability of the research processes and interventions to patient participants and their treating physiotherapists.

The objectives of this programme of research, as outlined in Chapter one, will now be reconsidered, discussing how they were achieved as well as highlighting the implications for clinical practice and areas of future research.

5.1.1 Objective 1: To determine the feasibility of implementing CFT in the UK NHS

The findings of the interview study (Chapter two) provided preliminary evidence that CFT can be delivered in the UK NHS setting by physiotherapists but that a number of barriers may threaten the delivery of a future trial and wider implementation. These were mainly related to the healthcare system including short initial consultation times, poor availability

of follow-up appointments and that the intervention was often provided at the wrong point in the care pathway for patients.

A number of contextual and environmental factors also needed to be minimised for the feasibility RCT to run smoothly. These factors were incorporated into the planning, design and conduct of the feasibility RCT (Chapter three). Initial physiotherapy appointments needed to be at least 60 minutes in duration, follow-up appointments for 30 minutes and all appointments were to be maintained with the same physiotherapist. Physiotherapist diaries required protected follow-up appointments to allow patients to be seen within a reasonable amount of time after their initial appointment.

Furthermore, to prepare the physiotherapist to deliver CFT to fidelity in the RCT, the CFT training programme needed to be extended. In addition to a three-day CFT workshop with embedded live patient demonstrations, this included six-months of experiential learning with support of a clinical mentor after training to develop, maintain and embed their newly acquired skills with confidence into clinical practice. This was followed by an assessment of competency in CFT.

The process evaluation in Chapter four provided deeper insights into the training requirements for CFT to be delivered well and implemented into the NHS and is discussed in relation to objective 5 (section 5.1.5).

5.1.2 Objective 2: To determine the feasibility of recruitment to a clinical trial and the willingness of patient participants to be randomised to either intervention.

The second objective of this study was to determine if it was feasible to recruit and randomise patient participants to the feasibility RCT in Chapter three. This aim was achieved by demonstrating full recruitment to the feasibility RCT within six months of commencing the study.

Only fifty nine per cent (79/135) of the referrals screened by the clinical team met the study inclusion criteria. This likely reflects the inadequacy of the physiotherapy referral forms at UHL to capture detailed information about LBP that allowed accurate comparison against the study eligibility criteria. However, the telephone triage system proved to be very successful and overall 87% of eligible patient participants provided consent to participate in the study. The *a priori* criteria for eligibility and recruitment were met.

The process evaluation in Chapter four, suggested that the recruitment, enrolment and randomisation processes were acceptable to patient participants. Participation in the study was motivated by altruistic reasons through a sense of helping others and personal factors to *'get better'*, regardless of the intervention received. This is consistent with findings of other rehabilitation interventions embedded within RCT's and is a common reason the general public participate in research [430, 431].

There was initial scepticism for taking part in the RCT as described by the majority of patient participants interviewed during the process evaluation (Chapter four). This was because previous LBP treatments, including

physiotherapy, had been unsuccessful. However, this did not appear to influence patients' decisions to enrol or bias their preference towards one intervention over the other. This is supported by very few patient participants (n=8) being excluded on the basis of preference for one intervention over the other. These findings may also suggest that the participant information sheet did not introduce any bias towards either intervention and that equipoise was maintained during the recruitment processes [432].

The eligibility criteria appeared to identify the target population for this study. The median duration of LBP was 5.5 years (range 4 months to 55 years) in both groups with moderate to high mean levels of baseline disability (RMDQ 12.25, SD 4.7) and pain intensity (6.75, SD 1.7) reported. The baseline demographic data for LBP duration, levels of disability and pain intensity is similar to other UK NHS RCT's of psychologically informed interventions for persistent LBP [233, 267, 268, 272, 273] suggesting a representative sample was recruited.

The randomisation procedures ran smoothly during the recruitment phase, allocation concealment was maintained and the administration procedures for booking appointments were adequate indicating that a RCT of this kind can be completed rigorously in a routine NHS hospital.

5.1.3 Objective 3: To determine the retention rates of enrolled patient participants to the feasibility RCT and the factors contributing to this

The feasibility criteria of >70% participant retention at three and six-month follow-up was met, achieving objective three. Only two patient participants (one CFT and one UPC participant) withdrew because they were dissatisfied

with their allocated intervention, which suggests that the interventions provided were acceptable to the majority of patient participants. Overall, forty eight patient participants (80%) were retained in the study at three months and 43 (71.6%) at six months which is comparable to other studies of CFT [292, 294].

Retention rates appear to vary considerably in musculoskeletal physiotherapy feasibility RCT's completed in the UK NHS with similar sample sizes and follow-up times [394, 395, 433]. There are a number of potential explanations for this including the use of retention strategies (e.g. financial incentives, telephone or text message reminders) [395], study administrative support [433] and whether the interventions provided were acceptable and beneficial for patients [433]. The limited resources meant that retention strategies were unable to be evaluated for feasibility in this study. A future definitive trial should be sufficiently resourced and include strategies that aim to maximise retention and thereby attempt to minimise this threat to validity [396].

The timing of follow-up data collection may have influenced the higher retention rates observed at three months. More than 50% of the feasibility RCT patient participants were still receiving their allocated intervention at three-month follow-up. Although follow-up appointment availability was protected in the physiotherapists' diaries they may not have always been convenient for patient participants and appointments were sometimes overbooked due to waiting list pressures. In some cases patient participants were not seen for four weeks between sessions and were still receiving

treatment which may have positively influenced response rates. A future study should consider a longer initial follow-up time of four months to allow treatment to be completed and the addition of booster sessions in the medium term, for those who experience an exacerbation of symptoms following discharge [72, 289].

5.1.4 Objective 4: To determine the feasibility of collecting PROM data within the feasibility RCT

The PROM's used in this study appeared to carry a low level of burden for patient participants. This was evidenced by the short duration patient participants took to complete them at baseline (mean 13 minutes) and the high response rates reported with very few missing items recorded at baseline and each follow-up time.

On the whole the PROM's were acceptable to patient participants (Chapter four) and met the *a priori* thresholds for completion for feasibility at baseline, three and six month follow-up (Chapter three). Two exceptions were the FABQ and WATOCI that were missing 10.8% and 8.7% of data respectively at three-month follow-up.

Fear, measured using the FABQ in the feasibility RCT, is an important construct to measure in persistent LBP due to the moderating effect it has on pain and disability [133, 139]. Fear reduction is an explicit target of CFT [72] with several previous studies, including the present, demonstrating significant reductions in pain-related fear following CFT [287, 288, 292]. Due to the poor utility observed of the FABQ, a different measure of fear avoidance that does not exclude people on the basis of their employment

status (e.g. being retired or unemployed) should be tested for feasibility prior to a future RCT. The Tampa Scale of Kinesiophobia may be one suitable alternative [398], validated for use in persistent LBP in physiotherapy previously [398]. The reasons why the WATOCI was returned with missing items are unclear.

In addition to being valid, reliable and responsive to change, the wording and burden of the outcome measures should be acceptable to the end user [409]. Although the PROM's appeared to be acceptable to the PPI group (evaluated at the protocol development stage), some of the PROM questions were described as being repetitive by patient participants during the process evaluation interviews. There is overlap between the RMDQ, STarT Back Tool and PCS employing the same questions. A future study should consider removing repeated questions to reduce the burden described.

The use of PROM's that asked about patient participants' psychological function and well-being were not acceptable to two participants who received UPC. In contrast, PROM's assessing these factors appeared to be more acceptable to patient participants in the CFT group. Findings from this and another study [338] suggests that patients who respond to CFT may accept psychological factors, such as fear, stress and low mood, as factors underlying their LBP, which may explain why they were happy to complete assessments in these areas. UPC patients were more likely to continue to explain their LBP through biomedical terms, such, *'disc degeneration'* after the intervention. Psychological factors are recognised as important determinants of outcome of persistent LBP [49, 122] and are recommended

as part of a core outcome set in persistent pain clinical trials [276]. Therefore, such measures need to be collected in a sensitive way that is acceptable to patients and will require careful explanation within the participant information sheet in a future definitive trial.

The response rates to the PROM's at three and six month follow-up (80% and 71.6% respectively) are similar to the response rates reported in two other RCT's of CFT [292, 294]. A reduction in the number of returned questionnaires at six months in the present study may suggest an element of questionnaire fatigue, problems with completion or other unknown factors such as the influence of the COVID-19 pandemic. A future trial could learn from a successful large scale LBP trial in the UK that reported an 89% response rate to the primary outcome using short messaging services [397]. Another study reported 84% retention at 12 months for people with persistent LBP when PROM's were administered online [268]. Indeed, electronic administration of the PROM's was a recommendation made by the majority of patients in the process evaluation and would become part of a definitive trial.

5.1.5 Objective 5: To determine if the interventions were delivered to fidelity during the feasibility RCT.

This objective was achieved in Chapters three and four using three differing methods to assess treatment fidelity. Intervention fidelity refers to the degree to which an intervention was delivered as intended [348] and was assessed within this study according to the National Institute of Health Behaviour Change Consortium framework for behaviour change in clinical trials [374].

Provider training, treatment delivery, treatment receipt and enactment was evaluated in three ways. Firstly, the content of the physiotherapists' clinical notes were audited against predefined fidelity checklists [373]. Secondly, the physiotherapists delivering CFT and UPC provided video recordings of one new patient each that were also evaluated against the same fidelity checklists. Thirdly, the physiotherapists' and patient participants' experiences and perceptions of the interventions were explored qualitatively in the process evaluation (Chapter four).

The CFT training programme gave the physiotherapists the capability to deliver CFT as intended within the feasibility RCT. CFT training was described as a career changing experience by the physiotherapists that provided them with an enhanced skillset to effectively manage the complexity of persistent LBP (Chapter four). This finding was validated through the notes audit and video analysis with the *a priori* thresholds being achieved for treatment fidelity. The perceptions of patient and physiotherapist participants' when describing their experiences of CFT within the trial provided clear descriptions of the CFT interventions and matched those described in the protocol and published literature [72], offering further support that CFT was delivered to fidelity. Examples include the use of behavioural experiments targeting feared and avoided functional tasks (described by both patient and the physiotherapist participants) and patient participants described a new understanding of LBP reconceptualised as multidimensional biopsychosocial disorder. Furthermore, the positive clinical outcomes observed in the feasibility RCT suggest that CFT was delivered well within the trial.

Previous CFT training programmes have been estimated to total more than 100 hours for experienced clinicians to achieve competency [327] which has obvious resource and cost implications. The findings of the feasibility RCT support the view that a lower intensity CFT training programme (circa 50 hours) is feasible to be delivered in the NHS and although not estimated, this would likely be delivered at a lower cost. This is also an encouraging finding for the future implementation of CFT within the NHS which will be of interest to physiotherapists, service managers and commissioners of services.

While the content and delivery of the UPC training met the physiotherapists' needs there was evidence through the notes audit, video analysis and from the physiotherapists themselves, during the focus group, that UPC was not always delivered as intended and not always consistent with the recommendations of LBP clinical guidelines [27]. This included the lack of screening for psychosocial factors, failure to identify patient-centred goals and the low utilisation of manual therapy and the back rehabilitation class as core components of UPC treatment. Instead, alternative interventions, not described in the UPC protocol, included observed and documented examples of motivational interviewing and graded exposure to feared and avoided movements which were also confirmed through the accounts of UPC physiotherapists in the process evaluation in Chapter four. These findings provided evidence of intervention drift and contamination with CFT.

This may have been because the UPC protocol may not have adequately captured contemporary physiotherapy practice for LBP and that the UPC physiotherapists themselves eluded to sources of contamination with CFT

through access to online resources, social media and regular talk of CFT within their clinical environments.

The last survey of physiotherapy clinical practice for LBP in the UK was more than twenty years ago [264]. Since this time more than 1500 RCT's, 481 systematic reviews and 34 clinical practice guidelines have been published reporting a plethora of conservative interventions for LBP (PEDro database. Accessed 16th November 2020) [434]. This significant increase in physiotherapy LBP research coupled with advances in pain neuroscience understanding during this time [71] presents a significant challenge for clinicians to translate this mass of evidence into clinical practice.

As described in Chapter one, efforts to develop models of care, including subgrouping methods and psychologically informed physiotherapy approaches for persistent LBP have failed to integrate the heterogeneity of LBP, resulting in modest outcomes for patients [194, 277]. Furthermore, despite long-standing recommendations for physiotherapists to adopt a biopsychosocial approach to LBP it is clear that their previous training does not adequately prepare them to do so [282]. Without a validated framework and adequate training to assess and treat people across multiple biopsychosocial dimensions of LBP, physiotherapists are left to integrate interventions based on their prior knowledge and experience. This may be another reason why the UPC intervention, delivered in the feasibility RCT, differed to that described in the protocol. Further research is required to quantify and describe the components of contemporary physiotherapy

practice that will inform the development of the UPC protocol for a definitive trial.

5.1.6 Objective 6: To determine adherence rates to the interventions during the feasibility RCT.

Intervention adherence in both groups was measured through attendance to scheduled appointments and a paper-based diary where patient participants recorded the frequency they completed their prescribed home exercise programme. Attendance rates to scheduled physiotherapy appointments surpassed the pre-defined threshold for feasibility (>80%) with 90% of all appointments attended by patient participants (Table 11, page 138). Very few appointments were missed without prior notice of cancellation. This may have been because participants were enrolled in a clinical trial.

Only six patient participants completed and returned their self-reported exercise diaries meaning that adherence to the prescribed home exercise programmes was not sufficiently measured. Although patient participants provided accounts of completing their home exercise programmes in the process evaluation (Chapter four), social desirability may have influenced these responses.

It was unfortunate that the smartphone application described in the original protocol to measure exercise adherence, through an accelerometer and a self-reporting feature, was unable to be used because of delayed payment for licences by the sponsor. A future study should once again attempt to trial the practicality and feasibility of using this type of technology to measure physical activity. In addition, collecting data that has been associated with

diurnal fluctuations in pain such as sleep quality, social engagement, perceived levels of stress and mood may also be important to capture in a future trial.

5.1.7 Objective 7: To determine the type and frequency of adverse events.

This objective was achieved in Chapter three. No adverse events (AE) or serious adverse events (SAE) were reported in the feasibility RCT, suggesting that both interventions were delivered safely to patient participants. This is consistent with two studies that have reported that AE's and SAE's in musculoskeletal physiotherapy practice occur infrequently and when reported are usually because of muscle soreness after exercise or a temporary exacerbation in pain [435, 436]. However, a systematic review of biopsychosocial interventions for persistent LBP reported that only three out of the seven included studies reported AE's and SAE's [437], meaning they may have previously been under recognised.

Consistent with the findings of the feasibility RCT, no AE's or SAE's have been reported in other RCT's of CFT [292, 294]. Confirmation that CFT is safe to deliver in UK physiotherapy services may also alleviate some of the concerns, reported in Chapter two and elsewhere [280, 350] that physiotherapists describe when addressing psychological factors, particularly with distressed patients.

5.1.8 Objective 8: To determine the most suitable primary outcome measure and calculate the sample size for a definitive RCT

In Chapter three and four, the RMDQ was determined as the most suitable primary outcome measure for a future definitive RCT, meeting objective 8 of this study. This decision was reached based on good utility of the RMDQ as observed in the feasibility RCT (the questionnaire was quick to complete and there were no missing items at all time points) and acceptability to patient participants as described in the process evaluation in Chapter four. Sample size calculations were completed for a future cluster RCT based on the moderate effect size (d=0.58) for the RMDQ at six-months for a number of constraints (Chapter three and Appendix P).

The strong psychometric properties reported (Table 8) and the widespread use in other large scale RCT's of psychologically informed physiotherapy interventions [233, 267, 268, 272, 273] further justifies the choice of the RMDQ as the primary outcome measure in a future study. The use of the RMDQ in a definitive study will allow comparison between these previous studies and assist the formulation of future guideline recommendations which will be of benefit to clinicians, researchers and commissioners of services.

5.1.9 Objective 9: To determine the acceptability of the research processes and interventions to patient and physiotherapist participants

The process evaluation (Chapter four) confirmed that the research processes (recruitment, randomisation, appointment processes and PROM's) within the feasibility RCT were acceptable to patient and physiotherapist participants. This was also confirmed through achieving objectives 2, 3, 4, 8 and 10.

The CFT and UPC training programmes were also described as being acceptable to the physiotherapists. The CFT training programme provided the physiotherapists with the necessary knowledge, skills and confidence to deliver CFT to fidelity within the feasibility RCT (Objective 5). The perceptions of the mechanisms of effect of CFT were evaluated through the experiences of patient participants and CFT trained physiotherapists providing novel insights into how CFT might work and be implemented within the context of the UK NHS (Objective 10).

5.1.10 Objective 10: To explore any indication of effectiveness of CFT

Although this was a feasibility study, not powered to detect between group differences, the clinical outcomes observed are worthy of discussion as there was an indication that CFT showed a larger magnitude of effect in comparison to UPC across all PROM's and time points. At six-month follow-up moderate and large between group effect sizes were reported for disability (RMDQ), pain intensity (NPRS), fear avoidance beliefs (FABQ), risk of LBP persistence (STarT Back tool) and global rating of change (GRC) in favour of CFT (Table 13).

These findings are consistent with a number of uncontrolled studies [287-291, 306] and two RCT's [292-294] that report changes following CFT are multifactorial and may reflect the complex interplay between biopsychosocial factors in persistent LBP. The findings of the feasibility RCT and process evaluation are now discussed in relation to this previous research and the multiple theoretical perspectives underpinning CFT.

The Common Sense Model of self-regulation (CSM) [301] provided a theoretical perspective of how patient participants LBP beliefs may have changed following CFT (discussed in detail in the process evaluation, Chapter four, section 4.4.2). The CSM has also been linked to the Fear Avoidance Model (FAM) of chronic pain [124] and used to describe the process of change following CFT [306]. For example, it is logical for a person who believes that their LBP is caused by a damaged structure (e.g. disc bulge) to protect their back and avoid activities that are provocative.

The FAM [38, 136] describes a vicious cycle of pain and disability whereby a negative representation of LBP, interpreted as sign of damage or threat, results in a cascade of unhelpful thoughts (e.g. catastrophising), behaviours (e.g. avoidance, hypervigilance) and emotional responses (e.g. low mood) that maintain pain and disability (Figure 2, Chapter one, page 14) [38, 136].

CFT adopts an experiential learning approach to behaviour change by using guided behavioural experiments that are intended to disrupt the negative feedback loop of fear and avoidance [72]. Guided behavioural experiments are proposed to work on the principle of graded exposure and inhibitory learning theory [72, 299, 438]. They are used to evaluate an individuals' response to reducing sympathetic arousal and abolishing safety behaviours through graded exposure to feared, avoided and/or provocative postures, movements and functional activities. This is achieved through relaxed diaphragmatic breathing, body relaxation and awareness and control of movement during these functional tasks [72]. Gradually exposing patients to their feared, painful and/or avoided tasks in this way frequently enables

patients to control their pain and violates expectations that pain is a sign of harm or damage. Repeated exposure allows these activities to be generalised in different contexts and situations which may lead to the formation of new beliefs and memories [299] and in turn disrupts the vicious cycle of fear and avoidance for patients [288]. A single case experimental design study showed that reduced LBP disability occurred at the same time as changes in pain intensity, pain control and fear following CFT. It was hypothesised that experiential learning, facilitated by behavioural experiments was a key mechanism of behavior change which disrupts an individuals' *'pain schema'* [288].

The findings of the feasibility RCT support these theoretical perspectives as evidenced by large mean reductions in fear avoidance beliefs, pain catastrophising, and disability which are all key components of the FAM [38, 136] and targets of CFT. Indeed, fear [133, 139] and catastrophising [439] have been identified as mediators of pain and disability following an episode of LBP and therefore represent an important target of treatment.

Modifying pain and safety behaviours during functional tasks through behavioural experiments was viewed as a powerful communication tool by the physiotherapists that provided opportunities for patients to reconceptualise beliefs as described in the process evaluation using CSM (Chapter four). This finding is also supported by physiotherapists experiences in two other qualitative studies of CFT which reported that pain control appeared to positively influence patients' beliefs and was a facilitator of patient engagement [281, 338]. This is an important finding that contrasts

with all other models of psychologically informed physiotherapy and pain management approaches which view pain as immutable [253, 266].

The findings of Chapter four suggest that behavioural experiments are a fundamental component of CFT that are a conduit to changing beliefs and behaviours through a number of mechanisms including gaining control over pain, reduced fear and effective communication. These factors appear to facilitate self-management through developing an internal locus of control and increased self-efficacy. The theories of locus of control and self-efficacy have been discussed in detail in Chapter four.

Communication and therapeutic alliance following CFT were discussed in detail in Chapter four. Briefly, the large effect sizes for positive therapeutic relationships observed in the feasibility RCT and described in the process evaluation suggests that the communication strategies used (open and reflective communication style, based on the theory of motivational interviewing) [305] by the CFT physiotherapists were effective.

In summary, it is reasonable to suggest, based on the findings of this PhD and previous research, that CFT is not aligned to one, but underpinned by a number of theoretical perspectives that integrate a multiplicity of biopsychosocial factors simultaneously.

Overall, CFT appeared to be a clinically effective intervention (Chapter three) that was acceptable to patient participants (Chapter four). This was reinforced by patient participants descriptions of achieving independent self-management (Chapter four) and the high levels of satisfaction with CFT (Chapter three). The physiotherapists also described feeling more satisfied in

their work following CFT training (Chapters two and four). Work satisfaction in the NHS has been linked to improved staff morale, motivation, reduced work absenteeism, staff retention and improved patient outcomes [440-444].

In contrast to other combined physical and behavioural interventions, CFT is delivered by a single professional and has shown significant cost savings in comparison to a multidisciplinary pain management programme in Denmark [289]. As described in Chapter one, NICE LBP guidelines [27], the National Low Back and Radicular Pain Pathway [243] and NHS RightCare [257] all support the implementation of combined physical and psychological programmes for people with persistent LBP in the NHS but so far very few services have been commissioned [309]. The escalating global disability levels and costs associated with persistent LBP, also described in Chapter one, suggests that current interventions are inadequate and should be a priority for investment for future research [1]. However, a recent analysis of the Global Burden of Diseases study 2019 reported an absence of rehabilitation services for people with persistent LBP [445]. CFT offers a potential solution to this problem but requires investment in a fully powered trial to fully determine the clinical and cost-effectiveness within the NHS and implementation studies beyond this.

5.2 Strengths and limitations

The strengths and limitations of each separate study have been provided within each chapter, this section will provide an overview of the main aspects.

The engagement of multiple stakeholder perspectives (patients and physiotherapists) in a sequential step wise manner, using a mixed methods design that followed the Medical Research Council Framework for developing and evaluating complex interventions [197] is a notable strength and novel aspect of this thesis.

Chapter two was the first ever study to explore the barriers and facilitators to CFT within the UK NHS through the perceptions and experiences of physiotherapist and patient participants. A number of novel findings from this study were identified and used to inform the development of the protocol for the feasibility RCT (Chapter three). Importantly, short appointment duration and availability of follow-up appointments were notable barriers to effective delivery of CFT within the NHS. Based on these findings, appointment times were increased and follow-up appointments were ring-fenced during the feasibility RCT. While increased time and appointment availability were valued by the physiotherapists and patient participants (Chapter four), this view may not be shared by other care providers and may be a challenge to delivering CFT in a future RCT in different NHS trusts. Careful negotiation with service providers, managers and research departments may be required in the planning of a future trial [446].

The physiotherapists interviewed in Chapter two described the workshop style of training as a suitable introduction to CFT but that they would require peer support and mentorship with a CFT educator to develop skills further. In response, the CFT training programme was expanded for the feasibility RCT (Chapter three) to include six months of practice based learning with peer support and mentorship sessions provided by a CFT educator. The process evaluation (Chapter four) confirmed that this additional support was a fundamental component of the CFT training programme that facilitated self-reflection and learning for each physiotherapist.

The CFT training programme, completed in preparation for the feasibility RCT, appeared to be comprehensive and of sufficient intensity for the physiotherapists to demonstrate competency and to maintain changes to their clinical practice, as demonstrated by the high levels of treatment fidelity within the feasibility RCT (Chapter three). This is a key finding of the thesis. If sustained implementation is not achievable then it is unlikely that CFT would be feasible for delivery within the NHS and therefore would not represent good value for future research or clinical investment.

The comprehensive assessment of treatment fidelity, measured using three separate methods, is another notable strength of the thesis. Few studies have reported the methods used to assess treatment fidelity in RCT's that have evaluated psychologically informed physiotherapy interventions for persistent LBP [437]. The high levels of treatment fidelity observed in this study means that the CFT training programme will require few refinements and is practical to be delivered in a future fully powered trial.

It must be acknowledged however, that the physiotherapists who delivered CFT were experienced clinicians and were not novices to the approach, having attended at least one CFT workshop prior to completing formal training. The training requirements may differ between those with and without prior experience of CFT, which should be a consideration in the planning of a future trial. For example, a successful CFT training programme provided an additional 17 hours of problem based learning sessions to physiotherapists novice to the approach [281].

While attempts were made to separate the UPC and CFT physiotherapists by locating them on separate hospital sites, there was evidence of possible contamination which is a weakness of the trial being completed within one NHS trust. The UPC physiotherapists were also aware that they may have modified their behaviour and content of the treatment delivered as a result of direct observation for the purposes of treatment fidelity assessment in the trial. The CFT physiotherapists were perhaps more familiar with direct observation as they had been recorded on several occasions during training. In a future study, UPC training should include an equal number of video recorded sessions, prior to fidelity checking, to engender familiarity and confidence in the process, making the study less susceptible to the Hawthorne effect [447].

Despite these limitations, the clinical findings of the feasibility RCT identified larger between group mean differences in favour of CFT for all of the collected of the PROM's at three and six-month follow-up, which suggests contamination may not have significantly influenced the results.

The clinical outcomes were reinforced by the perceptions of the patient participants and physiotherapists through the process evaluation in Chapter four. Importantly, the process evaluation provided insights into how and why the observed changes within the RCT may have taken place and gave an indication of the perceived mechanisms of effect of CFT in this study.

A novel aspect and strength of Chapter four was the application of the CSM of self-regulation [301] to the process evaluation data. By applying the CSM, clear differences were identified between the interventions such as how patient participants made sense of their LBP and the proposed mechanisms that brought about change (therapeutic alliance and behavioural experiments). Overall, by integrating quantitative and qualitative methods and comparing and contrasting patient and physiotherapist participants experiences throughout the thesis the validity of the findings may have been strengthened [448, 449].

Other methodological strengths of the thesis include the robust methods of data collection and analysis with a clear audit trail evident for both qualitative studies (Chapters two and four). The involvement of both patient and physiotherapist participants and in each qualitative study is unique. To the authors knowledge no prior qualitative studies of psychologically informed physiotherapy have simultaneously been grounded in both the voices and experiences of patients and their treating physiotherapists. Furthermore, qualitative research of psychologically informed physiotherapy interventions have not previously utilised PPI representatives as research partners in data collection and analysis. The role of a PPI representative in the data collection

and analysis was another novel component of this PhD which may have strengthened the credibility of the findings.

The position of the researcher (CN) should also be considered within the context of these studies. CN is a recognised CFT practitioner having demonstrated competency in delivering the intervention. This prior knowledge and experience of CFT may have biased the analysis. However, for balance the two qualitative studies involved blind coding of the transcripts by researchers with no prior knowledge or experience of CFT which may strengthen the credibility and trustworthiness of the findings. Furthermore, reflexive diaries were used to bring awareness to the researcher's (CN) prior knowledge, attitudes and beliefs regarding LBP and CFT in an attempt to minimise any bias during data collection and analysis. Both qualitative studies also contained large sample sizes and achieved data saturation. An imbalance between responders and non-responders to the interventions was a weakness of both qualitative studies. Future research should attempt to gather the experiences of non-responders to the interventions and those lost to follow-up to redress this balance.

In the feasibility RCT, in addition to concealed allocation and blinded assessments, missing data was appropriately dealt with by using intention to treat analysis, thus reducing the potential for bias in estimating the between group treatment effects [356]. A limitation of the feasibility RCT was the lack of funding for a health economist which meant that rehearsal of cost effectiveness analysis was not performed and will need to be incorporated into the protocol for a future study.

5.3 Recommendations

Before a definitive fully powered RCT to evaluate the clinical and cost-effectiveness CFT in comparison to UPC can be completed a number of recommendations are made. Firstly, a full trial should include an internal pilot, or stop go criteria, to monitor protocol adherence and address some of the uncertainties regarding feasibility before proceeding to definitive trial [450]. Secondly, a definitive trial should employ a cluster randomised design to mitigate any risk of contamination between the study arms [451]. A future trial should also employ a research assistant for the day to day study management, a clinical trials unit for distance randomisation and data management and employ retention strategies to limit attrition in a future study (e.g. text message reminders, electronic administration of PROM's). As recommended in Chapter two and delivered within the feasibility RCT the initial consultation time should be for one hour and follow-up appointments for 30 minutes in a future trial.

A future internal pilot study should therefore evaluate the following aspects of feasibility;

- The feasibility of recruitment in different NHS trusts.
- Determine the feasibility of an alternative PROM that measures fear and avoidance beliefs.
- Eliminate repetitive questions, where possible from PROM's.
- Complete regular treatment fidelity checking using video analysis in the UPC intervention.

- Extend the intervention period up to four months with booster sessions as required following discharge.
- Evaluate the feasibility of objectively measuring adherence to the prescribed exercise programme, physical activity levels and other biopsychosocial factors know to influence diurnal variations in pain (e.g. daily sleep, levels of stress, mood and social engagement), using a smartphone application.
- Evaluate the feasibility of collecting data that will permit economic analysis.

Evaluating these additional aspects of feasibility as well as the clinical and cost-effectiveness of CFT in a multi-centre trial will require further understanding of what, why and how the intervention may or may not work and the context in which it is delivered (e.g. different NHS trusts, geographical locations and populations). Implementation theory should underpin this future research. The Theoretical Domains Framework [452] and Consolidated Framework for Implementation Research [453] would be appropriate models to support this further evaluation. Both frameworks serve to synthesise existing implementation theories and the context in which complex interventions may be evaluated in the real world. For example, the CFIR incorporates 39 theoretical implementation constructs over five domains including the characteristics of intervention being implemented, the inner (e.g. cultural context) and outer setting (e.g. political, economic or social context), the individuals involved and how the process of implementation may be achieved [453].

Given that intervention drift, contamination and low levels of treatment fidelity were observed in the UPC group, further research prior to a definitive trial should also seek to define the core components of contemporary physiotherapy for persistent LBP. A clinical practice survey of UK physiotherapists would be an appropriate and timely method as it has been more than twenty years since the last published account [264]. By defining UPC, a more robust training programme with supporting manual to operationalise core components of contemporary practice could be developed and used to monitor treatment fidelity [148].

5.4 Reflections

There are a number of key personal reflections worthy of further discussion. I came into this PhD with a mind-set of a clinician, with pre-existing beliefs, attitudes, knowledge and experiences of working with people persistent LBP and positive experiences of CFT. I have the tendency to analyse information from a clinical perspective and not always through the eyes of a researcher, which meant I may not have always been in clinical equipoise. However, throughout this journey and in the thesis reflexivity was encouraged and nurtured through my supervision sessions and academic writing and was explicitly embedded in the research methods used. In my future clinical academic career I will continually need to reflect on my role as a researcher and clinician to bring conscious awareness to any influence of bias.

I found the data in Chapter two the most difficult to analyse because of the volume (18 interviews totalling more than 180,000 words) and the complexity of perspectives provided by both patient and physiotherapist participants

before and after CFT. On reflection, the use of an implementation framework such as the Theoretical Domains Framework [452] or the CFIR [453], may have assisted interpretation and conceptualisation of the data in this study [454]. However, Framework Method was particularly useful for organising the data [341].

Regarding study management, this is the first time I have been responsible for managing a study budget. In hindsight I was perhaps naïve to think that with my own budget that funds would be released by the NHS sponsor in time to pay for study items. Delayed payments meant that reimbursement for work undertaken by the PPI representative was not completed on time, that the study protocol was registered retrospectively and that licenses for the smartphone application, intended to measure exercise adherence, were not released prior to the first patient participants being enrolled in the feasibility RCT. This meant that the scope of target journals for the feasibility RCT protocol was limited and that an alternative paper-based exercise diary was used that did not sufficiently measure exercise adherence. Developing closer working relationships with the sponsors research accountants may have eliminated some of the problems encountered.

5.5 Conclusions

This PhD thesis has confirmed that a future fully powered RCT that will determine the clinical and cost effectiveness of CFT in comparison to UPC for NHS patients with persistent LBP is feasible and could be completed. The barriers and facilitators to CFT in the context of the UK NHS have been established. A lower intensity CFT training programme was sufficient to train

physiotherapists to competence and to deliver CFT to fidelity in the NHS. The feasibility RCT and process evaluation confirmed that the research process and interventions were acceptable to patient participants and physiotherapists and there were no safety concerns. While recognising that this was a feasibility study, the reported between group differences and moderate to large effect sizes across a range of outcomes suggest a signal of clinical effectiveness in favour of CFT at both three and six month follow-up and warrants further evaluation. Novel and original insights into the implementation of and perceived mechanisms of effect of CFT have also been gained within the context of the UK NHS. For a future definitive study, a multicentre cluster RCT design, incorporating an internal pilot study, is recommended.

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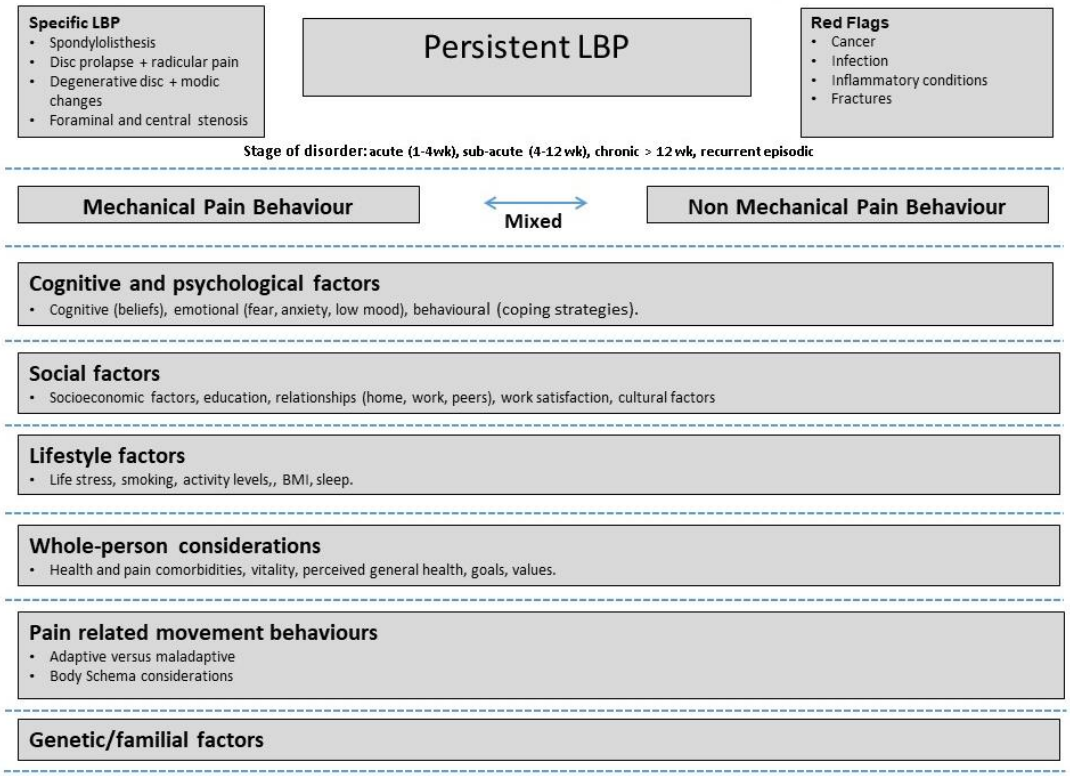
Appendices

Appendix A: CFT multidimensional clinical reasoning framework



O'Sullivan et al 2015 [285]

Appendix B: Ethics approval qualitative study chapter two

NHS
Health Research Authority
NRES Committee North West - Greater Manchester South
HRA NRES Centre Manchester
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0161 625 7830

21 March 2014

Mr Christopher Newton
Extended Scope Physiotherapist
University Hospitals of Leicester NHS Trust
Physiotherapy Department, Balmoral Building Level 0
Leicester Royal Infirmary
Leicester
LE1 5WW

Dear Mr Newton

Study title:	**A phenomenological study of patients' and physiotherapists' experiences of a novel multidimensional behavioural intervention for non-specific chronic low back pain.**
REC reference:	**14/NW/0189**
IRAS project ID:	**151132**

The Proportionate Review Sub-committee of the NRES Committee North West - Greater Manchester South reviewed the above application on 20 March 2014.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Acting REC Manager Miss Nicola Burgess, nrescommittee.northwest-gmsouth@nhs.net.

Ethical opinion

The Proportionate Review Committee reviewed the application.

It was noted that the interviews are unlikely to cause distress. The Committee were happy to see that the appropriate lone working policy will be adhered to.

There was discussion around the confidentiality of the data. The Committee acknowledged that the appropriate measures were in place to preserve the participant's anonymity.

It was raised as an issue that travel expenses were not being made available to participants but acknowledged that this has been addressed by the researcher's willingness to travel to the participants home to undertake the interviews.

The information sheet was discussed. The Committee's only concern revolved around the section 'What will the study involved'. Though the interview time is specified, the time taken to undergo the informed consent process is not. It was agreed to request a sentence detailing the time that this will take prior to the interview. Under the section ' Who has reviewed the study?', it was highlighted that GM South should be detailed.

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of

the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

Conditions of the Opinion

Participant Information Sheet

1. Under the section detailing what participation will involve, please add a sentence to reflect that time will be required for the informed consent process to take place prior to the interview.

2. Under the section 'who has reviewed this study?' Please detail it has been reviewed by the GM South REC.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*	
Covering Letter		11 March 2014	
Interview Schedules/Topic Guides	1	25 February 2014	
Investigator CV	Chris Newton	11 March 2014	
Letter of invitation to participant	Patients V1	25 February 2014	
Letter of invitation to participant	Physiotherapist V1	25 February 2014	
Other: Clinical Academic Internship Formal Letter		27 January 2014	
Participant Consent Form	1	25 February 2014	

Participant Information Sheet: Patients	1	25 February 2014	
Participant Information Sheet: Physiotherapist	1	25 February 2014	
Protocol	1	25 February 2014	
REC application	1	13 March 2014	
Referees or other scientific critique report	UHL Sponsor Peer Review	05 March 2014	
Summary/Synopsis	Study Gant Chart V1	13 March 2014	

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

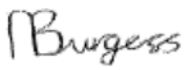
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
information is available at National Research Ethics Service website > After Review

14/NW/0189	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely



PP:
Professor Sobhan Vinjamuri
Chair

Email: nrescommittee.northwest-gmsouth@nhs.net

Copy to: *Carolyn Maloney, University Hospitals of Leicester NHS Trust*

NHS
Health Research Authority

National Research Ethics Service

NRES Committee North West - Greater Manchester South
HRA NRES Centre Manchester
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Manchester
M1 3DZ

Telephone: 0161 625 7815
Facsimile: 0161 625 7299

26 March 2014

Mr Christopher Newton
Extended Scope Physiotherapist
University Hospitals of Leicester NHS Trust
Physiotherapy Department
Balmoral Building Level 0
Leicester Royal Infirmary
Leicester
LE1 5WW

Dear Mr Newton

Study title: **A phenomenological study of patients' and physiotherapists' experiences of a novel multidimensional behavioural intervention for non-specific chronic low back pain.**
REC reference: **14/NW/0189**
IRAS project ID: **151132**

Thank you for your email of 22 March 2014. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 21 March 2014.

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering Letter		22 March 2014
Participant Information Sheet: Patient	2.0	22 March 2014
Participant Information Sheet: Physiotherapist	2.0	22 March 2014

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering Letter		11 March 2014

Covering Letter		22 March 2014
Interview Schedules/Topic Guides	1	25 February 2014
Investigator CV	Chris Newton	11 March 2014
Letter of invitation to participant	Patients V1	25 February 2014
Letter of invitation to participant	Physiotherapist V1	25 February 2014
Other: Clinical Academic Internship Formal Letter		27 January 2014
Participant Consent Form	1	25 February 2014
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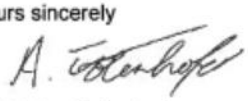
Participant Information Sheet: Physiotherapist	2.0	22 March 2014
Protocol	1	25 February 2014
REC application	1	13 March 2014
Referees or other scientific critique report	UHL Sponsor Peer Review	05 March 2014
Summary/Synopsis	Study Gant Chart V1	13 March 2014

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

14/NW/0189 **Please quote this number on all correspondence**

Yours sincerely



Dr Ashley Totenhofer
REC Manager

E-mail: nrescommittee.northwest-gmsouth@nhs.net

Copy to: Carolyn Maloney - University Hospitals of Leicester NHS Trust

Appendix C: Interview guides study one (Chapter two)

Interview guide for Cognitive Functional Therapy intervention participants

Opening questions – History of low back pain

- Could you me tell the story about your low back pain? When it started, how it started, how long you have had it for etc.?
- Did it become a problem for you? If so prompt further.
    - When did it become a problem for you? How did you know?
    - How did affect your life?

Introductory questions – Beliefs and previous treatment

- What did you understand to be the cause of your low back pain before you started this course of physiotherapy (CFT)?
    - Where do you think these ideas/beliefs came from?
    - How did this affect you?
- Who have you seen about your low back pain before you came to Physiotherapy this time?
- What treatments have you previously had for your low back pain?
    - For how long did you have these treatments?
    - Did they have any effect? If so, what were the effects? How long did these effects last?
    - Did these treatments have any influence on;
        - your ability to cope with your low back pain?
        - your ability to control/manage future episodes/flare ups.
        - your ability to move you lower back and use your body normally?
        - your capacity to perform everyday functional tasks (sitting, walking bending, lifting etc.)
        - your ability to perform activities of daily living (washing, dressing etc.), household chores or your work.
        - your lifestyle such as sleeping patterns, levels of exercise, sports and hobbies.
        - your confidence in your lower back and your ability to do these things you have mentioned?
        - your quality of life
- Did you experience any difficulties in accessing treatment? (e.g. waiting lists, access to referral?
- Prior to commencing this new approach, what were you expecting to happen?
    - What were your expectations of physiotherapy at this point? Treatments? Future outcomes?

Key questions CFT Intervention

- How did you find this new approach (CFT)?
- Was it what you expected? If not, what were you expecting?
- Did you encounter any difficulties or problems in with this treatment?
- What do you understand this treatment to be?
- Did it have an effect?
    - If not, why do you think it did not? What, if anything, was missing?
    - If so, what was the effect? What aspects did you find helpful?
    - Has this approach influenced,
        - your understanding of why you have/have had low back pain? Prompt for current beliefs.
        - how you cope with low back pain?
        - your ability to control pain or manage future episodes/flare-ups?
        - your ability to move your lower back and use your body normally?
        - your ability to perform everyday functional tasks (sitting, bending, lifting etc.), activities of daily living (washing, dressing etc.), household chores and your work.
        - your lifestyle such as sleeping patterns, levels of exercise, sports and hobbies.
        - your confidence in your lower back and your ability to do these things?
        - your future outlook and your prognosis?
        - your quality of life?
- How do you feel you got on with the therapist delivering CFT? What kind of relationship did you have?
    - Did they listen to you and to any concerns that you had?
    - Do you feel you were given enough time to speak and get your points across?

- Were explanations given to you in a language that you could easily understand?
- Was the educational material relevant to you? (e.g. outlining the vicious cycle of pain and functional exercises) If so, how was it useful?
- Do you think the therapist understood how this problem was affecting you?
- Would you like to make any further comments on the style of communication they used?
- Do you think it is important to develop a positive relationship with your physiotherapist?

- What do you think is the most important thing for a physiotherapist to remember when treating people with low back pain?

Ending questions

- How would you now summarise what is/was the cause of your pain?
- How do you feel about the future with regards to your lower back?
- How confident are you that you can cope with your pain and live a normal life? If so, why?
- What would be you recommendations/top tips for somebody experiencing low back pain?
- Is there anything else you would like to add?

Interview guide for physiotherapists

Opening questions

- Could you tell me about your current role and the qualifications you hold?
    - How long qualified?
    - Post graduate training/qualifications, where?
    - Years of experience
    - Which care setting do you work? Private, NHS, primary or secondary care?
- What types of conditions do you see and treat?
- How much training have you had in managing NSCLBP?
- Can you tell me about your previous experience of treating NSCLBP?
- What approaches have you previously used to treat NSCLBP?
- Has your approach to practice changed at any points during your career? Prompt with the growing evidence base, rise in treatment options available (exercise interventions, manual therapy, acupuncture, CBT etc.) and a variety of approaches available to manage NSCLBP e.g. Maitland, McKenzie, Edwards, Stability etc.
    - Have you integrated any these approaches into your clinical practice? If not why not?
    - If you have, on what basis have you done this? (Prompt with evidence, experience, beliefs, confidence etc.).
- How do you feel about treating people with complex persistent pain problems, where psychological issues such as distress, anxiety, depression, may be a contributing factor?
    - Have you ever had any previous training in managing psychological aspects of pain? If so, further prompts, type, level and amount of training.
- In your opinion, what factors do you feel contribute to a low back pain problem?
- Have you any personal experience of low back pain? If so, what do you believe was the cause of your back pain?

CFT questions

- Have you attended a previous CFT workshop(s)?
    - How many?
    - Why did you attend?
    - Did the workshop meet your expectations?
- Alternatively, have you been specifically trained by Professor Peter O'Sullivan in CFT?
    - When, where and how many hours of training?

Key questions

- When did you first become interested in CFT?

- What specifically interested you about this approach?

- When did you first apply CFT to your clinical practice?
- Did it change your clinical practice? If so, how?
- What do you see are the core elements of CFT?
    - Prompts for thoughts around cognitive, psychological, social, physical, lifestyle, neurophysiological?
- How transferable did you find this approach to your clinical practice?
- Were there any aspects of this approach that you found easy to implement?
- Were there any aspects of this approach that were difficult to implement?
- What components are required, in your opinion, to successfully implement CFT?
- Were there any barriers to applying this approach to your clinical practice?
- Does this approach differ to those previous approaches that you have been trained in or have knowledge of? If so how do you propose CFT differs? Are there any similarities?
- Do you think it is more of a hands off or hands on approach to managing LBP?
- What are your thoughts on the educational approach taken within workshops (live patient demonstrations, lectures, slides and work book provided).
    - Did this help to apply CFT to your practice? If so, how?
    - IS there anything that you think would be more helpful?
- Do you think that CFT is something that all musculoskeletal physiotherapists can 'do' after attending a workshop?
- How much training do you think is required to successfully implement CFT?

Ending questions

- Can you summarise how has CFT affected your clinical practice? (Only ask if it has).
- What advice would you give to a colleague trying to implement CFT to their practice?
- Is there anything else you would like to add?

Appendix D: Example of field notes

CFT Patient 2

Beliefs - knee caused back pain via gait, disc prolapse, misaligned vertebrae Uncertainty on cause, lack of explanation re diagnosis -Mechanical - needs a scan based on prior experience 'compressed discs in neck' pinching nerves. Surgery for pinched nerve in elbow Also from Physio - prominent vertebrae, reinforced structural belief = catastrophising 'is this the rest of my life' = dependence, lack of control - will need more regular physio Learned helplessness - have to adapt to my back pain putting socks on There are ways of sitting and doing things - created fear It's chronic 'it's not going to get better versus Acceptance - part if growing old.

Previous Referrals, GP, Sports Injuries, Physio x12-15, every 6/12 Treatment- failed intervention (electro acupuncture), postural strategies, manipulation, exercise, walking. Pushing disc back in against wall based on beliefs, Pilates - did nothing for my back, body belt to protect back to minimise flexion

No effect on function, fearful no confidence. Lifting - knew would be in pain for 2/7 based on prior experience. Couldn't bend, stopped badminton.

Psych factors - No mastery over pain symptom palliation, reacting to back pain no in control, Zero confidence but coping, low mood - fed up, acceptance/resignation/aged, catastrophising - 'this is it', Uncertainty. Coped by changing lifestyle - lives on hold, Became an old man, my life is now different. Lack of strategies to manage for the future and support once discharged leads to isolation, reliance learned helplessness

Unmet expectations based on prior experience - wanted something done (scan investigation) Fearful of movement - stopped badminton for the need to protect Impact on life - Gave up x 2 jobs Physical - Sitting >30mins

Accepting BPS - Understandingly looking for something different. Not cured but now got normal life, Controllability. Changed beliefs about back being resilience of structure, Optimism, future outlook.

Mastery over symptoms (I dug a pond) self-efficacy++++ mediated by mind set & experience of control - Can do anything I want to, Got life back can do stuff normally. Wouldn't let my back put me off anything 'new release' new lease of life'. Doubting is this really that good - will it come back based on prior experience. Dad doesn't have a bad back anymore. Quality of life - significant change Communication - we don't spend enough listening to patients - system not designed for effective comms. Normalisation - I have no picture if my back like a normal person.

Therapeutic alliance - listening, caring, empathy, taken seriously, understanding, interested, engaging, rapport, relationship building. Comradeship - taught me to think differently A lot closer to what I was feeling than any other Physio. Language - straight forward.

Therapeutic alliance is a prognostic indicator 'I would be where I am today, perhaps I wouldn't have listened if Physio was grumpy'. Climbing down from ivory tower be a human being in front of a human being - therapeutic alliance Previously consulting somebody with a problem rather than bring a human being who needed help. Needed fix opposed to help. Collaboration as partners in healthcare consumer versus provider Education - YouTube positive stories, confidence building.

CFT PT 5

Qualified 2001. No post graduate quali. Mixed acute/chronic. 40% chronic spinal pain.

Training in LBP - nil, no external courses. Manual therapy. Not teaching Clinical reasoning - all about how you do technique. CBT training - not linked to chronic pain - no influence over practice, no practical application for use in chronic pain. No exercise training, Acupuncture not to use in yellow flag people. Undergrad training - taught biomedical not to deal with psych

assessment **'big gap' Every Physio need training in bio psych factors and assessment Biomed approaches - lack specificity** Previous approached changed but effectiveness didn't change any Exercise - can have good effect, not specific or targeted.

Psych - frustration of when to apply techniques, loss of hope/ self-efficacy. Felt incompetent - I couldn't really help these people. Upset me. Then accepted that I couldn't change them. Further frustration. Outcomes - hit and miss with manual therapy, nags. Short-term effects. No lasting effects - adds to frustrations. Keep doing it but not getting desired results. Not very effective - because I skirted around important issues the heart of the issue. Difficult to treat people with back pain - did know how to manage people psychological, therefore treated with physical (use as quote). No bravery to address psych factors. Treatment was steered to Physio agenda

CFT - influenced by others who were enthusiastic in this approach during in-service training. Given hope of something new that could help people with LBP .CFT expectation - to be taught something revolutionary, evidence, Expectations were met and more.

Knowledge - hugely built my knowledge base, contrast of current management, early signs of evidence behind CFT.

It very different to what we have done before - communication 'tell you their story' that's the first big change. Gain confidence - therapeutic alliance. Communication had the biggest influence so far. Enthusiasm++ post course.

Barriers - time, something gets comprised, Should have one hour per patient. Questioning - works better, feels patient has better understanding of the problem build relationship better on the first session. Therapeutic alliance. Getting the hook is difficult - sometime feel like I'm feeling in the dark Feel stuck in the middle

Need more training to consolidate. Follow up training, one day follow-up – mentorship - movement analysis... It's not easy to let go of what you have been doing - changing biomed for BPS

Now not scared to let people talk- communication Confidence - don't get that heart sink, preconceived idea that I'm likely to fail. Feel like I've got a chance, hope & optimism. Explanation in two parts - cognitive & functional

Drip feed this approach, to undergrads, would confuse a lot of people. Everyone should be exposed to CFT and taught it. People pick up different aspects Similarities/differences - incorporate exercise and acupuncture but underpinned with CFT approach. Differences - individual treatment and communication (listening to people). Not more or less hands on/off. Would be easy for people not put hands on. Perception - people perceive it a woolly approach and not proper physiotherapy 'the physical'. Future training - smaller seminars, big environment intimidating, informal. See other people use the approach

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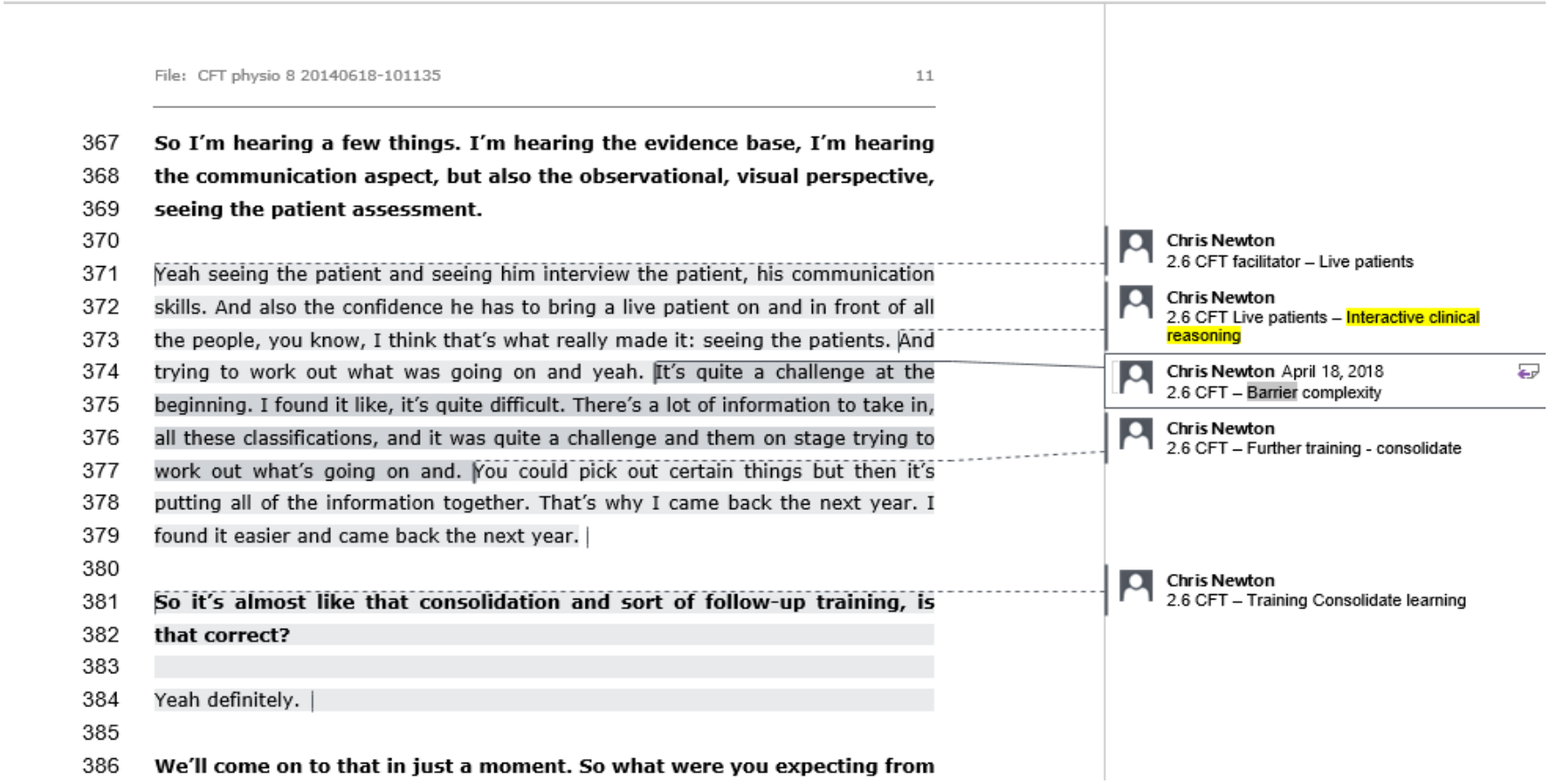
Appendix E: Coded transcript example



Appendix F: Analytic framework

Theme	Code	Sub-code & Comments
1. Healthcare system	1.1 Time	1.1a Communication 1.1b Clinical reasoning, 1.1c Appointment length & follow-up
	1.2 Access	1.2a Waiting lists, 1.2b Willingness of others to refer 1.2c Cost of specialist referral, 1.2d Delayed Rx
	1.3 Integrated system	1.3a Revolving door, 'still in the system of bad back'. 1.3b Mixed messages/biomedical diagnosis. 1.3c Passed around cohesion, not joined up
2. Therapists	2.1 Prior experience	2.1a Biomedical/medicalised 2.1b UG training 2.1c PG training, 2.1d Access, 2.1e Treatment, 2.1 f Career experience 2.1g Clinical reasoning
	2.2 Therapeutic alliance	2.2a Blaming/stigmatizing 2.2b Understanding/empathy/ communication 2.2c BPS acceptance, 2.2d Pain control 2.2e Self-management, valued activities, ,
	2.3 Self-efficacy, satisfaction, effectiveness	2.3a Self-efficacy 2.3b Satisfaction 2.3c Effectiveness
	2.4 Personal pain experience	2.4a Influenced beliefs 2.4b professional practice, treatment
	2.5 Therapist attributes	2.5a Mind set
	2.6 CFT	2.6a Facilitators (Enthusiasm, live patients) 2.6b Barriers (Training environment, complexity, not for every patient) 2.6c Self-efficacy
3. Patients	3.1 Prior experience	3.1a Lack of diagnosis/uncertainty 3.1b Poor therapeutic relationships

		3.1c Iatrogenesis, medicalised, 3.1d Low self-efficacy, 3.1e Fear 3.1f Catastrophising 3.1g Stigmatised, 3.1h Beliefs 3.1i Treatment 3.1j Expectations. 3.1k Impact on life and valued activities 3.1l Coping
	3.2 Therapeutic alliance	3.2a Understanding/empathy 3.2b BPS acceptance 3.3c Pain control 3.4d Self-management 3.5e Valued activities 3.6f Communication
	3.3 Self-efficacy, satisfaction, effectiveness	3.3a SE 3.3b Satisfaction 3.3c Effectiveness
	3.4 Attributes	3.4a Mind set
	3.5 CFT experience	3.5a Body awareness 3.5b Understanding, changing beliefs 3.5c Pain control 3.5d Educational material 3.5e Personlised, value/goal driven, integrated 3.5f Life impact 3.5g Mentorship
	3.6 Beliefs	3.6a Negative 3.6b Positive
	3.7 Diagnosis	3.7a Biomedical 3.7b BPS
	3.8 Psychological impact / social	3.8a Psych impact (mood, anxiety, stress, fear) 3.8b Social impact

Appendix G: Framework matrix (example)

2.6b Barriers	2.6c Therapist self-efficacy	2.6d Understanding	2.6e Changes in prof. practice	2.6f scope of practice	2.6g Mentorship, peer support	Other
Family life for CPD (247) WS environment - too big 'intimidating' (258) understanding movement behaviours/cataegories (268) Complexity (278) Doesnt view CFT as appropriate for all pain patients (315) only for failed cases 'people been around the mill' (at odds with all other interviwees) (471) not for hopeless cases no-one really, really wants (476) Training and understanding CRF (331) Percieved barrier - you cant teach this to novice clinicians (407-416) Need more experience, better reasoning (meta-cognition) and lack basic skills out of uni (407-416). Dont have life experience straight out of Uni, can teach theroy but not practical as no life experience (433) wouldnt be able to 'stand in their shoes'	Low self-efficacy 'tried CFt but didn't get very far' (285) felt patient was 'inappropriate' due to medications taking (morphine) - therefore took a different route (288)	CFT approach validated underlying belief systems not previously come to the fore or demonstrted in practice (345)	Recognised beliefs influenced behaviours (294) Putting a mirror up in front of patient' (294)	Recognising Psych factors but staying within scope NB (170) Changes in scope of practice around communication - learning new skills (297) Expanded role - comfortable with psych factors and distress and can manage them (341)	Need for mentorship (loses momentum) tops ups required (334) Top up training (451-454) Mindset 'can'tteach san old dog new tricks' (491)	Meeting patients exp[ectations difficult - cant change everyone got to be realistic in their goals (not patient specific) Physio centric goals (73-81) Managing expectations as a 'negotiation' of non-evidenced Rx's - contradicts +++ eg US but uses acupuncture and how to convince patients

Appendix H: Study protocol (Chapters three and four)

Newton C, Singh G, Nolan D, Booth V, Diver C, O'Neill S, O'Sullivan K, O'Sullivan P and Logan P (2021) Protocol for a feasibility randomised controlled trial comparing Cognitive Functional Therapy with usual physiotherapy care in people with persistent low back pain. Physiotherapy Practice and Research (accepted 30/10/2020).

Abstract

Background: Combined physical and psychological programmes (CPPP) are recommended for people with disabling low back pain (LBP). Cognitive Functional Therapy (CFT) is a physiotherapist-led low intensity CPPP with positive effects in previous studies. The clinical and cost effectiveness of CFT has not previously been evaluated in a randomised controlled trial (RCT) in the United Kingdom (UK) National Health Service (NHS). Before a definitive RCT can be completed it is necessary to determine if completing such a study is possible.

Purpose: To determine the feasibility of completing a definitive RCT, that will evaluate the clinical and cost-effectiveness of CFT in comparison to usual physiotherapy care for people with persistent LBP in the UK NHS.

Methods: A pragmatic two-arm parallel feasibility RCT comparing CFT with usual physiotherapy care for people with persistent LBP will be completed. Sixty participants will be randomly allocated to receive CFT or usual physiotherapy care. The primary outcome will be feasibility of completing a definitive RCT. Participant reported outcome measures will be recorded at baseline, three, six and twelve-month follow-up, including disability, pain intensity, quality of life and psychosocial function. Data will be analysed descriptively. A qualitative process evaluation will explore the acceptability of the research processes and interventions.

Discussion: The rationale and methodological design of a mixed methods feasibility RCT is presented. This study aims to inform the planning, design and completion of a future definitive RCT in the UK NHS. The results will be disseminated through peer reviewed open access journal publication.

Trial registration: ISRCTN12965286.

Key words: Low back pain, feasibility, RCT, Cognitive Functional Therapy.

Introduction

Low back pain (LBP) disability has increased by more than 50% in the last 25 years, maintaining its position as the primary cause of years lived with disability globally [1]. The economic impact is considerable with costs comparable to that of diabetes mellitus, cardiovascular disease, mental health disorders and cancer [2, 3]. It is suggested this burgeoning trend may be attributed to the inadequacy of previous models of care to effectively manage the complexity of LBP across the biopsychosocial spectrum [4]. An individual's LBP presentation may reflect a range of physical (i.e. movement avoidance, protective guarding), psychological (i.e. negative LBP beliefs, low self-efficacy, fear of pain and/or movement, depression, anxiety), social (i.e. family and work relationships, socio-economic factors, work satisfaction), lifestyle (i.e. activity levels, sleep) and co-morbid health-related factors (i.e. obesity, mental health) [5-11]. There is growing evidence that many of these factors may interact to mediate the transition from acute to persistent LBP [6, 12].

Existing interventions have been criticised for being reductionist by targeting singular dimensions of the disorder and have, so far, yielded suboptimal outcomes for patients [12]. Treatments that just target physical or psychological aspects of persistent LBP have shown consistently modest effects in reducing pain and disability [13-16]. One systematic review that compared physical, psychological and combined (physical and psychological) interventions for persistent spinal pain reported that only small reductions in pain (measured on a scale between 0-10) (mean difference (MD) <0.5, 95% confidence interval (CI) -1.38-0.38) and disability (standardised mean difference (SMD) = -0.25, 95% CI 0.07-0.43) were sustained across all between-group comparisons [17]. Consequently, identifying effective biopsychosocial interventions for persistent LBP remains a key goal of researchers and clinicians alike [18].

In the United Kingdom (UK), the updated National Institute for Health and Care Excellence (NICE) LBP and sciatica guidelines recommend access to combined physical and psychological programmes (CPPP) for those patients identified at risk of a poor outcome (using a validated risk stratification tool) [19]) or where previous self-management strategies and treatments delivered as a package of care (including exercise, manual therapy, pharmacological and psychological therapies) have been ineffective [20]. However, access to CPPP for LBP patients in the UK is limited and where available there is no standardised approach to delivery with heterogeneity in the type (e.g. multidisciplinary versus single profession delivery, outpatient versus residential), intensity, frequency, duration (e.g. daily/weekly attendance, total hours of contact time) and therefore cost of such programmes. The Department of Health Spinal Taskforce in the UK previously identified the absence of CPPP as the biggest gap in service provision for LBP patients [21], a group who cost the National Health Service (NHS) and society a significant proportion of resources [2].

The National Low Back and Radicular Pain Pathway was a commissioned NHS England pathfinder project that aimed to provide an end to end care pathway for people with LBP and radicular pain and was recently updated to align with the NICE

guidelines [22]. The pathway is designed to restrict unwarranted interventions, reduce variations in care and improve timely access to evidenced-based alternatives, including CPPP so that improved patient outcomes and system efficiencies are realised [22]. Whilst the overall pathway has projected significant cost savings and reported improved patient satisfaction [22], clinically important improvements in disability have not been observed in established CPPP [23, 24].

Psychologically informed physiotherapy is a lower intensity, physiotherapy-led form of a CPPP. Psychologically informed physiotherapy augments traditional physiotherapy interventions for LBP, such as manual therapy and exercise, with 'third wave' cognitive behavioural principles such as education, relaxation techniques, mindfulness, graded activity and exercise and acceptance-based therapy [25]. A number of psychologically informed physiotherapy approaches for LBP have been developed and evaluated in clinical trials [26-31]. However, a recent systematic review and meta-analysis did not identify long-term improvements in pain (0-10 scale) (MD=-0.25, 95% CI -0.63-0.12) or disability (SMD=-0.06, 95% CI -0.22-0.11) when psychologically informed physiotherapy was compared to usual physiotherapy care in LBP trials. It was postulated that interventions may have failed to adequately integrate cognitive, behavioural and physical aspects of pain and disability and individually tailor management [32]. Cognitive Functional Therapy (CFT), which explicitly integrates these elements, was noted as an outlier in this review with large effect sizes reported for reducing pain (0-10 scale) (MD=-1.50, 95% CI -2.33--0.67) and disability (SMD=-0.91, 95% CI-1.33--0.48) as well as fear of movement, anxiety and depression at twelve-month follow-up [32].

CFT is an individually tailored psychologically informed physiotherapy intervention for LBP, which aims to facilitate sustained self-management [33]. CFT utilises a multidimensional clinical reasoning framework that enables the clinician to identify modifiable and non-modifiable biopsychosocial factors underlying an individual's LBP. It targets these factors by, helping the patient 'make sense of their pain', develop confidence to engage in movement and activity, and adopt positive lifestyle behaviours [33]. CFT has shown clinically important (>30%) improvements in pain and disability in a number of previous studies [34-37], including two RCT's in Norway and Ireland [38, 39]. While the eligibility criteria and comparison interventions varied in these RCTs, both demonstrated sustained clinically important (>30%) improvements with CFT, especially for pain-related disability [38-40]. A recent case-control study, within a secondary care specialist pain centre in Denmark, that included a highly disabled cohort of LBP patients, reported larger reductions in pain-related disability (SMD=0.52, 95% CI 0.13-0.93) (measured using the Pain Disability Index on a scale of 0-50 where zero represents no disability)) and a 93% cost saving of €3,688.29 in favour of CFT in comparison to a multidisciplinary CPPP [36]. However, the clinical and cost effectiveness of CFT has not previously been evaluated in an RCT in the UK NHS or compared to usual physiotherapy care. This is important as there is evidence that complex LBP interventions might not be as effective in different countries and settings [27, 41].

RCT's are recognised as the 'gold standard' research design in determining the effectiveness of different healthcare interventions due to the methodological control

exerted over potential confounding factors [42]. Both CFT and usual physiotherapy care can be considered complex interventions [43], lending themselves to evaluation in a pragmatic RCT [44]. However, before the clinical and cost-effectiveness of CFT can be measured in a suitably powered RCT in the UK NHS, it is unknown whether such a trial can be completed [45]. To determine the feasibility of completing a definitive future trial, a pragmatic two-arm parallel feasibility RCT comparing CFT with usual physiotherapy care for people with persistent LBP is proposed.

Considering the concerns reported by physiotherapists regarding their ability to deliver psychologically informed physiotherapy safely and effectively [46-53], the willingness of some patients to engage in such programmes [54, 55] and the challenges inherent in completing RCTs, a nested qualitative study will evaluate the acceptability of the interventions and research processes to participants with persistent LBP and their treating physiotherapists.

The objectives of this feasibility RCT are to determine:

1. The number of eligible participants and actual recruitment rate.
2. Retention rates of enrolled participants.
3. If CFT can be delivered to fidelity by NHS Physiotherapists.
4. The acceptability, return and completion rates of the patient reported outcome measures.
5. The most suitable primary outcome measure and calculate the sample size for a definitive RCT, should feasibility be assured.
6. The type and frequency of adverse events.
7. Adherence rates to the interventions through attendance to scheduled physiotherapy appointments and a self-completed exercise diary.
8. The acceptability of the intervention and the research process as experienced by participants with LBP and physiotherapists.

Methods

The planning and reporting of this protocol has followed the recommendations of The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [56] the Template for Intervention Description and Replication (TIDieR) [57] and the extension of the Consolidated Standards of Reporting of Trials (CONSORT) for pilot and feasibility studies [58]. Qualitative data will be reported in accordance with the Consolidated Criteria for Reporting Qualitative Studies) [59].

This study conforms to the Declaration of Helsinki and received ethical approval from East Midlands Nottingham 1 Research Ethics Committee on the 1st February 2019, reference number 18/EM/0415. The trial was registered with www.isrctn.com on 10th May 2019, ISRCTN12965286, https://doi.org/10.1186/ISRCTN12965286.

The aims and objectives will be met through two phases. In Phase 1, a feasibility RCT will compare CFT to usual physiotherapy care in 60 participants with persistent LBP. In Phase 2, qualitative semi-structured interviews will explore the acceptability

of the research processes and interventions to a minimum of ten patient participants, enrolled in phase 1. Two focus groups will evaluate the acceptability of the training package and participation in the feasibility RCT to all usual care and CFT trained physiotherapists.

Recruitment

Phase 1

Participants will be recruited from a secondary care physiotherapy outpatient service waiting list at University Hospitals of Leicester NHS Trust. Recruiting 60 participants (30 per arm of the study) requires just over one patient per week to be enrolled for the 12-month recruitment phase. The recruitment target is thought to be achievable as the host physiotherapy service receives approximately 500 LBP referrals per month.

Referrals will be screened against the eligibility criteria by departmental physiotherapists during a telephone triage consultation, which is standard practice. Fifteen senior physiotherapists will receive training and supporting material, covering the aims and objectives of the study, the eligibility criteria and the recruitment processes during a departmental training session, lasting one hour. Those patients that are potentially eligible will be asked if they consent to being contacted by the research team. The research team will then provide information about the study, establish a postal or email address for the potential participant to receive the participant information sheet, and arrange a study screening appointment. This will be more than one week after the phone call to ensure the potential participant has the opportunity to consider the study information before providing consent.

All potential participants will be given the option of receiving physiotherapy care as usual or taking part in the study. It will be clearly stated that there are two active interventions and that based on current understanding it is not known which is superior. People willing to participate will be consented by the research team and will then complete the baseline assessments, prior to randomisation. The schedule of participant enrolment, intervention allocation and assessments is depicted in Table 1.

		STUDY PERIOD					
	Enrolment	**Allocation**	**Post-allocation**				**Close-out**
TIMEPOINT**	***April 2019 - April 2020***	**April 2019 - April 2020**	***Month 1***	***Month 3***	***Month 6***	***Month 12***	***April 2020 - April 2021***
ENROLMENT:							
Eligibility screen	X	X					
Informed consent	X	X					
Allocation	X	X					
INTERVENTIONS:							
Cognitive Functional Therapy			←	→			
Usual Physiotherapy			←	→			
ASSESSMENTS:							
Diagnosis	X						
Demographic data		X					
RMDQ		X		X	X	X	
NPRS		X		X	X	X	

PSEQ		X		X	X	X	
PCS		X		X	X	X	
FABQ		X		X	X	X	
DASS 21		X		X	X	X	
STarT Back		X		X	X	X	
EuroQOL (EQ-5D-5L)		X		X	X	X	
Satisfaction		X		X	X	X	
GROC		X		X	X	X	
WATOCI		X		X			
Exercise diary				X			

Table 1: Template for the schedule of enrolment, interventions, and assessments.

RMDQ; Roland Morris Disability Questionnaire, NPRS; Numeric Pain Rating Scale, PSEQ; Pain Self-efficacy Questionnaire, PCS; Pain Catastrophising Scale; FABQ; Fear Avoidance Beliefs Questionnaire, DASS 21; Depression, Anxiety and Stress Scale, STarT Back; Sub-groups for Targeted Treatment Screening Tool; GROC; Global Rating of Change Scale, WATOCI; Working Alliance Theory of Change Inventory

Sample size

As the primary aim of the proposed research is to determine the feasibility of conducting a full-scale pragmatic RCT of CFT, a sample size calculation is not required. A sample size between 40 and 60 participants is recommended to achieve the key objectives of feasibility studies [45]. An upper limit of 60 participants has been chosen to provide adequate data to assess the clinical parameters including the standard deviation and confidence intervals of the primary outcome data to calculate the sample size for a future definitive trial, should feasibility be assured, whilst allowing for drop-outs.

Phase 2

Initially, a purposeful sample of eight to ten participants, enrolled in Phase 1, will be invited to discuss the acceptability of the research processes (e.g. study recruitment procedures, randomisation and outcome assessments) and their experiences of the intervention they received. To enhance variability and to limit selection bias, a purposive sample of responders and non-responders to the interventions (identified using a minimum clinically important change threshold of <30% change in the Numeric Pain Rating Scale (NPRS) [60]) will be invited to participate. Data collection will continue until the research team is satisfied that data saturation has been reached.

Following completion of the intervention they will be contacted by the research team (CN) to determine participation in Phase 2. A second (phase 2) participant information sheet will be provided. An appointment will then be arranged at a mutually convenient date, time and venue (their own home or physiotherapy department) for consent and the interview to be completed.

To determine the acceptability of the training package and participation in the RCT, all ten physiotherapists delivering the interventions in Phase 1 will be invited to participate in a focus group. Two focus groups will be held. Focus group 1 will contain the intervention (CFT) physiotherapists and focus group 2 the physiotherapists delivering usual physiotherapy care. The interviews and focus groups will be completed by the research team (a trained patient and public involvement (PPI) representative and (CN)) in the physiotherapy department.

Eligibility criteria

The study eligibility criteria are reported in Chapter 3, section 3.2.

Interventions

Ten physiotherapists will be purposefully sampled to deliver the interventions based on a broad range of experience (NHS Band 5 to Band 7 clinicians). Attempts will be made to match the age, level of experience and job grade of physiotherapists between the two study arms. Five physiotherapists will complete CFT training in preparation for the RCT and to control for contamination between the study arms five different physiotherapists will provide usual physiotherapy care.

Cognitive Functional Therapy

A detailed description of the CFT intervention is provided in the supplementary file (Appendix 1) and has been reported elsewhere [33]. CFT will be delivered face-to-face by the trained physiotherapists. The Örebro Musculoskeletal Screening Questionnaire (short form) [61] followed by a comprehensive interview and a functional examination will inform the intervention.

Interview: the patient will be invited to 'tell their story' in order to communicate how they make sense of their LBP to the physiotherapist. A sensitive, non-judgemental interviewing style will be used throughout to facilitate disclosure and to consider the following components of the CFT multidimensional clinical reasoning framework [33].

1. Pain history and contextual factors (e.g. physical, cognitive, emotional, social, lifestyle and general health) at the time of onset to differentiate traumatic and non-traumatic causes.
2. Mechanical and non-mechanical pain characteristics to determine stimulus-response relationships to postures, movements, activities and rest.
3. Cognitions (e.g. beliefs regarding cause, future consequences, pain controllability) and emotional (e.g. fear, low mood, anxiety) responses to pain.
4. Painful and feared valued functional activities will be identified, as well as behavioural responses to pain such as movement and activity avoidance.
5. Social (e.g. work and home relationships) and cultural obstacles to adopting positive lifestyle and health behaviours.
6. Lifestyle factors, such as physical activity levels, sleep hygiene, stress levels diet and smoking.
7. Personally relevant short and long-term goals will be identified.
8. Past medical history to include, general health, vitality and co-morbidities and their relationship to pain.

Functional behavioural assessment: The specific functional tasks (spinal movements, postures and activities), identified during the interview, as provocative, feared and/or avoided will be evaluated for signs of safety behaviours (e.g. movement avoidance, abdominal bracing, breath holding, propping with hands) and sympathetic arousal (e.g. rapid apical breathing and body tension). Palpation will be used to identify levels of tissue sensitivity, trunk muscle activation and respiratory patterns. A series of behavioural experiments, guided from these observations, will be used to evaluate an individual's response to reducing sympathetic arousal and diminishing safety behaviours. This will be achieved through training relaxed diaphragmatic breathing, body relaxation, awareness of movement (i.e. mirror feedback) during graded exposure to their nominated feared, avoided and provocative postures, movements and functional activities. Discrepancies between expected and actual pain responses are highlighted to reinforce that engagement in relaxed confident movement is safe. This provides an opportunity for education

about the resilience of the spine, pain does not equal harm and a clear direction for management that is aligned to patient preferences and valued goals.

Intervention: Based on the interview and functional behavioural assessment, a management plan, tailored towards each presentation and context (e.g. social situation and work requirements), will be designed to enable the person with LBP to:

1) Make sense of their pain from a biopsychosocial perspective using their own narrative and personal experience.

2) Achieve pain control, where possible, through graduated exposure to feared, avoided and/or painful movements and valued activities.

3) Adopt healthy lifestyle behaviours (e.g. increase physical activity levels, improve sleep, healthy diet and stress management) [33].

To facilitate behaviour change and develop therapeutic alliance, motivational interviewing and empathetic communication will underpin this process [62]. An individualised self-management program will be provided, monitored and evolved that includes progressive functional exercises and lifestyle modifications, where indicated [33]. The dosage and intensity of the exercise programme will be tailored towards an individual's valued activities, goals, preferences and levels of physical conditioning, with the aim to coach people toward self-management of their condition. A personalised handout that outlines an individual's vicious cycle of pain and web-based educational resources (www.pain-ed.com) that address common misconceptions about LBP, physical activity, sleep hygiene and the role of imaging will be provided where appropriate.The initial consultation will be for one hour and subsequent appointments for 30 minutes. Participants will be seen over three months and will typically receive between five to ten individual sessions of CFT, as determined by the participant's confidence to effectively to self-manage their condition, through shared decision making with the physiotherapist [34-39]. At the end of the intervention, participants will be provided with a pain exacerbation plan to guide self-management in the event of an increase in LBP.

Cognitive Functional Therapy Training

Training in CFT will be based on the core components of the examination and intervention developed and refined over the previous 20 years (49). Training will include attendance at a three-day clinical workshop, delivered by a CFT educator (PO). During the workshop, evidence regarding the multidimensional nature of persistent LBP and an introduction to the multidimensional clinical reasoning framework underpinning CFT will be provided. Demonstration of the key components of the CFT intervention will be exemplified during live observation of four patients with persistent LBP, during a masterclass by a CFT educator (PO). Website resources (www.pain-ed.com) and two electronic-books, detailing the multidimensional clinical reasoning framework and CFT intervention, with embedded clinician and patient videos, will be provided to each physiotherapist to support a period of experiential learning following the workshop. During this time each physiotherapist will complete video-recorded assessments of two new patients

with persistent LBP to evaluate their progress in delivering CFT. Each video will be reviewed on a one-to-one basis with a clinical mentor (CN) and a bespoke action plan provided, including written and verbal feedback summarising key learning points. Peer support will include further clinical observations and case discussions between the physiotherapists and mentor during this period. Finally, an assessment of competency in the delivery CFT will be completed. Each physiotherapist will be observed by CN and PO whilst assessing and treating one new patient with persistent LBP within the clinicians own clinical environment. A pre-defined fidelity checklist covering the core components of the CFT examination and intervention will be used to determine physiotherapist competency to deliver the intervention (Appendix 2).

Usual Physiotherapy Care

Participants will receive usual physiotherapy care for LBP reflective of current practice and decision-making of physiotherapists managing LBP within the UK NHS [20, 63]. This will include psychosocial screening using the short form Örebro Musculoskeletal Screening Questionnaire) [61].

Interview: The interview will follow a structured format to include history of the presenting complaint, past medical, drug and social history. During the interview physiotherapists will seek to gather information regarding the onset and duration of symptoms, pain location and quality, behaviour of pain related to physical aggravating and easing factors, diurnal variation of symptoms and identify psychosocial factors.

Physical examination: This will include the observation of spinal posture, active and passive physiological spinal motion testing (including repeated movements, combined movements and over-pressure), muscle length and strength, as well as neurological and special tests where indicated.

Intervention: The usual care physiotherapy intervention may consist of manual therapy and exercise of various forms including stretching, strengthening, and cardiovascular as well as optional attendance at a back class. The back class will be weekly for one hour and include LBP education and general exercise. Participants will attend for a maximum of six sessions. Participants will be given written information on how to perform the prescribed exercises. The initial appointment be up to one hour in duration. Subsequent follow-up appointments will be scheduled to last for 30 minutes. There will be no limit on the number of treatments provided during the three-month intervention period.

Usual Physiotherapy Care Training

In contrast to the CFT intervention, no additional skills will be required for the physiotherapists to deliver usual physiotherapy care, they will do so in line with their existing skillset and scope of practice. However, to reinforce existing knowledge and skills each physiotherapist will attend a three-hour teaching session comprised of lectures and practical demonstrations covering the contemporary physiotherapy assessment and management of LBP, aligned to UK clinical guidelines (self-

management advice, psychosocial screening, manual therapy and exercise as a package of care) [20]. The teaching session will be delivered by a member of the research team (SO), who is an Associate Professor of Musculoskeletal Physiotherapy and has not received any formal training in CFT.

Assessment of treatment fidelity

Treatment fidelity will be monitored and evaluated during the intervention period in accordance with the behavioural change fidelity framework guidelines for treatment delivery [64]. Firstly, the physiotherapists' clinical notes, for all participants, will be evaluated against the intervention checklists (Appendix 2) by CN to determine protocol adherence. Secondly, up to two video assessments (~20%) will be competed at random for each physiotherapist, subject to informed patient consent. These videos will be analysed and assessed against the intervention checklists by CN (CFT group) and SO (usual physiotherapy care group) to ensure competency is maintained and that the interventions are being delivered as intended. Individual feedback will be provided on treatment delivery (e.g., intervention drift or protocol deviations). Fidelity of treatment delivery will be confirmed if >80% of the intervention components are delivered as intended, as measured against the pre-defined checklists for both the clinical notes and video recordings [64]. Thirdly, the qualitative interviews and focus groups will explore treatment differentiation and integrity further.

Outcome assessments

Demographic data will be collected at baseline to include participant's age, gender, duration of LBP and employment status. The chosen Patient Reported Outcome Measures (PROM's) include measures of disability, pain intensity, quality of life and psychological function and have been used widely in previous LBP RCT's, based on their strong psychometric profile and capacity to capture clinically important change [60]. The PROM's were deemed to involve an acceptable burden by the PPI group. The PROM completion schedule is reported in the SPIRIT figure (Table 1) and a description for each PROM, including psychometric properties, is provided (Table 7, Chapter 3).

Randomisation

Consenting participants will be randomly allocated to receive CFT or usual physiotherapy care. The randomisation order was generated using online software (www.randomization.com; accessed on 21st March 2019) and included blocks of variable size (block sizes 2, 4, 6, and 8). Group allocation will be concealed via sequentially numbered opaque envelopes, issued to the participants following baseline measurements and consent. Participants will take the sealed envelope to physiotherapy reception. The envelope will contain a colour coded card (blue for CFT, red for usual physiotherapy care) to indicate to the physiotherapy administrative staff which physiotherapist to book the initial physiotherapy appointment with. The researchers completing baseline and follow-up assessments will be blinded to treatment allocation throughout the trial. It is not possible to blind the physiotherapists.

Planned data analysis

Phase one

Descriptive statistics for participant demographic data will be reported using means, standard deviations (or medians and interquartile ranges) for continuous variables and totals and proportions for categorical variables. The number of eligible and recruited participants will be recorded each week. Number of participants lost to follow-up at each data collection period will be reported and the reasons for drop out documented. Feasibility of the selected PROM's will be assessed quantitatively by calculating the total time to complete, number of missing items, completion rates and qualitatively through the process evaluation in Phase 2. All data collection and analysis procedures will be completed by the lead author, CN.

Feasibility thresholds

The criteria for progression to continue to a future fully powered RCT include the following and are based on similar musculoskeletal feasibility RCT's [65, 66].

- 50% of screened referrals will meet the eligibility criteria.
- 50% recruitment rate into the study.
- 70% of participants are retained in the study at six-month follow-up.
- Intervention adherence by participants will be measured as greater than 80% attendance to the allocated intervention after randomisation.
- Less than 20% of data are missing on the returned patient PROM's at each follow-up time.
- Less than 5% of participants report adverse events.
- All physiotherapists trained in CFT will be deemed competent to deliver CFT

Phase 2

Qualitative data will be analysed using framework analysis [67]. Framework analysis shares the same analytical principles of thematic analysis but employs a systematic and visible approach to enhance methodological rigor [68]. Each interview will be played back several times to gain familiarity with the dialogue and then transcribed verbatim by CN. This will afford the opportunity to listen, reflect and re-examine the information [69]. Next, a coding framework will be formed for two transcripts based on patterns, threads, similarities, discrepancies and relationships that emerge through interpretation of the data. The first two transcripts will be coded blind by CN, the PPI representative, who will receive training in qualitative analysis, and VB who will then meet to discuss and reflect on their analyses of the data. Codes will be compared across the transcripts for coherence and pooled where patterns emerged to form an analytic framework. The analytic framework will be indexed against the remaining transcripts by CN. Data will be pooled and charted by case and code into a framework matrix. Cross comparison of codes within and between participants will be made and a final set of themes will be generated. Each theme will be discussed with the research team at a final meeting to confirm representation of the data.

Monitoring

As this is a feasibility study as part of the fulfilment for the lead authors' (CN) Doctoral studies and that funding arrangements did not allow, no formal trial management or steering committee will be convened. Safety and study management will be monitored by the lead authors' academic supervisory team at University of Nottingham during monthly supervision meetings, led by PL.

The dignity, rights, safety and well-being of participants and staff will be monitored and safeguarded in accordance with the sponsor's, University Hospitals of Leicester NHS Trust, standard operating procedures. The risk of adverse events associated with physiotherapy are reported to be low in previous studies [70]. The health of participants will be monitored through attendance to physiotherapy and the study monitored by the research team at University of Nottingham. Should any adverse events occur, they will be documented and reported to the sponsor (University Hospitals of Leicester NHS Trust) in line with standard operating procedures and the appropriate action taken.

Patient and public involvement (PPI)

Three patient advisers, who have previously attended the host physiotherapy service with persistent LBP have informed the development of this research protocol. They assessed the suitability and practicality of PROM's, which have informed the choice for the proposed study. One PPI representative will continue involvement in the study throughout. They will assist in developing the interview schedules for phase 2, will receive training in qualitative data collection and thematic analysis in preparation to interview participants and contribute to the qualitative data analysis in Phase 2.

Discussion

This paper has presented the rationale, aims and methodological design of a mixed methods feasibility RCT that will compare CFT to usual physiotherapy care for people with persistent LBP attending a secondary care NHS physiotherapy service in the UK. A nested qualitative process evaluation aims to understand the acceptability of the research process and interventions to participants with LBP and their treating physiotherapists. The parameters that will determine feasibility have been described. The findings will inform the planning, design and completion of a future, definitive RCT that will compare the clinical and cost-effectiveness of CFT in the UK NHS, should feasibility be established.

The results of the feasibility RCT and qualitative process evaluation will be published open access in separate papers, once available, and abstracts submitted to national and international physiotherapy and LBP specific conferences.

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Appendix I: Ethics approval for the feasibility RCT and process evaluation (Chapters three and four)

NHS
Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

01 February 2019

Mr Christopher Newton
Physiotherapy Department,
Infirmary Square,
Balmoral building, Level 0,
Leicester Royal Infirmary
LE1 5WW

Dear Mr Newton,

Study title:	**Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial.**
REC reference:	**18/EM/0415**
Protocol number:	**113690**
IRAS project ID:	**253668**

Thank you for your letter of 17 January 219, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will

be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter to Chairperson]		16 November 2018
Covering letter on headed paper [Covering letter to Chairperson]		12 January 2019
GP/consultant information sheets or letters [GP Letter Version 1 Final]	Version 1	12 December 2018
Interview schedules or topic guides for participants [Topic guide patients FINAL]	Version 1	13 November 2018
Interview schedules or topic guides for participants [Topic guide physio focus group FINAL]	Version 1	13 November 2018
IRAS Application Form [IRAS_Form_27112018]		27 November 2018
IRAS Application Form [IRAS_Form_17012019]		17 January 2019
Letter from funder		26 July 2017
Letter from funder [CLAHRC Funding letter Chris Newton]		29 November 2018
Letters of invitation to participant [Cover letter physiotherapists FINAL]	Version 1	24 October 2018
Letters of invitation to participant [Cover letter patients FINAL]	Version 2	22 December 2018
Letters of invitation to participant [Cover letter patient interviews Phase 2 Version 1]	Version 1	22 December 2018
Letters of invitation to participant [Cover letter physiotherapists Phase 2 Version 1]	Version 1	22 December 2018
Other [Consent to contact]	1	28 November 2018
Other [Pre-validation queries]		28 November 2018
Participant consent form [Consent form (patients) FINAL]	Version 2	22 December 2018
Participant consent form [Consent Form Phase 2 (patients) feasibility RCT FINAL Version 1']	Version 1	22 December 2018

Participant consent form [Consent form (physiotherapists) FINAL]	Version 2	22 December 2018
Participant consent form [Consent Form Phase 2 (physios) Focus groups feasibility RCT FINAL Version 1']	Version 1	22 December 2018
Participant information sheet (PIS) [Participant information sheet patients FINAL]	Version 2	22 December 2018
Participant information sheet (PIS) [Participant Information sheet Phase 2 patient interviews FINAL Version 1]	Version 1	22 December 2018
Participant information sheet (PIS) [Participant information sheet Physiotherapists FINAL]	Version 2	22 December 2018
Participant information sheet (PIS) [Participant Information sheet Phase 2 physio Focus group FINAL Version 1]	Version 1	22 December 2018
Referee's report or other scientific critique report [UHL Sponsor peer review]		02 October 2018
Research protocol or project proposal [Cognitive Functional Therapy for low back pain: A feasibility RCT]	Version 2	22 December 2018
Sample diary card/patient card [Exercise diary]	Version 1	24 October 2018
Summary CV for Chief Investigator (CI) [Curriculum vitae]		24 October 2018
Summary CV for supervisor (student research) [CURRICULUM VITAE (Supervisor)]		16 November 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Cognitive functional therapy for low back pain: A feasibility RCT. Study Summary]	Version 1	15 November 2018
Validated questionnaire [Baseline Questionnaires]	Version 1	22 December 2018
Validated questionnaire [Three month follow-up questionnaires]	Version 1	22 December 2018
Validated questionnaire [Six month follow-up questionnaires]	Version 1	22 December 2018
Validated questionnaire [Twelve month follow-up questionnaires]	Version 1	22 December 2018

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

18/EM/0415	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely,

pp

Mr Murthy Nyasavajjala
Chair

Email:NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Ms Carolyn Maloney, University Hospitals of Leicester NHS Trust*

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mr Christopher Newton
Physiotherapy Department, Balmoral Building, Level 0
Infirmary Square, Leicester Royal Infirmary,
Balmoral building, Level 0, Leicester Royal Infirmary
LE1 5WW

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

04 February 2019

Dear Mr Newton

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial.**
IRAS project ID:	**253668**
Protocol number:	**113690**
REC reference:	**18/EM/0415**
Sponsor	**University Hospitals of Leicester NHS trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

This is a single site study sponsored by the site. The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

The sponsor contact for this application is as follows:

Name: Christopher Newton
Email: christopher.newton@uhl-tr.nhs.uk

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **253668**. Please quote this on all correspondence.

Yours sincerely,

Natalie Wilson
Assessor

Email: hra.approval@nhs.net

Copy to: *Ms Carolyn Maloney, University Hospitals of Leicester NHS Trust, Sponsor and Lead NHS R&D contact*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Covering letter on headed paper [Covering letter to Chairperson]		16 November 2018
Covering letter on headed paper [Covering letter to Chairperson]		12 January 2019
GP/consultant information sheets or letters [GP Letter Version 1 Final]	Version 1	12 December 2018
Interview schedules or topic guides for participants [Topic guide patients FINAL]	Version 1	13 November 2018
Interview schedules or topic guides for participants [Topic guide physio focus group FINAL]	Version 1	13 November 2018
IRAS Application Form [IRAS_Form_27112018]		27 November 2018
IRAS Application Form [IRAS_Form_17012019]		17 January 2019
Letter from funder		26 July 2017
Letter from funder [CLAHRC Funding letter Chris Newton]		29 November 2018
Letters of invitation to participant [Cover letter physiotherapists FINAL]	Version 1	24 October 2018
Letters of invitation to participant [Cover letter patients FINAL]	Version 2	22 December 2018
Letters of invitation to participant [Cover letter patient interviews Phase 2 Version 1]	Version 1	22 December 2018
Letters of invitation to participant [Cover letter physiotherapists Phase 2 Version 1]	Version 1	22 December 2018
Other [Consent to contact]	1	28 November 2018
Other [Pre-validation queries]		28 November 2018
Participant consent form [Consent Form Phase 2 (patients) feasibility RCT FINAL Version 1']	Version 1	22 December 2018
Participant consent form [Consent form (physiotherapists) FINAL]	Version 2	22 December 2018
Participant consent form [Consent Form Phase 2 (physios) Focus groups feasibility RCT FINAL Version 1']	Version 1	22 December 2018
Participant consent form [Consent form (patients) FINAL]	Version 2	22 December 2018
Participant information sheet (PIS) [Participant information sheet patients FINAL]	Version 2	22 December 2018
Participant information sheet (PIS) [Participant Information sheet Phase 2 patient interviews FINAL Version 1]	Version 1	22 December 2018
Participant information sheet (PIS) [Participant information sheet Physiotherapists FINAL]	Version 2	22 December 2018
Participant information sheet (PIS) [Participant Information sheet Phase 2 physio Focus group FINAL Version 1]	Version 1	22 December 2018
Referee's report or other scientific critique report [UHL Sponsor peer review]		02 October 2018
Research protocol or project proposal [Cognitive Functional Therapy for low back pain: A feasibility RCT]	Version 2	22 December 2018
Sample diary card/patient card [Exercise diary]	Version 1	24 October 2018
Summary CV for Chief Investigator (CI) [Curriculum vitae]		24 October 2018
Summary CV for supervisor (student research) [CURRICULUM VITAE (Supervisor)]		16 November 2018
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Cognitive functional therapy for low back pain: A feasibility RCT. Study Summary]	Version 1	15 November 2018

Validated questionnaire [Baseline Questionnaires]	Version 1	22 December 2018
Validated questionnaire [Three month follow-up questionnaires]	Version 1	22 December 2018
Validated questionnaire [Six month follow-up questionnaires]	Version 1	22 December 2018
Validated questionnaire [Twelve month follow-up questionnaires]	Version 1	22 December 2018

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	At submission of the next amendment, PIS documents referencing DPA 1998 should be updated to DPA 2018.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	This is a non-commercial, single site study taking place in the NHS where the single participating NHS organisation is also the study sponsor. Therefore, no study agreements are expected.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	No comments
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics	Yes	No comments

Section	Assessment Criteria	Compliant with Standards	Comments
	Committee favourable opinion received for applicable studies		
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	
6.3	Devices – MHRA notice of no objection received	Not Applicable	
6.4	Other regulatory approvals and authorisations received	Not Applicable	

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
This is a non-commercial, single site study. There is one site-type involved in the research. Activities and procedures as detailed in the protocol will take place at participating NHS organisations. If this study is subsequently extended to other NHS organisation(s) in England or Wales, an amendment should be submitted, with a Statement of Activities and Schedule of Events for the newly participating NHS organisation(s) in England or Wales. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS, the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator (PI) is expected at participating NHS organisations. Sponsor will confirm any training requirements with research staff directly.

GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain an honorary research contract. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.

On 19 Mar 2019, at 09:45, Wann Lisa - Research and Innovation Manager <lisa.wann@uhl-tr.nhs.uk> wrote:

Dear Christopher Newton,

I am pleased to confirm with this email that the University Hospitals of Leicester NHS Trust has the capacity and capability to deliver the above research activity in accordance with the **Protocol** provided.

The research must be conducted in line with the Protocol and fulfil any contractual obligations agreed. If you identify any issues during the course of your research that are likely to affect these obligations you must contact the R&I Office as soon as possible.

Please note as this study is Sponsored by the University Hospitals of Leicester NHS Trust this email also serves as Sponsor Green Light.

In accordance with the Department for Health Performance in Initiation and Delivery of research UHL is actively managing research to ensure that we are delivering on all studies. There is an expectation that ALL research will deliver to Time & Target. It is understood that there are sometimes circumstances where it is not possible to recruit to the Time & Target set and in these cases we are expected to provide an adequate reason. In addition, we are required to publish the Title, REC Reference number, local target recruitment and actual recruitment as well as target data for this study on a quarterly basis on the UHL public accessed website.

It is essential that you notify the UHL Data Management Team as soon as you have started recruitment, and ensure that the date is recorded on the EDGE Database by your local EDGE User. The UHL Data Management team can be contacted on RIData@uhl-tr.nhs.uk or by phone 0116 258 4573.

Approved documents:

Document	Version	Date
GP/consultant information sheets or letters [GP Letter Version 1 Final]	1	12-Dec-18
Interview schedules or topic guides for participants [Topic guide patients FINAL]	1	13-Nov-18
Interview schedules or topic guides for participants [Topic guide physio focus group FINAL]	1	13-Nov-18

IRAS Application Form [IRAS_Form_17012019]		17-Jan-19
Letters of invitation to participant [Cover letter physiotherapists FINAL]	1	24-Oct-18
Letters of invitation to participant [Cover letter patients FINAL]	2	22-Dec-18
Letters of invitation to participant [Cover letter patient interviews Phase 2 Version 1]	1	22-Dec-18
Letters of invitation to participant [Cover letter physiotherapists Phase 2 Version 1]	1	22-Dec-18
Other [Consent to contact	1	28-Nov-18
Participant consent form [Consent Form Phase 2 (patients) feasibility RCT FINAL Version 1']	1	22-Dec-18
Participant consent form [Consent form (physiotherapists) FINAL]	2	22-Dec-18
Participant consent form [Consent Form Phase 2 (physios) Focus groups feasibility RCT FINAL Version 1']	1	22-Dec-18
Participant consent form [Consent form (patients) FINAL]	2	22-Dec-18
Participant information sheet (PIS) [Participant information sheet patients FINAL]	2	22-Dec-18
Participant information sheet (PIS) [Participant Information sheet Phase 2 patient interviews FINAL Version 1]	1	22-Dec-18

Participant information sheet (PIS) [Participant information sheet Physiotherapists FINAL]	2	22-Dec-18
Participant information sheet (PIS) [Participant Information sheet Phase 2 physio Focus group FINAL Version 1]	1	22-Dec-18
Research protocol or project proposal [Cognitive Functional Therapy for low back pain: A feasibility RCT]	2	22-Dec-18
Sample diary card/patient card [Exercise diary]	1	24-Oct-18
Summary CV for Chief Investigator (CI) [Curriculum vitae]		24-Oct-18
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Cognitive functional therapy for low back pain: A feasibility RCT. Study Summary]	1	15-Nov-18
Validated questionnaire [Baseline Questionnaires]	1	22-Dec-18
Validated questionnaire [Three month follow-up questionnaires]	1	22-Dec-18
Validated questionnaire [Six month follow-up questionnaires]	1	22-Dec-18
Validated questionnaire [Twelve month follow-up questionnaires]	1	22-Dec-18

Undertaking research in the NHS comes with a range of regulatory responsibilities. Please ensure that you and your research team are familiar with, and understand the roles and responsibilities both collectively and individually.

Documents listing the roles and responsibilities for all individuals involved in research can be found on the R&I pages of the Public Website. It is important that you familiarise yourself with the Standard Operating Procedures, Policies and all other relevant documents which can be located by visiting http://www.leicestersresearch.nhs.uk/standard-operating-procedures/

The R&I Office is keen to support and facilitate research where ever possible. If you have any questions regarding this or other research you wish to undertake in the Trust, please contact this office. Our contact details are provided on the attached sheet.

Please note that a letter confirming authorisation will not be sent. Please retain a copy of this email in your site file.

We wish you every success with your research.

Should you have any queries or require further information please do not hesitate to contact me.

Lisa Wann
R&I Manager
University Hospitals of Leicester NHS Trust
Research & Innovation, Leicester General Hospital, Gwendolen Road, Leicester, LE5 4PW.
Tel: +44 116 258 8239
Mob: +44 7534989523
Web: www.leicestersresearch.nhs.uk
Twitter: @LeicResearch

Appendix J: Cover letter, participant information sheet and consent form for the feasibility RCT

University Hospitals of Leicester NHS
NHS Trust

<Letterhead to be added>
<Telephone number to be added>

Name
Email address

Date

Dear {*name*},

Re: Cognitive Functional Therapy for persistent low back pain: A feasibility randomised controlled trial.

Thank you for talking to us on the telephone about the above named research study. I have enclosed the study information as discussed over the telephone, please can you read it before coming to your arranged appointment on (date to be added).

It is important for you to understand why we are doing this study. Please take time to read the participant information sheet carefully which tells you more about this study and what will be required if you decide to take part.

The appointment will be in the Physiotherapy Department at University Hospitals of Leicester NHS Trust (address given at the top of this letter). If you would like any further information about the study or you need to rearrange your appointment with the research team then do not hesitate to contact us on the number given above.

Yours sincerely

Mr Christopher Newton
Physiotherapist

Participant Information Sheet

Title of Study: **Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial.**

Name of Researcher(s): Mr Christopher Newton

You are invited to take part in a study that is comparing two physiotherapy treatments used for people with low back pain. Before you decide whether or not to take part in this study, we would like to explain why we are doing this research and what it will involve for you. Please read the following information and ask us if anything is not clear. If you would like more information, then please contact us using one of the options listed at the end of this leaflet.

Please note that this study is being performed as part of an educational qualification.

What is the purpose of the study?

This study will explore a treatment called Cognitive Functional Therapy in comparison to standard physiotherapy care for low back pain. The purpose of this study is to determine whether it is possible to carry out future, larger studies on this intervention. Both treatments involve exercise and education. Both treatments have shown promising results in reducing pain and disability in people with low back pain but we want to know if it is practical to do this study. For example, is it possible for NHS Physiotherapists to be trained and deliver Cognitive Functional Therapy in a hospital? We will also be inviting some people to discuss their experiences of taking part in the study during a short one-off informal interview, after they have completed their treatment.

Who is this study conducted by?

This research is being organised by University Hospitals of Leicester NHS Trust and University of Nottingham and is being funded by the National Institute of Health Research, Collaboration for Leadership in Applied Health Research and Care (East Midlands).

Why have I been invited?

You are being invited to take part due to the information in your physiotherapy referral letter, which states that you have low back pain. We are inviting 60 people with low back pain to take part.

Do I have to take part?

No, your participation is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep. You will be asked to sign a consent form and a copy will be given to you to keep. A copy of the consent form will also be filed within your physiotherapy records. We will also write to your GP to inform them that you have agreed to take part in this study. If you do decide to take part, you are still free to withdraw at any time, without giving a reason. This would not affect your medical care or legal rights.

What will happen to me if I take part?

You will be invited to attend the physiotherapy department to undergo an assessment carried out by a qualified physiotherapist. This is to see if you are eligible to participate in the study. The examination will last up to 30 minutes and will involve asking you simple questions about your low back pain, your prior medical health and a physical assessment of your lower back will be completed. If you do not meet the study criteria you will not be eligible to participate in the study. Your physiotherapy appointments will then continue as normal, in line with usual physiotherapy practice within the department and treatments will typically include education about low back pain, lower back exercises and manual therapy (e.g. massage).

If you meet the study criteria and still wish to take part, you will be asked to fill in several questionnaires to help us understand how low back pain affects you. You will be asked to complete the questionnaires before your treatment begins and again at three, six and twelve months from when you first started your treatment. In total, you will be asked to complete the questionnaires on four separate occasions. The questionnaires should take 20 minutes complete on each occasion. You will be provided with a stamped, addressed envelope to return the questionnaires. If you do not return the questionnaires a member of our research team will telephone you to remind you.

Because this is a new treatment we don't know which is the best and so we need to compare them. To impartially compare the treatments we perform a randomised controlled trial, where we put an equal number of patients into each group. To make sure that each group is similar, participants are put into their groups by chance (randomly). Once you have completed the questionnaires at your first appointment you will be randomly assigned to either an intervention group where you will receive Cognitive Functional Therapy under the guidance of a physiotherapist, or to the group where you will receive usual physiotherapy care, also under the guidance of a physiotherapist. There is equal chance you will be treated with one or the other option.

If you are allocated to usual physiotherapy care you will receive education about low back pain and how the spine moves, an exercise programme that may include strengthening, stretching and cardiovascular exercise and you may also receive treatments such as manipulation or massage.

Cognitive Functional Therapy is a new treatment for low back pain delivered by physiotherapists. Only one clinical trial of Cognitive Functional Therapy has been completed in the world, in Norway. Cognitive Functional Therapy has not yet been tested in the NHS. If you are allocated to Cognitive Functional Therapy you will receive education about all of the things that can contribute to low back pain to help you make sense of it to better manage your problem. You may be taught an exercise programme that will show you new postures and ways of moving that aims to help you to control your pain. Cognitive functional therapy also involves lifestyle advice that aims to improve your physical activity levels.

The first physiotherapy appointment will last for up to one hour and follow-up appointments for 30 minutes. There will be no limit on the number of times you are seen and your appointments will be arranged in agreement with you and your physiotherapist. The treatment will be at one of the three physiotherapy departments at University Hospitals of Leicester NHS Trust that is most convenient to you and at time most convenient for you.

If you take part in the study you will also be asked to complete a short exercise diary to let us know how much of the exercise you were able to complete. You will be asked to complete the diary daily.

This can be completed by using a smart phone/tablet application or if you prefer or do not have a smart phone or tablet device you will be given a paper exercise diary to complete.

It is important that the treatments you receive are delivered as we intend them to be. We are therefore going to video record a small number of treatment sessions (1-2). These video recordings are optional and should you wish, you can choose to not volunteer to take part in them while completing the consent form.

Expenses and payments

There is no payment for participating in this study.

What are the possible disadvantages and risks of taking part?

It will take additional time to complete the questionnaires, on 4 separate occasions. Apart from that there are no disadvantages to taking part in this research and there are no risks that we are aware of. You will be receiving a course of physiotherapy as you would expect following a referral to the physiotherapy department. The physiotherapy exercises in both groups may cause some short-term temporary pain and discomfort.

What are the possible benefits of taking part?

Both of the treatments offered in this study have been shown to reduce pain and disability in people with low back pain. It is expected that you will gain benefit from the treatment you receive, in terms of pain reduction and improved function the same as you would from seeing a physiotherapist. We cannot promise the study will help you in any other way. The information we get from this study may help inform future research and direct future treatment to other patients with a similar complaint.

What happens when the research study stops?

Your involvement in the study will be for twelve months and will end when you complete and return the final set of questionnaires. Your physiotherapy appointments will end at the discretion of your physiotherapist, in agreement with you.

What if I am harmed by the study?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the Chief Investigator, Mr Christopher Newton (contact details can be found at the bottom of page 5) who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service at pils.complaints.compliments@uhl-tr.nhs.uk. The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP Freephone: 0808 1788337

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University Hospitals of Leicester NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice in accordance with the Data Protection Act (1998) and all information about you will be handled in confidence. Your name and address will be removed (anonymised) from any information we collect about you and a unique code will be used so that you cannot be recognised from it. All data that you provide will be stored in a secure and locked office, and on a password protected computer database. Any information about you which leaves the hospital and transferred to secure computers at University of Nottingham will be anonymised.

University Hospitals of Leicester NHS Trust will collect information from you and/or your medical records for this research study in accordance with our instructions. University Hospitals of Leicester NHS Trust will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from University Hospitals of Leicester NHS Trust and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The Physiotherapy Department will pass these details to University Hospitals of Leicester NHS Trust along with the information collected from you and/or your medical records .The only people in University Hospitals of Leicester NHS Trust who will have access to information that identifies you will be people who need to contact you from the research team or to audit the data collection process. The people who analyse the information on behalf of the sponsor (University Hospitals of Leicester NHS Trust staff and regulatory organisations) will not be able to identify you and will not be able to find out your name, or contact details.

University Hospitals of Leicester NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished. After this time your data will be disposed of securely.

General Data Protection Regulation (GDPR)

University Hospitals of Leicester NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this research and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

http://www.leicestershospitals.nhs.uk/aboutus/our-news/general-data-protection-regulations-gdpr/

Information published by sponsor unit/department/organisation

As a NHS organisation we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Mr Saiful Choudhury and you can contact them at pils@uhl-tr.nhs.uk

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your medical care or legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of this research will be written up as part of the Chief Investigators, Mr Christopher Newton, Doctoral studies. It is anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands - Nottingham 1 Research Ethics Committee on 1st February 2019.

Further information and contact details

Mr Christopher Newton
Extended Scope of Practice Physiotherapist / PhD Candidate, University of Nottingham.
Physiotherapy Outpatients Department
Balmoral Building, Level 0
Leicester Royal Infirmary
Infirmary Square
Leicester.
LE1 5WW.
Tel: 0116 258 5815
E-mail:christopher.newton@nottingham.ac.uk

Professor Pip Logan
Professor of Rehabilitation Research
Head of Division Rehabilitation and Ageing
B108a, School of Medicine
University of Nottingham
Nottingham. NG7 2UH.
Tel: 0115 8230235
E-mail:pip.logan@nottinham.ac.uk

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

CLAHRC East Midlands

University Hospitals of Leicester NHS
NHS Trust

CONSENT FORM – Patient participants

Title of Study: Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial. Phase 1.

IRAS Project ID: 253668

Name of Researcher: Mr Christopher Newton

Name of Participant: Please initial box

1. I confirm that I have read and understand the Participant Information Sheet (Version 2 – 22/12/18) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University Hospitals of Leicester NHS Trust and University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the researchers require access to my personal contact details to send the postal questionnaires to me. ☐
5. **Optional:** I understand that I may be contacted after completion of the treatment to discuss my experiences in an interview. ☐
6. **Optional:** I agree to a physiotherapy consultation being video recorded for research purposes. ☐
7. **Optional:** I agree that the physiotherapy consultation video recording may be used for future training and education of health care professionals only. ☐
8. I understand that I may be asked to complete the study questionnaires once more, one year after I started the study. ☐
9. I agree to take part in the above study.

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the site file and 1 for the medical notes

University Hospitals of Leicester NHS
NHS Trust

Physiotherapy Department
Level 0, Balmoral Building
Leicester Royal Infirmary
Leicester
LE1 5WW
Tel: 0116 2585816

Name
Email address

Date

Dear {*name*},

We are a team of Research Physiotherapists from the University Hospitals of Leicester NHS Trust and we are writing to you to tell you about a research study that we are inviting you to participate in.

The study is called,

'Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial'.

This study is comparing two physiotherapy treatments used for people with low back pain. The purpose of this study is to determine whether it is possible to carry out a future large-scale study of Cognitive Functional Therapy in comparison to usual physiotherapy treatment for people with low back pain. As you have previously been trained to deliver one of the interventions we would like to invite you to participate in this study. At the end of the study we would also like to invite you to discuss your experiences of the interventions and the research process during a short one-off focus group interview.

It is hoped that this study will help tell us how acceptable the interventions are to clinicians and how feasible it might be to do in a larger trial. Such information may assist in the development of future training packages and tell us how to take this approach into clinical practice. We also hope to use this research to improve the care of people with persistent low back pain in the future.

Please take time to read the participant information sheet enclosed with this letter which tells you more about this study and what will be required if you decide to take part in the research

If you would like to take part in this study, please contact the Chief Investigator, Mr Christopher Newton on the email provided at the bottom of the accompanying participant information sheet. The research team will then contact you and an appointment will be arranged in the Physiotherapy Department at University Hospitals of Leicester NHS Trust to discuss the study further, answer any question you may have and gain your consent to participation.

Yours sincerely

Mr Christopher Newton
BSc MSc MSCP MMACP

Participant Information Sheet

Title of Study: **Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial.**

Name of Researcher(s): Mr Christopher Newton

You are invited to take part in a study that is comparing two physiotherapy treatments used for people with low back pain. Before you decide whether or not to take part in this study, we would like to explain why we are doing this research and what it will involve for you. Please read the following information and ask us if anything is not clear. If you would like more information, then please contact us using one of the options listed at the end of this leaflet.

Please note that this study is being performed as part of an educational qualification.

What is the purpose of the study?

The purpose of this study is to determine whether it is possible to carry out a future large-scale study of Cognitive Functional Therapy in comparison to usual physiotherapy treatment for people with low back pain. Both treatments have been shown to reduce pain and disability in people with low back pain but we want to know which one is more effective. But before we can complete this research on a larger scale we need to find out whether it is practical to do this study. As you have been previously trained to deliver one of the interventions we would like to invite you to participate in this study. We will also be inviting you to discuss your experiences of taking part in the study during a short one-off group discussion, called a focus group, at the end of the study.

Who is this study conducted by?

This research is being organised by University Hospitals of Leicester NHS Trust and University of Nottingham and is being funded by the National Institute of Health Research, Collaboration for Leadership in Applied Health Research and Care (East Midlands).

Why have I been invited?

You are being invited to take part as you are a physiotherapist and treat people with low back pain within physiotherapy at University Hospitals of Leicester NHS Trust.

Do I have to take part?

No, your participation is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form and a copy will be given to you to keep. If you do decide to take part, you are still free to withdraw at any time, without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

You will be asked to assess and treat people with low back in the intervention you have been trained in as you would do as part of your normal practice as a physiotherapist. Some of your treatment sessions may be video recorded. The purpose of this is to ensure that the interventions are being delivered in the ideal way.

Expenses and payments

There is no payment for participating in this study.

What are the possible disadvantages and risks of taking part?

There are no foreseen risks to taking part in this study. You will be delivering interventions to people with low back pain that you normally do as a qualified physiotherapist.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

What if I am harmed by the study?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the Chief Investigator, Mr Newton (contact details can be found on page 4) who will do his best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Professor Pip Logan, who is Mr Christopher Newton's academic supervisor at University of Nottingham. Professor Logan's contact details can be found on page 4 of this document.

What are the possible benefits of taking part?

The information we get from this study may help improve the knowledge we have about this condition, inform future research and improve the future treatment of people with low back pain.

What happens when the research study stops?

Your involvement in the study will end when you discharge your last enrolled patient in this study.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice in accordance with the Data Protection Act (2018) and all information about you will be handled in confidence. Your name and contact details will be removed (anonymised) from any information we collect about you and a unique code will be used so that you cannot be recognised from it. All data that you provide will be stored in a secure and locked office, and on a password protected computer database. Any information about you which leaves the hospital and transferred to secure computers at University of Nottingham will be anonymised.

University Hospitals of Leicester NHS Trust will collect information from you for this research study in accordance with our instructions. University Hospitals of Leicester NHS Trust will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded, and to oversee the quality of the study. Individuals from

University Hospitals of Leicester NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study. The Physiotherapy Department will pass these details to University Hospitals of Leicester NHS Trust along with the information collected from you. The only people in University Hospitals of Leicester NHS Trust who will have access to information that identifies you will be people who need to contact you from the research team or to audit the data collection process. The people who analyse the information on behalf of the sponsor (University Hospitals of Leicester NHS Trust staff and regulatory organisations) will not be able to identify you and will not be able to find out your name, or contact details.

University Hospitals of Leicester NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished. After this time your data will be disposed of securely.

General Data Protection Regulation (GDPR)

University Hospitals of Leicester NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this research and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

http://www.leicestershospitals.nhs.uk/aboutus/our-news/general-data-protection-regulations-gdpr/

Information published by sponsor unit/department/organisation

As a NHS organisation we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Our Data Protection Officer is Mr Saiful Choudhury and you can contact them at pils@uhl-tr.nhs.uk

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw you will no longer be eligible to assess and treat any further patient participants recruited into the study but you will continue with your

normal role within the Physiotherapy Department at University Hospitals of Leicester NHS Trust. If you withdraw the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of this research will be written up as part of a PhD thesis. It is also anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands - Nottingham 1 Research Ethics Committee on 1st February 2019.

Further information and contact details

Mr Christopher Newton
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Nottingham. NG7 2UH.
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E-mail:pip.logan@nottinham.ac.uk

CONSENT FORM - Physiotherapists

Title of Study: Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial. Phase 1.

IRAS Project ID: 253668

Name of Researcher: Mr Christopher Newton

Name of Participant: Please initial box

1. I confirm that I have read and understand the Participant Information Sheet (Version 2 – 22/12/18) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that my personal details will be kept confidential. ☐
4. **Optional:** I agree to my consultations being video recorded for research purposes. ☐
5. **Optional:** I agree that the video recordings may be used for future training and education of health care professionals only. ☐
6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant and 1 for the site file.

Appendix K: CFT competency checklist

Patient examination	Check list	Y/N	Comments
Subjective examination	1. **Patients story**….history including mechanism of pain onset and associated contextual. Explores previous treatments, and effectiveness (physio, meds, procedures etc) 2. **Beliefs** – cause of pain, scans, pain=harm, expectations for Rx, future etc 3. **Impact of pain** - *disability levels* – pain provocation / avoidance - *specific pain provocation and easing patterns* (postures, movements related to valued activities) - clear *targets for exposure* identified - *emotional responses / impact* – fear, distress, mood etc 4. **Contextual factors** ….home, work etc 5. Identifies **lifestyle factors** – PA, sleep etc 6. Patients **values and goals identified** 7. **General health** / scans / screen red flags if indicated	Y Y Y Y Y Y Y Y Y Y	Relates to driving job and also started after bereavement. Identified concerns re cause – cancer. OA hip, uncertainty++ Yes husband unwell Walking dog Self manage with exercise
Physical examination	1. **Observation** of pain provocative, feared and avoided behaviors 2. **Identifies safety behaviors** 3. **Behavioral experiments** – effectively teaches relaxation, abolishes safety behaviors prior to and during exposure 4. **Explores patients beliefs, emotions, pain responses** prior to, during and after exposure 5. Demonstrates ability to facilitate **behavior modification and pain control** during exposure 6. **Identifies discrepancies** between expectation and experience to feared / avoided activities 7. **Uses feedback** – visual, sensory, palpation	Y Y Y Y Y Y Y	Great assessment & explanation of tissue sensitivity, sensitive to light touch – reflective BE relaxing and loading right leg, avoidant of this

CFT intervention		Y/N	Comments
Making sense of pain	1. **Patient centred education** (taken from examination) Includes **context, beliefs, emotional and behavioral** response to pain 2. **Dispels biomedical myths**…and reinforces BPS approach to understanding pain 3. **Identifies key targets for change** – mindset, pain responses and movement habits, lifestyle factors 4. Clear **goal setting**…..aligned with patient 5. **Verbal and written info is clear** 6. Directs patient to **key resources** as indicated 7. Gives patient **homework** re goal setting / reading / diary 8. **Exacerbation plan** 9. **Appropriate referral if indicated**	Y Y Y Y Y Y Y N NA	
Exposure with control	Identifies 3-6 key **exercises of graded exposure** that are simple and **aligned to the patients goals** **Body relaxation, pain control and safety behaviors** considered **Dose is clear**	Y Y Y	Could have pushed more but achieved control
Lifestyle change	Where indicated: **Physical activity** program based on preference and sensitivity / load tolerance **Advice re sleep, diet** where indicated Directed to resources where indicated	 Y Y	
Communication style	Open questioning Reflective listening Validation / affirmation Delivers consistent messages Enables and facilitates disclosure Comfortable with emotional distress Identifies discrepancies in beliefs and behaviors Avoids conflict Summarises	Y Y Y Y Y NA Y Y Y	

Black list behaviours
Provides mixed messages – reinforcing fear and biomedical beliefs **Dismisses persons pain and distress** **Reinforces belief that pain is dangerous and passive treatments are needed** None
Feedback
Beliefs identified – unsure of cause but anxiety re OA or bone cancer Picked up on safety behaviours, holding back and validated experience Good reflection of beliefs and uncertainty. Identified safety behaviours Poor sleep sometimes due to lower back Validating- coper, carries on coper – you're a battler aren't you. Goals walking dog for longer Strong TA – patient felt understood, validated. Good humour Great summary of study and contextual factors – validated. Behavioural experiments – achieved pain control Great metaphor 'puppet' strings –let go flop down Feedback through palpation and mirroring during functional activity Graded bending and lifting, walking pace increased – generalised very quickly Reassured ++ not hip pathology due to behavioural experiments. Reassured through history and assessment not Ca Patients words – I now know I'm not going to injure myself or make anything worse – evidence of belief change through behavioural experiments Vicious cycle with contextual factors (stressful time of life). Great explanation of sensitivity due to numerous factors – sleep, uncertainty, lack of physical activity Home programme clear and lifestyle change with brisk walking

Appendix L: Exercise adherence diary

Exercise Diary

	Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Month 1																																
Month 2																																
Month 3																																
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Instructions: Please record the number of times you completed your exercise programme.

Appendix M: UPC fidelity checklists

Patient examination	Check list	Y/N	Comments
Subjective History	1. **History presenting complaint** including, onset, duration, mechanism, pain location, aggs and easing, 24 hour pattern	Y	From some other notes
	2. **General health** / scans / screen red flags	Y	
	3. **Drug history**	Y	
	4. **Social history**	Y	
	Any other factors discussed e.g. beliefs, lifestyle		
	5. **Psychological factors considered/addressed**	Y	
	5. **Identifies goals**	Y	
Physical examination	8. **Observation** e.g., posture, muscle bulk, gait etc	Y	
	9. **Active movement assessment** inc. joints above/below, combined, repeated movements, over-pressure	Y	
	10. **Passive movement assessment** e.g., PPIVM's, PAIVM's, other joints	Y	
	11. **Palpation** (structures, pain response etc)	Y	
	12. **Neurological examination**	Y	
	13. **Special tests** e.g. hip and SI	N	
Usual care intervention		Y/N	Comments
	10. **Education** (e.g., structural, postural, pain science, scans etc)	Y	
	11. **Exercise programme** (Type/Dosage clear)	Y	
	12. **Manual therapy**	N	
	13. **? Classes**	N	
	14. **Verbal and written info is clear**	Y	
	15. **Appropriate referral if indicated** (e.g. active lifestyle, IAPT etc)	NA	
	16. **Lifestyle advice**	N	
	17. **Other** (e.g., education re fear avoidance, pain neuroscience etc).	N	
Comm style	Questioning style	Y	Largely therapist
	Listening	Y	
	Summarises	Y	No MI.

Feedback
Very little patient talking time – her side. Much more him going through from medical standpoint.
Lots of re-assurance and BPS components to de-threaten the movement, challenge posture expectations and a variety of other aspects.
Consistent with usual care but I think we could say there is some contamination here with the CFT arm of what is done locally.
Possible the effect of the camera but also local learning/mindset.

Appendix N: Missing items from PROM's

Outcome measure	Missing items (number and %)		
	Baseline (n-60)	3 months (n=48)	6 months (n=43)
RMDQ	0/1140 (0%)	0/1152 (0%)	0/1032 (0%)
NPRS	0/60 (0%)	0/48 (0%)	0/43 (0%)
FABQ	**22/960 (2.3%)**	**83/768 (10.8%)**	**28/688 (4.0%)**
STarT Back	0/540 (0%)	0/432 (0%)	0/387 (0%)
PSEQ	0/600 (0%)	0/480 (0%)	0/430 (0%)
PCS	0/780 (0%)	**21/624 (3.4%)**	0/559 (0%)
DASS-21	0/1260 (0%)	**21/1008 (2.1%)**	**21/903 (2.3%)**
EQ-5D-5L index	0/300 (0%)	0/240 (0%)	0/215 (0%)
EQ VAS	0/60 (0%)	0/48 (0%)	0/43 (0%)
GRC	-	**1/48 (2.0%)**	0/48 (0%)
WATOCI	-	**67/768 (8.7%)**	-
Satisfaction	-	0/192 (0%)	0/102 (0%)
Total missing items	22/5700 (0.39%)	213/5808 (3.7%)	49/5203 (0.94%)

Number and percentage of missing items from the patient reported outcome measures at baseline, three and six-month follow-up. Each questionnaire is reported for total missing items versus total possible responses for each questionnaire and expressed as a percentage.

Appendix O: Treatment fidelity

To determine treatment fidelity, the individual components of the fidelity checklists were totalled and expressed as a percentage. Fidelity was confirmed if at least 80% of the intervention components were observed as being present or evidenced by documentation in the clinical notes. The table below summarises the notes audit and direct observation of the CFT interventions delivered within the feasibility RCT.

Components of CFT	**Notes audit**		**Observation**	
	n	**%**	**n**	**%**
Subjective assessment				
Patients story	28	100%	5	100%
Beliefs identified	28	100%	5	100%
Pain impact	28	100%	5	100%
Contextual factors	28	100%	5	100%
Lifestyle factors	28	100%	5	100%
Values and goals identified	28	100%	5	100%
General health inc. red flag screening	28	100%	5	100%
Use of psychosocial screening tool	23	82%	5	100%
Physical examination				
Observation (pain provocative, feared or avoided behaviours)	28	100%	5	100%
Identifies safety behaviours	28	100%	5	100%
Evidence of behavioural experiments	28	100%	5	100%
Explores beliefs, emotions, pain responses prior to during and after exposure	**20**	**71%**	4	80%
Behaviour modification with pain control	**21**	**75%**	5	100%
Identifies discrepancies between expectation and experience to feared/avoided activities	**18**	**65%**	4	80%
Visual, sensory, palpation feedback	26	93%	5	100%
Making sense of pain				
Patient centred education	28	100%	4	80%
Dispels biomedical myths	24	88%	4	80%
Identifies key targets for change	28	100%	5	100%

Evidence of patient centred goals	28	100%	4	80%
Written information is clear	**21**	**75%**	n/a	n/a
Directed to key resources (e.g. pain-ed.com)	**16**	**57%**	4	80%
Evidence of home programme	28	100%	5	100%
Exacerbation plan	**14**	**50%**	3	100%
Exposure with control				
Identifies 3-6 key exercise of graded exposure	28	100%	5	100%
Teaches body relaxation, pain control	25	93%	5	100%
Dose is clear	**16**	**57%**	**4**	**80%**
Lifestyle change (where indicated)				
Physical activity programme	26	93%	4	80%
Lifestyle advice (sleep hygiene, diet, smoking)	8	29%	2	40%
Communication				
Open questioning	-	-	5	100%
Reflective listening	-	-	5	100%
Validation / affirmation	-	-	4	100%
Delivers consistent messages	**-**	**-**	5	100%
Enables and facilitates disclosure	-	-	5	100%
Comfortable with emotional distress	-	-	n/a	n/a
Identifies discrepancies in beliefs and behaviours	-	-	4	80%
Avoids conflict	**-**	**-**	5	100%
Summarises	-	-	5	100%
Total (%)	668	88.4%	158	93%

Summary of the notes audit and direct observation of CFT intervention during the feasibility RCT. Text highlighted in bold font represents components of the intervention not achieving the 80% fidelity threshold.

UPC treatment fidelity

Components of usual physiotherapy care	Notes audit		Observation	
	n	%	n	%
Subjective assessment				
History of presenting complaint	20	100%	5	100%
General health inc. red flag screening	20	100%	5	100%
Identified psychosocial factors (e.g. beliefs, emotions)	**10**	**50%**	**2**	**40%**
Use of psychosocial screening tool	**0**	**0%**	**0**	**0%**
Patient-centred goals identified	**9**	**45%**	**3**	**60%**
Physical examination				
Observation (e.g. gait, posture, muscle bulk)	20	100%	5	100%
Palpation (e.g. structural, pain response)	**12**	**60%**	**3**	**60%**
Active movement assessment	20	100%	5	100
Passive movement assessment	**6**	**30%**	**3**	**60%**
Special tests (e.g. hip, sacroiliac joint)	**9**	**45%**	**4**	**80%**
Treatment				
Education (total)	**15**	**75%**	5	100%
Reassurance (e.g. imaging findings, hurt ≠ harm)	15	75%	5	100%
LBP booklet	**7**	**35%**	**2**	**40%**

Spinal anatomy	5	25%	1	20%
Pain neuroscience education	8	40%	3	60%
Posture	2	10%	2	40%
Exercise (total)	20	100%	5	100%
Cardiovascular	**7**	**35%**	**3**	**60%**
Stretching	**8**	**40%**	**4**	**80%**
Strengthening	14	70%	4	80%
Back class	**2**	**10%**	**0**	**0%**
Dose is clear	**3**	**15%**	**1**	**20%**
Written information is clear	**4**	**20%**	n/a	n/a
Manual therapy	**0**	**0%**	**2**	**40%**
Communication				
Evidence of therapeutic alliance	-	-	3	60%
Active listening	-	-	2	40%
Summarising	-	-	3	60%
Total (%)	161	62%	55	68.8%

Summary of the notes audit and direct observation of the UPC intervention during the feasibility RCT.
Text highlighted in bold font represents components of the intervention not achieving the 80% fidelity threshold

Other identified UPC interventions	Notes audit		Observation	
	n	%	n	%
Motivational interviewing style	-	-	1	20%
Lifestyle advice (e.g. sleep hygiene, diet, smoking)	7	35%	2	40%
Breathing control/relaxation exercises	11	55%	4	80%
Addressing safety behaviours	3	15%	0	0%
Mindfulness meditation	2	10%	0	0%
Graded exposure to feared/avoided movement(s)	3	15%	1	20%
Pain-ed website	2	10%	1	20%
Total (%)	28	23.3%	9	25.7%

Frequency and percentage of other treatments provided by UPC that were not listed in the study protocol.

Appendix P: Sample size calculation options

Email (16/12/2020) from Dr Helen Purtill, Lecturer in statistics, Department of Mathematics and Statistics, University of Limerick, Ireland who calculated a range of sample sizes for a future RCT.

Hi Chris,

For your thesis you would be recommending a cRCT as a possible design for a future trial to avoid contagion.

You can state that moderate/large effect sizes in your feasibility study give information that allows you to power a future cRCT. You could then give a couple of sample size calculations for a future Cluster RCT based on Cohen's D = 0.5 (moderate effect size). A Cohen's D of 0.5 is the same as a mean difference of 1 on VAS where SD = 2, or a mean difference of 3 on RMDQ with a SD = 6.

The reason I gave you the excel spreadsheet is that you might have different constraints on the number of clusters (sites you have available) or the number of people you recruit to the trial with within a site.

So you could report in your thesis a couple of different sample size calculations based on the constraints and maybe assume a conservative value for the ICC = 0.07 (that is assuming there is a non-negligible effect of site on the outcome – ie a clustering effect).

I've highlighted the ICC = 0.07 row in the spreadsheet and picked two sample size calculations (one for a constraint of 20 people per cluster in Table 1, and one for a constraint of having only 6 clusters in each arm of the trial).

1. A cRCT with 8 clusters of 20 participants in each arm of the 2-armed trial has 80% power of detecting a mean difference of 1 on the VAS with a standard deviation of 2 (ie a Cohen's D effect size of 0.5) at the 5% level of significance (two-tailed test), assuming an ICC of 0.07. Total sample size required = 320 (assuming no drop-out).

2. A cRCT with 6 clusters per arm requires 40 participants in each cluster of the 2-armed trial to have 80% power of detecting a mean difference of 1 on the VAS with a standard deviation of 2 (ie a Cohen's D effect size of 0.5) at the 5% level of significance (two-tailed test), assuming an ICC of 0.07. Total sample size required = 480 (assuming no drop-out).

Hope this helps. I'd be happy to talk you through the spreadsheet if you'd like?

All the best

Helen

Cluster RCT sample size options

Moderate effect size Cohen's D = 0.5, 64 individuals per arm is required to ensure 90% power in an individual RCT

n_I = 86 **(n_I = number required per arm for an individual two-armed RCT)**

Number of Particpants per Cluster is FIXED (Tables 1 & 2)

Table 1: Number of clusters per arm required

	Number of Particpants per cluster			
ICC	10	15	20	30
0.01	10	7	6	4
0.02	11	8	6	5
0.03	11	9	7	6
0.04	12	9	8	7
0.05	13	10	9	8
0.06	14	11	10	8
0.07	15	12	11	9
0.08	15	13	11	10
0.09	16	13	12	11
0.1	17	14	13	12

Table 2: Total sample size required per arm

	Number of Particpants per cluster			
ICC	10	15	20	30
0.01	100	105	120	120
0.02	110	120	120	150
0.03	110	135	140	180
0.04	120	135	160	210
0.05	130	150	180	240
0.06	140	165	200	240
0.07	150	180	220	270
0.08	150	195	220	300
0.09	160	195	240	330
0.1	170	210	260	360

Number of Clusters is FIXED (Tables 3 & 4)

Table 3: Number of participants per cluster Note: k > n_I * ICC, otherwise NA

	Number of Clusters						
ICC	6	7	8	9	10	11	12
0.01	17	14	12	11	10	9	8
0.02	20	16	14	12	11	10	9
0.03	25	19	16	13	12	10	9
0.04	33	24	19	15	13	11	10
0.05	49	31	23	18	15	13	11
0.06	97	44	29	22	17	14	12
0.07	NA	82	41	27	21	17	14
0.08	NA	660	71	38	26	20	16
0.09	NA	NA	301	63	35	25	19
0.1	NA	NA	NA	194	56	33	23

Table 4: Total sample size required per arm

	Number of Clusters						
ICC	6	7	8	9	10	11	12
0.01	102	98	96	99	100	99	96
0.02	120	112	112	108	110	110	108
0.03	150	133	128	117	120	110	108
0.04	198	168	152	135	130	121	120
0.05	294	217	184	162	150	143	132
0.06	582	308	232	198	170	154	144
0.07	NA	574	328	243	210	187	168
0.08	NA	4620	568	342	260	220	192
0.09	NA	NA	2408	567	350	275	228
0.1	NA	NA	NA	1746	560	363	276

Appendix Q: Cover letter, participant information sheets and consent forms for qualitative process evaluation (Chapter four)

Cover letter patient interviews Phase 2 Version 1 (22/12/18)
IRAS ID: 253668

University Hospitals of Leicester NHS
NHS Trust
Physiotherapy Department
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
Tel 0300 303 1573

Date

Dear {*name*},

Re: 'Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial: Phase 2 interviews'.

Thank you for talking to us on the telephone about the above named research study. I have enclosed the study information as discussed over the telephone, please can you read it before you come to your arranged appointment on (date to be added).

It is important for you to understand why we are doing this study. Please take time to read the participant information sheet carefully which tells you more about this study and what will be required if you decide to take part.

The appointment will be at your own home / in the Physiotherapy Department at University Hospitals of Leicester NHS Trust (delete as appropriate), (address given at the top of this letter).

If you would like any further information about the study or you need to rearrange your appointment with the research team then do not hesitate to contact us on the number given above.

Yours sincerely

Mr Christopher Newton
Physiotherapist

Participant Information Sheet

Title of Study: **Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial: Phase 2 interviews.**

Name of Researcher(s): Mr Christopher Newton

You have recently participated in a study that compared two physiotherapy treatments for people with low back pain, Cognitive Functional Therapy and usual physiotherapy care. We would now like to invite you to participate in the second phase of this study that aims to understand your experiences of participating in this research.

Before you decide whether or not to take part in this study, we would like to explain why we are doing this research and what it will involve for you. Please read the following information and ask us if anything is not clear. If you would like more information, then please contact us using one of the options listed at the end of this leaflet.

Please note that this study is being performed as part of an educational qualification.

What is the purpose of the study?

The purpose of this study is understand your experiences of participating in a previous study called 'Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial'. This will involve a short one-off discussion and aims to understand your experiences of the study processes and treatment that you received.

Who is this study conducted by?

This research is being organised by University Hospitals of Leicester NHS Trust and University of Nottingham and is being funded by the National Institute of Health Research, Collaboration for Leadership in Applied Health Research and Care (East Midlands).

Why have I been invited?

You are being invited to take part as you participated in the first phase of this study called, 'Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial'.

Do I have to take part?

No, your participation is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form and a copy will be given to you to keep. If you do decide to take part, you are still free to withdraw at any time, without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

You will be invited to participate in an informal discussion that will take place in your own home or the physiotherapy department at University Hospitals of Leicester NHS Trust, depending on your preference. The discussion will be arranged on a date and time convenient to you and is expected to last no more than 1 hour. The discussion will be with a member of the research team and will involve asking you simple questions about your experiences of the research study and the treatment you received. If, after talking to the researcher, you understand the requirements of the research and are interested in participating you will be asked to sign a consent form indicating your agreement to participate in the study.

The discussion will be audio-recorded using a Dictaphone and recordings will be converted into text and some quotes used in a written report for the University of Nottingham and future scientific publications. Any quotes or discussions will be anonymised, so no one will know it was you who made the comments. There will be no other use of the recordings. Once the discussion has finished no further participation is required by you.

Expenses and payments

There is no payment for participating in this study.

What are the possible disadvantages and risks of taking part?

There are no foreseen risks to taking part in this study. You will have to take time to complete the discussion. Apart from that there are no disadvantages or risks to taking part in this research. Should you feel uncomfortable with any of the questions during the discussion you are free to end the discussion at any point.

What if I am harmed by the study?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the Chief Investigator, Mr Christopher Newton (contact details can be found at the bottom of page 5) who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service at pils.complaints.compliments@uhl-tr.nhs.uk. The Firs, c/o Glenfield Hospital, Groby Road, Leicester. LE3 9QP Freephone: 0808 1788337

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against University Hospitals of Leicester NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What are the possible benefits of taking part?

The information we get from this study may help inform future research and direct future treatment to patients with low back pain.

What happens when the research study stops?

If you decide to participate your involvement will stop immediately at the end of the discussion.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice in accordance with the Data Protection Act (2018) and all information about you will be handled in confidence. The discussion will be recorded using a Dictaphone. At the end of the discussion the recording will be transferred and stored electronically on a University of Nottingham password protected computer and permanently deleted from the Dictaphone within 24 hours. Your name and contact details will be removed (anonymised) from any information we collect about you and a unique code will be used so that you cannot be recognised from it. The recording will be typed up by the Chief Investigator, Mr Newton, using the same password protected computer. Paper copies of the transcripts will be stored in a secure locked filing cabinet in a locked office at University Hospitals of Leicester NHS. All electronic and paper copies of the discussion will be stored as described and destroyed 5 years after study completion in line with University Hospitals of Leicester NHS Trust data archiving policy.

University Hospitals of Leicester NHS Trust will collect information from you for this research study in accordance with our instructions. University Hospitals of Leicester NHS Trust will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded, and to oversee the quality of the study. Individuals from University Hospitals of Leicester NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study. The Physiotherapy Department will pass these details to University Hospitals of Leicester NHS Trust along with the information collected from you. The only people in University Hospitals of Leicester NHS Trust who will have access to information that identifies you will be people who need to contact you from the research team or to audit the data collection process. The people who analyse the information on behalf of the sponsor (University Hospitals of Leicester NHS Trust staff and regulatory organisations) will not be able to identify you and will not be able to find out your name, or contact details.

University Hospitals of Leicester NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished. After this time your data will be disposed of securely.

General Data Protection Regulation (GDPR)

University Hospitals of Leicester NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this research and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

http://www.leicestershospitals.nhs.uk/aboutus/our-news/general-data-protection-regulations-gdpr/

Information published by sponsor unit/department/organisation

As a NHS organisation we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take

part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). Our Data Protection Officer is Mr Saiful Choudhury and you can contact them at pils@uhl-tr.nhs.uk

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of this research will be written up as part of an academic qualification. It is also anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands - Nottingham 1 Research Ethics Committee on 1st February 2019.

Further information and contact details

Mr Christopher Newton
Extended Scope of Practice Physiotherapist / PhD Candidate, University of Nottingham.
Physiotherapy Outpatients Department
Balmoral Building, Level 0
Leicester Royal Infirmary
Infirmary Square
Leicester.
LE1 5WW.
Tel: 0116 258 5815
E-mail:christopher.newton@nottingham.ac.uk

Professor Pip Logan
Professor of Rehabilitation Research
Head of Division Rehabilitation and Ageing
B108a, School of Medicine
University of Nottingham
Nottingham. NG7 2UH.
Tel: 0115 8230235
E-mail:pip.logan@nottinham.ac.uk

CONSENT FORM – Patient Participants.

Title of Study: Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial. Phase 2 – Qualitative patient participant interviews.

IRAS Project ID: 253668

Name of Researcher: Mr Christopher Newton

Name of Participant: Please initial box

1. I confirm that I have read and understand the Participant Information Sheet (Version 1 – 22/12/18) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University Hospitals of Leicester NHS Trust and University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview will be audio-recorded and that all information given will be strictly confidential. ☐
5. I understand that the audio recorded data will be transferred to a password protected computer and will be permanently deleted from the audio recording device (Dictaphone) within 24 hours. ☐
6. I understand that the audio recording will be transcribed verbatim but all personally identifiable data will be removed from the transcript. ☐
7. I understand that electronic data (audio file and transcript) will be stored on a password encrypted computer and then destroyed in line with University Hospitals of Leicester NHS Trust Research and Development policy 5 years after the study has been completed. ☐
8. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the site file and 1 for the medical notes

University Hospitals of Leicester NHS
NHS Trust

Physiotherapy Department
Level 0, Balmoral Building
Leicester Royal Infirmary
Leicester
LE1 5WW
Tel: 0116 2585816

Date

Dear

Re: 'Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial: Phase 2 Focus Group'.

You have recently participated in a study, as a physiotherapist, that compared two physiotherapy treatments for people with low back pain, Cognitive Functional Therapy and usual physiotherapy care. We would now like to invite you to participate in the second phase of this study that aims to understand your experiences of participating in this research.

Please take time to read the participant information sheet enclosed with this letter which tells you more about this study and what will be required if you decide to take part in the research.

If you would like to take part in this study, please contact the Chief Investigator, Mr Christopher Newton on the email provided at the bottom of the accompanying participant information sheet and an appointment will be arranged in the Physiotherapy Department at University Hospitals of Leicester NHS Trust to discuss the study further, answer any question you may have and gain your consent to participation. A date will then be arranged for you to participate in the focus group.

Yours sincerely

Mr Christopher Newton
Physiotherapist

Participant Information Sheet

Title of Study: **Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial: Phase 2 focus groups.**

Name of Researcher(s): Mr Christopher Newton

You have recently participated in a study, as a physiotherapist, that compared two physiotherapy treatments for people with low back pain, Cognitive Functional Therapy and usual physiotherapy care. We would now like to invite you to participate in the second phase of this study that aims to understand your experiences of participating in this research.

Before you decide whether or not to take part in this study, we would like to explain why we are doing this research and what it will involve for you. Please read the following information and ask us if anything is not clear. If you would like more information, then please contact us using one of the options listed at the end of this leaflet.

Please note that this study is being performed as part of an educational qualification.

What is the purpose of the study?

The purpose of this study is understand your experiences of participating in a study called 'Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial'. This will involve a short one-off discussion, known as a focus group, and aims to understand your experiences of the study processes and the intervention that you delivered.

Who is this study conducted by?

This research is being organised by University Hospitals of Leicester NHS Trust and University of Nottingham and is being funded by the National Institute of Health Research, Collaboration for Leadership in Applied Health Research and Care (East Midlands).

Why have I been invited?

You are being invited to take part as you are a physiotherapist who participated in the first phase of this study.

Do I have to take part?

No, your participation is entirely voluntary. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form and a copy will be given to you to keep. If you do decide to take part, you are still free to withdraw at any time, without giving a reason. This would not affect your legal rights.

'hat will happen to me if I take part?

ɔu will be invited to participate in a focus group discussion. We will be running two focus groups, one ith physiotherapists who delivered usual physiotherapy care and the other with physiotherapists who elivered Cognitive Functional Therapy. The focus group will contain up to five physiotherapists and ill be completed in a quiet room. The focus group will be a relaxed and informal discussion facilitated / a member of the research team. It will take place at your place of work, in the physiotherapy epartment at University Hospitals of Leicester NHS Trust. The focus group is expected to last no more an 1 hour and will be completed during your normal working hours. It will involve asking you simple uestions about your experiences of the intervention you delivered and the research process of the asibility study. If, after talking to the researcher, you understand the requirements of the research nd are interested in participating you will be asked to sign a consent form indicating your agreement participate in the study.

ne focus group discussion will be audio-recorded using a Dictaphone and recordings will be converted to text and some quotes used in future publications and the chief investigators PhD thesis. Any uotes or discussions will be anonymised, so no one will know it was you who made the comments. nere will be no other use of the recordings. Once the focus group discussion has finished no further rticipation is required by you.

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nere is no payment for participating in this study.

'hat are the possible disadvantages and risks of taking part?

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'hat if I am harmed by the study?

is very unlikely that you would be harmed by taking part in this type of research study. However, you wish to complain or have any concerns about the way you have been approached or treated in ɔnnection with the study, you should ask to speak to the Chief Investigator, Mr Newton (contact etails can be found on page 4) who will do his best to answer your questions. If you remain nhappy and wish to address your concerns or complaints on a formal basis, you should contact Mr ewton's academic supervisor, Professor Pip Logan at University of Nottingham (contact details can e found on page 4 of this document).

What are the possible benefits of taking part?

ne information we get from this study may help inform future research and direct future treatment patients with low back pain.

'hat happens when the research study stops?

you decide to participate in the focus group your involvement will stop immediately at the end of e focus group discussion.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice in accordance with the Data Protection Act (2018) and all information about you will be handled in confidence. The focus group will be recorded using a Dictaphone. At the end of the focus group the recording will be transferred and stored electronically on a University of Nottingham password protected computer and permanently deleted from the Dictaphone within 24 hours. Your name and contact details will be removed (anonymised) from any information we collect about you and a unique code will be used so that you cannot be recognised from it. The focus group recordings will be typed up by the Chief Investigator, Mr Newton, using the same password protected computer. Paper copies of the transcripts will be stored in a secure locked filing cabinet in a locked office at University Hospitals of Leicester NHS. All electronic and paper copies of the focus group data will be stored as described and destroyed 5 years after study completion in line with University Hospitals of Leicester NHS Trust data archiving policy.

University Hospitals of Leicester NHS Trust will collect information from you for this research study in accordance with our instructions. University Hospitals of Leicester NHS Trust will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded, and to oversee the quality of the study. Individuals from University Hospitals of Leicester NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study. The Physiotherapy Department will pass these details to University Hospitals of Leicester NHS Trust along with the information collected from you. The only people in University Hospitals of Leicester NHS Trust who will have access to information that identifies you will be people who need to contact you from the research team or to audit the data collection process. The people who analyse the information on behalf of the sponsor (University Hospitals of Leicester NHS Trust staff and regulatory organisations) will not be able to identify you and will not be able to find out your name, or contact details.

University Hospitals of Leicester NHS Trust will keep identifiable information about you from this study for 5 years after the study has finished. After this time your data will be disposed of securely.

General Data Protection Regulation (GDPR)

University Hospitals of Leicester NHS Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this research and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information

http://www.leicestershospitals.nhs.uk/aboutus/our-news/general-data-protection-regulations-gdpr/

Information published by sponsor unit/department/organisation

As a NHS organisation we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take

part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).Our Data Protection Officer is Mr Saiful Choudhury and you can contact them at pils@uhl-tr.nhs.uk

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far cannot be erased and this information may still be used in the project analysis.

What will happen to the results of the research study?

The results of this research will be written up as part of a PhD thesis. It is also anticipated that the results of the study will be published in scientific journals as well as being presented at relevant conferences. You are entitled to receive a summary of the results if you wish.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by East Midlands - Nottingham 1 Research Ethics Committee on 1st February 2019.

Further information and contact details

Mr Christopher Newton
Extended Scope of Practice Physiotherapist / PhD Candidate, University of Nottingham.
Physiotherapy Outpatients Department
Balmoral Building, Level 0
Leicester Royal Infirmary
Infirmary Square
Leicester.
LE1 5WW.
Tel: 0116 258 5815
E-mail:christopher.newton@nottingham.ac.uk

Professor Pip Logan
Professor of Rehabilitation Research
Head of Division Rehabilitation and Ageing
B108a, School of Medicine
University of Nottingham
Nottingham. NG7 2UH.
Tel: 0115 8230235
E-mail:pip.logan@nottinham.ac.uk

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

CLAHRC East Midlands

University Hospitals of Leicester NHS
NHS Trust

CONSENT FORM – Physiotherapists

Title of Study: Cognitive Functional Therapy for persistent low back pain: A mixed methods feasibility randomised controlled trial. Phase 2 – Physiotherapist focus groups

IRAS Project ID: 253668

Name of Researcher: Mr Christopher Newton

Name of Participant: Please initial box

1. I confirm that I have read and understand the Participant Information Sheet (Version 1 – 22/12/18) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my rights being affected. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
3. I understand that the data collected in the study may be looked at by authorised individuals from the University Hospitals of Leicester NHS Trust and University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview will be audio-recorded and that all information given will be strictly confidential. ☐
5. I understand that the audio recorded data will be transferred to a password protected computer and will be permanently deleted from the audio recording device (Dictaphone) within 24 hours. ☐
6. I understand that the audio recording will be transcribed verbatim but all personally identifiable data will be removed from the transcript. ☐
7. I understand that electronic data (audio file and transcript) will be stored on a password encrypted computer and then destroyed in line with University Hospitals of Leicester NHS Trust Research and Development policy 5 years after the study has been completed. ☐
8. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the site file and 1 for the medical notes

Appendix R: Process evaluation topic guides

University Hospitals of Leicester NHS Trust

Interview Schedule: Patients

1) **Meet and greet (1 mins)**
   'Hi, thank you for coming today, my name is …..and I am assisting in collecting data for this study'
2) **Gain consent (2 mins)**
   'You have agreed to take part in an interview which is an informal chat with me. This will be about the research trial you have taken part in and how you found it. It is a chance for you to tell me anything that you think is relevant.'
   'Do you have any questions so far?'
   'Are you happy for me turn on the Dictaphone to record the interview as it takes place?
   For the benefit of the tape it is …day…..time and present there is me (Research assistant) and (patient ID)'
3) **Withdrawal (2 mins)**
   'If anything we speak about today does make you feel uncomfortable you are free to not answer a particular question, you can ask for the recorder to be switched off to resume the interview after a short break or you can ask to terminate the interview all together at any point.'
   'We will start the interview now'
4) **Questions (35 mins)** (Please see below for individual interview questions)
5) **Close (5 mins)**
   'I have asked all the questions I need to, do you have anything else you would like to add? Thank you very much for your time and participation in today's interview. I will turn off the Dictaphone now. Do you have any questions?'

Questions for Participants

1) How did you hear about this research study?
2) How did you feel about the study?
3) What influenced your decision to take part in this study?
4) What were your expectations of entering the research study?
5) When you enrolled in this study you were randomly allocated to receive one of two intervention – usual physiotherapy care or Cognitive Functional Therapy. How did you feel about this? Did you have a preference? Do you know which intervention you received? If yes, how did they know? What was different?
6) How did you find this approach ?
7) Was it what you expected? If not, what were you expecting?
8) What do you understand this treatment to be?
9) Did it have an effect?
    - If not, why do you think it did not? What, if anything, was missing?
    - If so, what was the effect? What aspects did you find helpful?
10) Has this approach influenced,
    - your understanding of why you have/have had low back pain? Prompt for current beliefs.
    - how you cope with low back pain?
    - your ability to control pain or manage future episodes/flare-ups?
    - your ability to move your lower back and use your body normally?
    - your ability to perform everyday functional tasks (sitting, bending, lifting etc.), activities of daily living (washing, dressing etc.) , household chores and your work.
    - your lifestyle such as sleeping patterns, levels of exercise, sports and hobbies.
    - your confidence in your lower back and your ability to do these things?
    - your future outlook and your prognosis?
    - your quality of life?
11) How do you feel you got on with the therapist delivering CFT? What kind of relationship did you have?
12) Did they listen to you and to any concerns that you had?

13) Do you feel you were given enough time to speak and get your points across?
14) Were explanations given to you in a language that you could easily understand?
15) Was the educational material relevant to you? (e.g. outlining the vicious cycle of pain and functional exercises) If so, how was it useful?
16) Do you think the therapist understood how this problem was affecting you?
17) Would you like to make any further comments on the style of communication they used?
18) Do you think it is important to develop a positive relationship with your physiotherapist?
19) How did you feel about the exercise programme?
20) How did you get on following it at home?
21) Did you encounter any problems?
22) What did you enjoy?
23) Have you had any support during the programme? (healthcare professionals/ friends/family)
24) Did you use the smartphone app?
25) How did you find using the app? Prompts – were there any problems, what went well?
26) Has the intervention influence how you manage you manage your back pain?
27) Have you had any low back pain symptoms since starting the intervention? If yes, how did you manage this? What did you do?
28) You completed some questionnaires at the beginning and end of the intervention, how did you feel about this?
29) How suitable do you think they were? Prompts re questions, content and time to complete.
30) How do you feel about the whole experience of taking part in a research study?
31) Were there any factors that helped you maintain participation in the programme?
32) Were there any factors that prevented you from participating in the programme?
33) Do you have anything else you would like to add?

University Hospitals of Leicester NHS Trust

Interview Schedule

1) **Meet and greet (1 mins)**
   'Hi, thank you for coming today, my name is …..and I am assisting in collecting data for this study'
2) **Gain consent (2 mins)**
   'You have agreed to take part in this focus group which is an informal chat about the research trial you have taken part in and how you found it. It is a chance for you to tell me anything that you think is relevant.'
   'Do you have any questions so far?'
   'Are you happy for me turn on the Dictaphone to record the focus group as it takes place? For the benefit of the tape it is …day…..time and present there is me (Research assistant/PPI representative) and (Phyio ID's)'
3) **Withdrawal (2 mins)**
   'If anything we speak about today does make you feel uncomfortable you are free to not answer a particular question, you can ask for the recorder to be switched off to resume the interview after a short break or you can ask to terminate the interview all together at any point.'
   'We will start the interview now'
4) **Questions (35 mins)** (Please see below for individual interview questions)
5) **Close (5 mins)**
   'I have asked all the questions I need to, des anybody have anything else they would like to add? Thank you very much for your time and participation in today's interview. I will turn off the Dictaphone now. Does anybody have any questions?'

Questions for Participants

1) As you all know, this study compared two treatments for LBP, how did you feel about taking part in this study, when you were first approached?
2) What were your expectations of taking part in a research study?
3) What influenced your decision to take part in this study?

Separate group questions

4) You have previously been trained to deliver CFT/usual care? Can you tell me about your experience of the training you received? What was good, what could be improved, anything?
5) How did you find having your consultations video recorded? Did it help you practice? Did it hinder your practice? What was that experience like?
6) Would you like to make any further comments on the style of training used?
7) Was the educational material relevant to you? (e.g. workbooks, If so, how was it useful?)
8) What is usual care? What does this involve? What did you deliver to your patients? Prompts around fear, beliefs, mindset
9) Was your treatment effective? How do you know?
10) Did they do what you asked them to do, compliance/adherence. Self-management
11) Did your knowledge of being a treating physio in a research study influence your interactions and treatment with patients?
    a. Did you do anything differently, of so what

12) Were there any aspects of this approach that you found easy to implement?

13) Were there any aspects of this approach that were difficult to implement? Prompts, time, aspects of the intervention, availability of follow-up appointments and could the intervention be delivered at optimal dose? Was anything missing.

14) Do you think your patients knew which treatment they got?

15) How do you feel about the whole experience of taking part in a research study?

16) What went well? What could have been improved?

17) Do you have anything else you would like to add?

Appendix S: Coding list example

Patient 3 – codes

1 – Believes received CFT

2 – Perception of traditional physio – wouldn't have been pushed to do things

3 – Previously had private physio

4 – This approach different / opposite to any previous physio

5 – This treatment encouraged movement

6 – Previous physio as passive / stretching muscles

7 – Previous physio didn't involve physically doing things

8 – Treatment encouraged change in thought processes

9 – Positive reinforcement used by Physiotherapist

10 – Encouraged to believe he could do things

11 – Taught not to be scared of bending

12 – Taught not to stop activity due to pain

13 – Previous physio taught him avoidance

14 – Insightful into change of mindset needed

15 – Insight into prior to trial being stuck in a negative cycle

16 – Encouraged to move his body in a normal way

17 – Treatment used everyday activities

18 – Nervous about the treatment and the activities

19 – Insight into previous mindset being part of the problem

20 – Prior to the trial scared of the pain

21 – Prior to the trial had a lot of fear about movement

22 – Insight into previous fear compounding the pain

23 – Insight into previous avoidance of activities

24 – Now able to differentiate between level of pain

25 – Treatment has shown him he isn't causing himself damage

26 – Increased confidence post trial

27 -Treatment was a positive cycle of reinforcement

28 – Fear of pain is now reduced

29 – Low in mood prior to the trial

30 – Improved mood post treatment

31 – Now feels stronger and fitter

32 – recovery has exceeded his expectations

33 – Initial scepticism about taking part in the study / treatment

34 – Initial belief that pain had a physical cause

35 - Prior belief that he would need surgery

36 – Treatment was focused on coaching back to normal ways of moving

37 – Treatment has had a positive effect / improvement

38 – More relaxed now

39 – Back to an active lifestyle

40 – Back pain has stopped his previous active lifestyle

41 – Improved quality of life

42 – Prior to trial fear limited what he would do

43 – Now identifies BP to be linked with avoidance and reduced activity

44 – Insight into fear causing his body to tense

45 – Still thinks has some wear and tear but feels his reaction was disproportionate

46 – Insight into prior focus on pain

47 – Insight into previous avoidance of mvt due to pain

48 – Hard to trust someone when in pain

49 – Hard to accept the new advice given to him as conflicted with previous messages

50 – Initially intimidated by the forceful communication style of the Physio

51 – Deference to professional status

52 – Nervous for the first couple of sessions

53 – Seeing improvements led to trust in the physio

54 – conflict with advice he received from work and the advice from the PT

55 – Ingrained messages from work environment about how to carry out MH

56 – Conflicted as worried work wont accept his new ways of MH

57 – Other places need to change their MH practices

58 – Risk of relapse to old habits due to influence of wider environment

59 – Physio was able to judge correctly what communication approach would be effective

60 – Physios own belief in approach helped to influence him

61 – Felt vulnerable when initially asked to carry out activities

62 – Fear of consequences of doing the movements

63- Strategy for a flare up is to continue with exercise

64 – Pre-trial pain would have stopped him exercising

65 – Contacted PT for advice outside of appointments

66 – Mind set changed about flare ups – doesn't affect mood to extremes

67 – Confident about a recovery after a flare up

68 – No GP support needed during trial

69 – Happy to complete questionnaires as had a positive experience

70 – 20 mins to complete questionnaires

71 – Questionnaires were straightforward

72 – Questionnaires were viewed as positive as reflected back the improvements he had made

73 – All questions were relevant and reflect all aspects of BP

74 – BP impacted all aspects of life

75 – Treatment has improved whole quality of life

76 – postal questionnaires were OK

77 – Suggested questionnaires could be electronic

78 – Pre trial information was very clear

79 – Took part in the study as had ran out of options

80 – previously told nothing was wrong with him

81 – Felt this approach was more like being coached than physio

82 – Hoped he wouldn’t have usual care physio as hasn’t worked for him before

83 – wanted help with mental aspects linked to back pain.

Appendix T: Reflexive diary

Focus group usual care notes and reflections 19th December 2019

Viewed trial as improving own skills and ability to treat patients – learning opportunity Being involved in research – understanding how a trial works, processes of research/trial

Nervous about doing a good job, want to make sure what I am doing is right

Expectations that patients may ask what arm they are on, pressure on self – am I doing everything that is expected.

Some negativity about being in the trial – from other physios in department but that made some members 'prove' they can do research'.

At LGH – more of a support network eg organising booking out of trial patient slots in diaries. All thought protected follow-up slots were useful but some barriers from admin as were overbooking ring-fenced trial slots. LGH admin really were on-board.

Time

Having 60 minutes for NP Ax was seen as a positive – give patients more time to let of steam and listen to them, able to investigate things more because of extra time

'Story', ? influence of CFT (NP – doesn't fit with video Ax).

Ring fenced slots and extra time able to bring patients back in timely manner

ZT – would try and fit more in than usual as had more time.

ZT – F/U sometimes overbooked by reception staff.

Extra time allowed – would help with any patient – build rapport

JS – CFT takes more time anyway, so it was good for us to have extra time.

Extra time = education, rapport and discuss goals

Difference in sites – work differently, different patient types

CFT is a big thing at LGH – used regularly - ? contamination – causes bias, influenced by CFT clinicians, highlighted potential for contamination in UC arm on LGH site

LRI – CFT not such a hot topic

Glenfield – Paul has influence

Tried MI – tried not to use it during trial but then became confused about what was actually doing with patients

Contamination – as CR session influenced by practitioners doing CFT

Hear talk from behind cubicles – hard not to use it

What is usual care?

- Good communication, rapport, understanding patient expectations
- Goal setting
- Language
- Movement and confident with movement

Contrasts on UG training experience JS – intro to CFT and MI (graduated 2017)

CT graduated 2008 – contrasts this massage, hands on Rx

Then all agreed that it was very minimal on communication and more hands on and assessments & Rx. @Not a lot about communication' – one lecture

Now include myth busting, education about scans and movements/activities

NP – measured outcomes by patients doing more, bending, joining gym and more confidence

Recognised some won't change and expectation for passive Rx, outcome dependent of these expectations/motivations

Beliefs that in the trial patients were expecting CFT – influenced by referral from consultant – you are going have a 'life changing Rx'.

Some overlap between CFT and UC

Fidelity assessments

Initially conscious of what doing – but not doing anything different. One person wanted to show a perfect assessment but didn't turn out that way

Felt under pressure to deliver results but rewarding learning experience, natural to feel nervous

Positive impact – feedback on performance/learning – learnt more about the interaction – helped to rx the patient – recognised missed things like I didn't really listen as worried about being recorded. Did highlight things doing well.

Positive aspects of taking part in trial

Video feedback – useful for own development, increased confidence, enjoyable

Support from CI

Training – hands on knowing CN uses hands on, helped confidence

Would have liked to Rx more patients in trial

Suggestions

Manualised/standardised/guidelines of what to deliver in UC

Think nationwide results would be different as different areas practice differently

Other Trusts needed protected slots

Would like further training after the trial – felt trial training was good – to refresh knowledge and skills.

Reflections

Good dynamic, enthusiastic, flowing conversations similar and countering opinions. Good suggestions. Strong/enthusiastic views of one participant.

Usual care – eclectic, wide-ranging, evidence of contamination

Training good, manualise intervention for future trial.