
**DOES A PHYSIOTHERAPY
COGNITIVE-BEHAVIOURAL CHRONIC
LOW BACK PAIN PROGRAMME
ALTER PATIENTS' HEALTH LOCUS
OF CONTROL?**

A Thesis Submitted In Partial Fulfilment of the
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Sharon Braddock

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**Faculty of Health Psychology and Social Care
Manchester Metropolitan University**

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Abbreviations

CBCLBP	Cognitive-Behavioural Chronic Low Back Pain Programme
CBT	Cognitive-Behavioural Therapy
CLOC	Chance Locus of Control
ELOC	External Locus of Control
FAB	Fear-Avoidance Belief
FABQ	Fear-Avoidance Belief Questionnaire
FABs-W	Fear-Avoidance Beliefs about Work
FABs-PA	Fear-Avoidance Beliefs about Physical Activities
HLOC	Health Locus of Control
ILOC	Internal Locus of Control
LBP	Low Back Pain
MHLC	Multi-dimensional Health Locus of Control
MI	Multidisciplinary Intervention
NCCPC	National Collaborating Centre for Primary Care
NHS	National Health Service
NICE	National Institute of Health and Care Exchange
NSCLBP	Non-Specific Chronic Low Back Pain
NSLBP	Non-Specific Low Back Pain
PI	Principal Investigator
RCT	Randomised Controlled Trial
RMQ	Roland and Morris Questionnaire
SCQ	Self-Care orientation scale Questionnaire
TSK	Tampa Scale of Kinesiophobia
VAS	Visual Analogue Scale

DECLARATION

No part of the thesis has been submitted in support of an application for any degree of qualification of Manchester Metropolitan University or any other University or Institute of learning.

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ABSTRACT

BACKGROUND: Health locus of control (HLOC) is a person's belief of where responsibilities for his/her health condition lies. It is associated with health attitudes, behaviours and outcomes in non-specific chronic low back pain (NSCLBP). It is unknown whether a physiotherapy cognitive-behavioural chronic low back pain (CBCLBP) programme affects patients' HLOC.

AIMS: To examine: (1) the effect of a six-week CBCLBP programme on the patients' primary outcome-HLOC, and also pain intensity, disability, fear-avoidance belief (FAB) and self-care attitude; (2) the association between changes in pain intensity, disability and FAB and changes in HLOC; and (3) the cost of producing any effect.

METHODS: In an A-B-A same-subject design, patients referred to the CBCLBP programme with high FAB (TSK score > 37) were recruited. Patients attended a six-week programme. Outcomes were measured four weeks before (-4 weeks), at the start, at completion, 3- and 6-months after the programme. Friedman's ANOVA and Wilcoxon signed-rank tests determined changes between phases. Multiple regression determined the relationship between HLOC and outcome of interest. Significance was set at 0.05.

RESULTS: A total of 70 patients were recruited. Fifty-five patients entered the programme and all completed 6-months follow-up. The CBCLBP programme significantly improved HLOC ($p < 0.001$), pain intensity ($p < 0.001$), disability ($p < 0.001$), FAB ($p < 0.001$) and self-care attitude ($p < 0.001$), with such improvement being sustained for 6 months. Changes in HLOC explained 6%, 0.5% and 31.9% variances in changes in pain, disability and FAB respectively, after controlling other variables. Increased internal locus of control (ILOC) was a significant predictor of reduction in FAB ($p = 0.002$). HLOC was not predictive of reduction in pain intensity or disability. Mean provider cost of the programme was £285.82 per patient.

CONCLUSION: Our 6-week CBCLBP programme was effective in changing a person's belief about where responsibility for his/her health condition lies. It also improved their pain, disability, FAB and attitude to self-care. Making patients believe that they can take control, and they are the one responsible for their NSCLBP management is linked to reduction in FAB, highlighting the potential importance of improving ILOC in attaining better FAB outcome. We have also provided guidance to managers and budget allocators that this costs £285.82 per patient.

CHAPTER 1 INTRODUCTION TO THE STUDY

1.1 Introduction

This chapter provides the introduction and conceptual framework of this study. First, it briefly explains the complexity and the issues surrounding non-specific chronic low back pain (NSCLBP). Second, it describes how the research questions of this study were developed, underpinned by clinical experiences, and how they were interpreted in relation to the health locus of control (HLOC) and its potential importance within the major physiotherapy management tool for NSCLBP. Finally, this chapter explains how this study may contribute to the current knowledge of physiotherapy management of NSCLBP, and how new knowledge that emerged from this study may potentially impact on future physiotherapy practice and patients' care.

1.2 The complexity of NSCLBP

At first glance, pain seems to be fairly straightforward, hitting one's thumb with a hammer hurts one's thumb. Such experience is easily understood with a structural-pathology model, which supposes pain provides a reliable indication of the state of the tissues (Moseley, 2007). However, much of the NSCLBP patients we see in clinical practice do not fit into this straightforward category. Patients being diagnosed with NSCLBP continue to experience persistent or recurrent LBP (i.e. tension, soreness and/or stiffness in the lower back region) with or without leg pain, despite it being beyond the normal healing time (more than three months) and in the absence of any meaningful spinal pathology (Savigny et al., 2009; Chou, 2011).

1.2.1 Category of pain

Broadly speaking, pain can be categorized based on its duration (acute vs chronic) as well as its underlying pathophysiology (nociceptive, inflammatory and neuropathic) (Merskey & Bogduk, 1994). Nociceptive and inflammatory pain (producing mechanical and chemical pain) is often associated with identifiable painful stimuli and is frequently self-limiting (Woolf, 2004). Neuropathic pain is maybe caused by a lesion, resulting

from nerve damage or sensitization in the peripheral nervous system (PNS) and/ or central nervous system (CNS) (Clong & Bajwa, 2003; Van Wilgen & Keizer, 2012).

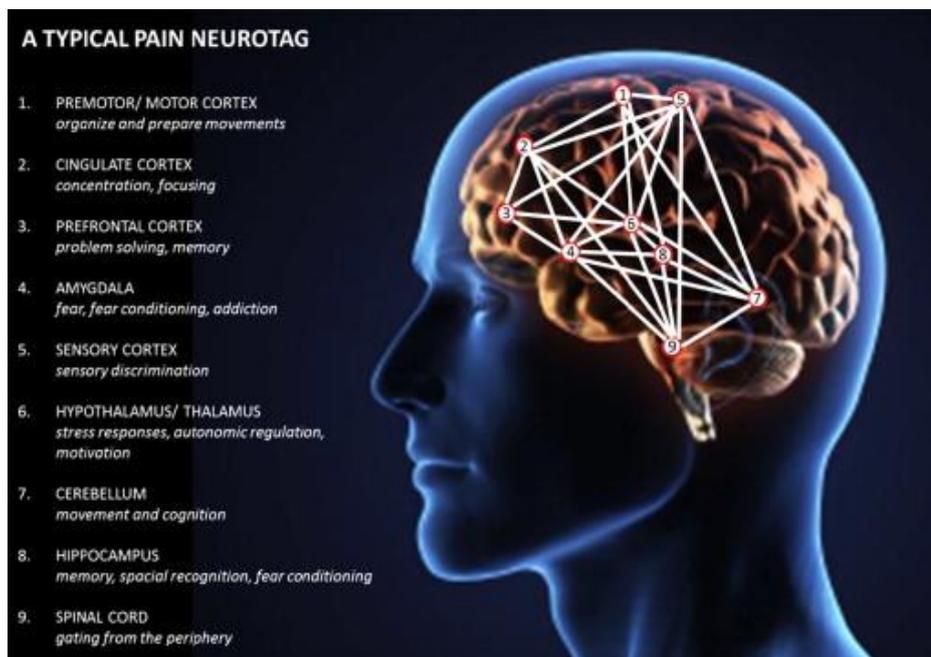
From a pathophysiological perspective, many patients with chronic pain such as NSCLBP, share the same mechanism: sensitization of the nervous system (Merskey & Bogduk, 1994; Van Wilgen & Keizer, 2012). It is typically persistent and frequently involves perception of spontaneous pain (to varying degrees) in the absence of an identifiable stimulus, as well as exaggerated responses to painful stimuli (hyperalgesia) or normally non-painful stimuli (allodynia) (Merskey & Bogduk, 1994; Woolf, 2004).

Not all pain syndromes are easily categorized, for instance, NSCLBP may involve a mix of two or more types of pain (Woolf, 2004). Evidence also suggested that nociception is neither sufficient nor necessary to evoke pain (Wall & Melzack, 1999). The maintenance and disability levels of NSCLBP are more closely associated with cognitive and behavioural aspects of pain than the sensory and biomedical ones (Gatchel et al., 2007; Campbell & Edwards, 2009).

1.2.2 Pain is a product of the brain

It is now clear from brain imaging studies that there is no single ‘pain centre in the brain’ as we used to believe. Rather, many areas in the brain (known as pain neuromatrix) are actively involved simultaneously in constructing and modulating a pain experience (Moseley, 2003a; Moseley, 2007). **Figure 1.1** shows a possible pain neurotag, where the parts of the brain are usually active during a pain experience. These parts all link up to each other electrically and chemically to create a perception of pain (Butler & Moseley, 2003).

Figure 1.1: Pain neuromatrix and pain neurotag (Butler & Moseley, 2003; Melzack, 1999)



Although consistent patterns can be seen during pain experience, the exact parts and amount of activity vary between people, and even between different occasions in the same person (Butler & Moseley, 2003). Therefore, every pain experience is unique and complex.

1.2.3 Definition of pain

The most popular and frequently used definition of pain is ‘an unpleasant sensory and emotional experience associated with actual or potential damage or described in terms of such damage’ (Merskey & Bogduk, 1994: 209). This definition about pain highlights that: (1) pain is both a sensory and an emotional experience that is unique to each individual; and (2) damage and pain do not always match. More recently, one of the world leading pain researchers Lorimer Moseley re-conceptualized ‘pain as a conscious correlate of the implicate perception that tissue is in danger’ (Moseley, 2007: 172). His way of thinking about pain shifts the concept of pain from one of pain as an accurate indicator of the state of the tissues, as many lay public have been conditioned to believe, to one of pain as an

indicator of threat and a conscious need for protection, especially as pain persists (Moseley, 2007).

According to Moseley, pain is the product of the brain that is based on the perception of threat. Many inputs across the physical, somatic, contextual, psychological and social domains into the brain determine the perceived degree of threat to body tissues, and pain is a multi-systematic output of the brain whenever the brain concludes the body tissue is in danger and protection is required (Moseley 2003a; Moseley, 2007). In chronic pain such as NSCLBP, the threat value of pain is more likely to be primarily contributed by psychosocial, behavioural and cognitive realm (such as attitudes and beliefs), rather than physical factors (Moseley, 2003a; Moseley 2007). The implication of increased threatening input includes: overprotective response (such as fear, anxiety, negative beliefs and avoidance behavior) and increased sensitivity of the pain neuromatrix (Moseley, 2003a). These responses consequently lead to increased disability, persistent pain, reduced movements, negative pain cognitions and diminished quality of life, results in a vicious downward cycle of pain and deterioration.

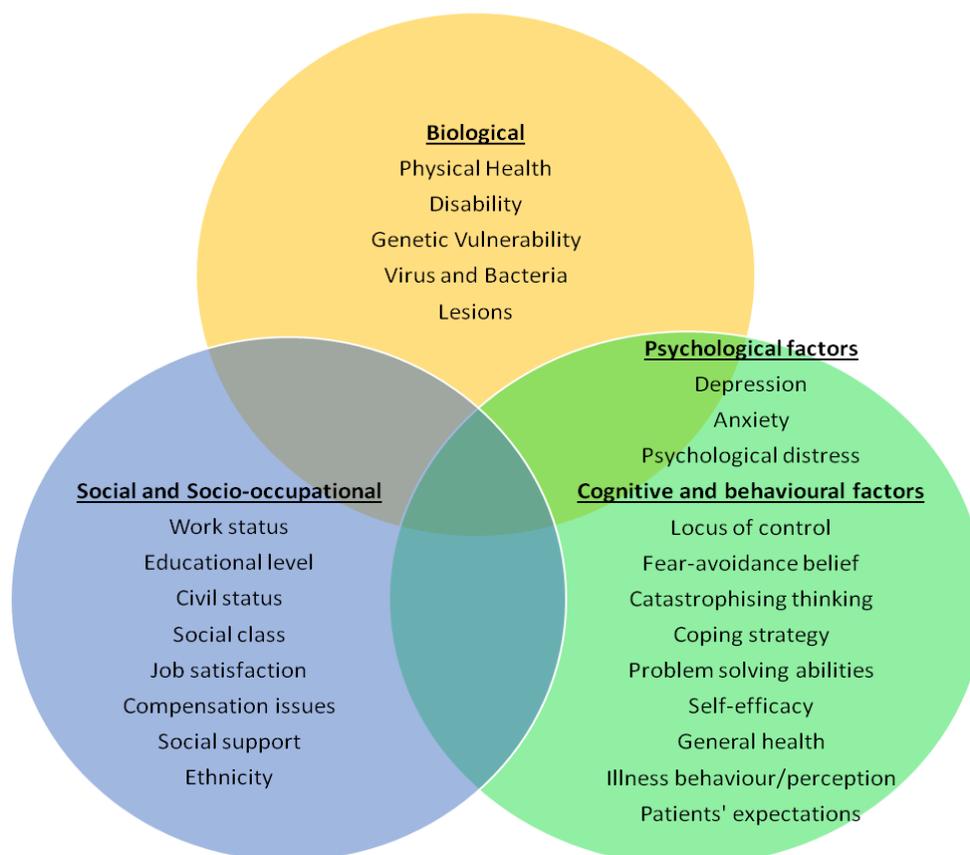
Moseley's conceptualization about pain acknowledges the multi-dimensional nature of pain, as in other experts in this field (Merskey & Bogduk, 1994; Waddell, 2004; O' Sullivan, 2005; Moseley, 2007; Wand & O'Connell, 2008). His research work also leads to an increased focus of addressing patients' pain belief and attitudes through pain education as a means of lowering threatening input that activates pain neuromatrix, normalizing pain cognition and improving physical performance in patients with NSCLBP (Moseley, 2002; Moseley, 2004; Moseley et al., 2004).

1.2.4 Different theoretical models in explaining NSCLBP

With pain being a multi-dimensional phenomenon, the biopsychosocial model of pain is still currently the most widely accepted model to understand chronic pain and its associated disability since it is proposed by Waddell in 1987 (Gifford, 2000; Waddell, 2004; Gatchel et al., 2007; Savigny et al., 2009).

The biopsychosocial model of pain integrates the psychological, social and biological factors (Waddell & Burton, 2005; World Health Organization, 2001) (**Figure 1.2**). It recognizes that all the three elements have a significant impact on the persistence of pain and the development of disability, and that the mind and body interact with and affect each other (Ogden, 2012).

Figure 1.2: The biopsychosocial model of NSCLBP (Waddell, 1987)



Other than the biopsychosocial model, there are also alternative theoretical models in the literature which help explain how NSCLBP is maintained and therapeutically reduced.

For example: (1) the pain-gate theory (Malzack & Wall, 1965) and the subsequent pain neuromatrix model (Melzack, 1999) acknowledge the role of multiple parts of the brain and spinal cord working together to contribute to the various aspects of experience of pain: the sensory, emotional, cognitive, motor, behavioral and conscious aspects. Briefly, these theories

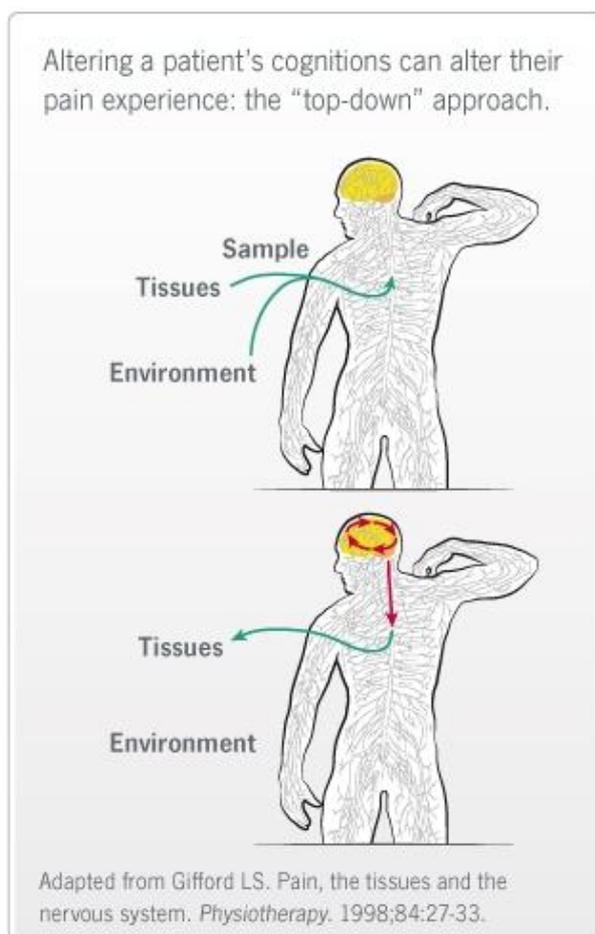
posit that psychological and physiological processes interact to affect perception, transmission and evaluation of pain, and recognize the influence of these processes as maintenance factors in NSCLBP; (2) the sensitization model provides a neurophysiological mechanism for understanding how peripheral and central sensitization are associated with pain hypersensitivity, in which they can be both modulated by cognitive and psychological factors in a positive or negative manner (Woolf, 2011; Nijs et al., 2011); (3) the fear-avoidance model (Vlaeyen & Linton, 2000) is seen as a central psychological mechanism in the maintenance of NSCLBP (Leeuw et al., 2007), in which pain-related fear and catastrophic beliefs are recognised as the primary force drives avoidance behaviour, which then leads to various associated physical (such as disuse and physical deconditioning) and psychological consequences (such as depression, anxiety, fear and distress); and (4) the motor control model (O’Sullivan, 2005) provides an understanding of NSCLBP from a motor control perspective. This model proposes that mal-adaptive movement and motor control impairment in response to pathophysiological pain and psychological factors lead to abnormal tissue loading of the lumbar spine and ongoing production of peripheral nociceptor sensitization, hence resulting in chronic pain.

These various explanatory models not only highlight the multi-faceted nature and complexity of NSCLBP, they also consistently recognize the influence of cognitive and behavioural factors involved in: (1) the maintenance of NSCLBP; (2) the variety of NSCLBP expression (severity and duration of clinical symptoms, and physical and psychological effects on the person); (3) patients’ sensory and behavioural response to pain; and (4) patients’ responses to treatment.

It is in this area that the ‘top-down’ treatment approach (i.e. altering pain by altering what people think and believe such as psychological and cognitive behavioural treatment) (**Figure 1.3**) may have more to offer to patients with NSCLBP than the traditional ‘bottom-up’ treatment model (i.e. intervene pain

on tissues levels such as manual therapy, electrotherapy and exercises) (Gifford, 1998).

Figure 1.3: The ‘top-down’ treatment approach (Gifford, 1998)

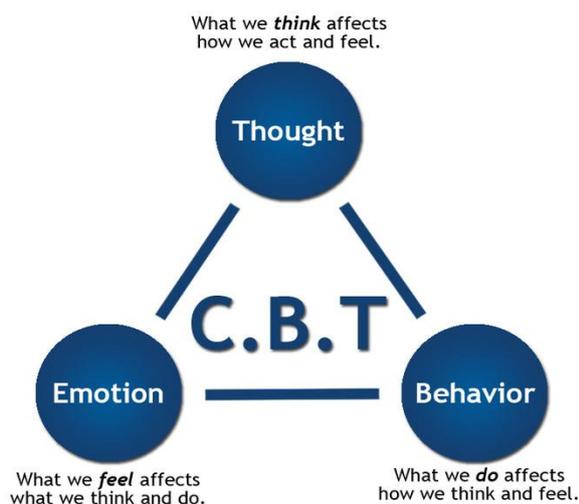


Consequently, the combination of physical exercises and cognitive-behavioural approach education (CBA) delivered in a group (namely the cognitive-behavioural chronic low back pain (CBCLBP) programme) has become one major and common physiotherapy treatment for patients with NSCLBP. This is also the most consistently recommended evidence-based treatment for NSCLBP in both the UK (Savigny et al., 2009) and international clinical guidelines (Chou et al., 2009; Koes et al., 2010).

1.3 Theory of the cognitive-behavioural principles

The key principle of the CBA is based on recognising that the aim is not directly to treat the pain or intervene at tissue level (i.e. bottom-up approach), but to modify patients' negative thoughts, feelings and behaviour, and thereby their experience of pain (i.e. top-down approach). The CBT model presumes a direct link between cognitions and behaviours. In other words, if maladaptive cognitions (such as FAB, catastrophizing thinking, problem-solving abilities, coping strategies, self-efficacy and appraisal of control) can be changed, positive behaviour change will follow. This then often inadvertently reinforces patients' positive thoughts, feelings and behaviour, hence creating a cycle effect (Adams et al., 1996; Beck, 1979a; Beck, 1979b; Kerns et al., 2011) (**Figure 1.4**).

Figure 1.4: The CBT model (Kerns et al., 2011)



The principle based upon the CBT model has consequently formed the basis of the treatment philosophy for physiotherapists. Although the composition of programmes may vary according to clinical settings and resources, the programme generally involves similar components (i.e. combined physical and CBA education) and has similar treatment philosophies. It is commonly considered that the general goal of a physiotherapy CBCLBP programme is to: reduce disability, minimize pain or increase control over pain, reduce avoidance of movement and increase self-management (Woby et al., 2004a; Smeets et al., 2006a; Critchley et al., 2007; Johnson et al., 2007; Woby et

al., 2008; Lamb et al, 2010). These goals are achieved by addressing the patients' cognitive, behavioural, and emotional facets of NSCLBP, as well as those physical and functional factors that contribute to its maintenance, severity and exacerbation.

Having recognised that an individuals' belief is the main driving force for behaviour (Greene & Murdock, 2013), one potential way to optimise patient's treatment outcome and improve their continued self-care abilities is to understand those cognitive factors which relate to patients' beliefs on how they deal with their NSCLBP, and their beliefs about who influences and is responsible for their health outcome. For example, physiotherapy advice to keep active and engage in self-care may not make much sense for patients who have a weak perception of personal control belief.

1.4 Conceptual framework underpinned by clinical experiences

In this current study, the Principal Investigator's (PI) clinical interest in NSCLBP grew as a consequence of treating patients with NSCLBP for over fourteen years in the NHS. The PI had had basic CBT and chronic pain training over the years. Despite being investigated and treated, many patients still faced pain, frustration and some level of disability. The chronic nature of the condition means patients are moved onto a management model rather than a curative model. However, the idea of pain chronicity, self-management and patients being told that a cure was not possible, was often received differently by patients. Some patients were positive and proactive, some were negative and passive; some believed that their actions and own responsibility would make a difference in managing pain; and some believed that their condition was solely attributed to fate or others such as their doctors, physiotherapists or families.

Despite patients undertaking the exact same CBCLBP programme, the treatment outcome varied. Clinical impressions indicate that patients who accept personal responsibility for their pain were generally more compliant to treatment recommendations than those who leave it to others. Those who feel it is entirely up to doctors or therapists or someone else to cure them

tend to be less proactive, less compliant and often seek further treatment following the CBCLBP programme. Furthermore, patients who perceive their actions as directly related to improved management are generally more engaged, have less fear to move, and report better physical and psychological health, than those who feel that they cannot do much about it for themselves. Gaining some feelings of personal control over back pain means patients actually managing the pain and disability so that they can master ordinary activities of daily living, and become less dependent on health care services. These clinical experiences show that patients' perceptions of control belief over their NSCLBP not only have an influence on their clinical outcomes, health attitudes and healthcare usage, they also have an influence on how patients behave, react and respond to the CBCLBP programme and the self-management skills taught by physiotherapists. In psychology, this belief is called health locus of control (HLOC).

If the ultimate goal of physiotherapy management is to engage patients to adopt a more active role in their rehabilitation process and to promote their continued ability to self-manage, these goals may only succeed if patients believe that they are the one responsible for, and able to feel control of their own chronic back condition. As a clinician, we would also like to think our treatment can improve patient's HLOC. However, the potential importance of HLOC in NSCLBP and how HLOC may change over the CBCLBP programme, were not being evaluated in both research and current practice.

This was when the PI began to study HLOC in NSCLBP, and develop the use of HLOC in the Trust's CBCLBP programme. Questions were developed, such as: What is the treatment effect of the physiotherapy CBCLBP programme on patients' HLOC? Is there any relationship between patients' HLOC and other important clinical outcomes such as pain, disability and fear-avoidance belief (FAB)? How do patients' HLOC beliefs change over time? Would HLOC be a predictor of treatment outcomes and a potential important cognitive factor to assess and target in future practice?

A brief introduction of the HLOC provides a useful starting point of the theories underpinning the present study, and demonstrates how the research questions developed.

1.5 A brief introduction of HLOC

The concept of locus of control was originally developed from Rotter's social learning theory of personality (Rotter, 1966), which discussed how the degree of control individuals believe they over events will affect their behaviour and the outcome (Rotter, 1966). Sources of locus of control are either internal (i.e. people who believe their own action and behaviour can influence outcome) and external (i.e. people who believe their actions and behaviour have little influence on outcomes, and that one's outcome is determined by others or fate and luck). The locus of control concept is later adapted and applied in medical or health related-condition and health behaviour, known as HLOC (Wallston et al., 1976).

1.5.1 Definition and a brief overview of HLOC in health research

HLOC is the concept used to understand a person's locus of control belief over their health condition, and a person's perception of who is responsible for his/her health condition (Wallston & Wallston, 1982). It is defined as "the degree to which individuals believe that their health is controlled by internal versus external factors" (Wallston & Wallston, 1982: 68), and is measured by the Multidimensional Health Locus of Control (MHLC) scale (Wallston et al., 1978).

Wallston et al. (1976) proposed that HLOC should be viewed as a multi-dimensional construct, with relatively independent dimensions. These dimensions reflect differences in attributions people hold about their responsibility for and control of their health. The three major categories of HLOC are (Wallston et al., 1978):

- Internal locus of control (ILOC)- the belief that the responsibility for one's health is attributed to oneself, and that one's behaviour will have an effect on one's health status;

- External locus of control (ELOC)- the belief that others, such as health professionals or family, are responsible for and have control over one's health status, and
- Chance locus of control (CLOC)- the belief that one's health condition is a matter of fate, chance or luck.

HLOC is associated with health behaviour, health outcomes and the utilization of health care (Luszczynska & Schwarzer, 2005). This health belief has been widely studied in health research for over thirty years, examples are: treatment compliance (Gopalkrishnan, 2014; Shneerson et al., 2015), substance abuse (Dielman et al., 1987), cancer practices (Park & Gaffey, 2007; Shneerson et al., 2015), diabetes (Schlenk & Hart, 1984; Tillotson & Smith, 1996; Gopalkrishnan, 2014), depression (Mollard, 2015; Aarts et al., 2015) and chronic pain such as arthritis and back pain (Harkapaa et al., 1991; Gustafsson & Gaston-Johansson, 1996; Cross et al., 2006; Richard et al., 2011).

Wallston and Wallston (1982), the developers of HLOC, summed up the common findings among numerous studies of a variety of patient population, including patients with chronic pain. Relationships have been found between HLOC and reports of physical symptoms, adherence to health recommendations, information-seeking behaviours, physical and mental health; and the desire for personal control over healthcare services (Wallston & Wallston, 1982).

1.5.2 Relevancy of HLOC for physiotherapy management of NSCLBP

The existing literature mainly offers evidence on HLOC for a variety of patient population, whilst studies that specifically examine patients with NSCLBP are very limited. Research commenting on back pain population, has suggested that HLOC is associated with both the risk and prognosis of LBP (Clays et al., 2007; Koleck et al., 2006; Linton, 2000; Waddell & Burton, 2001). Significant relationship has also been reported between HLOC and quality of life, disability and pain in NSCLBP (Sengul et al., 2010).

Literature has demonstrated that NSCLBP patients with higher ILOC report lower level of pain (Sengul et al., 2010; Harkapaa, 1991), lower level of disability (Harkapaa et al., 1991; Haldorsen et al., 1998; Sengul et al., 2010), use more active coping strategies (Harkapaa, 1991), have better physical function (Keedy et al., 2014; Sengul et al., 2011), have more active involvement with health intervention, respond better with CBA treatment, learn their exercises better and practise them more frequently during follow-up (Harkapaa et al., 1991). Patients with back pain would do better if they believe that they have a role in managing their condition (Watson & Kendall, 2000), and would be more likely to agree with the goals of active interventions (Braman & Gomez, 2004; Hashimoto & Fukuhara, 2004).

Conversely, patients with chronic pain with high ELOC or high CLOC do not believe they are one responsible for their own health and their behaviour influence outcome, thus avoiding increasing their activity level, and report poor ability to reduce and control their pain (Wallston & Wallston, 1982; Crisson & Keefe, 1988; Cross et al., 2006). NSCLBP patients with a higher level of ELOC and CLOC are more likely to report higher level of pain (Sengul et al., 2010), more likely to rely on maladaptive coping strategies (Harkapaa, 1991), and have a higher level of pain-related fear (Richard & Dionne, 2011).

In short, ILOC belief is associated with increased ability to control pain, more effective coping strategies, less impairment, less distress, and increased functioning, whilst ELOC and CLOC are associated with passive coping strategies, greater impairment, and more distress and decreased functioning.

In light of the above, it can be implied that patients' HLOC belief may influence their uptake of and responses to treatment modalities and self-management tasks. Their HLOC belief may directly or indirectly relate to other key clinical elements of NSCLBP such as pain intensity, disability, FAB, coping strategies use, self-care and general functioning. These are all key areas physiotherapists seek to address in their treatment.

It is acknowledged that HLOC is only one piece of the much wider psychological context in understanding NSCLBP. Nevertheless, assessment of HLOC may provide some clues and new knowledge to help unravel the complexity of this condition. It may also give new direction for clinicians and researchers to further improve the existing physiotherapy management programme in order to achieve better treatment outcomes. This is particularly important in the current climate of the NHS, where physiotherapists are under constant pressure to prove their service to be clinically effective and value for money.

1.6 A gap in literature

Having considered the theoretical construct of HLOC, and the extant research in the area, it is reasonable to suggest that HLOC may be an important cognitive factor to explore and assess when evaluating the physiotherapy CBCLBP programme. However, none is known about whether a physiotherapy CBCLBP programme may alter patients' HLOC in short-term and longer-term, and if there is any association between HLOC and the main clinical elements of NSCLBP such as pain intensity, disability and FAB. These gaps in knowledge are addressed and answered in this study.

To date, there has been no previous study specifically looking at the effect of a physiotherapy CBCLBP programme on patients' HLOC, and its relationship with other clinical outcomes. This has prompted this study with the research question and specific aims as the following:

1.7 Research question and specific aims of the study

Research question: Does a physiotherapy CBCLBP programme alter patients' HLOC?

Aims of the study:

1. To assess the effects of the physiotherapy CBCLBP programme on patients' HLOC.
2. To examine the effects of the CBCLBP programme on pain, disability and FAB.
3. To determine if there is any relationship between patients' HLOC and pain, disability and FAB.
4. To examine patients' self-care attitude toward their back pain in terms of their desire in future use of healthcare and prescription pain medication as a result of the programme.
5. To investigate the cost of back care per change of ILOC, and the cost of the CBCLBP programme from a provider's, patient and societal perspective.

1.8 Conclusion

With the clearly defined research question and study aims, this study intended to contribute additional evidence on the effectiveness of a physiotherapy CBCLBP programme conducted in a primary setting. It also intended to contribute new evidence regarding the potential importance (or not) of HLOC in the management of NSCLBP.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter focuses on literature that is relevant to the current study. It is divided into two parts. **Part I** focuses on evidence of the group-based active exercise CBA intervention, which is the major management tool of NSCLBP employed by physiotherapists in clinical practice. This section includes the review of relevant evidence for its effectiveness on (1) clinical outcomes (**Section 2.6.1** and **Section 2.7**); (2) HLOC (**Section 2.8.1** and **Section 2.8.2**); (3) patients' self-care attitude (**Section 2.9.1**), and (4) cost of the programme (**Section 2.10.1**).

The influence of psychological factors in NSCLBP is well documented. Knowledge of these relationships may help increase our understanding of the underlying mechanism of how desired clinical outcomes can be achieved. **Part II** of this review focusses on the association between pain, disability, FAB and HLOC.

Each section has its own summary which provides the themes and limitations that emerged from a set of selected studies accordingly:

- Section 2.5.2** Summary of evidence on the effectiveness of exercise therapy
- Section 2.6.2** Summary of evidence on the clinical effectiveness of CBA active rehabilitation delivered by physiotherapists
- Section 2.7.1** Summary of evidence on the effectiveness of CBA intervention when targeting patients with psychosocial characteristics
- Section 2.8.3** Summary of evidence on the effect of CBA intervention in altering HLOC
- Section 2.9.2** Summary of evidence on the effectiveness of CBA active rehabilitation in patients' self-management
- Section 2.11.4** Summary of evidence on the relationship between pain

intensity, disability and FAB

Section 2.13.3 Summary of key findings of HLOC in NSCLBP

An overview of summary of this literature review is drawn and presented in **Section 2.14**.

Some sections of the literature review (**Section 2.10.1**, **Section 2.11.1** and **Section 2.11.2**) are presented in table, because it was decided that relevant information is too lengthy to present in paragraph form whereas it is much clearer presented in the format of table.

The amount of research on NSCLBP is substantial. There is high heterogeneity between studies such as: research design, patients' inclusion criteria, outcome measures, interventions and statistical methods, thus preventing the PI from carrying out systematic review and meta-analysis. A meta-synthesis review is possible. However, considering the nature and scope of the literature relating to the research questions, a narrative review is more appropriate in this instance. Therefore, this is chosen as the method of literature review for the present study.

First, a set of selected studies (including randomised controlled trial (RCT), cohort study, systematic review and meta-analysis) which are relevant to each research question are identified. Risk of bias of these studies was then assessed according to the Cochrane Bias Methods Group's recommendation (Higgins et al., 2011). This is a seven-item checklist that covers reports on: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other biases. The scores are ranged from 'high', 'low' and 'unclear' risk of bias. This tool is comprehensive, easy to use and covers a wide variety of domains allowing the PI to assess the relevant paper appropriately. Finally, the themes and conclusions emerged from the set of studies are drawn.

The aim of this chapter is to provide the context and critique of what research has already been found, also to identify what the problems and

limitations are in the current evidence. The present study attempts to address these gaps by extending the literature and contributing new evidence. This chapter also gives the basis of evidence to help comparing and discussing the findings of the present study (**Chapter 5**).

PART I

2.2 LBP- The clinical problem

Low back pain (LBP) is a common and prevalent problem throughout the world (Hoy et al., 2012). Although most episodes of LBP appear self-limiting (Pengel et al., 2003; Balagué et al., 2012), recurrence is high (Costa et al., 2009; Stanton et al., 2010), with approximately 20% cases leading to NSCLBP, and 11-12% are disabled by it (Airaksinen et al., 2006; Gurcay et al., 2009). Most challenging is this subgroup of patients with NSCLBP. It accounts for three-quarters of the total direct and indirect costs of medical care and lost productivity (Fourney et al., 2011), and often associates with poor rehabilitation outcomes (Jamison, 2011).

NSCLBP is now the number one cause of years lived with disability globally (Murray et al., 2013), with an estimated 632 million affected people (Lim et al., 2013). Epidemiological evidence suggests that the number of people seeking medical attention and the cost in economic and health terms still seems to be increasing (Fourney et al., 2011). In respect of physiotherapy, NSCLBP is one of the least successfully treated musculoskeletal conditions (Harland & Lavalley, 2003). In order to decrease burden to patients, to health professionals and to society, the use of intervention with demonstrated effectiveness is essential.

2.3 Clinical guidelines of the management of NSCLBP

The National Collaborating Centre for Primary Care (NCCPC) and the NICE guidelines group in the UK provide evidence-based guideline for the management of NSLBP (Savigny et al., 2009). The NICE guidelines are similar to most of the other guidelines (Chou et al., 2009; Koes et al., 2010), and are consistent with experts' recommendations (Dagenais et al., 2010).

First-line recommendation

First-line guideline recommendation for NSLBP includes: use of advice and educational information, promote self-management, discourage bed rest, advice to stay active, and offer pain medication to adequately manage pain so that patients could keep active (Savigny et al., 2009).

Second-line recommendation

Second-line recommendation includes the use of adjunctive analgesics, strong opioids, and possibly anti-depressants (Savigny et al., 2009), but there is a high risk of side-effects (Kuijpers et al., 2011). Recommended therapies include: a course of supervised exercise therapy, manual therapy or acupuncture (Savigny et al., 2009; Dagenais et al., 2010).

Third-line recommendation

Where patients fail to respond to at least one recommended therapies, and display sign of significant disability and psychosocial risk factors, the NICE guidelines recommend a course of combined physical and psychological treatment programme. This is broadly consistent to that recommended in the 'Recommended Guidelines for Pain Management Programmes for Adults' issued by The British Pain Society (2013).

The combined physical and psychological programme may be delivered in various forms, such as multi-disciplinary rehabilitation by a combination of professions as in-patient or out-patient, or delivered primarily by physiotherapists in a form of group rehabilitation consisting physical exercise and CBA education component (Savigny et al., 2009). The duration and intensity of the programme falls into two main categories: (1) daily intensive programme with more than 100 hours, and (2) once or twice weekly programmes with less than 30 hours, depends on clinical settings.

2.3.1 The 100 hours guideline recommendation

The Cochrane Back Review Group (Sagnivy et al., 2009) stated that the best evidence for the combined physical and psychological programmes was of at least 100 hours of exposure over a maximum of eight weeks. This recommendation is made universal to all NSLBP patients who failed to improve with secondary recommendation (Sagnivy et al., 2009), without offering clear clarification of what level of patients' disability or what risk factor profiles may be appropriate for the 100 hours therapy.

When reviewing evidence of the 100 hours guideline (Guzman et al., 2001; Sagnivy et al., 2009), a number of serious limitations were identified. First, the NICE guideline is predominantly based on the findings of only one systematic review (Guzman et al., 2001), in which only a small number of trials (10 RCTs) were considered. Seven out of the 10 included trials in this review (Alaranta et al., 1994; Basler et al., 1997; Bendix et al., 1996; Harkapaa et al., 1989; Juckel et al., 1990; Lukinmaa, 1989 and Nicholas et al., 1991) did not fulfilled methodological quality criteria such as: concealment allocation, blinding of assessor, blinding of care provider, use of intention-to-treat analysis and consideration of acceptable dropout rate.

Secondly, despite of these aforementioned biases, six out of the 10 included trials (Alaranta et al., 1994; Bendix et al., 1995; Lukinmaa, 1989; Mitchell & Carmen, 1994; Nicholas et al., 1992 and Nicholas et al., 1991) were regarded as high quality. This led to the question on how the methodological quality was assessed in this review. It was found that the authors lowered the cut-off points for high quality from 7 to 5 out of 10. If the cut-off was set at 7 or more points as recommended by the Back Review Group, all the trials would be considered low quality. It appears that the authors and the Cochrane Back Review Group applied inappropriate criteria and thereby misjudging the methodological quality of these included trials.

Thirdly, much emphasis was placed on return to work as the primary outcome measure, while physical measurements and psychological scales were ignored in this review. An undue focus on return to work to define effectiveness of the treatment leads to low generalizability in non-workers such as older patients and homemakers who frequently presented in primary

care. Lastly, this review selectively looked at literature where patients with severe disabling back pain were treated in well-established daily intensive multi-disciplinary rehabilitation. Again, the conclusions drawn from these studies may not be applicable to the wider category of NSCLBP patients with moderate disabling back pain seen in primary care and less intensive programmes.

To summarise, the guideline recommendation of 100 hours is high risk of bias. It did not seem to consider enough the heterogeneity of NSLBP patients, the variability of clinical settings, the heterogeneity of the types of programme and the variability of relevant clinical outcome measures. Lowering the cut-off point when assessing methodological quality and only focusing on selected clinical outcomes and selected patients sub-group in a relatively small number of studies may also weaken the validity of finding, introduce publication bias and lower generalizability to the wider population of NSCLBP. Further evidence and clarification on (1) treatment hours, and (2) how to select the optimal level of combined physical and psychological based treatment for different NSCLBP patients (such as the use of screening tools to inform decision-making) seems to be much needed to refine the current NICE guideline recommendation.

2.4 Role of physiotherapist

Where a combination of physical factors (such as poor core strength, maladaptive movement, motor control impairment, spinal instability), and cognitive factors/ psychosocial factors are the possible underlying mechanism for ongoing pain, the physiotherapy CBA active rehabilitation may have the potential to impact on both the physical and cognitive drivers of NSCLBP (O' Sullivan, 2005).

Two major components of physiotherapy management in NSCLBP are: (1) exercise therapy, which can be delivered in the form of graded therapeutic exercise, functional training in self-care or home exercise programme (World Confederation for Physical Therapy, 2014); and (2) CBA education in addition to physical exercises.

2.5 Exercise therapy in NSCLBP management

Based on the assumption of the biopsychosocial model (Waddell, 1987), patients with NSCLBP are physically de-conditioned. Lower physical activity level leads to physical changes such as muscle atrophy, changes in metabolism, decreased muscle strength and obesity, as well as psychological and behavioural changes such as distress, depression, anxiety and avoidance behaviour (Bortz II, 1984). Evidence also suggests that low level of physical activity is correlated with future episodes of persistent LBP (Hurwitz et al., 2005; Thomas et al., 2007). Therefore, exercise therapy is one important component in NSCLBP management (Frost et al., 2000; Lively, 2002; Hayden et al., 2005a; Hayden et al., 2005b), and it is consistently recommended across various guidelines in primary care (Pillastrini et al., 2012).

2.5.1 Evidence on exercise therapy in NSCLBP

Several systematic reviews of NSCLBP (Krismer & Van Tulder, 2007; Hayden et al., 2005b; Liddle et al., 2004) investigated the efficacy of exercise therapy. These reviews consistently conclude that, even with a wide variety of exercise programmes, exercise therapy only demonstrates modest improvement in pain and function in NSCLBP. A high quality systematic review (Van Middelkoop et al., 2011) concluded that there is low quality evidence (serious methodological limitations, imprecision) for the effectiveness of exercise therapy when comparing to waiting list control, usual care (such as receiving home exercise and advise to stay active) and behavioural treatment on pain intensity and disability at short- and long-term. However, it must be noted that the inclusion of different quality trials, the heterogeneity of included studies and the use of different quality scores to categorise articles in these systematic reviews may over- or underestimate results.

A systematic review by Hayden et al. (2005b) aimed at identifying the type, quality and mode of delivery of exercise therapy to improve CLBP outcomes. The review covered 43 relevant RCTs, providing adequate information of the included trials, and presented their findings with confidence intervals. The authors concluded that the positive effect of exercise therapy, particularly a supervised, patient-specific, graded exercise programme (including stretching and strengthening) may improve pain and function in NSCLBP. However, the included trials of the review are predominantly of poor methodological quality (only 6 of the 43 trials were rated as high quality). The main shortcomings in methodological quality of these included studies were: inconsistent and poor reporting, lack of relevant outcome measures, unacceptable drop-out and no intention-to-treatment analysis. These different sources of bias may weaken the internal validity and result in over-estimation of the effect of exercise therapy.

In contrast, the quality of included studies in the systematic review by Liddle et al. (2004) was reported as high and medium quality (16 RCTs). Their findings were in agreement with Hayden et al. (2005b), which also concluded the positive effect of exercise in CLBP patients in improving pain

and function. Although the authors clearly presented how the methodological quality of included studies was assessed, and demonstrated that they had considered the rigour of included studies, the results of this review was based on 16 RCTs all with positive results, leading to reference bias. Besides, no statistical method was used to analyse and summarise results. This may reduce the validity of conclusion drawn from this review.

A cross-sectional study, with low risk of bias by Mannion et al (2001) showed that exercise reduced FAB, possibly because of the experience of completing the prescribed exercises without undue harm. Smeets et al (2006b) also found that physical exercise programme without deliberately targeting cognitive factors demonstrated substantial cognitive change such as reduction in depression and catastrophizing (i.e. holding a overly pessimistic interpretation of one's symptoms and prognosis).

A RCT by Smeets et al. (2006b) compared the effectiveness of physical treatment, CBT and a combination of both, with waiting list control group in 212 patients with NSCLBP. It was found that all the three active treatments were more effective than the waiting list group in reduction in pain, disability and pain catastrophizing. There was no clinical relevant difference between the three active treatments, and only the physical treatment group showed a significant decrease in pain catastrophizing. The overall methodological quality of this study was satisfactory, including: concealment of randomization, clearly defined validated outcome measures, highly structured treatment protocols and control for patients' expectation bias. There were differences in follow-up outcome data (%) between the three active treatments: physical treatment group (85%), compared to the CBT (80%) and the combined group (69%). Therefore, it is possible that attrition bias may over-inflate the effectiveness of the physical treatment group. In sum, this study provides moderate evidence that exercise therapy may be useful in reducing pain catastrophizing, which is a psychological factor significantly associated with disability in NSCLBP (Picavet et al., 2002; Woby et al., 2004b). This study is low risk of bias.

2.5.2 Summary of evidence on the effectiveness of exercise therapy

Overall, the quality of evidence for the effectiveness of exercise therapy on physical and psychological outcome in NSCLBP is low to moderate, when compared to no treatment, usual care and CBA treatment. In most individual studies and analysis, there were limitations regarding the methodological quality, and in most analysis, there was imprecision of data because of sparse data and wide confidence intervals. Additionally, there is heterogeneity in some of the analysis among the studies. This heterogeneity could have been caused by: differences in methodological qualities and risk of bias, variation in sample size, patient characteristics, interventions and choice of outcome measures. Therefore, the results of these studies should be interpreted with some caution.

2.5.3 Role of psychological factors on the effect of exercise therapy

It is noteworthy that long-term maintenance of the potential benefits of exercise requires patients' motivation and patients' beliefs towards behavioural change and exercise compliance. For instance, there is evidence to suggest that patients who demonstrate less FAB about activity are more likely to comply with a physical programme (Twomey & Taylor, 2000). An internal sense of personal control is also shown to be associated with positive psychological and physical adaption to illness, and more engagement in beneficial health behaviours (Affleck et al., 1987; Burker et al., 2005). Several high quality RCTs have shown that when patients with CLBP are taught more about their pain (by pain physiology education), their pain and catastrophizing reduces, and in conjunction with physiotherapy, it improves functional and symptomatic outcomes (Moseley, 2002; Moseley, 2003b; Moseley et al., 2004; Moseley 2005). Changes in pain attitude and beliefs are directly associated with change in physical performance in patients with CLBP even there is no opportunity for the patients to be physically active during the treatment (Moseley, 2002; Moseley, 2004).

Collectively, this evidence suggests that patients' beliefs (such as FAB, ILOC and pain perception) may be the underlying mechanism to facilitate the physical and psychological effects of exercise, and to achieve more desired symptomatic outcomes. It is well documented that psychosocial factors are more powerful factors than the physical ones to persistent pain and disability in NSCLBP (Linton, 2000; Takakura & Sakihara, 2001; Braman & Gomez, 2004; Waddell, 2004; Klaber Moffett et al., 2006; Gatchel et al., 2007; Bakker et al., 2009; Hansen et al., 2010; Foster & Delitto, 2011). Thereafter, the addition of CBA treatment to exercise therapy, as opposed to exercise therapy alone, may have more to offer to patients with NSCLBP and with high FAB, as recommended by most clinical guidelines.

2.6 The CBA treatment in physiotherapy management of NSCLBP

Since physiotherapy is the largest paramedical profession responsible for back pain management in the UK (Maniadakis & Gray, 2000), it is common for physiotherapists to receive some basic training in CBA techniques when treating patient with NSCLBP (Critchley et al., 2007; Johnson et al., 2007; Hay et al., 2005; Lamb et al., 2010). In addition, there is a wide acceptance that the management of LBP should begin in primary care (Koes et al., 2010). Consequently, a group-based physical exercise combined with CBA programme delivered by physiotherapists in primary care has witnessed a rise in popularity and recognition. The following section will critically review the literature in detail.

2.6.1 Evidence on the clinical effectiveness of CBA active rehabilitation led by physiotherapists

A large RCT (N=701) by Lamb et al. (2010) studying patients with subacute or chronic LBP. They compared the clinical and cost effectiveness between a 15-minute session of active management advisory consultation by primary care clinicians (control group), with the Back Skills Training (BeST) programme based on CBT principle. The BeST programme was run by physiotherapists, nurses, psychologists and occupational therapists, comprising a 5 hour initial assessment, and six sessions of group therapy (1.5 hour duration each). This study found that the BeST programme group demonstrated improvement in both disability and FAB from baseline to 3-month, 6-month and 12-month follow up. When compared with the control group, the BeST programme group was statistically significantly more effective in reducing disability and fear-avoidance behaviour. This study concluded that the BeST programme, was superior to best care in primary care. In addition, the BeST programme also demonstrated a sustained positive effect at 12-month follow up. This study is low risk of bias, with a robust design including: use of adequate powered sample, randomisation to assignment, concealed allocation, clinician and assessor blinding, and relevant outcome measures. Sufficient detail of the intervention and long period of follow up were also included. However, because of the nature of the treatment assignment, it was impossible to mask patients which may introduce performance bias.

A well-conducted RCT based at two London hospitals (Critchley et al., 2007) compared the clinical and cost effectiveness of the three commonly used physiotherapy treatments in NSCLBP. Patients (N=212) were randomized to usual outpatient individual physiotherapy (included combination of joint mobilization, manipulation, home exercise and back care advice. Up to 12 sessions of 30 minutes were allowed), spinal stabilization class (consisted of specific exercise for spinal stabilization, up to 8 sessions of 90 minutes were allowed), and a physiotherapy-led pain management programme using group exercise and CBA education (consisted of 8 sessions of 90 minutes). Findings showed that all the three

physiotherapy regimes significantly reduced disability, with concurrent improvement in pain, health-related quality of life, time off work and health service utilization. The pain management programme was marginally more clinically effective from baseline to 18-month follow-up. This study concluded that the physiotherapy-led pain management programme, with simple exercise and no requirement of special equipment, produced clinically important improvement. Besides, it had a less health-service consumption and was more cost-effective than other treatments. The pragmatic nature of this trial in clinical practice and inclusion of moderately disabled NSCLBP patients represented good generalizability. This study was also characterized by a number of strengths, including: a thorough study design, adequate sample size, homogeneous population, adequate randomization, concealed allocation, successful assessor blinding, highly structured interventions, use of intention-to-treat analysis, and adequate reporting with sufficient data. It is noted that the response rate during follow-up in the pain management group was lower in comparison to other two groups. Many participants also withdrew from the class early (attrition was 17% in individual physiotherapy group; 25% in spinal stabilization class; 32% in pain management). However, the authors acknowledged these issues and mentioned inputting missing data using the last value carried forward method did not change any of the above conclusions. Overall, this study is low risk of bias.

A RCT by Johnson et al. (2007) comparing the clinical and cost effectiveness of a group structured active exercise and CBA intervention (consisted of eight 2-hour sessions delivered by physiotherapist only) with usual care supplemented by education material (control group). Participants were all diagnosed with NSCLBP (N=196) and referred to out-patient physiotherapy by their GP. Primary outcome measure was disability as evaluated by RMQ. Secondary outcome measures were pain, health-related quality of life, and time off work. The healthcare usage such as visits to GP and other healthcare professions, medications usage, care from hospital was also collected for economic evaluation. This study found that both intervention and control group showed relatively substantial amount of improvement in pain and disability over the course of follow up (at 3-

month, 6-month and 12-month post-treatment). However, the intervention group only showed a small and non-significant additional benefit in reduction of pain, disability and general health measures when compared to the control group at one year follow-up. This study partially supports the clinical effectiveness of the CBA intervention provided by physiotherapists, yet it is likely to be a cost-effective option to treat patients with NSCLBP. This study employed adequate sample size, homogeneous population, randomization, use of highly structured programme, independent review of treatment fidelity and relevant outcome measures. However, the authors were unclear about concealed allocation (selection bias), and blinding of outcome assessor, personnel and participants (performance bias). Besides, there was loss of follow-up over the study period (95%, 87% and 84% response rates at 3, 9 and 15 months) and poor treatment compliance of the study participants (attrition bias). These different sources of bias may reduce the validity of the findings. This study is at moderate risk of bias.

Smeets et al. (2006a and 2008) conducted a multi-centre RCT in 172 NSCLBP patients with moderate to severe functional limitation. They compared the effectiveness of the three common out-patients treatment models: 1). the active physical treatment; 2). the CBA psychological treatment; and 3). the combination of both, with waiting list group. Each treatment was delivered three times a week for 10 weeks (exposure to CBA component was approximately 78 hours) by multi-disciplinary members. A number of outcome measures were used, including disability, pain, depression, patient's global assessment, treatment satisfaction and physical performance tasks. At 6-month and 12-month following treatment, all the three treatment groups were more effective than the waiting list group. When comparing the three treatment groups, the combined group (active exercise treatment plus CBA treatment) showed no additional benefit statistically than the active exercise group and the CBA treatment group alone. There were differences in follow-up data between groups, leading to attrition bias. But overall, this study demonstrated a number of strengths including: adequate randomization, concealed allocation, highly structured intervention, adequate reporting of data and use of relevant outcome measure. Smeets et al. (2006a and 2008) had carried out rigorous blinding

procedure of outcome assessor and addressed expectation bias from patients appropriately, while other similar studies were unclear about these potential biases (Critchley et al., 2007; Johnson et al., 2007; Lamb et al., 2010). This study is low risk of bias.

A multi-centre RCT compared the clinical effectiveness of an intensive rehabilitation programme based on CBT principles and daily exercises (five days a week for three consecutive week, with an average of 75 treatment hours, predominantly led by physiotherapists) with spinal fusion surgery (Fairbank et al., 2005). A total of 349 NSCLBP patients who were potential candidate for spinal stabilization were included. Results showed that both treatments demonstrated similar clinical improvement during two years of follow-up. The findings reported no significant difference in all outcome measures between the groups, except the disability score was marginally more in favor of surgery. In addition, nearly three quarters of patients allocated to rehabilitation avoided surgery by two years. This study is low risk of bias on account of thorough research design, randomization, adequate sample size and use of relevant outcome measures. However, the missing follow-up data in this study was high (20% loss to two-year follow-up), and the authors dealt with missing data with multiple imputation (i.e. treating missing data as if they were real measurements). This consequently introduces attrition bias and limits the internal validity of the findings.

A systematic review by Van Middelkoop et al. (2011) determined the effectiveness of physical and rehabilitation intervention (such as exercise therapy, back school, behavioural treatment and multi-disciplinary treatment) for NSCLBP. This review included 83 RCTs. Risk of bias of the included studies was assessed using criteria list outlined by the Cochrane Back Review Group. This review concluded that the most promising interventions for NSCLBP were multi-disciplinary treatment or behavioural treatment. In addition, there is moderate evidence that the use of behavioural treatment (such as CBA) combined with other treatment such as physiotherapy or exercise therapy can reduce pain and disability at short-term, as well as reduce sick leave and costs due to sick leave. This systematic review is low risk of bias. The authors adequately reported the

risk of bias assessment using criteria list and considered methodological flaws of the included studies thoroughly. Besides, an inclusion of a homogenous patient population (i.e. NSCLBP) has methodological advantages. The quality of papers was generally poor in this review. Only a small number (28 out of 83) of studies were rated as high quality. Inclusion of low quality trials may lead to over-estimation of treatment effect. There may also be reference bias and reporting bias in this review, since the authors selectively included published trial with positive results.

2.6.2 Summary of evidence on the clinical effectiveness of CBA active rehabilitation delivered by physiotherapists

Among the seven RCTs and one systematic review being appraised, five are considered as low risk of bias (Lamb et al., 2010; Critchley et al., 2007; Smeets et al., 2006a; Smeets et al., 2008; Fairbank et al., 2005 and Van Middelkoop et al., 2011) and one is moderate risk of bias (Johnson et al., 2007). Literature seems to demonstrate moderate evidence to support the clinical effectiveness on CBA active rehabilitation CBA delivered by physiotherapists.

The greatest benefits were observed in studies when comparing CBA with waiting list or usual-care control groups (Lamb et al., 2010; Klaber Moffett et al., 1999; Van Middelkoop et al., 2011; Kent & Kjaer, 2012), whereas the least benefit when comparing CBA with other active intervention (U.K. Beam Trial Team, 2004a; Fairbank et al., 2005; Smeets et al., 2006a; Smeets et al., 2008; Johnson et al., 2007; Critchley et al., 2007).

With respect to short-term and long-term effectiveness, studies that followed up beyond six months reported mixed results (Klauer Moffett et al., 1999; U.K. Beam Trial Team, 2004a; Fairbank et al., 2005; Critchley et al., 2007; Johnson et al., 2007; Lamb et al., 2010; Van Middelkoop et al., 2011; Kent & Kjaer, 2012). Possible explanation for varied results between trials may include: inadequate sample size, level of expertise of professionals delivering the programme, method of delivery, component of the programme, rigour of the adherence to CBT principle, mix of duration of NSLBP population and use of heterogeneous group (i.e. including

patients low on psychosocial risk factors and NSLBP of any duration), variation in intensity and duration of programme, outcome measures, outcome timing and statistical methods.

So far, the emerging picture is that the CBA interventions deliver moderate effect, which are mostly seen when against passive controls, and are mostly of short-term. So why have CBA treatments failed to deliver against active controls? One possible explanation could be that the majority of the trials targeting heterogeneous group including those patients low in psychological risk (e.g. low in FAB). Inclusion of patients without psychological needs to receive treatment that include psychology not only potentially results in reduced treatment effectiveness, but is also irrational and unethical (Pincus & McCracken, 2013).

2.7 Evidence of the effectiveness of CBA rehabilitation when targeting patients with psychosocial characteristics

Some primary clinicians (including the PI) are inclined to believe that treatment targeted to patients with particular psychosocial characteristics may improve patients' outcome such as pain, disability and psychosocial factors (Kent & Keating, 2004). A hypothetical example would be "CBA provides more positive clinical outcome in patients with high FAB".

Klamer Moffett et al. (2004) conducted a RCT in 179 patients with LBP of mixed duration (acute, subacute and chronic). The hypothesis was that physical exercise classes based on CBA (active rehabilitation) were more effective than usual GP care, when targeted patients with high fear-avoidance (a score of >14 on the Fear Avoidance Beliefs Questionnaire). The only outcome used was the RMQ, which assesses pain-related disability. This study demonstrated that active rehabilitation was more effective than GP care. In addition, the active rehabilitation group showed a more favourable treatment effect at all time points in the high-fear group than the low-fear group, and the size of effect when targeting patients with high fear is clinically important. However, the size of effect between two

groups only reached its statistical significance at one time-point (i.e. 12-months). This study included a number of strengths including: adequate randomisation, concealed allocation, outcome assessor blinding and baseline similarity between groups. However, blinding of patients and clinicians were not conducted, hence introducing performance bias. Besides, the only outcome measure used was RMQ, which may limit reporting on other important outcomes. Overall, this study is moderate risk of bias.

In contrast, the trial by Hough et al. (2007) reported a different finding from Klaber Moffett et al. (2004). Hough et al. (2007) conducted a RCT in patients with NSLBP of mixed duration. The hypothesis being tested was that physical exercise class with CBA (namely active rehabilitation) were more effective than manual therapy when targeting patient at high risk of chronicity (a score of > 106 on the Orebro Musculoskeletal Pain Screening Questionnaire (OMPQ) score). The OMPQ is a valid and reliable 'yellow flag' screening tool that predicts long-term disability and failure to return to work in workers following musculoskeletal soft tissues injury (Linton & Hallden, 1998). Outcome measures were pain (evaluated by VAS) and disability (evaluated by RMQ). This study found that active rehabilitation was no more effective in improving pain and reducing disability than manual therapy in the high-risk subgroup, and overall the treatment effect was not significant. The authors concluded that using active rehabilitation targeting patients at high risk of chronicity (OMPQ > 106) was not any more useful. However, this study included small sample size (only 39 patients). In addition, no randomisation, no concealed allocation, no patient and clinician blinding were conducted. The manual therapy arm was not standardised where physiotherapists were free to select any treatment. The authors also did not consider dropout rate and did not analyse data according to treatment allocation. This study demonstrated poor validity of their findings to support its conclusion. This study is high risk of bias.

A systematic review (Kent & Kjaer, 2012) aimed to determine if the efficacy of treatment when targeting NSLBP patient (of any duration) with particular psychosocial characteristics (e.g. high pain-related fear, catastrophization, anxiety and depression). The hypothesis was that

psychosocial intervention was more effective when targeting patients with certain psychosocial characteristics. This review concluded that there was only limited evidence that active rehabilitation (physical exercise class with using CBA) was more effective than usual care at reducing activity limitation when targeting NSLBP patient with high pain-related fear. Although the authors adequately assessed the risks of bias of included studies (as outlined by the Cochrane Back Review Group), this review only included 4 RCTs (papers in English, Danish and Norwegian), hence there is potential for their findings to contain cultural and publication bias.

2.7.1 Summary of evidence on the effectiveness of CBA rehabilitation when targeting patients with psychosocial characteristics

Surprisingly, only limited literature offers evidence for the effectiveness of CBA treatment targeting NSLBP patients with psychosocial risk factors. Overall, the quality of evidence was low. Among all studies being appraised, the included patients were of mixed duration of NSLBP. No studies specifically looked at NSCLBP with psychosocial characteristics. This has highlighted the need for further investigation in this subgroup of LBP patients.

Despite the limited and low quality evidence in this field, experts remained optimistic about the importance of this line of research and acknowledged the research importance of examining CBA intervention targeting at NSCLBP patients with high psychosocial risk factors (such as high FAB) (Van der Windt et al., 2008; Kent & Kjaer, 2012). This current study aims to extend the literature in this line.

2.8 Effectiveness of CBA intervention in altering HLOC

Among the different psychological factors of NSCLBP, those of a cognitive nature play a prominent role, largely due to the fact that pain is a perceptual phenomenon. In fact, cognitive factors are largely responsible for the final (cortical) part of the perception process, therefore, without subtracting importance from the more sensorial and emotional aspects of pain, the final integrating point is cognitive in character (Moreno et al., 1999).

Of the cognitive factors affecting pain experience, HLOC, which refers to a person's belief in his own control over health condition (Wallston & Wallston, 1982), receives increasing research interest in chronic pain and NSCLBP. This is probably because HLOC has meaningful relationships to health attitudes, behaviours, coping and outcomes (Wallston & Wallston, 1982; Armitage, 2003; Masters & Wallston, 2005; Janowski et al., 2013), all of which are the keys for effective management of NSCLBP.

HLOC has been predominantly measured by the MHLC scale (Wallston et al., 1978), which is a valid and responsive assessment tool to measure HLOC in medical or health-related condition (Wallston et al., 1994). Studies with a focus on examining HLOC in patients with a medical or health condition often employed Form C of MHLC to assess the three subscales (Haldorsen et al., 1998; Sengul et al., 2010; Sengul et al., 2011; Richard et al., 2011; Klaber Moffett et al., 2006; Oliveira et al., 2009; Keedy et al., 2014).

2.8.1 Evidence reviewing the effect of CBA intervention in altering HLOC using MHLC

Limited evidence (only four studies) was found using MHLC to assess HLOC in NSCLBP patients following CBA intervention (Klaber Moffett et al., 2006; Keedy et al., 2014; Rybarczyk et al., 2001; Harkapaa et al., 1991). There is also heterogeneity among these studies such as: patient selection, research design, intervention, professionals delivering the intervention, outcome measures and follow-up.

A RCT by Klaber Moffett et al. (2006) compared the effectiveness of a brief physiotherapy pain management programme using CBA (approximately 3 hours duration) with a biomechanical hands-on physiotherapy approach (McKenzie treatment, 4 sessions) in patients with neck pain and back pain of mixed subacute and chronic duration (N=649). Each group then subdivided into with and without information booklet. A large number of outcome measures were used such as FAB (as evaluated by TSK), disability (as evaluated by RMQ), ILOC, CLOC and ELOC-powerful others (as evaluated by MHLC). Findings showed no significant difference in all outcomes between the two groups, except the brief pain management programme group (with booklet) reported significantly less reliance on health professional (reduction on ELOC) at any time point, compared to the McKenzie group. In the brief pain management group (with booklet), there was no improvement in ILOC and CLOC at 6-week, 6-month and 12-month (<3%), whilst ELOC (powerful others) steadily improved up to 6-month. This study included randomisation, concealed allocation and blinded outcome assessors. Performance bias may be present due to no blinding of patients and clinicians. Included patients were with neck pain and back pain with mixed subacute and chronic duration, hence this may introduce heterogeneity. A large amount of outcomes were included (14 in total) but the authors only selectively reported some of them (reporting bias). These different sources of bias weaken the validity of conclusion regarding the effect of CBA intervention in altering HLOC in NSCLBP. Overall, this study is moderate risk of bias.

A longitudinal study by Keedy et al. (2014) evaluated whether a two-week CLBP multidisciplinary intervention (MI) altered patients' mental health, physical function and pain related belief (i.e. HLOC and self-efficacy). They also examined whether HLOC and self-efficacy predicted treatment-related changes in general mental health, depression and physical function following intervention. Sixty-one patients with CLBP completed the 80-hours programme, delivered by physiotherapists and other multidisciplinary members. A large number of outcome measures were used such as HLOC, self-efficacy, floor-to-waist lift (physical function), disability and depression. Outcome measures were taken before, after and 1-month following the MI programme. The study showed that the MI programme was effective in improving physical and mental health, as well as ILOC, CLOC and ELOC (for others) at 1-month. However, it had no impact on ELOC (for medical professionals). Regression analysis found that higher ILOC and lower ELOC (for medical professionals) predicted better physical functioning outcome at 1-month were not a predictor of mental health outcomes (depression and self-reported mental health). A limitation of this study is its short follow-up time (1-month), therefore, the effectiveness of the MI programme can only be suggested as short-term. This study did not mention blinding of outcome assessors, which may introduce detection bias. The dropout rate of this study was 22% from baseline to end of study (1-month). It is unclear how the authors handled the incomplete data as the sample size across analysis at each time point was varied, which is likely to bias the results. The MI programme of this study was an intensive tertiary two-week rehabilitation which involved psychiatrist and vocational rehabilitation. Therefore, generalizability of their findings may be limited for primary care physiotherapy patients. Overall, this study is high risk of bias.

A study by Rybarczyk et al. (2001) aimed to evaluate the effect of a mind-body wellness intervention consisting of CBT and exercise component. They compared physical and psychological outcomes (including HLOC as outcome measure) between the mind-body wellness intervention and control group. All participants had a chronic illness (including NSCLBP, osteoarthritis, rheumatoid arthritis, diabetes and hypertension) and had six

or more primary care visits in the preceding year. The mind-body wellness intervention group (2 hours of eight sessions programme) showed reduction in CLOC and ELOC up to 1 year post-treatment. However, poor response of outcome data was seen in control group, resulting in attrition bias. Besides, this study included patients with a variety of chronic condition, hence findings are not solely representative of NSCLBP patients. The authors were also unclear with respect to their statistical methods in handling incomplete outcome data. These limitations may over-inflate the effectiveness of the intervention. This study is high risk of bias.

A RCT by Harkapaa et al. (1991) examined the relationship between HLOC and outcome in a MI programme in patients with NSCLBP. A total of 459 patients were randomised into three groups: a 3-week inpatient MI (included CBT component), a 15-session outpatient treatment (two hour sessions held twice a week) and a control group (received written and oral self-care instructions and back exercise only). Both inpatient and outpatient treatment groups were similar in content; both were carried out in groups of 6-8 patients, led by physiotherapist. Outcome measures included disability, HLOC, psychological distress and back exercise compliance. At 3-months follow-up (completed by 96% of participants), the two treatment groups (inpatient and outpatient treatment) showed significantly greater improvement in HLOC and reduction in disability when compared with control group; significantly more inpatients than controls experienced greater reduction in disability; and inpatients performed their exercises significantly more than both outpatients and control group. With respect to the association between HLOC and treatment outcome, improvement of HLOC was found to be significantly associated with positive treatment outcomes (i.e. reduction in disability, more accomplishment and frequency of back exercises and less psychological distress), the ELOC was found to be significantly associated with less exercise at follow-up across treatment groups. The two treatment groups showed a more favourable outcome in HLOC, less disability and better accomplishment of back exercises at 3-months, than the control group. The authors concluded that patients with higher ILOC, after the MI programme, improved more, learnt their exercises better, and practised them more during the follow-up.

Although a large enough sample size, randomisation and adequate data analysis were performed, the authors were unclear of the sample calculation, concealed allocation, and outcome assessors blinding. The follow-up period was only short (3-months), therefore whether these benefits will be sustained in longer-term is unknown. All subjects of this study were selected among blue-collar workers with low disability, therefore the finding may not be generalizable to patients in primary care setting or patient groups moderately or severely disabled by NSCLBP. This study is high risk of bias.

2.8.2 Evidence reviewing the effect of CBA intervention in altering HLOC using composite scores or outcome measure that is re-constructed on the basis of MHLC

There are other outcome measures seen in the literature that assessing subscale of HLOC, for example, the Multiple Pain Locus of Control (MPLC) and Pain Locus of Control (PLOC) are re-constructed on the basis of MHLC. The limitation of these outcome measures is that their responsiveness and validity are not established. Some authors used composite measures such as: the Pain Coping and Cognition List (PCCL), the Pain Cognition List (PCL), and the Survey of Pain Attitude (SOPA). Although these questionnaires provide composite scores for overall measurement of pain coping, pain cognitions and subscale of HLOC (such as ILOC and ELOC), they do not specifically assess HLOC.

A possible explanation for using different outcome measures could be that each study was designed with other specific targets and goals, and HLOC (as evaluated by MHLC) is not always the focus of these studies. Therefore, caution should be taken when interpreting findings of these studies that using composite scores or outcome measure that is re-constructed from the MHLC.

A cohort study by Coughlin et al. (2000) assessed the efficacy of a MI programme in altering chronic pain patients' PLOC. Participants included 73 patients with chronic pain. Treatment was a 4-week outpatient pain programme (40 hours a week) based on exercise and CBA education. Two outcome measures: the control subscale of the SOPA and the PLOC were taken before and after the 4-week programme. They found that the MI programme simultaneously increased patients' ILOC and decreased both CLOC and ELOC over pain following a MI programme. This study concluded that patients' PLOC belief can be changed with MI programme. Included patients were with a wide variety of chronic pain, therefore findings were not representative of CLBP patients alone. There is also limitation of the outcome measures being used. First, evidence of the reliability and validity of the PLOC is limited (Penzien et al., 1989), Second, this outcome measure is not widely used in research. Hence its responsiveness is questionable. The authors did not mention whether there was any blinding of outcome assessors, any dropout of the programme and how incomplete data were addressed. These methodological flaws are likely for findings to contain detection and publication bias. This study is high risk of bias.

A RCT (N= 148) by Spinhoven et al. (2004) aimed to evaluate whether a MI programme alter NSCLBP patients' pain control belief and pain coping strategies. Outcome measure used in this study was PCCL, which is a composite measure. The PCCL was re-constructed on the basis of three other questionnaires (PCL, Coping Strategy Questionnaire (CSQ), and MPLC). This study concluded that the MI group showed significantly greater increase in ILOC over pain, greater decrease in ELOC, and greater decrease in catastrophizing than the two comparison groups (discussion group and waiting list group) immediately after treatment. Both ILOC over pain and catastrophizing showed continued significant improvement at 12-months follow-up, whereas the reduction in ELOC over pain was no longer significant at 12-months. This study has a robust design including: randomisation, concealed allocation, blinding of outcome assessors and patients' compliance and treatment integrity checks. However, 32% participants dropped out from pre-treatment to 12-months follow-up, hence

incomplete outcome data may introduce attrition bias. Despite the psychometric properties of the PCCL were shown to be satisfactory (Stomp-van den Berg et al., 2001), it cannot assume that this study still yields the same results as found with PCCL if MHLC was administered to assess HLOC specifically. This study is moderate risk of bias.

Smeets et al. (2006b) conducted a RCT in 211 patients with NSCLBP. This study compared three active treatments (i.e. active exercise treatment (1 hour 45 minutes, 3 times a week for 10 weeks), CBT treatment (1.5 hours for 10 sessions), combined active exercise and CBT, with waiting list group. Each treatment lasted for 10 weeks. Outcome measures were taken before and after the 10 weeks of active treatments by research assistants who were blinded from patients' assigned treatment. Outcome measures included disability (as evaluated by RMQ), pain (by VAS), depression (by Beck Depression Inventory), pain catastrophizing and internal control of pain (by the subscale of PCL). Findings showed that disability, pain and pain catastrophizing significantly reduced in all three active therapies, whereas internal control of pain did not change significantly in all active treatments. This study included use of randomization, blinded outcome assessors, application of intention-to-treat on patients who withdrew and with poor compliance. However, the authors assessed internal control of pain by using the subscale of PCL. Currently, there is no information about the responsiveness of this outcome measure, therefore the influence of CBA treatment on patients' internal control of pain may not be adequately measured.

2.8.3 Summary of evidence on the effect of CBA intervention in altering HLOC

To our knowledge, there is no study in the literature examining the effectiveness of a physiotherapy CBA active rehabilitation (similar to the CBCLBP programme) in altering HLOC using MHLC specifically in NSCLBP patients.

From the seven studies being appraised (Klaber Moffett et al., 2006; Keedy et al., 2014; Rybarczyk et al., 2001; Harkapaa et al., 1991; Coughlin et al., 2000; Spinhoven et al., 2004 and Smeets et al., 2006b), they all consistently showed evidence to support the effectiveness of CBA intervention in improving HLOC. However, the quality of evidence was generally poor.

Among the four studies assessing HLOC by MHLC, three of them are of high risk of bias (Keedy et al., 2014; Rybarczyk et al., 2001; Harkapaa et al., 1991), whilst one is of moderate risk of bias (Klaber Moffett et al., 2006). Of the three studies assessing HLOC using composite scores and outcome measures re-constructed based on MHLC, one is of high risk of bias (Coughlin et al., 2000), one of moderate risk of bias (Spinhoven et al., 2004) and one of low risk of bias (Smeets et al., 2006b). Many methodological criteria regarding internal and external validity were not fulfilled in most studies.

In addition, more than half (4 out of 7) of these studies had a short follow-up period (< 3-months). Therefore, it can only be concluded that there is low quality evidence that the CBA intervention has a positive effect on HLOC at short-term, while its long-term effectiveness is unclear.

The low number of relevant studies found, together with the methodological flaws (including lack of outcome assessors blinding, incomplete follow-up data, insufficient information about the intervention and data analysis, and selective reporting), and the heterogeneity of the reviewed studies (such as variation in population being studied, the professionals delivering the programme, the content, frequency and duration of treatment, follow-up period, and outcome measures), limits any valid evidence regarding the effect of CBA intervention on HLOC in NSCLBP patients. The need for this kind of data seems apparent, considering the acknowledged role of cognitive factors and patients' belief structure may affect their response to treatment. This current study aims to contribute additional evidence in this line.

2.9 Importance of self-management of NSCLBP

Self-management has been described as a model of care where patients use strategies to manage and monitor their own health, retaining a primary role in management, and where they learn skills to be used in the daily management of their health condition (Lorig & Holman, 2003). From the patients' perspective, self-management has the advantage that patients can provide themselves with symptoms relief at anytime. From the healthcare service perspective, self-management could reduce dependence on healthcare services and decrease the costs of the condition (Toye & Barker, 2012). From the societal perspective, effective self-management may have a positive impact on work absenteeism, future health care utilization and long-term sickness (Linton et al., 2005).

A RCT by Linton et al. (2005) examined the effectiveness of three types of intervention: minimal treatment group (examination, reassurance, activity advice), minimal treatment plus CBA group (physiotherapists involved, six sessions, once a week for 2 hours), and minimal treatment plus CBA with physical exercise (at least one session providing exercise programme and various physiotherapy treatments) in a primary care setting. A total of 158 patients with NSLBP and neck pain completed the 1-year study. The CBA treatment emphasized various core self-management components such as problem-solving, coping skills, graded activity, relaxation and managing flare-ups. A total of 20 outcome measures were included, in which the key outcome measures were future healthcare utilization, work absenteeism, and long-term sickness. Results showed that although all three groups improved at 1-year follow-up, the two groups with "added" treatment (CBA and CBA with physical exercise) significantly reduced future healthcare utilization and work absenteeism at 1-year. The two groups with 'added' treatment were also found to reduce the risk of future long-term sickness by five-fold, compared to the minimal treatment group. There was no significant difference between the CBA and CBA with physical exercise group, despite the CBA with physical exercise group produced better results among the 20 variables being studied. This study highlighted the effectiveness of CBA

and CBA with physical exercises, and the importance of self-management in reducing healthcare and economic burden of NSLBP and neck pain.

This study included randomization, outcome assessor blinding, and use of a best-worst-intermediate case analysis to consider the effects of dropout (15% dropout at 1-year) may have on their findings. The design was featured with a stepped approach where each group represented additional care as recommended by guideline. This has the advantage of reflecting the primary care situation where care is normally ‘added on’ (Sagnivy et al., 2009). However, one limitation of this study was the unequal amounts and intensity between the three types of interventions, therefore there was a possibility of demand effect (i.e. patients receive more extensive treatment and attention may experience higher ‘demand’ to report success) in the CBA and CBA with physical exercise group. Besides, participants of this study was made up of workers, with the mean aged of 40s’, who volunteered and sought help for back and neck pain. Thus, this sample may have been representative of younger and more motivated workers, which may limit generalizability of primary care patients in clinical settings. This study is low risk of bias.

Despite self-management being endorsed and encouraged in most NSLBP guidelines (Savigny et al., 2009; Chou et al., 2007; Koes et al., 2010), the assumption that the use of self-management is beneficial for patients with NSLBP may not be as optimistic as we thought. A well-conducted systematic review with meta-analysis reviewing effectiveness of self-management of NSLBP (Oliveira et al., 2012a) concluded that there was moderate-quality evidence showing that the use of self-management (in the form of rehabilitation programme, self-care booklet, online information) only had small effect on improving pain and disability when compared to minimal intervention (such as usual care and waiting list) in patients with NSLBP. When compared to other interventions such as physiotherapy, exercise, education, massage, yoga and acupuncture, there was high quality evidence that the effect of self-management was equally or less effective in reducing pain and disability. A total of 13 RCTs from the community, primary care services and rehabilitation clinics were included in this review without language restriction. Inclusion criterion were patients with NSLBP

of any duration and when at least one intervention was indicated by the authors using the terms ‘self-management’ and ‘self-care’. The mean score for methodological quality of included trials was 6.5 out of 10 using the PEDro scale. Outcome measures were pain and disability. Selection of literature adequately addressed the review’s question. The authors provided sufficient information on study population, the interventions and the outcome measures. Besides, the between-trial heterogeneity was also identified using appropriate statistical method. Although the number of included trials was relatively small (N=13), this was the first meta-analysis of self-management for NSLBP to assess the content validity of the self-management programme. The authors have provided precise pooled estimates of the treatment effects of self-management compared to minimal intervention. Results were presented with confidence intervals; sensitivity analysis was also conducted to determine the effectiveness of those included trials fulfilling the core components of self-management. Included trials were from various settings, suggesting the generalizability to NSLBP population was good. This is a well-conducted meta-analysis with a low risk of bias.

2.9.1 Evidence of the effectiveness of CBA active rehabilitation on patient’s self-management

A RCT (N=187) by Klaber Moffett et al. (1999) evaluated the clinical and cost-effectiveness of an exercise with CBA programme versus usual primary care management. Findings showed that those patients with subacute or recurrent NSLBP who attended a physiotherapist-led CBA education with active exercise programme utilised fewer healthcare services, fewer resources and took almost 50% less working days off sick at 12-month, than those who were under GP ‘best care’. Klaber Moffett et al. (1999) developed a ‘Back to Fitness’ programme, which consisted of exercise and CBA education (eight sessions of 60 minutes). It was found that the “Back to Fitness” programme was significantly more effective in the reduction of pain, disability, and healthcare usage, when compared to routine management from GP. These clinical benefits were observed at one-year follow-up. The design of this study was a conventional RCT where randomization and allocation were conducted. However, double blinding

was not feasible, which may result in performance bias. Because of recruitment difficulty, this study did not achieve a desired powered sample size of patients. The baseline of RMQ disability score and clinical status (Aberdeen back pain scale) of included patients was relatively mild in the 'Back to Fitness' group. Inclusion of mildly disabled sub-acute LBP patients may have explained why the 'Back to Fitness' group resulted in less healthcare usage. These limitations may weaken the generalizability of the wider population of NSLBP patients. This study is moderate risk of bias.

Critchley et al. (2007) (see **Section 2.6.1**) provided high quality evidence that physiotherapy-led CBA intervention was effective in reducing healthcare usage in moderately disabled NSCLBP patients. This study found that patients with NSCLBP who attended a physiotherapy-led pain management programme based on CBA principles (8 sessions of 90 minutes) reported significantly fewer secondary care visits, in-patient procedure and investigations, compared to patients who had individual physiotherapy and spinal stabilisation classes at 18-months follow-up. Klaber Moffett et al. (2006) reported that a brief physiotherapy pain management programme significantly reduced patients' reliance on health profession, compared to McKenzie hands-on physiotherapy treatment at 12-months in patients with neck and back pain with mixed subacute and chronic duration (see **Section 2.8.1**).

A brief self-care intervention with CBA education (consisted of two two-hour sessions, with 12-16 participants per group) showed modest improvement in reducing worries about back pain, pain intensity, activity limitation, fear-avoidance and improving patients' attitudes toward back pain self-care (as evaluated by SCQ), when compared to usual care at 6-months in primary care (Moore et al., 2000). A total of 226 patients volunteered for the study and were randomised into either self-care group or usual care. This study included back pain patients of > 6 weeks (i.e. mixed both subacute and chronic onset). Randomization and concealed allocation were not clearly described in the paper. All patients, clinicians and outcome assessors were not blinded. Dropout and compliance rate were not discussed or considered in their analysis. Besides, evidence of the psychometric

properties of some of the outcome measures used in this study (such as back pain worry rating) are limited. The different sources of bias weaken the internal validity of their findings. This study is high risk of bias.

A prospective cohort study by Van Hooff et al. (2010) evaluated the effect of an intensive pain management programme based upon CBT principles, using a multi-disciplinary approach and was of a 100 hours duration following NICE guideline. A total of 107 CLBP patients entered the 2-weeks group-based residential programme (consisted of 50 hour CBT training, 35 hours physical activities and 15 hour education). The main outcome parameters were daily functioning (evaluated by RMQ), self-efficacy (by pain self-efficacy questionnaire) and quality of life (by Short Form 36 Physical Component score). Outcome measures were measured up to one-year. Results showed that patients demonstrated significant improvement in daily functioning and self-management. All outcome parameters were sustained at 1-year follow-up. Results were also shown to be comparable with spinal surgery (Fairbank et al., 2005) and better than results from less intensive rehabilitation programme (Smeets et al., 2008). The authors used multivariable adjustment, sensitivity analysis when analysing missing data, and strict standardization of their programme. This therefore enhanced internal validity, and minimized the potential bias and confounding on the outcome factors. This study provided evidence that this type of intensive pain management programme could be an alternative when fusion surgery was considered, in a selected group of patients who were motivated and engaged in self-management for their CLBP problem. This study is low risk of bias.

2.9.2 Summary of evidence on the effectiveness of CBA active rehabilitation in patients' self-management

Of the seven individual studies and review examining the effectiveness of CBA active rehabilitation on patients' self-management, four of them are considered low risk of bias (Linton et al., 2005; Oliveira et al., 2012a; Critchley et al., 2007 and Van Hooff et al., 2010), two were moderate risk of bias (Klaber Moffett et al., 1999; Klaber Moffett et al., 2006) and one was high risk of bias (Moore et al., 2000). Despite the variations in interventions, outcomes, involvement of physiotherapist in delivering the programme, and heterogeneous population, the literature seems to provide moderate evidence supporting the effectiveness of CBA active rehabilitation in enhancing patients' ability to self-care their NSLBP.

Self-management is a desirable ingredient in the effective management of NSCLBP. With the high economic and social burden of NSCLBP, effective self-management and better patients' self-care attitude could at least partly reduce financial impact on both the healthcare system and to patients themselves (Chou et al., 2007).

2.10 Cost

According to the Health Survey for England 2011, back pain was responsible for 37% of all chronic pain in men and 44% in women (Bridges, 2011). Chronic pain was highlighted as a massive socio-economic burden, it is estimated the cost of back pain alone are around £12.3 billion per year (Donaldson, 2009).

The rising use of healthcare services

The use of healthcare services for back pain has increased substantially over the past two decades. For instance, studies have documented that there is a greater use of spinal injection (Weiner et al., 2006; Friedly et al., 2007), surgery (Deyo & Mirza, 2006; Gray et al., 2006), and opioid medication (Luo et al., 2004). Studies have also demonstrated that there is an increased use of prescription medication, visits to physicians, physiotherapists and chiropractors (Feuerstein et al., 2004; Martin et al., 2008). Many of these treatments are utilised by patients with CLBP. Therefore, an evaluation of

prescription medication and healthcare usage should be considered as a means of quantifying how effective an intervention has been achieved.

Increased healthcare use for CLBP could be due to: (1) a substantial increase in prevalence of CLBP over the past few decades (Harkness et al., 2005; Palmer et al., 2000); (2) a larger proportion of those with CLBP who seek care; (3) an increased use of healthcare resources; and (4) a combination of these factors (Thorpe et al., 2004). One way to reduce the socio-economic burden and healthcare usage is to continuously seeking for clinical treatment improvement and cost-effective option.

2.10.1 Evidence on cost evaluation of the physiotherapy-led CBCLBP programme

There are four economic studies of a similar intervention conducted in a clinical setting (physiotherapy-delivered, combined active exercise and CBA education) that are relevant to the current study (Klaber Moffett et al., 1999; Lamb et al., 2010; Critchley et al., 2007; Johnson et al., 2007). These studies have already been described and appraised in **Section 2.6.1** and **Section 2.9.1**.

Figure 2.1 summarised the relevant information of these economic studies. These studies did not evaluate costs from a societal perspective. i.e. indirect costs. The box left blanked indicates the authors did not investigate or report these variables.

Figure 2.1: Table to summarise the relevant information of these economic studies

				RESULTS						
Author	Comparative treatment	Details of economic evaluation	Follow-up	Mean provider costs per patient to provide:	Mean provider costs per patient over 1 year	Patient costs	Healthcare utilization	ICER for treatment per QALY gained	Author's conclusion	Methodological quality (CHEC-list)
Lamb et al. (2010)	Group CBT intervention plus advice (N=327) Vs Advice (N=163)	<u>Type:</u> CEA/CUA <u>Setting:</u> United Kingdom, 2008 <u>Perspective:</u> healthcare sector	12-months	Group CBT intervention plus advice: £187 Advice: £16.32	Group CBT intervention plus advice group: £421.52 Advice: £224.65		Following treatment, 50% of all participants re-visited GP 19% used NHS physiotherapy 23% used private physiotherapy	ICER for group CBT intervention plus advice group= £1786 per QALY gained (EQ-5D)	Group CBT intervention plus advice is likely to be more cost-effective than other active intervention such as acupuncture, exercise, manipulation and postural approaches.	Moderate
Critchley et al. (2007)	Individual physiotherapy (N=53) Vs Spinal stabilization exercise class (N=53) Vs Pain management programme using CBT (N=44)	<u>Type:</u> CEA/CUA <u>Setting:</u> United Kingdom, 2002-2005 <u>Perspective:</u> healthcare sector	18-months	Pain management programme: £165 Spinal stabilization exercise class: £379 Individual physiotherapy: £474		Costs for all participants: <u>Before baseline:</u> £169.29 <u>0-6 months:</u> £70.49 <u>6-12 months:</u> £92.14 <u>12-18months:</u> £103.03	Pain management group had less time off work, less hospital visits, in-patient procedures and investigation, paid-for prescription compared to spinal stabilization exercise and individual physiotherapy	Pain management group is likely to be the most cost-effective at all costs per QALY (EQ-5D)	Pain management programme associated with least costs and it is likely to be the most cost-effective than the two comparison groups.	High

Continued:				Results				ICER for treatment per QALY gained	Author's conclusion	Methodological quality (CHEC-list)
Author	Comparative treatment	Details of economic evaluation	Follow-up	Mean provider costs per patient to provide:	Mean provider costs per patient over 1 year	Patient costs	Healthcare utilization			
Johnson et al. (2007)	GP care (N=149) Vs Exercise and education using CBT approach (N=78)	<u>Type:</u> CEA/CUA <u>Setting:</u> United Kingdom, 2002-2005 <u>Perspective:</u> healthcare sector	18-month					ICER for exercise and education using CBT compared to GP care: £5000 per QALY gained (EQ-5D)	Acceptability curve showed the exercise and CBT education group was found to have a relatively low cost, but comparison to GP care was not provided.	Moderate
Klaber Moffett et al. (1999)	GP care (N=74) Vs Exercise and education using CBT approach (N=70)	<u>Type:</u> CEA/CUA <u>Setting:</u> United Kingdom, Year of study not known <u>Perspective:</u> healthcare sector	12-month		GP care: £ 508.43 Exercise and education using CBT approach: £360.15		<u>Number of GP visits over 1-year:</u> GP care: 266 Exercise and education using CBT approach: 139 <u>Number of physiotherapy visits over 1-year:</u> GP care: 266 Exercise and education using CBT approach: 139		Patients in the exercise and CBT education group used much less healthcare, and other resources. They also took much less days off work, compared to those in the GP care group. The exercise and CBT education group was clinically and cost-effective than GP care.	Moderate

CEA-Cost-effectiveness analysis CUA-Cost-Utilization analysis ICER-Incremental cost-effectiveness ratio CHEC-list-Consensus on Health Economic Criteria

As shown in **Figure 2.1**, these studies support the view that physiotherapy CBA active rehabilitation is cost-effective and requires less healthcare utilization, compared to treatment alternatives such as conventional physiotherapy (Critchley et al., 2007), GP care (Johnson et al., 2007; Klaber Moffett et al., 1999), and as an addition to GP care (Lamb et al., 2010). This evidence is also supported by a high quality systematic review (Lin et al., 2010), which concluded that the guideline-endorsed treatments (such as interdisciplinary rehabilitation, exercise, and CBA treatment) were more cost-effective treatment compared to advice to stay active and a variety of treatment alternatives (such as massage, yoga and relaxation) in NSCLBP patients.

The overall quality of this review is low risk of bias (Lin et al., 2010). It included 26 relevant economic evaluations alongside RCTs investigating clinical and cost effectiveness of the guideline-endorsed treatments. Study selection and quality assessment of this review was thorough. The authors used the criteria from the Cochrane Back Review Group (Furlan et al., 2009; Van Tulder et al., 2003) to assess the risk of bias, and the Consensus on Health Economic Criteria (CHEC-list) (Evers et al., 2005) to assess the methodological quality of the economic evaluation. Fifteen (out of 26) of the included studies had a low risk of bias, which means conclusions were predominantly drawn from good quality studies. Appropriate information of the included studies was provided. The authors also identified methodological limitations of included studies and acknowledged the complexity of comparing economic data between different settings, countries and healthcare systems. The main methodological flaws of the included trials are: lack of assessor blinding, incomplete reporting of costs and resource utilization and short follow-up period. There is also heterogeneity in study population, study treatments, differences in economic perspectives and settings. These may weaken the validity and generalizability of the conclusion drawn from this review.

In sum, there is moderate evidence to support the cost-effectiveness of combined exercise and CBA intervention in NSCLBP. The advantage of being

cost-effective allows management to be suited to the budget of the healthcare provider.

PART II

The first part of this review provides the relevant evidence of the effectiveness of the physiotherapy CBA active rehabilitation. Next is to understand why and how this treatment approach works. One way is to study those factors associated with the maintenance of NSCLBP, and the relationship between them. It is beyond this present review to appraise the complex relationship of various factors within the biopsychosocial framework. However, one of the study aims is to examine the correlation and regression relationship between pain intensity, disability, FAB and HLOC. This second part of the review focuses on the relevant studies related to this aim.

2.11 The fear-avoidance model and its constitutive components

Based upon previous work (Lethem et al., 1983), Vlaeyen & Linton (2000) proposed a cognitive-behavioural model known as the fear-avoidance model. The fear-avoidance model proposes that the way in which pain is interpreted may lead to two different pathways (**Figure 2.2**).

Figure 2.2: Fear-avoidance model (Vlaeyen et al., 1995b; Vlaeyen & Linton, 2000)



The influence of high FAB in NSCLBP is well documented. For instance, a high quality systematic review by Ramond et al. (2011) concluded high FAB is a significant predictor of persistent disability in primary care. Another high quality review found that low level of FAB is a significant predictor to positive treatment outcomes at 1-year in NSCLBP (Chou & Shekelle, 2010). This evidence highlights that addressing high FAB is particularly important in attaining better outcome in NSCLBP patients.

The fear-avoidance model has inspired a vast amount of research and has become the leading paradigm for understanding disability in NSCLBP. Since the review by Vlaeyen and Linton (2000), a large body of study attempts to further validate the fear-avoidance model and the relationship between the key elements such as pain intensity, pain-related fear and disability.

2.11.1 Pain intensity

Pain intensity and disability

In their review, Vlaeyen & Linton (2000) concluded that pain intensity is not a predictor to avoidance-behaviour or disability. Some studies observed a weak or even non-existing association between pain and disability in NSCLBP (Waddell et al., 1992; Waddell et al., 1993; Vlaeyen et al., 1995a; Vlaeyen et al., 1995b; Reneman et al., 2007; Meyer et al., 2009), whilst some reported a positive relationship between pain and disability (Thomas et al., 2010; Bair et al., 2008; Peters et al., 2005; Woby et al., 2004a; Turner et al., 2004).

In regard of the predictive importance of pain intensity, evidence is also inconsistent. Some NSCLBP studies reported that pain intensity accounted for a relatively large proportion of the variance in disability (Woby et al., 2004a; Woby et al., 2004b; Woby et al., 2007a; Woby et al., 2008). For example, it has been showed that pain intensity reported an additional 27% of the variance in disability (Woby et al., 2007a), and reduction in pain intensity explained an addition of 22% of the variance in reduction in disability (Woby et al., 2008) in NSCLBP patients attending physiotherapy.

On the other hand, some have shown that pain intensity has little predictive value in disability (Waddell et al., 1992; Mannion et al., 2001; Meyer et al., 2009). For instance, Waddell et al. (1992) found that pain intensity only explained 10% of the variance in disability. Mannion et al. (2001) found reduction in pain intensity only explained 16% of the variance in CLBP disability. Meyer et al. (2009) reported that pain made no significant contribution to explaining the variance in disability.

Figure 2.3 summarised the key findings of the relevant studies examining the relationship between pain intensity and disability. Description and appraisal of these studies are provided later in this section.

Figure 2.3: An overview of relevant evidence on the relationship between pain intensity and disability

Author	Type	Note	Number of patients	Follow-up	Results				Risk of bias
					Positive relationship between pain and disability	No relationship between pain and disability	Pain intensity as significant predictor to disability	Pain intensity has no predictor value to disability	
Woby et al. (2004b)	Cross-sectional	Before physiotherapy CBA programme	83				✓		Low
Woby et al. (2004a)	Prospective cohort	Before and after a 8-week physiotherapy CBA programme	54	8-weeks	✓		✓		Moderate
Woby et al. (2008)	Prospective cohort	Before and after a 6-week physiotherapy CBA programme	137	6-weeks			✓		Moderate
Thomas et al. (2010)	Cross-sectional	Specialist rehabilitation centre	50 patients		✓				High
Woby et al. (2007a)	Cross-sectional	Referred to physiotherapy CBA programme	183 patients				✓		Low
Meyer et al. (2009)	Cross-sectional	Secondary care	78 patients			✓		✓	Moderate

A physiotherapy cross-sectional study by Woby et al. (2004b) examined the predictive relationship between pain intensity (by VAS), disability (by RMQ) and a number of cognitive factors (including FABs about work (FABs-W) and FABs about physical activity (FABs-PA), catastrophizing and perception of control over pain). A total of 83 NSCLBP patients were included, who were about to start a physiotherapy-led CBA rehabilitation programme in a hospital outpatient physiotherapy department. This study found that (1) pain intensity accounted for an additional 24% of the variance in disability; (2) the three psychological factors (FABs-W, FABs-PA and catastrophizing) explained an additional 22% of the variance in disability, but only FABs-PA was found to be a significant predictor to disability and, (3) FAB was not a predictor to pain intensity. This study concluded that pain intensity accounted for a relatively large proportion of the variance in disability, whilst psychological factors particularly FABs-PA explained a large proportion of the variance in disability. A number of methodological criteria regarding internal validity of this study were fulfilled. This included: the use of valid and reliable assessment tools, adequate reporting of data analysis, and low attribution bias. However, the authors did not report powered sample size calculation and, it was unclear whether blinding of outcome assessors were conducted. These biases may limit the validity of the findings. This study is low risk of bias.

In a subsequent study, Woby et al. (2004a) conducted a prospective cohort study of NSCLBP patients before and after an 8-week physiotherapy-led CBA rehabilitation. The aim was to examine whether changes of a number of cognitive factors (including catastrophizing, FABs-W, FABs-PA and appraisal of control) were predictors of changes in pain intensity and disability. A total of 54 NSCLBP patients were included who completed a physiotherapy-led CBA active rehabilitation (five sessions, 3.5 hours each, over a period of 8 weeks). Outcome measures were taken before and after the programme. This study found that (1) reduction in pain intensity was significantly predictive of reduction in disability, accounting for an additional 43% of the variance in changes in disability after controlling demographics; (2) Changes in cognitive

factors (particularly reduction in FABs-W, FABs-PA and increased perception of control over pain) were significant predictor to reduction of disability, in which they explained an additional 22% of the variance in changes in disability; (3) Changes in cognitive factors were not associated with changes in pain intensity and (4) Increased perception of control over pain (as evaluated by the subscale of Coping Strategies Questionnaire (CSQ) was related to the reduction of disability. This study highlighted the predictive importance of both reduction of FAB and increased perception of control over pain on reduction in disability. This study is well-conducted methodologically within the context of an existing physiotherapy service. A number of strengths are identified: the use of valid outcome measures, adequate statistical test and a comprehensive picture of the intervention integrity was provided. However, there was a big dropout rate in follow-up data (65% of the original sample). Again, there was no mention whether power calculation and blinding of outcome assessors were used. This study is moderate risk of bias.

Woby et al. (2008) conducted another observational before-after study, with the aim to evaluate the effect of a 6-week physiotherapy-led CBA programme on pain intensity, disability, depression and a set of cognitive factors (including FAB, catastrophizing, functional self-efficacy, perception of control over pain and perception of ability to decrease pain). The authors also examined the association between them. An inclusion of 137 NSCLBP patients (of moderate pain and disability, and high FAB) was recruited in an outpatient physiotherapy department. Outcome measures were taken before and after the 6-week programme (five sessions, 3.5 hours each). Relevant findings of this study were (1) Patients demonstrated a significant cognitive improvement (significant reduction in FAB and significant increase in perception of control over pain and perception of ability to decrease pain) after the programme; (2) Reduction in pain intensity explained an additional 22% of the variance in reduction in disability and (3) Reduction in FAB and increase in self-efficacy explained a further 17% of the variance in disability. This study supports the clinical effectiveness of a physiotherapy-led CBA programme in improving NSCLBP

patients' pain cognition and beliefs. It also demonstrates the predictive importance of FAB to reduction in disability. The methodological quality of this study is good, including sufficient sample size, use of valid and reliable assessments tools, adequate report of information of the intervention and appropriate use of statistical tests. The main limitations are the high dropout (25% dropout) and unclear of blinding of outcome assessors and personnel. This study is moderate risk of bias.

Pain intensity and FAB

The relation between pain intensity and FAB is mixed. Some studies observed a weak-moderate positive relationship between FAB and pain intensity (Guclu et al., 2012; George et al., 2001), whilst some reported weak association (Thomas et al., 2010; Crombez et al., 1999; Vlaeyen et al., 1995a; Vlaeyen et al., 1995b), and that FAB has no predictive importance to lower level of pain intensity (Woby et al., 2004b).

Figure 2.4 summarised the key findings of the appraised studies examining the relationship between pain intensity and FAB.

Figure 2.4: An overview of relevant evidence on the relationship between pain intensity and FAB

Author	Type	Note	Number of patients	Follow-up	Results				Risk of bias
					Positive relationship between pain and FAB	No relationship between pain and FAB	FAB as significant predictor to pain intensity	FAB has no predictor value to pain intensity	
Woby et al. (2004b)	Cross-sectional	Before physiotherapy CBA programme	83					✓	Low
Guclu et al. (2012)	Cross-sectional	Neurosurgery outpatient	105		✓				Moderate
Thomas et al. (2010)	Cross-sectional	Specialist rehabilitation centre	50 patients			✓			High
Crombez et al. (1999)	Cross-sectional	Laboratory-based setting	35 patients			✓			High
Meyer et al. (2009)	Cross-sectional	Secondary care	78 patients				✓		Moderate

A cross-sectional study by Guclu et al. (2012) aimed to examine the relationship between pain intensity, disability, quality of life and FAB in patients with NSCLBP. A total of 105 patients were recruited in a neurosurgery outpatient clinic in Turkey. A large set of valid outcome measures were used. Relevant findings were (1) there was a positive association between pain intensity (by VAS) and FAB (by FABQ), and (2) A positive association was found between FAB and disability (by RMQ). This study employed valid assessment instruments and appropriate statistical analysis. However, the authors did not report how the sample size was derived and how data were collected. These potential biases may limit the validity of the findings. Again, this is a cross-sectional study, therefore it does not yield information regarding cause-effect relation. This study is moderate risk of bias.

2.11.2 Pain-related fear

Pain-related fear has been described with a variety of conceptual definitions among which: pain-related fear, fear of movement, fear of work or activity, fear of (re)injury and kinesiophobia are the most commonly used (Turk and Wilson, 2010; Lundberg et al., 2011). These terms are often used interchangeably in literature with regard to pain-related fear and FAB (Leeuw et al., 2006).

FAB and disability

The association between FAB and disability is evident even after controlling for pain intensity and other important co-variables in NSCLBP (Woby et al., 2004b; Elfving et al., 2007). Persistence of FAB has also been seen even after spinal surgery (den Boer et al., 2006; Brox et al., 2010) and physiotherapy (Al-Obaidi et al., 2005; Sorensen et al., 2010). In addition, high levels of FAB influence performance of functional physical tasks (Al-Obaidi et al., 2003) and are significant predictors of long-term work disability (Gheldof et al., 2005). Consequently, pain-related fear has become an integral part of our understanding in explaining disability in patients with NSCLBP.

The relation between FAB and disability is fairly well-established in the literature. A systematic review (included 18 relevant RCTs worldwide) with low risk of bias by Ramond et al. (2011) concluded that FAB is strongly correlated to disability. This review examined sixteen different psychosocial factors for CLBP in primary care. FAB were analyzed in seven studies of moderate-high quality according to the assessment criteria from the Cochrane Collaboration back review group for spinal disorders (Van Tulder et al., 1997). The conclusion of this well-conducted review is also supported by a number of studies (of poor to moderate methodological quality), which consistently observed a positive association between FAB and disability (Thomas et al., 2010; Elfring et al., 2007; Woby et al., 2004b; Crombez et al., 1999; Meyer et al., 2009; Guclu et al, 2012).

Figure 2.5 summarised the key findings of the appraised studies examining the relationship between FAB and disability.

Figure 2.5: An overview of relevant evidence on the relationship between FAB and disability

Author	Type	Note	Number	Follow-up	Results				Risk of bias
					Positive relationship between FAB and disability	No relationship between FAB and disability	FAB as significant predictor to disability	FAB has no predictor value to disability	
Woby et al. (2004b)	Cross-sectional	Before physiotherapy CBA programme	83 patients				✓		Low
Woby et al. (2004a)	Prospective cohort	Before and after a 8-week physiotherapy CBA programme	54 patients	8-weeks			✓		Moderate
Woby et al. (2008)	Prospective cohort	Before and after a 6-week physiotherapy CBA programme	137 patients	6-weeks			✓		Moderate
Guclu et al. (2012)	Cross-sectional	Neurosurgery outpatient	105 patients		✓				
Ramond et al. (2011)	Systematic review	16 psychosocial factors	18 RCTs worldwide		✓				Low
Thomas et al. (2010)	Cross-sectional	Specialist rehabilitation centre	50 patients		✓				High
Woby et al. (2007a)	Cross-sectional	Before physiotherapy CBA programme	183 patients			✓		✓	Low
Crombez et al. (1999)	Cross-sectional	Laboratory-based setting	35 patients		✓		✓		High
Meyer et al. (2009)	Cross-sectional	Secondary care	78 patients		✓		✓		Moderate

A cross-sectional study by Thomas et al. (2010) studied the correlation between pain (evaluated by VAS), disability (by RMQ) and a large set of psychosocial factors including FAB (by TSK), depression and catastrophizing. A total of 50 CLBP patients were recruited in a specialist rehabilitation centre, where they were about to start a CLBP programme. Relevant findings of this study included: (1) Pain intensity was positively correlated with disability and depression, but it had no association with FAB, and (2) Disability was positively correlated with FAB and catastrophizing. Outcome measures used in this study were valid and reliable instruments. However, several methodological criteria regarding the internal validity were not fulfilled. This included selection bias (70% of the included patients were male and 62% were unemployed, this may not generalisable to the wider population of CLBP), detection bias (due to absence of blinded outcome assessors), no report of sample calculation and selective reporting of their results. This study is high risk of bias.

Only few studies have shown that there is no or only a weak association between FAB and disability (Pincus et al., 2006; Woby et al., 2007a; Denison et al., 2004), and that FAB had no significant predictive importance to disability (Woby et al., 2007a). Conversely, a number of studies illustrated that pain-related fear is a significant predictor to disability (Crombez et al., 1999; Vlaeyen & Linton, 2000; Pincus et al., 2002; Meyer et al., 2009; Woby et al., 2004a; Woby et al., 2004b; Woby et al., 2008).

A cross-sectional study by Woby et al. (2007a) examined the relation between a large set of cognitive factors (such as self-efficacy, catastrophizing, perception of control over pain and depression), and levels of pain and disability in 183 NSCLBP patients who had been referred to a CBA intervention delivered by physiotherapists. Relevant findings were: (1) FAB did not emerge as a significant predictor to disability; (2) When pain intensity was an outcome of interest, the cognitive factors accounted for an additional 30% of the variance in pain intensity. Among all cognitive factors, both functional self-efficacy and

catastrophizing emerged as a stronger predictor to lower levels of pain intensity. However, perceptions of control over pain (as evaluated by CSQ) was not a significant predictor to pain, and (3) With disability as the outcome, pain intensity explained an additional 27% of the variance in disability, and the cognitive factors accounted for an additional 32% of the variance in disability. In particular, higher levels of functional self-efficacy and lower levels of depression both uniquely contributed to the prediction to disability. Again, perceptions of control over pain showed no predictive value to disability statistically. This study highlighted the significant association between cognitive factors and the levels of pain and disability in NSCLBP patients presenting for physiotherapy. However, perception of control over pain demonstrated no significant predictive value to both pain and disability. This study is methodologically sound, including adequate sample size, use of valid and reliable assessment tools, and sufficient information on statistical analysis. This study is low risk of bias.

A cross-sectional study (N=35) by Crombez et al. (1999) examined the role of pain intensity and pain-related fear (as assessed by TSK and the two subscales of FABQ (FABs-W and FABs-PA) in predicting self-reported disability and pain intensity in NSCLBP patients. Relevant findings were (1) Correlation analysis revealed that pain related-fear (as assessed by TSK, FABs-W and FABs-PA) was significantly correlated with disability, but pain-related fear has no association with pain intensity; (2) Regression analysis showed that pain-related fear is a much stronger predictor of disability than pain intensity. In particular, FAB (as evaluated by TSK) explained an additional 31% of the variance in disability after controlling age and the two subscales of FABQ. This study suggested that patients' levels of disability are mainly predicted by pain-related fear, but not by pain intensity. The overall methodological quality is poor in this study. The authors were unclear about whether sample calculation and blinding of outcome measures were carried out. It is a relatively small sample size, therefore the error variability of the beta-coefficients is probably large. In addition, the included patients were 'participants' in a

psychophysiological laboratory-based setting. Hence, the degree to which this small cohort of participants reflected those patients seen within a clinical treatment context is limited. This study is high risk of bias.

A cross-sectional study by Meyer et al. (2009) examined the relationship between a range of psychological factors and self-reported pain and disability in 78 patients who were seeking care for their CLBP in secondary care. Multiple regression analysis revealed that (1) demographics and psychological variables explained 42% of the variance in pain intensity and 59% of the variance in disability. Among all psychological independent variables, only FABs-W is significant predictors to both variances in pain intensity and disability; (2) Pain intensity has no predictive value to disability. This study concluded the predictive importance of FAB to disability and pain intensity in patients with CLBP. It demonstrated a number of strengths including adequate sample size, use of valid and reliable assessment tools, and appropriate report of data analysis. However, it suffered from detection bias due to absence of blinded outcome measures assessment. There may also be selection bias. This study is moderate risk of bias.

2.11.3 Disability

Disability may be the logical consequence of prolonged pain and heightened pain-related fear. This is evident in the aforementioned evidence, where a number of studies found the association between disability and pain (Thomas et al., 2010; Bair et al., 2008; Peters et al., 2005; Woby et al., 2004a; Turner et al., 2004; Woby et al., 2004b; Woby et al., 2007a; Woby et al., 2008), and between disability and FAB (Ramond et al., 2011; Thomas et al., 2010; Elfring et al., 2007; Woby et al., 2004a; Woby et al., 2004b; Crombez et al., 1999; Meyer et al., 2009; Guclu et al., 2012).

Interestingly, no study can be found that reporting the predictive importance of disability to pain intensity and FAB in NSCLBP. This may be due to the sequential concept proposed in the fear-avoidance model. Disability is in the

last position in the model, therefore most studies may dedicate to examine it as an outcome, rather than as a predictor.

2.11.4 Summary of the evidence on the relationship between pain intensity, disability and FAB

- No firm conclusion can be drawn on the relationship between pain and disability, due to inconsistent evidence in literature.
- No firm conclusion can be drawn on the relationship between pain and FAB, due to inconsistent evidence in literature.
- Moderate evidence on the relationship between FAB and disability.

The inconsistency is likely due to the high heterogeneity among studies, including difference in sample size, patients' baseline characteristics, study design, outcome measures, follow-up period and methodological quality. This may also highlight the complexity of the relationship between these variables, since a wide array of physical and psychosocial characteristics of LBP have been identified as having some prognostic importance and mediating effect (Hill & Fritz., 2011). For instance, epidemiological evidence suggested that a strong prognostic factor for persistent LBP is depression (Croft et al., 2006). Self-efficacy is found to be a strong predictor to disability in NSCLBP (Woby et al., 2007a), and a mediator between FAB and disability (Woby et al., 2007b). A large and high quality prospective cohort study identified illness perception, self-efficacy, perception of personal control, and acute/chronic timeline, were independent predictors of disability at 6-months in patients with LBP (Foster et al., 2010). This evidence implies that variation in outcome measures and patients' baseline variables are likely to be the confounding factors, which may distort the relationship between pain intensity, disability and FAB under investigation.

Regarding methodological quality, most of them were suffered from moderate or high risk of bias. Evidence largely comes from cross-sectional studies that do

not allow for directional conclusion. Due to the difference in study population and clinical settings, these studies are also likely to have selection bias. Therefore, findings may have limited external validity to a wider NSCLBP population.

2.11.5 Re-think the fear-avoidance model

The key concept of the fear-avoidance model is the prospective, sequential inter-relationships between its constitutive components (**Figure 2.2**). However, the inconsistent findings between pain intensity, disability and FAB may suggest that this model is likely to be a far more complex dynamic interactive process than we thought. This is supported by Wideman et al. (2013), who proposed that the components in the fear-avoidance model are unlikely relate to one another through the simplistic pathway. Rather, other psychological risk factors and multiple pathways related to persistent pain and pain-related disability should be considered in a wider context.

With clinical presentation of most of the NSCLBP patients in clinical setting often simultaneously face multiple factors, it is also thought that multiple factors anticipate the fear pathway. It is not possible for patients to avoid pain, but it is possible for them to avoid activities, become less engaged with positive behaviour and to assign management to an outside source. This is when HLOC may add value to the complex and dynamic relationship of pain, disability and FAB.

2.12 HLOC- The relationship between HLOC and health-related behaviour in patient and healthy population

There has been a great diversity of studies attempting to relate HLOC to a host of health-related behavior, with the aim to demonstrate correlations with each subscale of HLOC. In their review, Wallston & Wallston (1982), the developer of the MHLC, offer a wealth of information regarding these correlations. These common findings are based on numerous of studies conducting in both patients with chronic conditions (such as chronic pain, chronic back pain, diabetes,

arthritis) as well as healthy population (**Figure 2.6**). Despite these conclusions not being specific to NSCLBP population, they offer some theoretical support for the potential importance of how HLOC may influence NSCLBP patients' clinical outcomes and their responses to the CBCLBP programme and self-management tasks.

Figure 2.6: To summarise some of the common findings on the association between HLOC and health-related behaviour in patient and healthy population studies (Wallston & Wallston, 1982)

ILOC	ELOC	CLOC
<ul style="list-style-type: none"> • Higher self-motivation • Higher life satisfaction • Better will to live • More desire for control of the healthcare delivery process • Positive information seeking behaviour • More active involvement in healthcare treatment • Better physical (e.g. less pain) and mental health • More proactive health behaviour (e.g. sufficient rest, eating and drinking in moderation) 	<ul style="list-style-type: none"> • Active involvement and adherence to treatment recommendation (recommendations by doctors or medical professions) • Less desire for control over healthcare treatment • More likely to utilize health service • More likely to develop chronic pain • Less proactive health behaviour • Less desire for behavioural involvement such as self-care and active participation in medical care • More likely to report physical symptoms and disability 	<ul style="list-style-type: none"> • Higher level of depression • More likely to report physical symptoms and disability • Less desire for control of the healthcare delivery process • Poorer physical and mental well-being • More likely to develop chronic pain • Less desire for control over healthcare treatment • Less desire for behavioural involvement such as self-care and active participation in medical care

2.13 Evidence on HLOC in NSCLBP outcomes

Only a limited number of studies (N=8) using MHLC to examine the relationship between HLOC and NSCLBP outcomes. These results generally support those mentioned by Wallston and Wallston (1982), in which improvement of HLOC may associate with positive clinical and cognitive-behavioural outcomes in NSCLBP. Caution should be taken when interpreting these studies due to study heterogeneity and variation in methodological qualities.

2.13.1 Relationship between HLOC and the clinical outcomes of NSCLBP

Relationships exist between HLOC and reports of pain and disability in NSCLBP. Patients with higher ILOC reported less pain (Sengul et al., 2010; Harkapaa, 1991), and lower level of disability after treatment, than patients with high ELOC (Haldorsen et al., 1998). A RCT of moderate risk of bias (Harkapaa et al.,1991) (see **Section 2.8.1**) showed that higher ILOC was correlated with reduction in disability, less psychological distress, and more frequent exercising.

A cross-sectional study by Sengul et al. (2010) investigated the relationship between HLOC and pain intensity, disability and quality of life in patients with CLBP (N=113). A set of valid and reliable assessment tools were used for data collection, included the MHLC, VAS, Oswestry Disability Index (ODI) and the World Health Organization Quality of Life (WHOQOL) scale. Included patients were recruited from a neurosurgery department in Turkey; they were separated into two groups according to their levels of disability: high disability and low disability group. Key findings were: (1) Correlation analysis revealed ILOC was strongly correlated with pain intensity on activity, moderately correlated with disability and quality of life; (2) A strong correlation was found between ELOC and pain intensity at rest, and (3) A significant positive correlation was found between CLOC and pain intensity, disability and quality of life. A number of methodological limitations are identified in this study,

including selection bias, no report of sample calculation and the authors were unclear if blinding of outcome assessors were used. This study is high risk of bias.

Haldorsen et al. (1998) conducted a 12-month prospective study in 260 workers who had been on sick leaves for 8-12 weeks due to their NSCLBP. The objective was to examine whether medical, psychological or social factors predict failure to return work within 12-month. A large set of outcome measures were used. Outcome measure for psychological factors was HLOC as evaluated by MHLC. Participants were treated with a light mobilization programme and were followed up one year after treatment. Results revealed that the most significant psychological variable in predicting return to work was high ILOC, while non-returners were associated with higher ELOC and higher CLOC. Higher ILOC was also found associated with less pain and lower level of disability after treatment, than patients with high ELOC and high CLOC. This study has a number of methodological limitations included: selection bias (all participants were workers referred from National Insurance offices), attrition bias (due to incomplete follow-up data), performance bias (no mention of blinding of outcome assessors, personnel and participants) and the authors did not give any information of the light mobilization programme being used. This study is high risk of bias.

A longitudinal study by Keedy et al. (2014) reported that higher ILOC and lower ELOC predicting better physical function (floor-to-waist lift) at 1-month following an intensive two-week MI programme in patients (N=61) with CLBP. However, both changes in ILOC and ELOC did not emerge as predictor to mental health outcomes (depression and self-reported mental health). As appraised in **Section 2.8.1**, this study suffered from methodological flaws that may limit the internal validity of their findings. This included variable sample size across analysis, variable time for data collection, lack of outcome assessor blinding, selection bias and high attribution bias. This study is high risk of bias.

A cross-sectional study by Sengul et al. (2011) examined if HLOC and disability are related to static and dynamic postural balance in patients with NSCLBP (N=22). Relevant findings were: (1) There was a correlation between CLOC and reaction time, and (2) There was a correlation between ELOC and CLOC with static and dynamic postural balance. This study suggested that ELOC and CLOC have stronger influence on patients' physical function, than ILOC. However, this study has several major methodological flaws that limit the internal and external validity of their findings. This included: under-powered small sample size, selection bias (as it was a laboratory-based study), no report of data collection method and unclear statistical reporting. This study is high risk of bias.

2.13.2 Relationship between HLOC and cognitive-behavioural variables of NSCLBP

Evidence suggested that chronic pain patients with higher ILOC use more active coping strategies and have less psychological distress. Conversely, those with stronger ELOC are associated with higher levels of helplessness, psychological distress and use of passive coping strategies, such as praying, to deal with pain (Crisson & Keefe, 1998). Higher ILOC is associated with a more active approach to manage pain (Jensen & Karoly, 1991), therefore attribution of control to internal rather than external factors has become an emphasis in the clinical treatment of NSCLBP.

More specifically to CLBP population, an 18-month prospective study by Harkapaa (1991) found that there is an association between HLOC and use of coping strategies in patients with CLBP. Include subjects were of blue-collar workers in a number of private enterprises in Finland. Data was collected via questionnaire and was answered by 415 subjects (87% of the original sample). Relevant findings included (1) Higher pain intensity was correlated with higher level of psychological distress, lower ILOC and higher ELOC; (2) Active coping strategies were related to higher ILOC, whilst higher ELOC and CLOC were associated with passive coping strategies, and (3) use of active self-care

was significantly associated with higher ILOC and lower ELOC. Several methodological merits were identified in this study including sufficient sample size, low attribution bias, use of valid outcome measures, and adequate reporting of statistical analysis. The main drawback is its high selection bias. This study only included subjects with CLBP from among blue-collar workers (from state railway, the post and telecommunications) who had been physically strenuous in their job for at least 10 years, had LBP for at least two years with record of sickness and absence. Mean age of included subjects was 45. Their results may be applicable to subjects with similar characters, but it has poor generalisability to NSCLBP presenting in primary setting. This study is moderate risk of bias.

Richard et al. (2011) conducted a two-year prospective study in Canada, with the aim to examine the association of self-efficacy and HLOC with pain intensity, FABs-W, FABs-PA, and “return to work in good health” (RWGH) among 867 workers with occupational NSLBP and disability. RWGH is a composite measure of occupational outcomes for workers having back pain (Dionne, 2005; Dionne et al., 2007), which consists of four categories: occupational status, functional limitation, number of days of work absence due to back pain, and the presence or not of attempts to return to work. Outcome measures were collected via telephone interview. Relevant findings included: (1) ILOC was moderately correlated with FABs-PA, but it had no association with pain intensity; (2) ELOC was strongly correlated with both FABs-PA and pain intensity, and moderately correlated with FABs-W, and (3) No association was found between CLOC and any of the pain related measures or pain intensity. This study concluded that ILOC and ELOC are significantly related to FABs in workers with NSCLBP. Several methodological strengths were seen in this study including sufficient sample size, long follow-up period, use of valid and reliable assessment tools, use of appropriate statistical analysis and a relatively low attrition bias (86% of original sample completed the 2-year telephone review follow-up). However, the authors did not take any measure to control potential confounders that may influence the outcomes (such as any

other treatment or medication during the 2-year study period). There is also a high selective bias because included subjects were worker (mean age of 38.7) with NSLBP who had self-reported at least a day of incapacity due to LBP presenting of Emergency Department. This limited the generalisability of findings to a wider population of NSCLBP presenting in primary setting. This study is moderate risk of bias.

In term of treatment participation, Koleck et al. (2006) found that CLBP patients with high ELOC participated less treatment decision, whilst higher ILOC indicated that patients participated more in treatment decisions. Evidence also suggested that CLBP patients with higher ILOC were more likely to agree with the goal of active intervention such as motor control exercises, whilst those with higher ELOC were more likely to agree with the goals of passive treatment such as spinal mobilization (Braman & Gomez, 2004; Hashimoto & Fukuhara, 2004).

A cross-sectional study by Oliveira et al. (2009) found that NSCLBP patients with higher ELOC needed to see greater improvements in symptoms to consider motor control exercises worthwhile. A total of 86 NSCLBP patients were recruited in an out-patient physiotherapy department in Brazil. The authors found that ELOC was the only significant predictor of patients' perception of worthwhile in motor control exercises. Their results suggested that if physiotherapists could reduce ELOC to the lowest possible score (ELOC= 6, range 0-36) via their treatment, the chance of a patient being satisfied would increase by up to 24%. This study highlighted that patients' HLOC may influence their perception of worthwhile effect of physiotherapy treatment, which is important for both prognosis and patients' satisfaction in NSCLBP. This study demonstrated a number of strengths including sufficient sample size, report of power calculation, use of valid and reliable outcome measures, precision of data analysis, and a narrow confidence interval (95%), suggesting precision of findings. This study is low risk of bias.

2.13.3 Summary of key findings of HLOC in NSCLBP

To summarize: Patients with NSCLBP with higher ILOC are more likely to describe their pain and disability as less intense (Sengul et al., 2010; Haldorsen et al., 1998), have more effective coping strategies to deal with pain (Harkapaa, 1991), have less psychological distress (Harkapaa et al., 1991), have better physical health (Sengul et al., 2011; Keedy et al., 2014), have less pain-related belief (Richard et al., 2011) and are more likely to take an active role and engage with treatment programme (Harkapaa et al., 1991). On the other hand, those patients with higher ELOC and higher CLOC are more associated with greater pain intensity and disability (Sengul et al., 2010; Haldorsen et al., 1998), use of maladaptive coping strategies (Harkapaa, 1991), report of more pain-related fear (Richard et al., 2011) and being less proactive with treatment (Harkapaa et al., 1991).

2.13.4 Methodological consideration of evidence on HLOC in NSCLBP

Among the seven studies included, four are of high risk of bias (Sengul et al., 2010; Haldorsen et al., 1998; Keedy et al., 2014 and Sengul et al., 2011), two are of moderate risk (Harkapaa, 1991; Richard et al., 2011), and only one (Oliveira et al., 2009) is considered as low risk of bias. There is only low to moderate evidence to support the relationship between HLOC and NSCLBP variables. Many methodological criteria regarding internal and external validity of these studies were not fulfilled. This included: selection bias, small sample size, performance bias, detection bias, attrition bias, and unclear reporting of statistical analysis. Besides, the majority of them conducted cross-sectional correlation, thus preventing directional conclusions of causality between HLOC and NSCLBP outcomes.

While the existing research on HLOC in NSCLBP population supports the theoretical construct of HLOC, the limited number of studies warrants more examination. In addition, the cross-sectional nature of these correlations may

also warrant further analysis, including the predictive component, to determine causality.

2.14 Summary: Current state of knowledge relevant to present study

- There is low to moderate evidence for the effectiveness of exercise therapy on physical and psychological outcome in NSCLBP at short-term and long-term
- There is moderate evidence for the effectiveness of combined physical exercise and CBA programme (delivered by physiotherapists with or without multidisciplinary members) on clinical outcomes of NSCLBP. Effects are mostly seen when against passive controls (i.e. usual care or waiting list), and are mostly of short-term.
- There is limited and low quality evidence for the effectiveness of CBA intervention targeting NSLBP patients (of any duration) with psychosocial risk factors.
- There is limited and low quality evidence that the CBA intervention has a positive effect on HLOC at short-term (< 3-months).
- There is moderate evidence supporting the effectiveness of CBA active rehabilitation in enhancing patients' ability to self-care their NSLBP (of any duration).
- There is moderate evidence supporting the cost-effectiveness of combined exercise and CBA intervention in NSCLBP, when compared to GP care, conventional physiotherapy and other active modalities.
- Regarding relationship between pain intensity, disability and FAB:
 - i. No firm conclusion can be drawn on the relationship between pain and disability, due to inconsistent evidence.
 - ii. No firm conclusion can be drawn on the relationship between pain and FAB, due to inconsistent evidence.
 - iii. Moderate evidence on the relationship between FAB and disability.

- There is limited and low to moderate evidence supporting the relationship between HLOC and NSCLBP outcomes.

2.14.1 Limitations of our knowledge

Limitations in the literature that are relevant to the study have already been mentioned in each section. For instance, there is no study which examines the effectiveness of CBA intervention targeting only NSCLBP patients with psychosocial risk factors (such as high FAB). There is also no study which assesses the effectiveness of a physiotherapy CBA active rehabilitation in altering HLOC in NSCLBP patients. In addition, there is only limited and poor quality evidence to support the relationship between HLOC and NSCLBP outcomes. It is recommended by several authors that the dimension of personal sense of control warrants further evidence to delineate the specific role it plays in NSCLBP treatment outcome (Woby et al., 2004a; Foster et al., 2010; Henschke et al., 2010). Lastly, the majority of studies in the literature were conducted in an ideal, controlled research condition. This may not truly reflect and represent how a physiotherapy CBA rehabilitation programme works in an ordinary clinical environment. Research that works under optimal research conditions may be challenging to implement in clinical practice as it may fail to consider the relevant clinical issues and practicalities in real practice (Chan & Clough, 2010). This highlights the need of research to be conducted in an ordinary clinical setting, where no extra resource and additional research manpower exist.

2.15 Conclusion

With the key themes and limitations being identified, this study was conducted to contribute evidence in these lines. The next chapter goes on to outline the methodology employed in this study, with the aim of addressing the research questions appropriately.

CHAPTER 3 METHODOLOGY

3.1 Introduction

The aim of this chapter is to describe and justify the methodology used in this study, including its research design, ethics consideration, sampling and recruitment procedure. This chapter also details the intervention and the five outcome measures used in this study. Reliability and validity of these outcome measures and the method of data collection are also discussed. Finally, this chapter outlines the data analysis employed to examine each of the research questions accordingly.

The chosen approach and methodology of the present study was based upon the research questions, the relevant literature and the practicality of the busy NHS clinical setting. Implementation of practitioner-based research in the current NHS can be challenging, due to demanding clinical workload, time constraints and limited staffing. However, every attempt has been made to reduce potential sources of bias with the aim to enhance validity of the findings.

3.2 Overall design

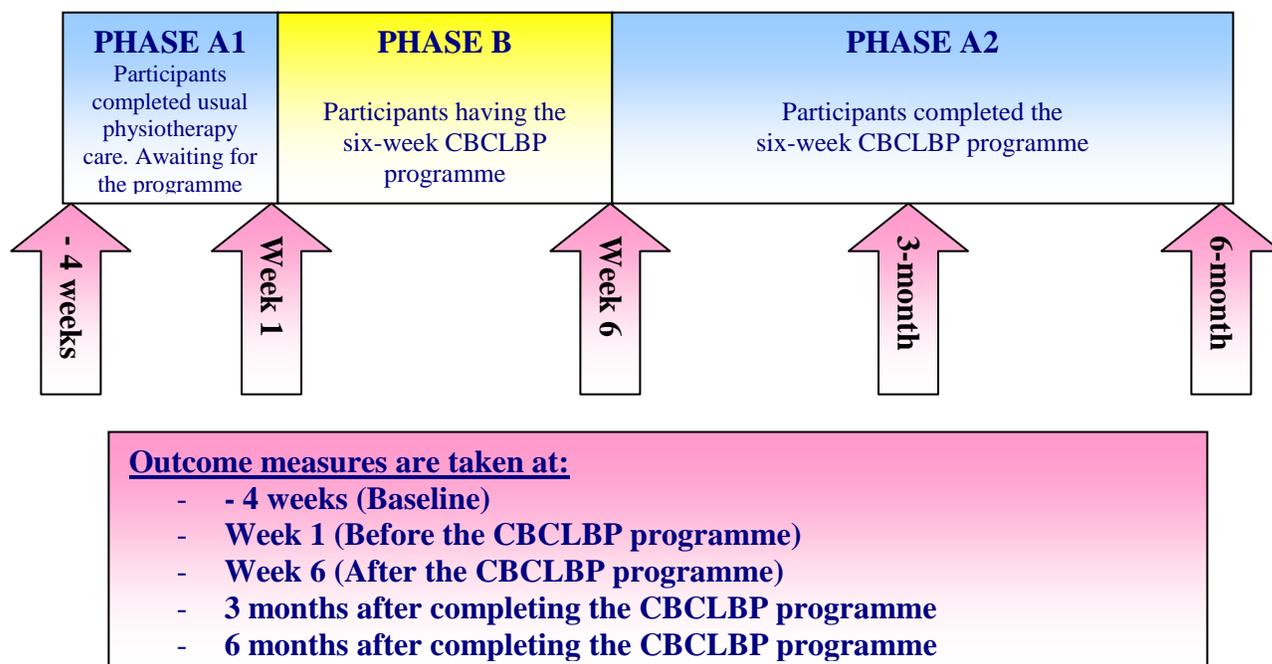
A quantitative longitudinal A-B-A same-subject design was conducted in the Stockport NHS Primary Physiotherapy Service. Included patients were with NSCLBP and with TSK score more than 37 (TSK score > 37 indicating patients with high level of FAB due to fear of movement causing pain or (re)injury) (Kori et al., 1990; Swinkels-Meewisse et al., 2006).

There were three major phases of this study: before (Phase A1), during (Phase B), and after (Phase A2) the CBCLBP programme (**Figure 3.1**). Phase A1 was the collection of the baseline data, which was four weeks before the programme. Phase B was the intervention phase, where participants received the six-week CBCLBP programme. Phase A2 was where participants completed the programme and outcome measures were assessed at 3 months and 6 months.

A series of reliable and valid outcome measures were obtained in a consistent and standardised manner during each phase of the study, including at baseline (-4 weeks), at the beginning of the programme (week 1), at completion (week 6) and at 3 months and 6 months follow-up.

The primary outcome measure was HLOC, evaluated by the Form C of the MHLC scale (Wallston et al., 1978). Secondary measures were pain evaluated by VAS (Huskisson, 1974), disability evaluated by RMQ (Roland & Morris, 1983), FAB measured by the TSK questionnaire (Vlaeyen et al., 1995a) and patients' attitudes toward back pain self-care were assessed by the Self-Care Orientation Scale questionnaire (SCQ) (Von Korff et al., 1998). At 6 months, a cost questionnaire developed for this study was used to examine cost of back care from the provider, patients' and societal perspective.

Figure 3.1: To illustrate the study design and time point at which outcome measures were taken



3.3 Methodological consideration

3.3.1 Selection of research method

When weighing up which research design to use, the considerations were the nature of the research questions, the objectives of the study and the practicalities of the study setting.

The aim of this study is to assess the effect of the CBCLBP programme on HLOC and other co-variables in patients with NSCLBP before, during and after programme. Research designs that are often used to evaluate the effect of intervention in clinical settings include before and after studies, comparative trials and RCTs (Hicks, 2009). RCTs are widely regarded as the gold standard design to study the effect of an intervention in the research community. However, there were several reasons why RCT design was not chosen for the present study. First, the CBCLBP programme is a recommended second-line treatment in accordance with local departmental policy and evidence-based guidelines for NSCLBP (Savigny et al., 2009; Chou et al., 2009; Koes et al., 2010). Since this is already an existing second-line treatment for this subgroup of NSCLBP following an initial contact and individual treatment with physiotherapists. There is no other form of second-line physiotherapy care can be randomised into. Second, the main intention of this study is to determine the effect of the CBCLBP programme over time. Therefore, a chosen method should allow meaningful comparison between treatment and no treatment phase by repeated assessment over the study period, instead of between treatment and no treatment group. Third, there are practical issues. RCTs are often difficult to conduct in terms of cost, time, manpower and resources. Besides, RCTs often involve a large number of patients, which is particularly challenging for a single-handed researcher like the PI who works in a busy NHS setting with limited allocated resources and time. Lastly, it can be ethically problematic because once patients are referred into the physiotherapy service, having “no treatment” control group is considered as unethical.

3.3.2 Same-subject design

Alternatively, a same-subject design is a practical and useful evaluation method for applied research to assess effectiveness of an intervention on same group of subjects (Kratochwill & Levin, 2015). This methodology is often utilised by researchers in rehabilitation and social sciences to test the efficacy of an intervention on a particular problem (Backman et al., 1997; Horner et al., 2005). It is used in many fields by various professional groups such as applied behaviour analysts, clinical psychologists, social workers (Kratochwill & Levin, 2015), and cognitive-behaviour therapists (Engel & Schutt, 2012).

One of the most unique features of same-subject design is that the baseline data of this same group of people serves as its own control, thus error variance is reduced. Besides, this method is ethically safe, because all participants received treatment and treatment did not have to be withdrawn. In addition, it allowed the PI to observe the effect of the CBCLBP programme before, during and after the programme. Therefore, the single-subject design method is considered to be an appropriate design for the current study for both conceptual and practical reasons.

3.3.3 Comparing different types of same-subject designs

There are various types in the same-subject design, such as A-B, A-B-A, and A-B-A-B design (Engel & Schutt, 2012). The A-B-A design was chosen in this study due to three main reasons. First, this type of experimental design allows the changes before, during and after treatment to be observed. As a result, the PI can see what effect, if any, the CBCLBP programme had on the HLOC and other co-variables. Further, the treatment principle of the CBCLBP programme is based on the idea that the therapeutic effects will carry over following the programme (Hansen et al., 2010; Ostelo et al., 2005). By re-introducing the baseline condition (Phase A2) following treatment (Phase B) (see **Figure 3.1**), the effect of the CBCLBP programme may persist, and how long the effect of

the programme may persist up until six months post-intervention can be observed.

Secondly, the A-B-A design is ethically safe because all study participants received treatments. The CBCLBP programme received by the study participants is the routine care provided by the Physiotherapy Department for patients with NSCLBP. The only difference between the study participants to routine patients was that the study participants were asked to complete additional questionnaires, and were followed up until six months following the programme.

Finally and importantly, the normal physiotherapy service and patients' waiting time were not compromised as a result of the A-B-A design because the routine waiting time for entering the CBCLBP programme was about 4 weeks on average. The PI also did the majority of the research work, and put in extra hours to recruit patients and collect data. Hence, no extra staffing was required. Both are considered to be crucial by the NHS management and the Research and Development (R&D) of the Trust.

Comparing the A-B-A design to the basic A-B design, the A-B design only offers quick assessment of the programme by collecting measurements during the baseline phase (Phase A), and repeating the same measures during the intervention phase (Phase B) (Engel & Schutt, 2012). However, the A-B design does not provide any post-treatment follow up which examines if the effect of the CBCLBP programme persisted, and how long it may persist after patients stopped the intervention, which is the intention of this study.

The A-B-A-B design is similar to the A-B-A design, except that the A-B-A-B design reintroduces the intervention in the second intervention period, based on the assumption that the effect of the treatment may reverse by withdrawing intervention and there may be second improvement by reintroducing treatment. Although the A-B-A-B design may give stronger support that changes between

no treatment and treatment phases are due to the intervention, and not due to the natural history of the condition (Engel & Schutt, 2012), there is no guarantee that the effect will be reversed, particularly because the CBA treatment is based on the practice theory that the therapeutic effect may carry over, and is designed to reduce the target problems without the need for ongoing intervention. Therefore, the A-B-A-B design was not chosen.

3.3.4 Implications of the clinician-researcher dual role

Because of the resource issues, the PI had to act as both researcher and clinician. The PI was involved in gaining all informed consents, carried out the majority of the treatment, and collected all data at 3 months and 6 months post intervention. There is advantage and disadvantage of the PI being a clinician-researcher dual role in the current study. An advantage for having the PI to collect data helped to ensure data quality, and minimize missing data during follow-up. However, the disadvantage of this approach included the possibility of expectancy effect (Bootzin, 1985) and halo effect (Nisbett & Wilson, 1977), both factors would have influence on patients' self-reported data on pain intensity, disability and perceived control (Klaber Moffett & Richardson, 1997). Besides, there is detection bias due to lack of blinding of outcome assessors. These limitations (which are discussed in **Chapter 6**) may reduce the internal validity of the findings. It is acknowledged that it would have been preferable for the PI to act as an independent researcher, with no input into treatment and data collection. However, this was not possible in the current study.

3.4 Ethical considerations

The Bristol Research Ethics Committee reviewed and approved the present study; with REC reference 12/SW/0197 (**Appendix 1**). The Ethics Committee of the Manchester Metropolitan University (**Appendix 2 & Appendix 2a**) and the Research and Development (R&D) Department of the Stockport NHS Foundation Trust (**Appendix 3**) also supported and granted ethical approval for this study.

It is imperative that any piece of research fully accounts for ethical issues, and informed consent must be obtained from the subject prior to commencing (Burns, 1997; Brody, 1998). The following ethics considerations were taken:

1. The study was performed in accordance with the protocol, the International Conference on Harmonisation (ICH) Guideline for Good Clinical Practice (GCP) (E6 (R1) Good Clinical Practice, 1996), and the Research Governance Framework for Health and Social Care (Department of Health, 2005).
2. All interventions used in this study represent current best clinical practice in the UK (Savigny et al., 2009; Koes et al., 2010). Therefore participants were not disadvantaged compared to other forms of physiotherapy care.
3. The PI ensured all participants fully understood the nature and risks of the treatment prior to giving consent. Eligible subjects were given a participant's information sheet (**Appendix 4**) and a full verbal explanation about the study. They were given at least a week to consider whether to take part. Informed consent (**Appendix 5**) was obtained during their next visit and their GP and physiotherapist were informed that they had entered the study (**Appendix 6**). Study participants had the full right to withdraw at anytime during the study period without giving any reason and without compromising the same high standards of care (Wilkie et al., 2001).
4. Patients who did not satisfy the inclusion/exclusion criteria (**Figure 3.2** in **Section 3.5.3**) or who did not wish to participate continued through the usual physiotherapy pathway without disadvantage. Therefore, the CBCLBP programme was not established exclusively for research participants. Rather, there was a mix of research participants and non-research participants in the same group over the study period.
5. All the subject recruitment, assessment and the rehabilitation programme were approved by the Trust (**Appendix 3**) to take place at

the Stockport NHS Primary Physiotherapy Service, where Health and Safety at Work Act (1974) is operated at all times.

6. To ensure anonymity and safeguarding the confidentiality of participant records, all data kept complied with the requirements of the Data Protection Act (1998). Participants were given an identification number known only to the PI, her co-workers and the project supervisors. Data was computed and stored using identification numbers, on a password secure computer within the Physiotherapy Department. Hard copies of the research data were kept in the locked cabinet within the Department during the study period. All research data was then transferred off site and kept confidentially at the NHS designated storage site for at least ten years following completion of the project, so incorporating the requirements of the Data Protection Act (1998).

3.5 Selection of participants

3.5.1 Sample selection

Subjects were incidentally and purposely sampled within the Stockport NHS Primary Physiotherapy Service between September 2012 and June 2013 (i.e. the last participant was recruited in June 2013). This method of sampling may not be representative to the wider population of NSCLBP as it is a non-probability method of collecting a sample and the process is not random (Powers & Knapp, 2010; Crombie & Davies, 1996). However, this sampling method was chosen because this is the most appropriate and most accessible method of obtaining a reasonable number of targeted subjects over a limited period of time (Hicks, 2009). In addition, incidental sampling also reflects accurately what happens in the clinical situation (Burns, 1997; Hicks, 2009). A number of physiotherapy CLBP research studies taking place in the NHS have also utilised incidental sampling (Klaber Moffett et al., 2006; Critchley et al., 2007; Johnson et al., 2007; Woby et al., 2007a, and Woby et al., 2008).

This study aims to examine patients with NSCLBP, and who exhibit a high level of FAB (TSK score > 37 indicating patients show higher level of pain-

related fear (Vlaeyen et al., 1995a). This particular population was chosen because: (1) patients with NSCLBP and high FAB are often considered challenging to treat by clinicians in clinical practice (Rainville et al., 2011); (2) NSCLBP is very costly to the Health Service but often with poor rehabilitation treatment outcome (Jamison, 2011); and (3) it is well-documented that FAB is one of the strong cognitive factors associated with back pain intensity, disability and the likelihood of treatment success or failure (Wertli et al., 2014a; Thomas et al., 2010; Vlaeyen et al., 1995b).

3.5.2 Setting

This study was conducted at the Stockport NHS Primary Physiotherapy Service, where the CBCLBP programme has been well-established for over 15 years, and where the PI works. This clinical setting was chosen because it is a natural environment where patients with NSCLBP normally attend for their routine physiotherapy treatment. It is important to conduct practice-based research in a relevant clinical environment in order to obtain the natural interaction from the subjects and reflect reality. Also, due to its controlled clinical environment, it is also beneficial for data collection (Marrow, 1996; Trochim & Donnelly, 2001; Trochim, 2005). These factors are essential to ensure successful implementation of research findings in the future (Marrow, 1996; Trochim, 2005). Another reason to choose this setting is because it is the largest department in NHS Stockport offering the CBCLBP programme to patients. This consequently increased the availability of eligible subjects for the study. The Physiotherapy Department is located in the centre of Stockport and it provides free on-site parking, making it easily accessible and economical for all patients who attended the six-week programme and their follow-up evaluation.

3.5.3 Inclusion and exclusion criteria

The inclusion and exclusion criteria (**Figure 3.2**) are based upon the previous relevant literature, the targeted population of the study, the treatment principle of the CBCLBP programme and the objectives of the study.

Figure 3.2: Inclusion and exclusion criteria of the study

Inclusion criteria were:

- Patients with NSCLBP with or without leg pain (Waddell, 2004), and diagnosed by their physiotherapists with NSCLBP;
- Age >16years, as the Stockport NHS Physiotherapy Service is an adult service;
- TSK score >37 (indicating that patient shows a high level fear of movement and associated avoidance behaviour (Vlaeyen et al., 1995a);
- Patients were physically and medically fit to take part in the exercise programme (Department of Health, 2005; E6 Good Clinical Practice, 1996); and
- Patients were able to give consent and positively opt in to the programme (Department of Health, 2005; E6 Good Clinical Practice, 1996).

Exclusion criteria were:

- Evidence of serious pathology (red flags) or low back pain is caused by specific spinal pathology such as malignancy, vertebral fracture, severe spinal stenosis, acute herniated disc with nerve root entrapment, rheumatoid arthritis, unstable spondylolisthesis (CSAG, 1994; Savigny et al., 2009);
- Patient is not medically fit to participate in an exercise programme (Department of Health, 2005; E6 Good Clinical Practice, 1996);
- Unable to read and understand the English language, as it is important for patient to understand the education component and follow the instructions during the exercise session;
- Patients who demonstrate psychological distress, both pain and non-pain related, which is beyond the scope of the physiotherapy and requires CBT delivered by psychologists or CBT therapists.
- Where the assessors perceived a significant level of psychological distress based on clinical experience, this exclusion criterion is further assessed objectively by a score of 11 or higher on each subscale of the Hospital Anxiety and Depression Scale (HADS) and a score of “high risk” on the STarT Back Tool (Hill et al., 2011); and
- Patients who participated in a similar type of chronic low back pain programme within the preceding six months. This aims to eliminate threats to internal validity by ruling out history, so it is possible to conclude that the treatment in this study caused the change (Engel & Schutt, 2012).

3.5.4 Sample size calculation

Sample size calculation was made on the primary outcome measure, namely the HLOC based on previous studies (Oliveira et al., 2008; Oliveira et al., 2009) utilising similar methodology and instruments. The standard deviation of the ILOC of 5.2 and a minimal clinically important difference (MCID) of 6.77 (in the ILOC) were set. Using a power calculation, a sample size with 15 participants per subscale would have 95% power to detect a 6.77-point difference using a two-tailed test and 5% significance level. Considering the HLOC consists of three independent subscales: ILOC, ELOC and CLOC, the sample size of at least 45 is required to examine the relationship of each of these subscales with other outcome measures individually. With a 20% dropout rate allowance, this study aimed at recruiting 55 patients and their complete data to reach any statistically significant conclusion.

Based on the referral rate, the average number of patients with low back pain referred to Stockport NHS Primary Physiotherapy Service was approximately 250 per month. Many of them were referred onto the CBCLBP rehabilitation programme. Considering there were three programmes running each week, with each group of about 8 participants, a desired sample size of 55 participants in nine months was achievable and realistic.

3.6 Study protocol

3.6.1 Recruitment process

General Practitioners (GPs) and physiotherapists working within the Stockport NHS were informed of the study by letter and an information sheet (**Appendix 7**) detailing the aims of the study and the inclusion/ exclusion criteria (**Figure 3.2**). They were made aware of the study and were encouraged to refer eligible patients.

Patients consulted their GP and were referred into the NHS Primary Physiotherapy Service due to their persisting back pain condition. Patients made at least one prior back pain visit assessed by specialist physiotherapists, who confirmed the diagnosis of NSCLBP. During the one-hour assessment and advice session, all patients were given an explanation of diagnosis NSCLBP, back care advice, back pain information booklet and home exercise programme. Following the initial one-hour assessment and advice session, patients may receive some form of physiotherapy treatments from their physiotherapists. The number of individual physiotherapy treatments that patients received depended on the physiotherapists' recommendation and the severity of patients' symptoms. Individual physiotherapy treatments (approximately 45 minutes per session) may include joint mobilisation, manipulation, home exercise programme and self-management advice. Number of treatments (up to a maximum of six sessions based on departmental policy) patients received prior to the entry of the CBCLBP programme was recorded. Once the individual physiotherapy was completed, physiotherapists then considered referring appropriate patients into the group therapy, i.e. CBCLBP rehabilitation programme, in accordance with departmental protocol (**Appendix 8**). The CBCLBP rehabilitation programme was the routine care provided by the NHS Physiotherapy Department, which followed the NICE guidelines for NSCLBP (Savigny et al., 2009) and the recommendation of the Chartered Society of Physiotherapy (CSP).

When both physiotherapists and patients agreed to be referred onto the programme, patients were put on the waiting list for the CBCLBP programme which was about 4 weeks waiting time. This was when the baseline measurements were taken (4 weeks before the start of the programme). It is routine practice for physiotherapists to advise patients to continue their home exercise programme and self-management techniques while waiting to be entered the CBCLBP programme.

All patients referred onto the CBCLBP rehabilitation programme were asked by their referring physiotherapists to complete the TSK questionnaire in order to assess eligibility for entering the study. Those who fulfilled the criteria relating to inclusion/ exclusion (**Figure 3.2**) and were interested in learning more about how to self-manage their back pain condition were invited to participate in the study.

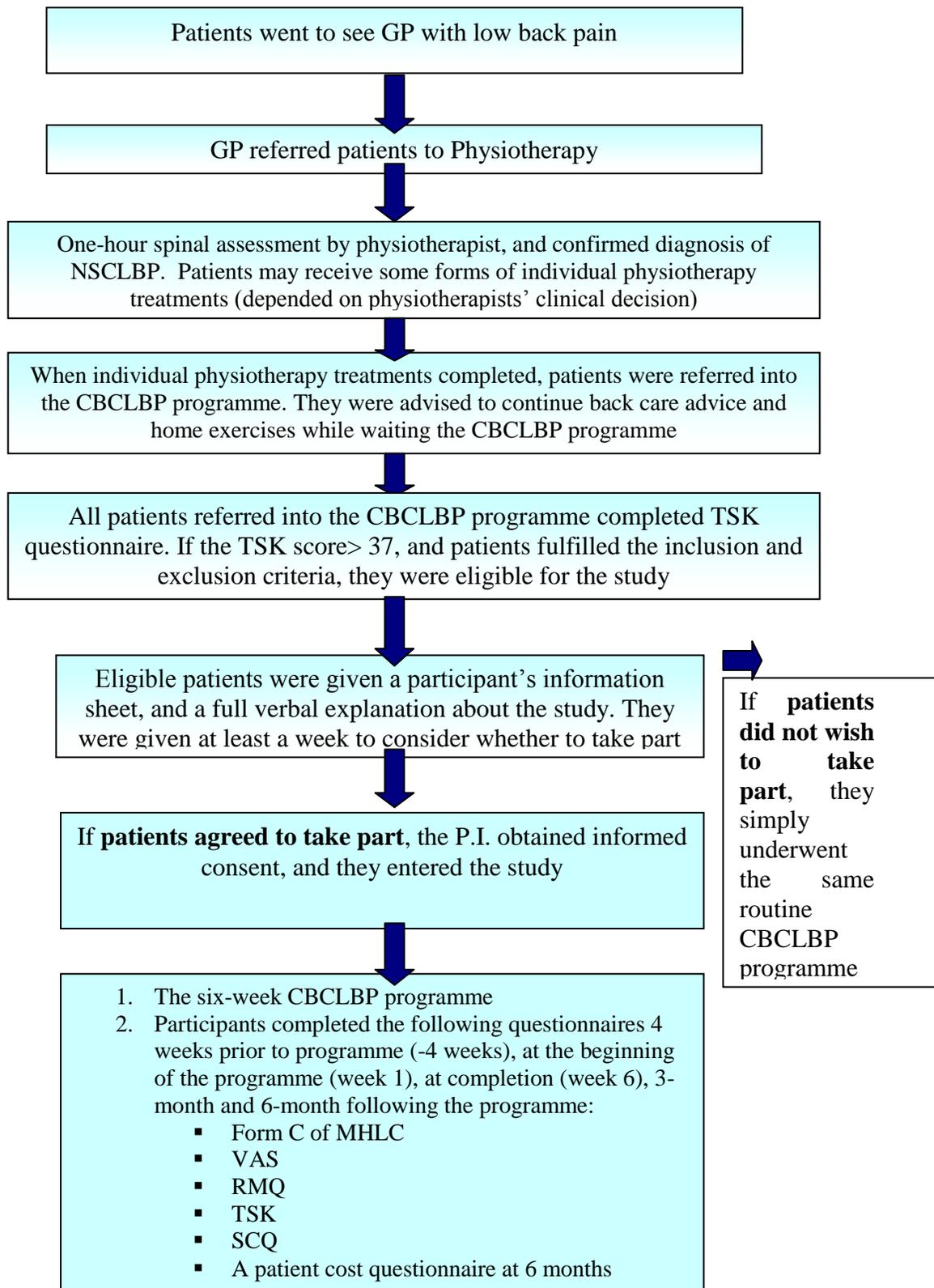
Eligible patients were given an invitation letter to the study (**Appendix 9**) and a participant's information sheet (**Appendix 4**) and a full verbal explanation about the study. They were given at least a week to consider whether to take part. Informed consent (**Appendix 5**) was obtained during their next visit by the author. Their GP and referring physiotherapist were informed that they had entered the study (**Appendix 6**). All participants were free to withdraw from the study anytime during the study without giving a reason, without the standard of treatment and care being affected. Whether patients decided to take part in the study or not, they still received the same exact programme as in normal practice.

In routine care, patients who take part in the CBCLBP programme were asked to complete the TSK questionnaire and the RMQ at week 1 and week 6 only, which is before and after the six weeks programme. This was to evaluate the service, as in other physiotherapy group therapy services in the Physiotherapy Department. With the research participants, the only difference compared to routine practice was that all study participants were asked to complete additional questionnaires (in addition to the TSK and RMQ, participants were asked to complete the Form C of MHLC questionnaire, VAS, and the SQC questionnaire) at 3 months and 6 months after the completion of the programme. By the end of the study, participants were given a cost questionnaire developed by the PI and supervisor. This was to examine patient, provider and societal cost of back care when participants were undertaking the CBCLBP programme and six months after the completion of the programme. Participants were also asked to attend all sessions of the six-week programme,

and commit to daily home exercises and homework given during the programme.

If patients did not wish to take part in the study, they simply underwent the same routine CBCLBP rehabilitation programme as planned. An overview of the recruitment of present study is provided in **Figure 3.3**.

Figure 3.3: Recruitment of study participants



3.6.2 Intervention

Study participants took part in a six-week (two hours weekly) CBCLBP programme, which is a well-established service (over 15 years) at the Stockport NHS Primary Physiotherapy Department. It has been developed based on the best available evidence (Koes et al., 2010; Savigny et al., 2009; Airaksinen et al., 2006), current physiotherapy practice in the UK, the recommendation from the NICE guidelines (Savigny et al., 2009) and the clinical experience and expertise within the service.

3.6.3 Aims of the intervention

The programme was based on the key features of the CBA to address patients' maladaptive thoughts, feelings, and their behavioural consequences (Turner & Jensen, 1993).

The ultimate aims of the CBCLBP programme is to: reduce disability, minimize pain or increase control over pain, reduce avoidance of movements and increase patients' ability for self-management (Woby et al., 2004a; Critchley et al., 2007; Johnson et al., 2007; Woby et al., 2008; Lamb et al., 2010). These aims were achieved by:

1. Altering patients' pain perception by increasing their understanding about pain physiology (Moseley, 2003a; Moseley, 2007);
2. Addressing unhelpful thoughts and beliefs, and to promote their understanding of the link between thoughts, beliefs, feelings and behaviour (Turner & Jensen, 1993; Main et al., 2010).
3. Reducing fear-avoidance of movement and improving physical performance via graded exercise programme, planning and pacing techniques, resumption of ceased activities/work and goal setting (Fordyce, 1976; Sanders, 1996).
4. Improving patient's perception of personal control (Main et al., 2010), by promoting active coping strategies (Harkapaa, 1991) and

emphasizing the importance of active participation toward their own rehabilitation, hence enabling patients to develop a sense of personal control over their NSCLBP (Jensen et al., 1991; Harkapaa et al., 1996; Coughlin et al., 2000).

5. Empowering patients to have a primary role in their own management (Crowe et al., 2010) by teaching a range of self-management skills (e.g., cognitive restructuring techniques, positive behavioural changes, alternative pain relief, relaxation and physical exercises), hence reducing their dependence on the healthcare services (Ferreira et al., 2010; Critchley et al., 2007).
6. Preparing patients to independently self-manage future episodes of flare-up and use healthcare services appropriately in the future (Ferreira et al., 2010; Toye & Barker, 2012).

3.6.4 Delivery of the intervention

Each session consisted of a combination of education (**Section 3.6.5**), graded supervised exercise (**Section 3.6.6**) and homework (**Section 3.6.7**). It was delivered to groups of approximately eight patients. The programme was led by the PI or a trained musculoskeletal specialist physiotherapist (a Band 7 and above physiotherapist) and a physiotherapy assistant. All specialist physiotherapists involved in the study were existing staffs who delivered the CBCLBP programme in the Physiotherapy Department. They all had special clinical interest in NSCLBP, were highly experienced in managing NSCLBP, had training in CBA management techniques, and were experienced to deliver and lead the groups according to the highly structural protocol.

In order to guard against threats to internal validity (Logan et al., 2008), the intervention and data collection were standardised. Training was given to all physiotherapists and assistants involved prior to the start of the study. The training was given by the PI, which consisted of two, two-hour sessions. It included aims and methodology of the study, teaching materials for each session, method of data collection, refreshing psychosocial risk assessment (yellow flags assessment) and the key principles of CBA for NSCLBP. The

training was to ensure that adequate skills and competencies that needed for professionals who delivered CBT approach in primary care (Main et al., 2007; Turk & Okifuji, 2003). Experts considered these competencies (**Figure 3.4**) were more important than professional background (i.e. not only for clinical psychologists, but also for nurses, physiotherapists, or GPs who deliver a primary intervention that uses a CBT approach) (Van der Windt et al., 2008).

Figure 3.4: Competencies and skills needed for CBA in primary care (Main et al., 2007; Turk & Okifuji, 2003)

- Being an active listener, to be caring and confident
- Able to conduct a simple psychosocial assessment
- Able to identify key psychosocial obstacles to recovery
- Able to provide clear and adequate information, and explain physiological medical information in terms appropriate to the patient's level of understanding
- Helps patients to make an informed decision about participation in treatment
- Able to integrate patients' social circumstances into the management plan
- Able to help patients to define clear, measurable and achievable rehabilitation goals
- Reinforces positive behaviours and goal achievement
- Empowers patients, encourages self-management and active participation for rehabilitation
- Helps patients see an alternative scenario to incapacity- future oriented
- Facilitates acceptance of chronic pain

The CBCLBP programme was highly structured by using the same timetable, and standardised educational materials, audiovisual resources, activities and exercise components. An overview of the six sessions is provided in **Appendix 10**. All study participants were also provided with an information pack containing written education material each week (**Appendix 11**), homework (**Appendix 12**) and home exercise workbook (**Appendix 13**).

3.6.5 Education

The education session was interactive and supportive. It lasted for approximately an hour each session, whereby participants were encouraged to be actively involved in the programme and took part in the discussions and

activities. Over the six-week programme, the perspective was to give patients the opportunity to develop a range of techniques and strategies that allowed them to minimize the impact of their pain and disability on their daily activities, and enable them to self-manage their condition more independently and confidently. Participants were given the opportunity to share experiences in the group on how they manage their back problems in their daily life. They were also offered the opportunity to discuss their personal barriers and pain-related fear in small groups or individually with the physiotherapist.

Throughout the programme, participants addressed a variety of issues as shown in **Figure 3.5**. All the six education sessions were presented visually in a power point presentation. Particular attention was targeted to increase patient's ability and confidence for self-management, reduce fear of movement and promote patients to hold more internal belief towards their NSCLBP condition. Participants received the support they required from the course physiotherapist as well as written information for each session, in order to optimise their uptake of the self-management tasks they learnt from the course (Oliveira et al., 2012b).

Figure 3.5: Education component of the CBCLBP programme:

Understanding NSCLBP	<ul style="list-style-type: none"> • Overview of spinal anatomy & common causes of LBP. • Promote understanding on the diagnosis of NSCLBP, and clarify any misunderstanding on diagnostic languages.
Explanation of detrimental effect of FAB and role of exercises	<ul style="list-style-type: none"> • Detrimental effect of fear-avoidance behaviour and lack of movement on physical and psychological health. • Role of exercise- provide patients with a model of the relationship between graded movement and reducing pain and tension. • Explanation of “cycle of change”- to promote positive behavioural/ lifestyle change.
Pain physiology education	<ul style="list-style-type: none"> • Basic pain physiology • Explanation of acute pain vs chronic pain • Factors predisposing to chronic pain • Mechanism of pain gate theory and pain neuromatrix • Explaining sensitization • Explaining pain ≠ harm
Managing and addressing negative thinking and belief	<ul style="list-style-type: none"> • Identify and modify patient’s cognitions regarding their pain (the meaning of pain, expectations regarding control over pain). • Promote understanding in the link between beliefs, fears, thoughts, and subsequently mood and pain. • Helping patients to learn techniques to identify unhelpful thoughts, feelings and behaviour, to develop effective responses to challenges. • Introducing cognitive restructuring techniques such as imagery and attention diversion.
Pacing	<ul style="list-style-type: none"> • Activity management- planning/ pacing/ prioritising (3Ps’ technique). • Graded exposure to exercise and activity.
Goal setting	<ul style="list-style-type: none"> • Personal goal setting- use of short-term and long-term goal setting to encourage patients returning to ceased hobbies/ activities/ work.
Posture	<ul style="list-style-type: none"> • Postural workshop, lifting and handling workshop.
Relaxation	<ul style="list-style-type: none"> • Explore other causes of pain (e.g. stress, emotional tension, work, family) and address psychosocial issues accordingly. • Relaxation technique- introducing relaxation CD, relaxation breathing, and ways to aid good sleep.
Alternative pain relief	<ul style="list-style-type: none"> • Alternative pain relief i.e. non-pharmalogical option of pain control.
Flare-up management	<ul style="list-style-type: none"> • Flare-up plan to manage future setbacks. • Introduction to red flags, equip patients with knowledge to decide when to self-manage or to seek medical help appropriately.
Future self-care plan	<ul style="list-style-type: none"> • Lifestyle changes- such as weight reduction, diet, exercise & fitness, new activities and hobbies. • Discussion on self-management plan, and appropriate healthcare usage. • Explain the importance of self-care and the stability of new positive changes.

3.6.6 Exercise

Each session included approximately 45 minutes group exercise circuit, which consisted of core stability work, stretching exercise, lightweight training, and cardiovascular work (**Appendix 14**). A physiotherapist and an assistant supervised the exercise session in order to ensure safety and correct exercise technique.

An operant approach formed the basis of the graded exercise programme in this study. The operant approach, according to a biopsychosocial model (Fordyce, 1976; Lindström et al., 1992), implies that activity is guided by the patients' functional abilities and that time-contingent methods are used to increase the level of the patient. The treatment philosophy focuses on reducing pain behaviours (operants), and increasing healthy behaviour (Fordyce, 1976; Lindström et al., 1992). In this study, patients were instructed to decide their own repetition and the level of difficulty within their comfort zone, but they were encouraged to build up the level gradually each week. An exercise-circuit diary (**Appendix 14**) was given to participants to record and monitor their own progress. A variety of exercises were included because it is believed that back pain patients are often fearful of activities. Therefore, it was felt that exposing patients to various types of activities in a graded and paced manner would help to reduce their pain-related fear (Woby et al., 2008).

In addition to the graded exercise programme, participants also had a session of hydrotherapy (**Appendix 15**) and Pilates (**Appendix 16**) during the course. Hydrotherapy and Pilates session were run by physiotherapist who has special interest and qualification in teaching them. These activities were included, as it was felt that introducing patients a variety of exercise options would promote their confidence to try new activities, and reduce boredom from their normal exercise routine.

Participants agreed to perform home exercises every day as part of their self-management plan. They were instructed how to perform these exercises

correctly, and they were encouraged to increase the repetition in their own pace. A home exercise diary (**Appendix 13**) was given to participants to monitor their progress.

3.6.7 Homework

Participants were given homework (**Appendix 12**) most weeks. They were required to practice their new learnt skills and some simple behavioural experiments each week, including cognitive restructuring technique, paced activity, resumption of ceased hobbies, goal setting, relaxation and individual self-management plan. Participants were required to identify their own barriers and unhelpful thoughts about pain and activity, and they were encouraged to apply these simple behavioural techniques to monitor and change their maladaptive thoughts, feelings and behaviours. Homework was discussed at the beginning of each session, and problem-solving sessions were followed as a group or individually where appropriate.

3.7 Outcome measures

In order to assess the effectiveness of the CBCLBP programme and the impact of NSCLBP on patients' life, a reliable and valid measurement tool that accurately assesses function and monitors change over time is required (Hicks, 2009). The NICE guidelines recommend that any intervention should have a high impact on patients' outcomes, particularly pain, disability and psychological distress (Savigny et al., 2009). Therefore this study evaluated these core domains of NSCLBP.

There are a number of patient-based outcome measurements that are commonly used in research and clinical setting in the NSCLBP population. However, there is no consensus on which specific outcome measure(s) best measures the effectiveness of a therapeutic intervention. For the current study, a number of factors were considered when deciding which outcome measures to use.

First, if the design of the assessment tools accurately answered the objectives of this study. Second, the validity and reliability of the assessment instrument. A

valid self-reported questionnaire measures accurately what it is supposed to measure, and if it is reliable, whether it can be reproduced (Berzon, 1998; Deyo et al., 1991). Third, the responsiveness, i.e. the ability of the instrument to detect real or important change over time when it has occurred (or when it has not occurred) (Terwee et al., 2003). This then led to a search for the minimal clinically important difference (MCID). The MCID is referred as the smallest difference in a score of a domain of interest that patients perceive to be beneficial (Jaeschke et al., 1989). MCID is commonly addressed in the NSCLBP literature, mainly because statistical significance does not correspond to clinical relevance of the treatment effect (Hurst & Bolton, 2004). Change in score on the scale of a measurement instrument exceeding the MCID is regarded as clinically relevant. There is no uniform method to measure MCID (De vet et al., 2006; Ostelo et al., 2008). However, as a general rule, an international consensus panel concluded that 30% change in almost any scale can be considered to be “meaningful” (Ostelo et al., 2008), this recommendation to measure MCID applied in this study where applicable. Finally, the ease of use of the questionnaires, including administration and understandability for patients, is also important to consider.

In this study, five validated outcome measures were chosen as these five variables address the main domains of NSCLBP. They were administered: at baseline (-4 weeks), at the beginning of the treatment (week 0), at completion (week 6) and at 3-months and 6-months follow up (**Figure 3.1**). They are:

1. HLOC, evaluated by the Form C of the Multidimensional Health Locus of Control (MHLC) scale (Wallston et al., 1994).
2. Pain, evaluated by a Visual Analogue Scale (VAS) (Huskisson, 1974).
3. Disability, evaluated by Roland and Morris Disability Questionnaire (RMQ) (Roland & Morris, 1983).
4. FAB, measured by the Tampa Scale of Kinesiophobia (TSK) questionnaire (Vlaeyen et al., 1995a).
5. Patients’ attitude toward back pain self-care, measured by the Self-Care Orientation Scale questionnaire (SCQ) (Von Korff et al., 1998).

Primary outcome measure is the HLOC, which is the main interest of the study. HLOC has been shown to be both predictors of poor outcome, as well as potentially modifiable through clinical intervention (Klaber Moffett et al., 2006; Keedy et al., 2014). However, evidence in this aspect is limited. This study aims to extend the current literature and specifically looked at the effect of physiotherapy-led intervention on HLOC.

Pain, disability and FAB were secondary measures because they represented the complex nature of NSCLBP (Waddell, 2004). Pain intensity and disability are the two important domains directly related to LBP (Ostelo & de Vet., 2005), whereas FAB has shown to be a predictor of poor outcomes (Boersma & Linton, 2006a; Boersma & Linton, 2006b; Leeuw et al, 2007; Ramond et al., 2011) and associated with back pain related disability (Thomas et al., 2010; Elfving et al., 2007; Woby et al., 2004b; Grotle et al., 2004; Mannion et al., 2001; Crombez et al., 1999; Vlaeyen & Linton, 2000). Additionally, the objective and treatment principle of the CBCLBP programme were based on the idea that the therapeutic effect is to reduce pain, disability and pain-related fear (Guzmán et al., 2001; Ostelo et al., 2005). Therefore, it is logical to employ these self-reported measures to assess the effect of the programme.

Self-care is an important and clinically desirable ingredient in the effective management of NSCLBP (Fordyce, 1976; Deyo, 1983; Von Korff, 1999). The SCQ was used to examine changes in healthcare utilisation and prescriptive medicine as a result of the intervention (Saunders et al., 1999), since patients' attitude toward back pain self-care has an impact on the dependence of the health service (Tait & Chibnall, 1998; Saunders et al., 1999). This means better self-care attitude have a financial impact on both the healthcare service and to patients themselves.

3.7.1 Outcome measure 1: HLOC

HLOC was measured using Form C of the MHLC scale developed by Wallston et al. (1978). The MHLC scale was presented in three forms (A, B and C). The first two forms determined general HLOC, and have been typically used with

healthy individuals (Wallston, 2005). Form C of the MHLC (**Appendix 17**), the version used in this study, was specifically designed to assess HLOC beliefs in individuals with existing medical problems or health conditions such as chronic pain and CBLBP (Wallston et al., 1994). This scale has been proven to be a valid and responsive assessment tool to measure health locus of control beliefs in any medical or health-related condition (Wallston et al., 1994). In the present study, Form C was used to assess HLOC in reference to NSCLBP.

Form C of the MHLC scale consists of three independent, six-item subscales:

- ILOC is measured by Item 1, 6, 8, 12, 13 and 17; individuals with high scores in these items believe that they are responsible for their own health.
- ELOC is measured by Item 3, 5, 7, 10, 14 and 18; individuals with high scores in these items believe that others such as medical professionals or family are responsible for their health.
- CLOC is measured by Item 2, 4, 9, 11, 15 and 16; individuals with high scores in these items believe that chance is responsible for their health.

Each of the subscales were scored independently on 6-item scales that use Likert-type responses ranging from 1 (strongly disagree) to 6 (strongly agree). This gives a range of 6-36 for each subscale, with higher values reflecting higher level of the construct. Form C has proven to be a relatively easy instrument to administer, and has been successfully used with a wide variety of different conditions and populations, ranging from rheumatoid arthritis to HIV disease (Wallston et al., 1994).

Regarding reliability and validity, Form C has demonstrated sufficient alpha reliability (with Cronbach's alpha ranging from 0.70- 0.87) (Wallston et al., 1994). The subscales are also considered to be moderately stable over time and possessed adequate construct validity and convergent validity (Wallston, 2005). Regarding construct validity, Form C subscale scores were shown to change in

theoretically predicted direction following a six-week pain intervention (i.e. as the mean score of ILOC increased, ELOC and CLOC reduced significantly) (Wallston, 2005). With regard to convergent validity, ILOC was shown to be significantly and negatively correlated with pain and helpfulness; whilst CLOC was significantly and positively correlated with depressive symptoms and helpfulness in both arthritis and chronic pain subjects (Wallston, 2005). The study by Oliveira et al. (2008) suggested the minimal detectable change scores were: 6.77 for ILOC; 6.72 for ELOC; and 5.91 for CLOC.

To date, MHLC is the only validated assessment tool that is specifically designed to assess HLOC beliefs in individuals with existing medical problems or health conditions such as chronic pain (Wallston et al., 1994). The original version of the instrument, i.e. Form A and Form B, are more or less equivalent in form. The only difference between the three MHLC forms is that Form A and Form B tap beliefs about control of one's health status, while Form C taps belief about control of one's illness or disease. Form C gives flexibility to further analyze ELOC dimension into two subscales: Doctors and Other people, each with three items (Wallston, 2005).

The developer of MHLC, Wallston (1991) stated that the dimension of the MHLC can always be combined, but the most important differentiation is the internal and external domain. This is because the internal and external dimension shows the most potential for meaningful results in the health area (Wallston, 1991). The three-dimensional structure (ILOC, ELOC and CLOC) of the MHLC has been supported in most patients' population studies, LBP and NSCLBP studies without further distinguishing the two sub-scales of ELOC (Doctors and Other people) (Harkapaa et al., 1991; Haldorsen et al., 1998; Sengul et al., 2010; Sengul et al., 2011; Richard et al., 2011; Klaber Moffett et al., 2006; Oliveira et al., 2009; Oliveira et al., 2012b). The current study therefore analyzed and reported data according to the three unique domains- ILOC, ELOC and CLOC.

Another assessment tool found in the literature that aims at detecting the extent of cognition to which patients can control, and decrease, their pain, is the Coping Strategies Questionnaire (CSQ) (Rosenstiel & Keefe, 1983). However, these two-single items scales possess only acceptable test-retest reliability over a 14-day period (Woby et al., 2004b), and more importantly, it is not designed to measure the HLOC specifically, which is the primary objective of this study.

Some authors used Pain LOC (PLOC) (Coughlin et al., 2000; Penzien et al., 1989) or Multidimensional Pain Locus of Control Questionnaire (MPLC) (Engstrom, 1983) to measure ILOC, ELOC and CLOC over pain. These assessment tools are re-constructed on the basis of MHLC. However, its use in literature appears not as dominant as MHLC. More important, evidence on their validity and reliability are limited.

Because each study has its own targets and goals, some authors used composite scores which include subscale to measure patients' pain beliefs and their cognitions about (in)ability to control one's pain. Examples are the Pain Cognition List (PCL) (Vlaeyen et al., 1990) and the Pain Coping and Cognition List (PCCL) (Stomp-van den Berg et al., 2001). The PCL is a 39-item self-report questionnaire which includes pain catastrophizing and internal control of pain subscales. There is evidence to support its reliability and stability in CLBP patients (Vlaeyen et al., 1990), however there is no information about the responsiveness of this scale. The PCCL is developed on the basis of three existing Dutch questionnaires (PCL, CSQ and MPLC). It aims to measure cognitions related to pain, covering four categories including: catastrophizing, pain coping, internal pain control and external pain control. It has been shown the construct validity of PCCL is satisfactory (Stomp-van den Berg et al., 2001). However, this assessment tool measures patients' cognition and beliefs in a comprehensive way and it does not measure patients' HLOC specifically. Therefore, these composite assessments are not considered in current study.

3.7.2 Outcome measure 2: Pain intensity

Severity of pain “today” was measured on a Visual Analogue Scale (VAS) (Huskisson, 1974) (**Appendix 18**). This scale has a 100 mm plain line with endpoints labelled no pain to unbearable pain, requiring patients to rate their pain. Higher score indicating higher pain intensity. Since pain is subjective, patient’s self-reporting provides the most valid measure of the experience and is considered as the gold standard in pain management (Ong & Seymour, 2004). The VAS was chosen because it is simple, easy to understand and readily reproduced on successive presentations. Besides, it is more sensitive to clinical changes than Visual Rating Scale (VRS) (Price et al., 1994) and Numerical Rating Scale (NRS) (Ong & Seymour, 2004). The VAS has been widely used in pain research (Huskisson, 1974; Jensen et al., 1986), and found to be the most reliable and sensitive tool for measuring pain, with test-retest reliability of >90 (Flandry et al., 1991; Ong & Seymour, 2004), and with moderate to good responsiveness (Vermeulen et al., 2005; Ong & Seymour, 2004). For patients with CLBP, the MCID for improvement on the 0-100mm VAS is approximately 20mm (Haefeli & Elfering, 2006; Ostelo & de Vet, 2005).

There are some debates whether the VAS is an ordinal or interval/ratio level of measures (Altman, 1990; Hicks, 2009). Assessment of pain scale involves a distance; therefore it can be viewed as interval/ ratio scale (Myles et al., 1999; Hicks, 2009). However, because pain is a subjective commodity, it can be argued that it should be regarded as an ordinal scale (Gracely & Dubner, 1981; Altman, 1990; Hicks, 2009). For example, patients were asked to express the amount of pain they are feeling “today” on a 100 mm plain line with end-points labelled no-pain-to-unbearable-pain. A score of 70 mm means more pain than a score of 50 mm, and that is more than a score of 30 mm. But the difference between the 70 mm and the 50 mm may not be the same as that between 50 mm and 30 mm. The values simply express an order, but not the difference between values. In this study, the PI regards VAS as an ordinal measure (McCrum-Gardner, 2008), and an appropriate statistical test is applied.

The VAS was administered consistently in the same manner over the course of the study period (see **Section 3.8** for data collection and data management). The VAS scores were calculated by measuring and recording in centimetres from the left hand end of line to the point that the patient marks, and they were rounded up to the nearest half centimetres.

3.7.3 Outcome measure 3: Disability

The Roland and Morris Disability Questionnaire (RMQ) (Roland and Morris, 1983) (**Appendix 19**) has been widely used in the clinical and research setting, designed to measure self-reported disability from low back pain. This measure has often been used in studies evaluating conservative treatments such as cognitive behavioural therapy and supervised exercise therapy in patients with chronic low back pain (Airaksinen et al., 2006; Van Hooff et al., 2010). The RMQ demonstrates excellent reliability, validity and responsiveness for functional disability (Smeets et al., 2008; Ostelo et al., 2004; Roland & Fairbank, 2000), with a MCID of 2-3 points (Roland and Fairbank, 2000).

The Oswestry Disability Index (ODI), another widely used disability measure, has also shown to be valid, reliable and responsive in evaluating the extent of disability in patients with chronic low back pain (Roland & Fairbank, 2000). However, the RMQ was chosen over the ODI. This is because this study aims to assess conservative treatment for NSCLBP, yet the ODI has often been used to evaluate orthopaedic interventions such as surgery and facet steroid injection (Van Hooff et al., 2010).

The RMQ asks patients to think of their disability due to back pain “today” (Roland & Morris, 1983). This measure includes 24 items of dichotomous (yes/no) response option. Total scores range from 0 (no disability) and 24 (maximum disability), with higher scores indicate greater disability, and a score more than 13 reflecting significant disability (Roland & Morris, 1983). A standardised data collection and data management were carried out over the course of study period (**Section 3.8**).

3.7.4 Outcome measure 4: FAB

FAB is a belief that certain activities should be avoided due to fear of causing pain or re-injury, and it has been suggested to predict future disability (Swinkels-Meewisse et al., 2003a). Fear of movement related to pain (labelled fear-avoidance belief) was measured using the Tampa Scale of Kinesiophobia (TSK) (Vlaeyen et al., 1995a) in this study (**Appendix 20**). The TSK is one of the most frequently employed measures for assessing pain-related fear in back pain patients (Woby et al., 2005). It is based on the model of fear avoidance, fear of work-related activities, and fear of movement/re-injury (Vlaeyen et al., 1995a). It has also been linked to elements of catastrophic thinking (Burwinkle et al., 2005). The TSK has been recommended for the study of the role of general fear of movement and re-injury, reflecting patients' somatic focus and activity avoidance in patients with chronic low back pain (Kori et al., 1990).

The TSK is based on 17 items each with a four-point Likert scale, with scoring options ranging from 1 = "strongly disagree" to 4 = "strong agree". A total score is calculated after inversion of the individual scores of item 4, 8, 12 and 16. The total score ranges between 17 and 68, with higher scores reflecting greater level of fear avoidance (Lundberg et al., 2004). A score of 37 differentiates between high and low level of FAB (Vlaeyen et al., 1995a).

The 17-item TSK scale (Vlaeyen et al., 1995a) has good psychometric properties (Lundberg et al., 2004; Woby et al., 2005). It has been widely used in chronic low back pain researches, and demonstrates good validity (Lundberg et al., 2004), reliability (Bunketorp et al., 2005; Lundberg et al., 2004; Vlaeyen et al., 1995a) and responsiveness (Bunketorp et al., 2005). A study by Swinkels-Meewisse et al. (2003b) reported that TSK with good internal consistency (range from $\alpha = 0.70$ to 0.83), good test-retest reliability (range from $r(s) = 0.64$ to 0.80 ($p < 0.01$) and moderate concurrent validity (range from $r(s) = 0.33$ to 0.59 ($p < 0.01$)).

Another questionnaire frequently used in assessing pain-related fear is the FAB Questionnaire (FABQ) (Waddell et al., 1993). The FABQ is a 16-items measure aimed at quantifying the beliefs about how work and physical activity affect pain and whether they should be avoided (Waddell et al., 1993). Although the FABQ is a validated assessment tool for chronic low back pain (Waddell et al., 1993), with good reliability (Jacob et al., 2001; Waddell et al., 1993), and it may help identify acute back patients at risk of poor treatment outcome (Fritz & George, 2002). The FABQ is not designed as a tracking instrument. Therefore the meaningful change has not been determined for this questionnaire as a whole (Woby et al., 2005). In comparison, the TSK, frequently used in chronic low back pain research and in clinical practice, is designed for tracking. A change of at least 4 points on the TSK scale has been considered as clinically meaningful and ideal for assessing effectiveness of treatment (Murphy & Hurwitz, 201). Therefore, the TSK was included in the study over the FABQ.

There have been some further modifications to the 17-items TSK scale described in the literature. For example, Woby et al. (2005) tested the psychometric properties of a shorter version of the TSK (TSK-11). They concluded that the original 17-items TSK and the TSK-11 both possessed similar psychometric properties and offered the advantage of brevity. However, further research is warranted to investigate the utility of TSK-11 and its cut-off score in a wider group of chronic pain patients in different clinical settings.

3.7.5 Outcome measure 5: Attitudes Toward Back Pain Self-Care

Patient attitudes and beliefs about their back pain affect treatment outcomes and their attitudes towards reliance on medical care and pain medications (Tait & Chibnall, 1998; Saunders et al., 1999). Experts generally agree that excessive reliance on prescription medicine and professional services for chronic pain control is undesirable for effective self-care and effective back pain

management (Fordyce, 1976; Deyo, 1983; Waddell, 1991). Consequently, a number of self-report instruments have been developed to assess these constructs. In this study, a five-item Self-Care Orientation scale questionnaire (SCQ) (see **Appendix 21**) developed by Von Korff et al. (1998), was used to assess patient attitudes toward the use of health care and prescription medications for back pain. Items included in this scale were shown to predict future use of health care and prescription pain medications for back pain (Von Korff et al., 1998). Participants indicated on a five-point Likert-scale (1 to 5 points for each item) whether they strongly agree, agree, neutral, disagree or strongly disagree. Although the measure only demonstrates moderate internal consistency reliabilities (Saunders et al., 1999), the five items in this scale were shown to be sensitive to change following educational intervention, and able to predict future use of healthcare for back pain and/ or future use of prescription pain medications (Saunders et al., 1999). Besides, it is practical and easily administered in comparison to the Survey of Pain Attitude (SOPA) questionnaire.

The Survey of Pain Attitudes (SOPA) is a well-researched instrument that assesses seven dimensions of patients' pain attitudes. It includes: patients' feelings about pain control, solicitude (solicitous responses from others in response to one's pain), medication (as appropriate treatment for pain), pain-related disability, pain and emotions (the interaction between emotions and pain), medical cures for pain, and pain-related harm (pain as an indicator of physical damage or harm). The factor structure of the SOPA, however, has not been verified. It is longer than the SCQ and its length makes its administratively cumbersome (Tait & Chibnall, 1998).

3.8 Data collection and data management

Prior to the study, all the questionnaires used in the present study were piloted on the first five eligible patients (who were not included in the study). This was aimed at uncovering any problems relating to wording, layout, length, instructions or coding, so that amendments could be made accordingly. The questionnaires took about 20 minutes to fill in (**Appendix 22**).

reported was the faded print with photo-copying, there was no major issue otherwise. Therefore, the PI printed the questionnaire instead of photocopying during the study period, making it easier for participants to read.

Study participants were asked to complete the questionnaires in the waiting area when they attended their rehabilitation programme. Data collection at 4 weeks prior to intervention, week 1 and week 6, were supervised and collected by a physiotherapy assistant in order to reduce experimenter bias (Burns, 1997). The PI then checked each of the self-reported measures after they had been completed and patients were required to answer any questions that they had missed. This ensured that completed pre- and post-treatment data was available for statistical analysis.

After completion of the six-week rehabilitation programme, study participants were offered to complete their 3-month and 6-month follow-up questionnaires either via face-to-face appointment or by post. Participants were contacted a maximum of three times, inviting them to complete their post-treatment questionnaires. At 6 months, a patient cost questionnaire (**Appendix 23**) was used to examine patients' cost of back care including patients' travel costs to attend the programme, and any prescription charges, loss of pay, and other therapy charges during and up to six months following completion of the programme. Again, the PI checked each of the self-reported questionnaires after they had been completed, and patients were required to answer any questions that they had missed. This ensured that completed pre- and post-treatment data was available for all 55 patients for statistical analysis.

Baseline data was collected four weeks prior to the intervention because four weeks was the routine waiting time for the CBCLBP programme in the Physiotherapy Department and this is appropriate to overcome the ethical dilemma. It was decided to collect data up until six months. This was based upon the relevant literature, time constraints and the practicalities in the clinical setting. Kazdin (2010) suggested that a minimum of three baseline data points

(no treatment time points) are required to establish dependent measure stability. In the current study, it involved three baseline data points (i.e. -4 weeks, 3-month and 6-month), and the total study period for each participant was eight and a half months. Therefore, this is considered long enough to achieve stability in the dependent variables.

The standardised manner of data collection method was used during both the baseline and intervention period in order to guard against threats to internal validity in the single-subject design (Riddoch & Lennon, 1994; Bithell, 1994). Data at each follow-up measurement was kept separately, and data was not analysed until end-of-study outcome measures had been collected.

3.9 Data analysis

Statistical analysis was run using IBM SPSS version 19.0 for Windows. The relevant part of the SPSS output was reported (see **Chapter 4**), with the aim of answering each research question clearly and accurately. Results indicating $p \leq 0.05$ were considered significant for all analysis.

Data was re analysed in four stages. First, descriptive analysis was used to describe the characteristics of the sample. A series of statistical tests was also performed to explore whether the baseline characteristics of patients who completed the programme differed from those who dropped out of the programme. The Pearson Chi-Square and Fisher's Exact test were used to explore differences in categorical measures (Bland, 2000; McCrum-Gardner, 2008), including gender, on-set of LBP, duration of LBP, employment status, financial status and previous history of LBP. Mann Whitney *U*-tests were used to explore differences in continuous variables (Bland, 2000; McCrum-Gardner, 2008), including age, ILOC, ELOC, CLOC, pain intensity, disability, FAB and self-care attitude.

Second, the Friedman's ANOVA was computed to compare repeated measures of HLOC at each time point, in order to determine if significant changes had occurred in patients' HLOC pre- and post- CBCLBP programme statistically (McCrum-Gardner, 2008). This analysis is to answer **Aim 1** of the present study (**Chapter 1, Section 1.7**). The Friedman's ANOVA was chosen, because Form C of the MHLC questionnaire is a Likert scale, and is regarded as ordinal data (Wallston & Wallston, 1981). Therefore, a non-parametric analysis is chosen.

The Friedman's ANOVA was also used to determine whether significant changes had occurred in patients' pain intensity, disability, FAB, and back pain self-care attitude pre- and post- treatment. This is to answer **Aim 2** and **Aim 4** of the present study (**Chapter 1, Section 1.7**). The Friedman's ANOVA was employed because the VAS (Huskisson, 1974), the TSK questionnaire (Vlaeyen et al., 1995a) and the SCQ (Von Korff et al., 1998) are regarded as ordinal data. Therefore, a non-parametric analysis was chosen (McCrum-Gardner, 2008). With disability, the RMQ is considered as nominal data (Roland & Morris, 1983). Analysis of data normality was performed using the Shapiro-Wilk test. The Shapiro-Wilk test indicated that the disability data was not normally distributed. Consequently, a non-parametric analysis was used when analysing disability pre- and post- treatment (Bland, 2000).

For the Friedman's ANOVA to demonstrate any significant treatment-related changes in HLOC, pain intensity, disability, FAB and back pain self-care attitude, the ANOVA was conducted post-hoc analysis using a Wilcoxon signed-rank test with a Bonferroni correction applied to reduce the probability of Type I error. The Wilcoxon signed-rank test aims to examine significant differences between mean scores of HLOC and other co-variables at each phase. More specifically, it determines where the significant treatment-related changes had occurred (Bland, 2000). i.e. whether it is before treatment (Phase A1); after treatment (Phase B), and/or 3 months and 6 months following the end of the programme (Phase A2) (**Figure 3.1**).

Third, the Pearson's product-moment correlation coefficients were computed to investigate the inter-relation between the changes that emerged in HLOC and other co-variables. Change scores of these variables were calculated by 6 months post-treatment mean score minus 4 weeks pre-treatment mean score. These time points (-4 weeks and 6 months) were selected as they showed how the HLOC and other co-variables changed from the start of the study to the end of it. The Pearson's product-moment correlation was used because the Shapiro-Wilk test indicated that change scores that emerged on each of the self-reported measures were approximately normally distributed. Therefore, the parametric Pearson's product-moment correlation coefficients were performed to show the inter-relation between these variables (McCrum-Gardner, 2008).

Finally, the hierarchical multiple regression analysis was performed to determine the extent to which a series of predictor (independent) variables (i.e. ILOC, ELOC and CLOC) were related to the outcome of interest (dependent variable) (i.e. (1) change in pain intensity; (2) disability and; (3) FAB (Bland 2000; McCrum-Gardner, 2008)). This is to answer **Aim 3 (Chapter 1, Section 1.7)**.

According to the literature, HLOC beliefs are best conceptualised as independent variables predicting another variable (Wallston & Wallston, 1981). Using a hierarchical approach enabled predictor (independent) variables to be entered in a specific order, which enabled determination of the extent to which the subscale of the HLOC contributed to the outcome of interest (dependent variable) after controlling other potentially important variables.

In the current study, a hierarchical regression was conducted for each of the outcome of interest, measured as: (1) change in pain intensity; (2) disability and; (3) FAB. A series of predictor variables was then entered in a specific order. Since this study has particular interest in the HLOC, change scores in ILOC, ELOC and CLOC were therefore entered in the final step of the regression analysis in order to illustrate which beliefs are affected and which do

not contribute to changes in pain intensity, disability and FAB beyond those predictor variables entered in earlier steps of the analysis. Values of $p < 0.05$ were considered significant.

When change in pain intensity was the outcome (dependent variable), the first block of regression included age and sex. The second block consisted of change scores in disability and FAB, and the final block consisted of the change scores in IHLC, ELOC and CLOC.

When change in disability was the outcome (dependent variable), the first block of regression included age and sex. The second block consisted of change scores in pain intensity and FAB, and the final block consisted of the change scores in IHLC, ELOC and CLOC.

When change in FAB was the outcome (dependent variable), the first block of regression included age and sex. The second block consisted of change scores in pain intensity and disability, and the final block consisted of the change scores in IHLC, ELOC and CLOC.

3.10 Economic evaluation

It is apparent that the burden and the economic impact of NSCLBP are huge. Considering the current financial climate of the NHS, the decision-makers in the NHS including individual clinicians, managers or commissioners, often consider the cost of healthcare services (Cohen & Reynolds, 2008). Clinical outcomes are not the only important factors considered by clinicians and policy makers. Rather, the cost of services is also heavily considered when deciding how the limited resources can be allocated (Donaldson et al., 2002; Cohen & Reynolds, 2008). Therefore, it is useful to combine economic evaluation alongside with clinical study, in order to provide information that may help decision-making and evaluation of services in terms of cost (Goodwin et al., 2003). In addition, NSCLBP is a chronic condition that often results in ongoing

health care, patient and societal cost. This further highlights the importance of examining the economic impact from a provider's, patient and societal perspective as a result of the recommended form of treatment such as the CBCLBP programme in the present study.

Following the initial NRES approval for the present study, the PI and the supervisory team decided to include an economic evaluation. A minor amendment request was subsequently submitted and an approval was obtained to conduct the economic evaluation of the CBCLBP programme (**Appendix 24**).

The **objectives** of the economic evaluations are:

1. To determine the cost of a six-week CBCLBP programme from a provider's, patient and societal perspective.
2. To calculate the cost per change of ILOC.
3. To determine the longer-term (6-months) cost of back care for patient and provider.

A patient cost of back care questionnaire (**Appendix 23**) developed for this study was administered at 6-months. This questionnaire was aimed at examining: (a) the cost of back care from a provider's, patient and societal perspective when patients undertaking the CBCLBP programme (**Objective 1**); and (b) the provider's and patient cost six months following completion of the programme (**Objective 3**).

ILOC was chosen to calculate cost-effectiveness ratio (**Objective 2**). The cost per change of ILOC was calculated by division of provider's cost for the CBCLBP programme by change score of ILOC between week 1 and week 6. An alternative option to determine cost-effectiveness ratio would be the use of the EQ-5D questionnaire. The EQ-5D instrument is recommended by Department of Health (2010) and the CSP (Jette et al., 2009) to assess cost effectiveness in relation to musculoskeletal physiotherapy outpatient services. It

is also widely used in many existing studies. However, since HLOC is the primary outcome measure of the current study, and the PI concerned the risk of respondent fatigue (Lavrakas, 2008), that participants having too many questionnaires to complete, the ILOC was therefore chosen.

Expenses associated with LBP have been studied in the context of both direct and indirect costs (Ekman et al., 2005). In this study, costs were referred to as:

- Provider costs (i.e. direct medical (NHS) costs);
- Patient costs (i.e. direct non-medical costs); and
- Societal costs (i.e. indirect costs).

3.10.1 Provider costs

Provider costs are the NHS costs directly relating to the provision of the CBCLBP programme, the following costs were calculated such as staffing costs (physiotherapists, physiotherapists' assistant and GPs' time); departmental costs (allocated overheads); medication (prescribed by the GP); and equipment (both physiotherapy gym and hydrotherapy).

Staffing costs included all NHS staffing required to provide the CBCLBP programme, and staffing costs incurred six months following the programme.

For entering the CBCLBP programme, all patients had to visit their GP for a physiotherapy referral, and to be seen by a specialist physiotherapist for a full spinal examination. Therefore, these costs (including an average GP consultation of 11.7 minutes and an average specialist physiotherapy assessment of an hour) were included as part of the provider costs before the start of the programme.

To provide the six-week CBCLBP programme, calculation of staffing time included: a Band 7 physiotherapist and a physiotherapy assistant once a week for six weeks, and a Band 7 physiotherapist and a physiotherapy assistant for

one hydrotherapy session at the end of the six-week programme. This resulted in a total number of seven sessions. Given each session (including administration time) was 2.5 hours, thus the total staffing time to provide the CBCLBP programme included 17.5 hours of one specialist physiotherapist and 17.5 hours of one physiotherapy assistant.

Staffing costs of GP, physiotherapist and physiotherapy assistant were based on the Personal Social Services Research Unit (PSSRU) (Curtis, 2013) (see **Figure 3.6**). The sum included salary on costs, qualifications, indirect and capital overheads and training.

In the six months following the completion of the CBCLBP programme (i.e. between week 6 and 6 months), calculation of staffing costs included: the number of visits made to a GP or other NHS services. GPs' time was calculated from an average surgery consultation of 11.7 minutes then multiplied by the number of visits made. Each consultation was £45 per 11.7 minutes (Curtis, 2013). The sum included practice expenses, qualifications, on-going training, capital costs and overheads. Where patients indicated in their questionnaire that they had visited their GP and omitted a spending on prescription charge in the six months following the CBCLBP programme, it was assumed that there was a prescription pain medication of £8.80 per head incurred out of the provider's budget. The costs of other NHS services were calculated based on the actual amount reported by patients in their questionnaire. Any private or self-funded treatments were also regarded as patients' cost.

Figure 3.6: To show the key items consumed during the study

Item	Unit	Cost (£)	Reference
GP	Per 11.7 minutes	45	PSSRU (Curtis, 2013)
Prescription pain medication	Per head	8.80	NHS Information Centre and Office for National Statistics (2010-2011)
Specialist physiotherapist (Band 7)	Per hour	58	PSSRU (Curtis, 2013)
Physiotherapist's assistant (Band 3)	Per hour	21	PSSRU (Curtis, 2013)
AWR for employer in the Northwest, UK	Per hour	10.75	Office for National Statistics (2014)
Value for non-working time (e.g. housework and leisure time)	per hour	6.04	Department for Transport (2014)
Car usage	Per mile	44 pence	The Automobile Association Developments Limited (2014)
PSSRU, Personal Social Services Research Unit, 2013 (Curtis, 2013)			

Equipment Costs

Equipment costs during the CBCLBP programme were calculated and expressed as Equivalent Annual Cost (EAC) (Drummond et al., 2005; Drummond et al., 1997). The capital outlay annuitized was calculated on a standardised 3.5% interest rate and assumed an equipment life expectancy of five years (Building Cost Information Service, 2011; Curtis, 2013). The formula used to calculate the EAC was:

$$E = r (\text{NPV}) / 1 - (1+r)^{-n}$$

E = equivalent annual cost, r = discount rate (interest) 3.5%, NPV= net present value, n = useful life of equipment (Drummond et al., 2005; Drummond et al., 1997).

The EAC was apportioned to reflect the time it was in use by these patients. In this study, this was calculated based on equipment used by each patient for two hours per session for seven sessions (six sessions in the gym and one session in the pool). **Figure 3.7** showed the price of all equipments used in this study:

Figure 3.7: Price of gym equipments (from Pattersonmedical.co.uk) and hydrotherapy equipments (from JPLennard Ltd, 2012)

Equipment item	Cost per unit (£)	Number of item	Total cost (£)	Equivalent Annual Cost (EAC) (+VAT)* (£)
Treadmill*	4635	1	4635	1026.57
Cross trainer*	695	1	695	153.93
Trampette*	201.5	2	403	89.26
Pulley weight*	1963	1	1963	434.77
Bike*	495	2	990	219.27
Dumb bell 1kg*	8.49	2	16.98	3.76
Dumb bell 2kg*	12.17	2	24.34	5.39
Dumb bell 3kg*	17.04	2	34.08	7.55
Mat*	21.31	10	213.1	47.2
Pillow	14.99	10	149.9	149.9
Relaxation CD	12	1	12	12
CD player	20	1	20	20
Laptop*	442.14	1	442.14	97.93
Projector*	510.38	1	510.38	113.04
Theraband	4.40	4	17.6	17.6
Gym ball 65cm*	17.41	1	17.41	3.86
Gym ball 75cm*	21.71	1	21.71	4.81
Step*	29.47	2	58.94	13.05
Woggle noodles	5.9	8	47.2	47.2
Kickboard	6.3	8	50.4	50.4
Arm ring	3.67	16	58.72	58.72
Pool ball	7.5	2	15	15
Chlorination machine*	520	1	520	115.17
Chlorine tablets	12.95	2	25.9	25.9
Maintenance	2300	1	2300	2300
Sodium hypochlorate	35.9	4	143.6	143.6
Polyalum chloride	39.13	4	156.52	156.52
Sodium bicarbonate	41.25	4	165	165
Thyosulphate flakes	36.75	4	147	147
Sodium biosulphate	32.62	4	130.48	130.48
Delivery	55	4	220	220
Plumbers	147	1	147	147
Total EAC (£): 6141.88*				
Cost of equipment for the six-week CBCLBP programme per patient (£): 9.82				

*Total [annuitized 3.5*5 years]

3.10.2 Patient costs

Patient costs (also known as direct non-medical costs) are out-of-pocket expenses incurred by patient, family, or partner during their attendance to the CBCLBP, and six months following the programme. These included travel costs (patients, family, or partner); lost wages (patients, family, or partner); prescriptions costs and other costs (such as other therapy costs that are indicated as self-funded).

Travel costs described modes of travel to the physiotherapy department in Stockport. This included car, bus or train, taxi, walking and other such as cycling or motorbike. The cost of these journeys was doubled when patients indicated in their questionnaire that they were accompanied by a companion who did not have an appointment in the physiotherapy department. If the companion did have a clinical appointment, the travel costs halved. Car usage was at 44 pence per mile based on a petrol car costing up to £12000 travelling an average of 10,000 miles per year, including standing charges and running costs (The Automobile Association Developments Limited, 2014) (**Figure 3.6**). There is free on-site parking in the physiotherapy department, thus there should be no car parking fees unless patients indicated otherwise. In the six months following the CBCLBP programme, travel costs were taken as the actual amount reported in the questionnaire (i.e. Question 1 and 3). Travel costs were not included if the subject was eligible for reimbursement.

Lost wages were regarded as patients' cost when patients responded as taking 'time off with loss of pay' for attending. This was taken as the Average Wage Rate (AWR) for employer in the Northwest, UK (£10.75 per hour per employee) (Office for National Statistics, 2014) (**Figure 3.6**). However, the AWR was substituted with the actual amount of loss of pay where it was indicated by patients in their questionnaire.

Prescription charges from GP visits were taken as the amount reported by patients in the cost questionnaire.

Other costs while attending the CBCLBP programme, in addition to travel or prescription costs, were gained from answers to a general question (Question 20 and 21). Other costs during the six months following the programme were taken the actual amount indicated in Question 3 and Question 7.

3.10.3 Societal costs

Because of attending the CBCLBP programme, the lost productivity of a patient, or family member or partner were the main societal costs to be accounted. Such costs included:

1. Value of time (refers to the cost to the patient of the time foregone attending the CBCLBP programme. Two aspects of time are considered: travel and time spent for attending the programme).
2. Time lost from usual activities foregone attending the CBCLBP programme, which could be: time lost from work or time lost from non-working activities.

The total time lost from travel and attending the programme was calculated (in minutes). Where patients indicated that they lost time from work activities, i.e. those would have been in “paid occupation” during the CBCLBP programme, and responded as having “annual leave” and “time off without loss of pay”, this was regarded as time lost from work at the employers cost. The value of **time lost at the employers cost** was the AWR (£10.75 per hour in the Northwest UK) uplifted by 13.8% to reflect employers’ National Insurance and superannuation contributions (HM Revenue and Customs, 2014). Where patients indicated that they lost time from non-working activities or leisure, the value of **time lost to non-working activities** was calculated. This included those who responded ‘would otherwise be looking after children, other relatives, or friends’, or who responded ‘other’ or those who responded having a paid occupation and ‘rearranged their hours’. The value of time for non-working time is £6.04 per hour (Department for Transport, 2014) (**Figure 3.6**)

3.11 Minimising bias and confounding variables

In order to maximize the quality of the data, every practicable measure was taken to reduce bias and confounders. Particular attention was paid to control threats to internal validity, as internal validity is suggested to be a threat in single-subject design (Bithell, 1994; Logan et al., 2008).

Bias was controlled by the following:

- Strict inclusion and exclusion criteria and investigation of a homogenous group of subjects;
- Standardised intervention and education materials throughout the study;
- Standardized and consistent manner of data collection;
- The use of different objective measurements of high validity and reliability in order to establish baseline stability and allow accurate comparison across phases;
- Physiotherapy assistants supervised and collected data as much as possible, instead of the PI, to reduce experimenter bias;
- The PI to check each of the self-reported measures after patients had been completed and they were required to answer any questions that they had missed, to reduce attrition bias;
- Data at baseline and all follow-up measurements was kept separately; and
- Data was not analysed until end-of-study outcome measures were all collected.

3.12 Conclusion

This chapter illustrates the methodology and data collection used for the current study. It demonstrates the consideration of validity issues and outcome measures used. Data were collected using the method as described. The next chapter goes on to provide the results of this study, and the analysis of data that answers the research questions accordingly.

CHAPTER 4 RESULTS

4.1 Introduction

This chapter provides the results and interpretation of the descriptive and statistical analysis conducted for the present study. It is divided into two sections.

The first section provides:

- A comparison of demographics and baseline characteristics between patients who completed the programme and those who dropped out (**Section 4.3**).
- Baseline characteristics of included patients who completed the study (**Section 4.4**).

The second section describes the results of statistical analysis conducted to examine each of the research questions, namely:

- **Aim 1:** To assess the effect of the CBCLBP programme on the primary outcome, (HLOC) (**Section 4.5**);
- **Aim 2:** To examine the effect of the CBCLBP programme on the secondary outcomes pain, disability and FAB (**Section 4.6**);
- **Aim 3:** To determine if there is any relationship between patients' HLOC and pain, disability and FAB (**Section 4.7**);
- **Aim 4:** To examine patients' self-care attitude toward their back pain in terms of their desire in future use of healthcare and prescription pain medication as a result of the programme (**Section 4.8**), and
- **Aim 5:** To investigate the cost of back care per change of ILOC, as well as the cost of the CBCLBP programme from a provider's, patient and societal perspective (**Section 4.9**).

4.2 Overview of recruitment and data collection

Study recruitment commenced in September 2012 and ended in June 2013. During this period, a total of 70 patients were initially recruited. Fifteen

patients dropped out of the CBCLBP programme (i.e. patients who were consented for the programme, but they never attended or only attended the first session of the programme). A total of 55 patients completed the study and all follow-up assessments, which is 79% of the original sample. Data collection was completed in January 2014. Throughout the recruitment and data collection period, the PI remained contactable and extra hours were put in to maximise recruitment and minimise loss of follow-up outcome data.

4.3 Demographics and background information of recruited patients

The demographics and background information of patients who completed the programme and those who dropped out are shown in **Table 4.1**, as frequency (N) and percentage (%).

Table 4.1: To show demographics and background information of patients completed the intervention compared with patients who dropped out

Variables	Participants N (%)	Drop out N (%)
<u>Sex</u>		
Male	15 (27%)	7 (46%)
Female	40 (73%)	8 (53%)
<u>Nature of Onset</u>		
Gradual	52 (95%)	15 (100%)
Sudden	3 (5%)	0 (0%)
<u>Duration of back pain</u>		
3-12 months	0 (0%)	0 (0%)
>12 months	55 (100%)	15 (100%)
<u>Employment status</u>		
Employed & currently working	34 (62%)	10 (67%)
Employed but currently on sick leave	1 (2%)	0 (0%)
Unemployed due to back pain	3 (6%)	5 (33%)
Unemployed but not due to health	0 (0%)	0 (0%)
Housewife/ househusband	1 (2%)	0 (0%)
Student	0 (0%)	0 (0%)
Retired	16 (29%)	0 (0%)
<u>Finance</u>		
Received wage compensation	4 (7%)	0 (0%)
Pursue medico-legal compensation	0 (0%)	0 (0%)
Working and earning or pension	48 (87%)	10 (67%)
Disabled/ retired due to back pain	3 (6%)	5 (33%)
Disabled/ retired but not due to back pain	0 (0%)	0 (0%)
<u>Previous history of back pain</u>		
One previous episode	3 (5%)	0 (0%)
Two or more previous episode	52 (95%)	15 (100%)

4.3.1 Comparison of demographics and background information between patients who completed the programme and those who dropped out

The Pearson Chi-Squared and Fisher's exact tests were conducted to examine statistical differences in categorical measures, including gender, onset of LBP, the duration of LBP, employment status, financial status and previous history of LBP, between the two groups (Table 4.2).

Table 4.2: To summarize the Pearson Chi-Square and Fisher's exact tests to a series of categorical variables between those patients who completed the programme and those who dropped out the programme

Categorical variables	Value	Degree of freedom	<i>p</i> - value
Gender	2.06	1	0.152
Onset of LBP	0.86	1	0.355
Duration of LBP	0.855	1	0.355
Employment status	13.0	5	0.024*
Financial status	9.71	2	0.008*
Previous history of LBP	0.855	1	0.355

* $p < 0.05$

The two groups were statistically significantly different in terms of employment status ($X(5) = 13.0, p = 0.024$) and financial status ($X(2) = 9.71, p = 0.008$). Aside from these differences, there was no statistical significant difference found in gender ($p = 0.152$), onset of LBP ($p = 0.355$), duration of LBP ($p = 0.355$), or history of previous LBP ($p = 0.355$) between the two groups.

4.3.2 Comparison of baseline outcome measures between patients who completed the programme and those who dropped out of the programme

Table 4.3 shows baseline characteristics (i.e. variables used in this study) of patients who completed the CBCLBP programme and those who dropped out, as mean and standard deviation (SD). Mann-Whitney *U*-test was then followed to examine the differences in continuous variables between those who completed and those who dropped out of the programme (**Table 4.4**).

Table 4.3: Baseline characteristics of patients who completed the intervention compared with patients who dropped out

Variables	Completed (N= 55) Mean(SD)	Dropped out (N= 15) Mean(SD)	p-value
Internal locus of control (ILOC) [6-36; 6 = low ILOC, 36 = high ILOC]	20.4 (7.09)	18.0 (4.96)	0.20
External locus of control (ELOC) [6-36; 6 = low ELOC, 36 = high ELOC]	23.3 (5.55)	27.5 (4.27)	0.006*
Chance locus of control (CLOC) [6-36; 6 = low CLOC, 36 = high CLOC]	17.7 (6.70)	18.3 (4.61)	0.57
Pain intensity (VAS) [0-10; 0 = no pain, 10 = worse ever pain]	6.04 (2.03)	6.33 (1.45)	0.58
Disability (RMQ) [0-24; 0 = no disability, 24 = high disability]	11.8 (5.55)	14.4 (3.66)	0.07
Fear avoidance movements/ behaviour (TSK) [17-68; 17 = low pain related fear, 68 = high pain related fear]	42.3 (5.31)	42.3 (4.71)	0.90
Self-care attitude (SCQ) [5-25; 5 = passive self-care attitude, 25 = positive self-care attitude]	10.3 (3.33)	10.5 (3.98)	0.92

[VAS, Visual Analogue Scale; RMQ, Roland & Morris Disability Questionnaire; TSK, Tampa Scale for Kinesiophobia; SCQ, Attitude toward back pain Self-Care Questionnaire] * $p < 0.05$

Table 4.4: Mann-Whitney *U*-Test to examine the differences in continuous variable between those patients who completed the programme and those who dropped out

Continuous variables	Mann-Whitney <i>U</i>	<i>Z</i>	<i>p</i> -value
Age	371.0	-0.60	0.56
ILOC	321.5	- 1.31	0.20
ELOC	223.5	- 2.71	0.006*
CLOC	372.0	- 0.58	0.57
Pain intensity	373.5	- 0.57	0.58
Disability	284.5	- 1.84	0.07
Fear-avoidance belief	403.0	- 0.14	0.90
Self-care attitude	405.0	- 0.11	0.92

[ILOC, internal locus of control; ELOC, external locus of control; CLOC, chance locus of control] **p* < 0.05

Those who dropped out of the programme were more likely to have a significantly higher ELOC (*U*= 223.5, *Z*= -2.712, *p*= 0.006). But besides from this difference, there were no other significant baseline differences found in continuous variables (including age, ILOC, ELOC, CLOC, pain intensity, disability, FAB and self-care attitude) between the two groups.

To summarize: those who dropped out of the programme (N=15) were significantly of (a) poorer employment status; (b) poorer financial status and (c) higher ELOC, compared to those who completed the study (N=55).

4.4 Baseline characteristics of included patients who completed the study

A total of 55 patients completed the study. Prior to the baseline data taken (-4 weeks), included patients have had an average of 4 sessions of individual physiotherapy treatments before referring onto the CBCLBP programme by their physiotherapist. During the programme (week 1 to week 6), 25% attended five out of six sessions, while 75% attended the full programme. Complete data of all outcome measures were available for each data points (i.e. -4 weeks, week 1, week 6, 3-months and 6-months) in all the 55 patients.

Of those 55 patients who completed the study, 73% were female (N=40), and 27% were male (N=15). They were all diagnosed with NSCLBP, 95% reported more than two previous episodes of back pain, and all reported back pain symptoms for > 1 year. The majority of patients were currently working (62%), only 6% reported that they are not working because of their back pain (**Table 4.1**)

The baseline characteristics of patients (**Table 4.3**) in this study were of:

- Low level of ILOC (mean= 20.4, SD= 7.09);
- Moderate level of ELOC (mean= 23.3, SD= 5.55);
- Moderate level of CLOC (mean= 17.7, SD= 6.70);
- Moderate level of pain intensity (mean VAS = 6.04, SD= 2.03);
- Moderate level of disability (mean RMQ = 11.8, SD= 5.55);
- High level of FAB (mean TSK= 42.3, SD= 5.31), and
- Moderate level of self-care attitude towards back pain (mean SCQ = 10.3, SD= 3.33).

4.5 Aim 1- To assess the effect of the CBCLBP programme on patients' HLOC

4.5.1 The effect of the CBCLBP programme on ILOC

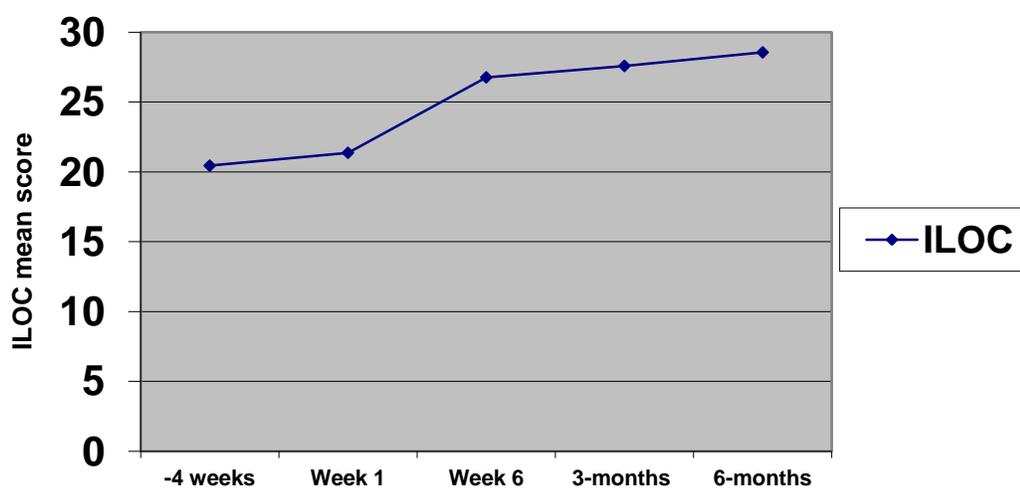
Table 4.5 gives the descriptive analysis of the ILOC data, including the mean, standard deviations, and interquartile ranges of pre- and post- treatment changes of ILOC.

Table 4.5: Pre- and post-treatment mean values and standard deviation of Internal Locus of Control (ILOC) [6-36; 6 = low ILOC, 36 = high ILOC]

	N	Mean	SD	Min	Max	Percentiles		
						25th	50th (Median)	75 th
ILOC -4 weeks	55	20.44	7.089	6	36	14.00	19.00	27.00
ILOC week 1	55	21.36	7.317	6	36	17.00	21.00	26.00
ILOC week 6	55	26.76	6.119	11	36	22.00	27.00	33.00
ILOC 3 months	55	27.58	5.672	13	36	23.00	28.00	32.00
ILOC 6 months	55	28.55	5.315	17	36	24.00	29.00	33.00

The increase of ILOC over time suggested that patients' ILOC steadily improved before, during and after the programme (range of ILOC 6 to 36, 6 indicates low ILOC; 36 indicates high ILOC). The mean score at each time point was then plotted (**Figure 4.1**).

Figure 4.1: Graph to show the effect of the CBCLBP programme on patients' internal locus of control (ILOC)



[ILOC 6-36: 6=low ILOC; 36= high ILOC]

As shown in **Figure 4.1**, the mean ILOC gradually increased from – 4 weeks to 6-months. The sharpest increase of ILOC was seen between week 1 and week 6. This was the phase when study participants were undertaking the CBCLBP programme. After completion of the programme, patients' ILOC continued to increase at 3-months and 6-months, but at a much slower rate.

Comparison of the ILOC at each time point showed that there was a statistically significant change in ILOC ($\chi^2 (4) = 87.6, p < 0.001$) from baseline to 6-months (**Table 4.6**).

Table 4.6: To examine the significant difference of patients' mean ILOC score between each phase using Wilcoxon signed-rank test

ILOC	-4 weeks and week 1	Week1 and week 6	Week 6 and 3 months	3 months and 6 months
Mean difference	0.92	5.4	0.82	0.97
Z	-1.157	-4.84	-.945	-1.895
p- value	.247	<0.001	.345	.058

[ILOC range 6-36]

When examining the significant difference between each phase, ILOC had significantly improved (between week 1 and week 6) during the CBCLBP programme ($Z= 4.84, p < 0.001$). However, there was no statistically significant change between -4 week and week 1 ($Z= 1.157, p=0.247$) (i.e. when patients had had the usual physiotherapy care and were waiting for the CBCLBP programme), between week 6 and 3-months ($Z= 0.945, p= 0.345$), i.e. three months after completing treatment, and between 3-months and 6-months ($Z= 1.895, p= 0.058$).

4.5.2 The effect of the CBCLBP programme on ELOC

Table 4.7 illustrated the mean ELOC at baseline (-4 weeks), at the beginning of the programme (week 1), at completion (week6), and 3-months and 6-months after the programme.

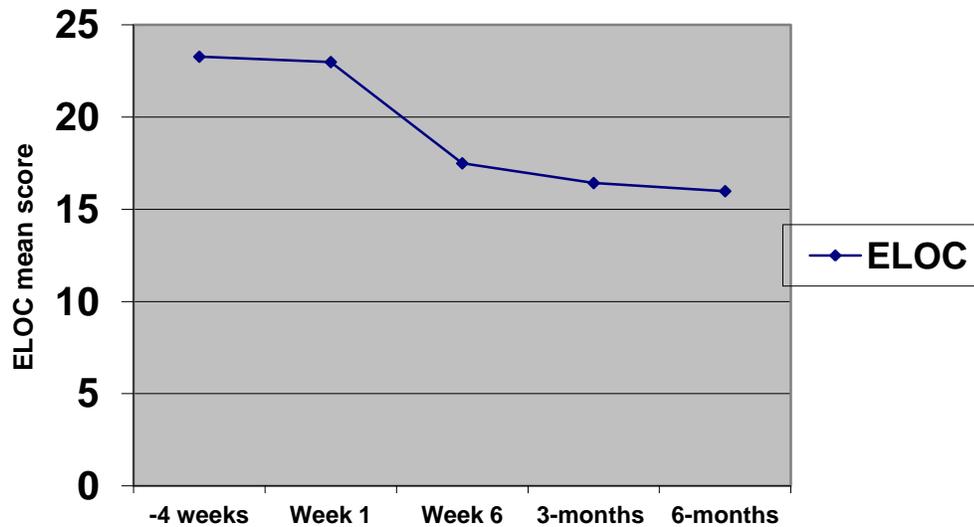
Table 4.7: Pre- and post-treatment mean values and standard deviation of External Locus of Control (ELOC) [6-36; 6 = low ELOC, 36 = high ELOC]

	N	Mean	SD	Min	Max	Percentiles		
						25 th	50 th (Median)	75 th
ELOC -4 weeks	55	23.27	5.509	13	35	19.00	22.00	27.00
ELOC week 1	55	22.98	6.314	12	35	19.00	22.00	29.00
ELOC week 6	55	17.49	5.091	8	28	13.00	18.00	21.00
ELOC 3 months	55	16.42	5.469	6	31	12.00	18.00	20.00
ELOC 6 months	55	15.98	5.370	6	26	12.00	17.00	20.00

As seen in **Table 4.7**, patients' ELOC gradually reduced from -4 weeks to 6-months, indicating ELOC improved as a result of the CBCLBP programme (range of ELOC 6 to 36, 6 indicates low ELOC; 36 indicates high ELOC).

Figure 4.2 illustrates the change in mean ELOC score from baseline to 6-months.

Figure 4.2: Graph to show the effect of the CBCLBP programme on patients' external locus of control (ELOC)



[ELOC 6-36: 6= low ELOC; 36= high ELOC]

There was a gradual decrease of ELOC from baseline to 6-months which was statistically significant ($\chi^2 (4) = 91.7, p < 0.001$) (Figure 4.2). The reduction was at its sharpest at week 6, which was just after the completion of the CBCLBP programme (Table 4.8).

Table 4.8: To examine the significant difference of patients' mean ELOC score between each phase using Wilcoxon signed-rank test

ELOC	-4 week and week 1	Week1 and week 6	Week 6 and 3 months	3 months and 6 months
Mean difference	0.3	5.5	1	0.5
Z	-.497	-5.323	-2.467	-1.898
p- value	.619	< 0.001	.014	.058

[ELOC range 6-36]

As illustrated in **Table 4.8**, there was no significant change ($Z= 0.497$, $p= 0.619$) while patients completed usual physiotherapy care and were on the waiting list for the programme (between -4 week and week 1). A significant reduction of ELOC was seen during the intervention phase, which was between week 1 and week 6 ($Z= 5.32$, $p< 0.001$), indicating significant improvement in ELOC at completion of the programme. Patients' ELOC continued to reduce statistically significantly at 3-months follow-up ($Z= 2.467$, $p= 0.014$). The reduction between 3- and 6-months was not significant ($Z= 1.898$, $p= 0.058$).

4.5.3 The effect of the CBCLBP programme on CLOC

The mean CLOC at baseline (-4 weeks), at the beginning of the programme (week 1), at completion (week6), and 3-months and 6-months were shown in **Table 4.9**. As shown, the mean CLOC steadily improved from before, during and after the programme.

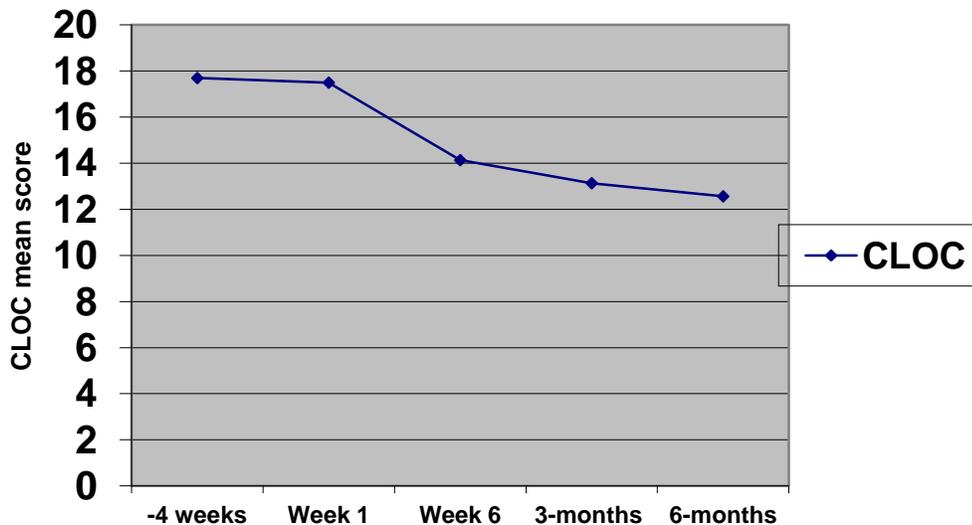
Table 4.9: Pre- and post-treatment mean values and standard deviation of Chance Locus of Control (CLOC) [6-36; 6 = low CLOC, 36 = high CLOC]

	N	Mean	SD	Min	Max	Percentiles		
						25 th	50 th (Median)	75 th
CLOC -4 weeks	55	17.69	6.702	6	33	13.00	17.00	22.00
CLOC week 1	55	17.49	6.790	6	33	13.00	17.00	22.00
CLOC week 6	55	14.13	6.313	6	36	10.00	13.00	18.00
CLOC 3 months	55	13.13	6.287	6	28	8.00	11.00	17.00
CLOC 6 months	55	12.56	6.137	6	29	7.00	10.00	18.00

[CLOC 6-36: 6= low CLOC; 36= high CLOC]

Figure 4.3 demonstrates the change in mean score of the CLOC from baseline to 6-months.

Figure 4.3: Graph to show the effect of the CBCLBP programme on patients' chance locus of control (CLOC)



[CLOC 6-36: 6= low CLOC; 36= high CLOC]

The mean CLOC reduced from baseline to 6-months (**Figure 4.3**). Again, the sharpest improvement was seen between week 1 and week 6, which was the intervention phase. Following the completion of the programme, patients' CLOC continued to decrease at 3- months and 6-months, but at a slower rate.

There was a statistically significant change in CLCO ($\chi^2 (4) = 41.3, p < 0.001$) from baseline to 6-months (**Table 4.10**).

Table 4.10: To examine the significant difference of patients' mean CLOC score between each phase using Wilcoxon signed-rank test

Chance locus of control (CLOC) [6-36, 6=low CLOC, 36= high CLOC]	Between -4 week and week 1	Between Week1 and week 6	Between Week 6 and 3 months	Between 3 months and 6 months
Mean difference	0.2	3.36	1	0.57
Z	-0.223	-3.562	-0.794	-1.376
p- value	0.824	<0.001	0.427	0.169

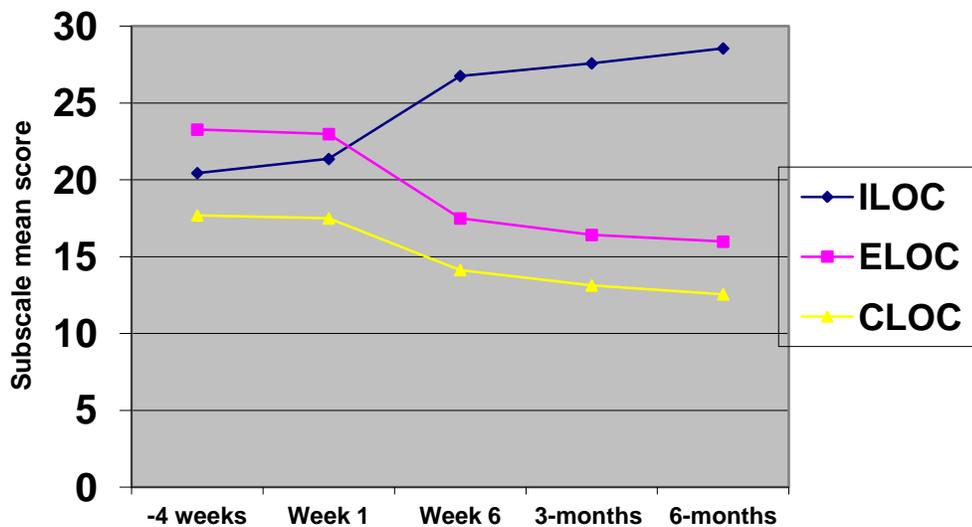
[CLOC range 6-36]

As shown in **Table 4.10**, there was no significant change ($Z= 0.223$, $p= 0.824$) while patients were on the waiting list for the programme (between -4 week and week 1). Patients' CLOC had significantly improved during the CBCLBP programme, which was between week 1 and week 6 ($Z= 3.562$, $p< 0.001$). However, there was no statistically significant improvement after the programme, i.e. between 6 weeks and 3-months ($Z= 0.794$, $p=0.427$), and between 3- and 6-months ($Z= 1.376$, $p= 0.169$).

4.5.4 Summary of the effect of the CBCLBP programme on patients' HLOC

Figure 4.4 summarised the changes of the mean ILOC, ELOC and CLOC at baseline (-4 weeks), during (week 1, week 6) and after the CBCLBP programme at 3-months and 6-months.

Figure 4.4: Graph to show the effect of the CBCLBP programme on the health locus of control (HLOC) subscale



[ILOC 6-36: 6= low ILOC; 36= high ILOC]

[ELOC 6-36: 6= low ELOC; 36= high ELOC]

[CLOC 6-36: 6= low CLOC; 36= high CLOC]

As seen in Figure 4.4, as the mean score of the ILOC increased, both mean score of the ELOC and CLOC reduced over the study period.

4.6 Aim 2- To examine the effect of the CBCLBP programme on pain intensity, disability and fear avoidance belief

Data at each time point (i.e. -4weeks, week 1, week 6, 3-months and 6-months) was plotted in simple line graphs and analysed for trends and to establish whether significant changes in pain intensity, disability, FAB had occurred between phases statistically as a result of the CBCLBP programme.

4.6.1 The effect of CBCLBP programme on pain intensity

Table 4.11 demonstrates the descriptive analysis of the pain intensity data, including the mean, standard deviations, and interquartile ranges.

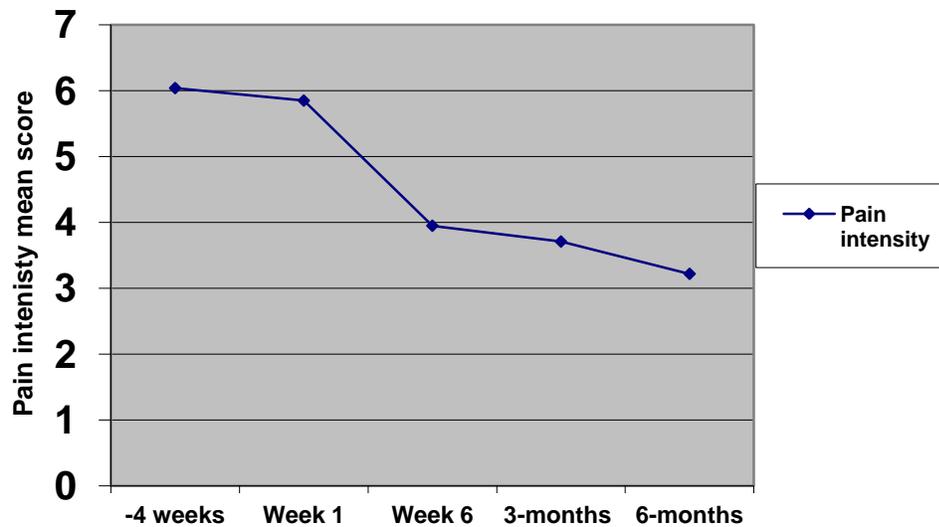
Table 4.11: Pre- and post-treatment mean values and standard deviation of pain intensity as evaluated by Visual Analogue Scale (VAS) [Range 0-10, 0 = no pain, 10 = worst pain ever]

	N	Mean	SD	Min	Max	Percentiles		
						25 th	50th (Median)	75th
Pain [VAS] -4 weeks	55	6.04	2.027	0	10	5.00	6.00	8.00
Pain [VAS] week 1	55	5.85	2.352	0	10	5.00	6.00	8.00
Pain [VAS] week 6	55	3.95	2.094	0	9	3.00	3.00	5.00
Pain [VAS] 3 months	55	3.71	2.347	0	9	2.00	4.00	5.00
Pain [VAS] 6 months	55	3.22	2.192	0	8	1.00	3.00	4.00

(VAS) [Range 0-10, 0 = no pain, 10 = unbearable pain]

Overall, there was a gradual decrease of pain intensity from baseline to 6-months (range 0-10, 0 indicates no pain; 10 indicates unbearable pain). Such improvement was statistically significant ($\chi^2 (4) = 91.5, p < 0.001$) (**Table 4.11**). Specifically, the greatest reduction was observed at week 6, which is just after the completion of the programme. Improvement of pain intensity was continued until 6-months follow-up (**Figure 4.5**).

Figure 4.5: Graph to show the effect of the CBCLBP programme on patients' pain intensity as evaluated by VAS



[VAS Range 0-10, 0 = no pain; 10 = unbearable pain]

Table 4.12: To examine the significant difference of patients' mean pain intensity score between each phase

Pain intensity (VAS) [0-10, 0=no pain, 10= unbearable pain]	Between -4 week and week 1	Between Week1 and week 6	Between Week 6 and 3 months	Between 3 months and 6 months
Mean difference	0.19	1.9	0.24	0.49
Z	-0.657	-5.124	-0.510	-2.165
p- value	0.511	<0.001	0.610	0.030

[VAS Range 0-10]

A significant reduction of pain intensity occurred between week 1 and week 6 ($Z= 5.124, p < 0.001$), which was the intervention phase, and between 3-months

and 6-months ($Z= 2.165$, $p= 0.030$) (**Table 4.12**). There was no significant reduction in pain intensity ($Z= 0.657$, $p= 0.511$) while patients were on waiting list (i.e. between -4 weeks and week 1), and between week 6 and 3-months ($Z= 0.510$, $p= 0.610$).

4.6.2 The effect of CBCLBP programme on disability

Table 4.13 shows the mean changes in disability scores at each time point.

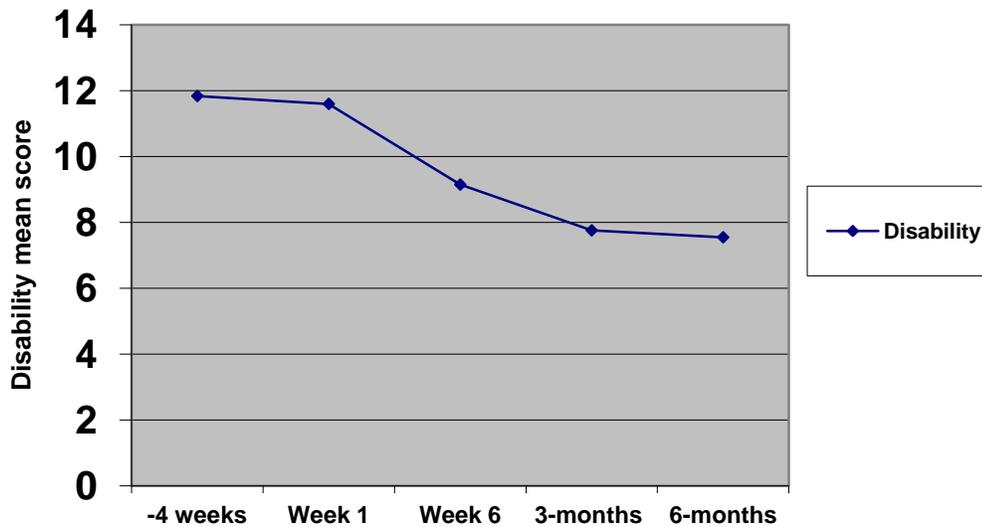
Table 4.13: Pre- and post-treatment mean values and standard deviation of disability as evaluated by Roland and Morris Disability Questionnaire (RMQ)

	N	Mean	SD	Min	Max	Percentiles		
						25 th	50 th (Median)	75 th
Disability RMQ) -4 weeks	55	11.84	5.547	1	23	8.00	12.00	16.00
Disability (RMQ) week 1	55	11.60	5.656	0	23	8.00	11.00	15.00
Disability (RMQ) week 6	55	9.15	6.148	0	24	4.00	8.00	15.00
Disability (RMQ) 3 months	55	7.76	6.357	0	24	3.00	6.00	12.00
Disability (RMQ) 6 months	55	7.55	5.840	0	24	3.00	6.00	12.00

[RMQ range 0-24, 0= no disability; 24= high disability]

The mean RMQ score at each time point was presented in **Figure 4.6** to show the changes as a result of the programme.

Figure 4.6: Graph to show the effect of the CBCLBP on patients' disability as evaluated by RMQ



[RMQ range 0-24, 0= no disability; 24= high disability]

There was a gradual reduction of disability during the study period (**Figure 4.6**). Such improvement from -4 weeks to 6-months was significant ($\chi^2 (4) = 63.6, p < 0.001$). More specifically, there was a significant reduction between week 1 and week 6 ($p < 0.001$), and between 6 weeks to 3-months ($p = 0.016$) (**Table 4.14**).

Table 4.14: To examine the significant difference of patients' mean disability score between each phase using Wilcoxon signed-rank test

Disability (RMW) [0-24, 0= no disability, 24= high disability]	Between -4 week and week 1	Between Week1 and week 6	Between Week 6 and 3 months	Between 3 months and 6 months
Mean difference	0.24	2.45	1.39	0.21
Z	-0.891	-4.506	-2.418	-0.769
p- value	0.373	<0.001	0.016	0.442

[RMQ range 0-24]

A significant reduction of disability occurred between week 1 and week 6 ($Z= 4.506, p < 0.001$), which was the intervention phase, and between week 6 and 3-months ($Z= 2.418, p= 0.016$) (**Table 4.14**). There was no significant reduction in disability ($Z= 0.891, p= 0.373$) while patients were on waiting list (i.e. between -4 weeks and week 1), and between 3-months and 6-months ($Z= 0.769, p= 0.442$).

4.6.3 The effect of CBCLBP programme on FAB

Table 4.15 demonstrates the descriptive analysis of the FAB data, including the mean, standard deviations, and interquartile ranges.

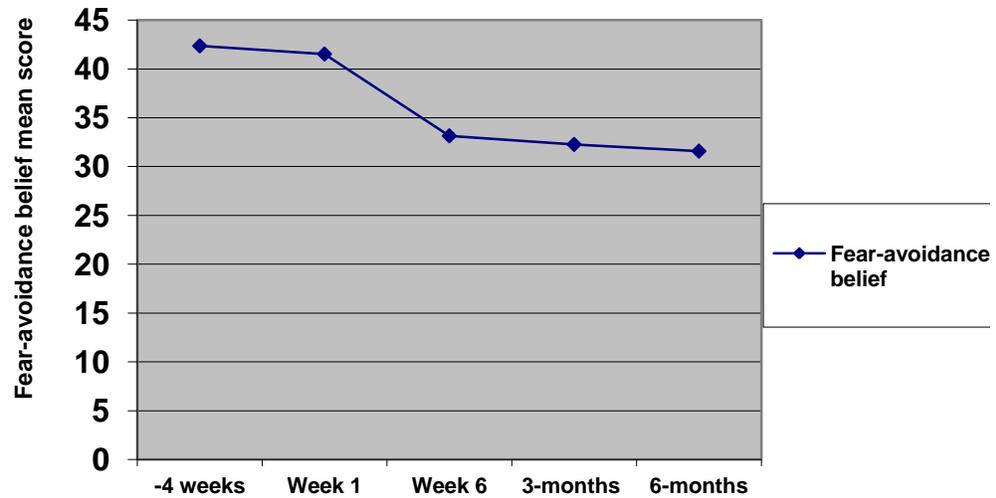
Table 4.15: Pre- and post-treatment mean values and standard deviation of fear-avoidance belief as evaluated by TSK

	N	Mean	SD	Min	Max	Percentiles		
						25 th	50 th (Median)	75 th
Fear-avoidance belief(TSK) -4 weeks	55	42.36	5.307	37	56	39.00	42.00	46.00
Fear-avoidance belief (TSK) week 1	55	41.53	6.582	27	56	37.00	41.00	47.00
Fear-avoidance belief (TSK) week 6	55	33.15	7.420	20	50	26.00	33.00	40.00
Fear-avoidance belief (TSK) 3 months	55	32.27	7.109	18	47	27.00	34.00	37.00
Fear-avoidance belief (TSK) 6 months	55	31.58	7.322	17	48	27.00	33.00	36.00

[Tampa Scale for Kinesiophobia (TSK) Range 17-68, 17 = low pain-related fear; 68 = high pain-related fear]

A gradual reduction of TSK score was observed over the study period (**Figure 4.7**), suggesting improvement of patients' FAB as a result of the programme. The mean disability score at each time point was presented in a graph to demonstrate the effect of the programme on patients' FAB (**Figure 4.7**).

Figure 4.7: Graph to show the effect of the CBCLBP programme on patients' fear-avoidance belief as evaluated by TSK



[Tampa Scale for Kinesiophobia (TSK) Range 17-68, 17 = low pain-related fear, 68 = high pain-related fear]

The Friedman's ANOVA revealed such improvement from baseline to 6-months was a statistically significant ($\chi^2 (4) = 109.1, p < 0.001$). More specifically, the reduction was statistically significant between week 1 and week 6 ($p < 0.001$), which was just after the completion of the six-week intervention (**Table 4.16**).

Table 4.16: To examine the significant difference of patients' mean fear avoidance belief score between each phase using Wilcoxon signed-rank test

Fear-avoidance belief (TSK)	Between -4 week and week 1	Between Week1 and week 6	Between Week 6 and 3 months	Between 3 months and 6 months
Mean difference	0.83	8.35	0.88	0.62
Z	-1.113	-5.851	-1.397	-1.266
p- value	.266	<0.001	.163	.206

[Tampa Scale for Kinesiophobia (TSK) Range 17-68]

A significant reduction of FAB occurred between week 1 and week 6 ($Z= 5.851, p < 0.001$), which was the intervention phase. Otherwise, there was no significant reduction between -4 weeks and week 1 ($Z= 1.113, p= 0.266$), between week 6 and 3-months ($Z= 1.397, p= 0.163$) and between 3-months and 6-months ($Z= 1.266, p= 0.206$) (**Table 4.16**).

4.7 Aim 3- To determine if there is any relationship between patients' HLOC, pain intensity, disability and FAB

Change scores of ILOC (Table 4.5), ELOC (Table 4.7), CLOC (Table 4.9), pain intensity (Table 4.11), disability (Table 4.13) and FAB (Table 4.15) were calculated by 6-months post-treatment mean score minus pre-treatment mean score at -4 weeks. These time points were chosen because the CBCLBP programme is based on the theory that the therapeutic effect may carryover. This is one of the objectives of the current study, which aims to examine if the effect of the CBCLBP may carryover up until six months when there was no treatment.

4.7.1 Correlation

Table 4.17 illustrates the correlation coefficients (r) between change scores that occurred for each of the outcome measures (they are ILOC, ELOC, CLOC, pain intensity, disability and FAB). A number of significant correlations were evident between them.

4.7.1.1 Correlation between pain intensity, disability and FAB

A significant relationship was evident between reduction in pain intensity, reduction in disability and reduction in FAB. These three variables were shown to be inter-related with each other.

4.7.1.2 Correlation between HLOC and pain intensity

Reduction of pain was related to increase of ILOC; reduction of ELOC and reduction of CLOC.

4.7.1.3 Correlation between HLOC and disability

Reduction of disability was only associated with increase of ILOC. There was no significant association between reduction of disability and both reduction in ELOC and CLOC.

4.7.1.4 Correlation between HLOC and FAB

A reduction in FAB was associated with increase of ILOC, reduction of ELOC and reduction of CLOC.

None of the correlation coefficients exceeded 0.90. This indicated that the data was not affected by singularity, which means they could be entered as separate predictor variables in the regression analysis (Tabachnick & Fidell, 2007).

Table 4.17: Correlations between the change scores that occurred for each of the self-reported measures

Correlations

		1. Δ in ILOC	2. Δ in ELOC	3. Δ in CLOC	4. Δ in pain	5. Δ in disability	6. Δ in FAB
1. Δ in ILOC	Correlation		-.371**	-.188	-.469**	-.357**	-.573**
	Sig. (2-tailed)		.005	.170	.000	.007	.000
	N		55	55	55	55	55
2. Δ in ELOC	Correlation	-.371**		.656**	.340*	.207	.550**
	Sig. (2-tailed)	.005		.000	.011	.129	.000
	N	55		55	55	55	55
3. Δ in CLOC	Correlation	-.188	.656**		.344*	.213	.496**
	Sig. (2-tailed)	.170	.000		.010	.119	.000
	N	55	55		55	55	55
4. Δ in pain	Correlation	-.469**	.340*	.344*		.573**	.417**
	Sig. (2-tailed)	.000	.011	.010		.000	.002
	N	55	55	55		55	55
5. Δ in disability	Correlation	-.357**	.207	.213	.573**		.332*
	Sig. (2-tailed)	.007	.129	.119	.000		.013
	N	55	55	55	55		55
6. Δ in fear-avoidance belief (FAB)	Correlation	-.573**	.550**	.496**	.417**	.332*	
	Sig. (2-tailed)	.000	.000	.000	.002	.013	
	N	55	55	55	55	55	

** . Correlation is significant at the $p < 0.01$ level (2-tailed).

* . Correlation is significant at the $p < 0.05$ level (2-tailed).

4.7.2 Hierarchical multiple regression

Hierarchical multiple regression was to determine which of these predictor variable(s) (i.e. ILOC, ELOC, CLOC and other measures) was the best predictor of the outcome (i.e. pain intensity, disability and fear-avoidance), and the extent of how these predictor variables contributed to changes of these outcome of interest statistically. The variables used in each of the regression analyses had variance inflation factors that were less than 10, and tolerance levels that were all notably higher than 0.10, indicating that multicollinearity was unlikely to be a problem (Tabachnick & Fidell, 2007), and data was suitably examined through multiple regression.

4.7.2.1 When pain intensity as the outcome

Table 4.18 shows the results of the regression analysis when change in pain intensity was the outcome of interest. When change in pain intensity was the dependent variable, the first block of regression included age and sex. The second block consisted of change scores in disability and FAB, and the final block consisted of the change scores in IHLC, ELOC and CLOC.

Table 4.18: Hierarchical regression analysis with change (Δ) in pain intensity as the outcome and Δ in cognitive factors as predictor variables (N= 55)

Step	Variable	R^2	R^2 change	F change	B	T	Sig
1	Age	0.018	0.018	0.471	- 0.036	- 0.256	0.80
	Sex				- 0.123	- 0.880	0.58
2	Δ FAB	0.340	0.371	15.160***	0.248	2.093	0.041*
	Δ Disability				0.486	4.141	<0.001***
3	Δ ILOC	0.367	0.060	1.720	- 0.257	-1.823	0.075
	Δ ELOC				0.022	0.133	0.895
	Δ CLOC				0.183	1.153	0.255

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

R^2 = amount of variance explained by IVs

R^2 change= additional variance in DV

F change= is testing whether that most recent contribution represents a significant improvement in the predictor power of the regression equation

β = Standardized regression coefficient (Beta values for each variable are converted to the same scale so they can be compared)

t = estimated coefficient (B) divided by its own Standard Error (SE)

Sig= Values of $p < 0.05$ were considered significant

As shown, age and sex (block 1) were not significantly associated with changes in pain intensity. After controlling for these two variables, the change that

occurred in FAB and disability (block 2) accounted for an additional 37.1% of the variance in pain intensity. This block was statistically significantly associated with level of pain intensity, as indicated by significant $F(2, 50) = 15.160$; $p < 0.001$). Examination of the β - value revealed that the predictor variables most strongly related to reduction in pain intensity were reduction of disability ($\beta = 0.486$, $p < 0.001$), and reduction in FAB ($\beta = 0.248$, $p = 0.041$). With disability recording a higher beta value, suggesting disability was a stronger predictor than FAB when pain intensity was the outcome. After adjusting age, sex, FAB and disability, the HLOC (block 3) explained a non-significant 6% of the variance in pain intensity ($F(3,47) = 1.720$; $p > 0.05$), showing that the HLOC was not the cognitive variable related to a reduction in pain intensity. The final model explained 37% of the total variance in changes in pain intensity.

4.7.2.2 When disability as the outcome

When change in disability was the dependent variable, the first block of regression included age and sex. The second block consisted of change scores in pain intensity and FAB, and the final block consisted of the change scores in ILOC, ELOC and CLOC (**Table 4.19**).

Table 4.19: Hierarchical regression analysis with change (Δ) in disability as the outcome and Δ in cognitive factors as predictor variables (N= 55)

Step	Variable	R^2	R^2 change	F change	B	T	Sig
1	Age	0.008	0.008	0.219	-0.027	-0.194	0.847
	Sex				-0.083	-0.592	0.556
2	Δ Pain intensity	0.339	0.331	12.503** *	0.525	4.141	<0.001** *
	Δ FAB				0.113	0.886	0.380
3	Δ ILOC	0.344	0.005	0.129	-0.081	-0.511	0.611
	Δ ELOC				-0.061	-0.343	0.733
	Δ CLOC				0.013	0.073	0.943

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

R^2 = amount of variance explained by IVs

R^2 change= additional variance in DV

F change= is testing whether that most recent contribution represents a significant improvement in the predictor power of the regression equation

β = Standardized regression coefficient (Beta values for each variable are converted to the same scale so they can be compared)

t = estimated coefficient (B) divided by its own Standard Error (SE)

Sig= Values of $p < 0.05$ were considered significant

As can be seen in Table 4.19, age and sex (block 1), which accounted for a non-significant 0.8% of the variance, were not significantly associated with

changes in disability. After controlling these two variables, the change that occurred in pain intensity and disability (block 2) accounted for an additional 33.1% of the variance. This block was significantly associated with level of disability ($F(2, 50) = 12.503; p < 0.001$). The associated β -value revealed the predictor variable most strongly related to reduction of disability was the reduction of pain intensity ($\beta = 0.525, p < 0.001$). Specifically, lower level of disability was associated with lower level of pain intensity. However, the FAB ($\beta = 0.113; p = 0.380$) was not significantly associated with changes in disability. After adjusting age, sex, pain intensity and FAB, the HLOC (block 3) explained a further non-significant 0.5% of the variance in disability ($F(3, 47) = 0.129; p > 0.05$), suggesting that the HLOC was not the cognitive factor related to a reduction in disability. The final model explained 34.4 % of the total variance in changes in disability.

4.7.2.3 When FAB as the outcome

Table 4.20 shows the results of the regression analysis when change in FAB was the outcome. When change in FAB was the dependent variable, the first block of regression included age and sex. The second block consisted of change scores in pain intensity and disability, and the final block consisted of the change scores in IHLC, ELOC and CLOC.

Table 4.20: Hierarchical regression analysis with change (Δ) in fear-avoidance belief as the outcome and Δ in cognitive factors as predictor variables (N= 55)

Step	Variable	R^2	R^2 change	F change	B	T	Sig
1	Age	0.025	0.025	0.659	-0.013	-0.097	0.923
	Sex				-0.154	-1.111	0.271
2	Δ Pain intensity	0.197	0.172	5.372**	0.325	2.093	0.041*
	Δ Disability				0.137	0.886	0.380
3	Δ ILOC	0.516	0.319	10.328***	-0.407	-3.314	0.002**
	Δ ELOC				0.189	1.253	0.216
	Δ CLOC				0.277	1.908	0.062

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

R^2 = amount of variance explained by IVs

R^2 change= additional variance in DV

B = Standardized coefficient (values for each variable are converted to the same scale so they can be compared)

T = estimated coefficient (B) divided by its own Standard Error (SE)

Sig= Values of $p < 0.05$ were considered significant

As can be seen in **Table 4.20**, age and sex (block 1), accounted for a non-significant 2.5% of the variance, which were not significantly associated with changes in FAB. After controlling these two variables, the change that occurred in pain intensity and disability (block 2) accounted for an additional 17.2% of

the variance in FAB. This block was statistically significantly associated with levels of FAB, as indicated by significant $F(2, 50) = 5.372; p < 0.01$. Examination of the β -value revealed the predictor variables most strongly related to reduction of FAB was the reduction of pain intensity ($\beta = 0.325, p = 0.041$). Specifically, lower level of FAB was associated with lower level of pain intensity. However, disability ($\beta = 0.137; p = 0.380$) was not significantly associated with changes in FAB. After adjusting age, sex, pain intensity and disability, the HLOC (block 3) explained a further significant 31.9% of the variance ($F(3, 47) = 10.328; p < 0.001$). According to the β value, higher levels of ILOC ($\beta = -0.407, p = 0.002$) was uniquely related to the prediction of outcome. Specifically, increase in ILOC was the cognitive factor most strongly related to a reduction in FAB ($\beta = -0.407, p = 0.002$). The final model explained 51.6% of the total variance in changes in FAB.

4.8 Aim 4- To examine patients’ self-care attitude toward their back pain in terms of their desire in future use of healthcare and prescription pain medication as a result of the programme

This question was answered by using the five-item self-care orientation scale questionnaire (SCQ), which is designed to predict patients’ attitude toward back pain self-care and to predict their future use of health care services for back pain and/ or future use of prescription pain medications (Von Korff et al., 1998; Moore et al., 2000) (see **Chapter 3, section 3.7.5**).

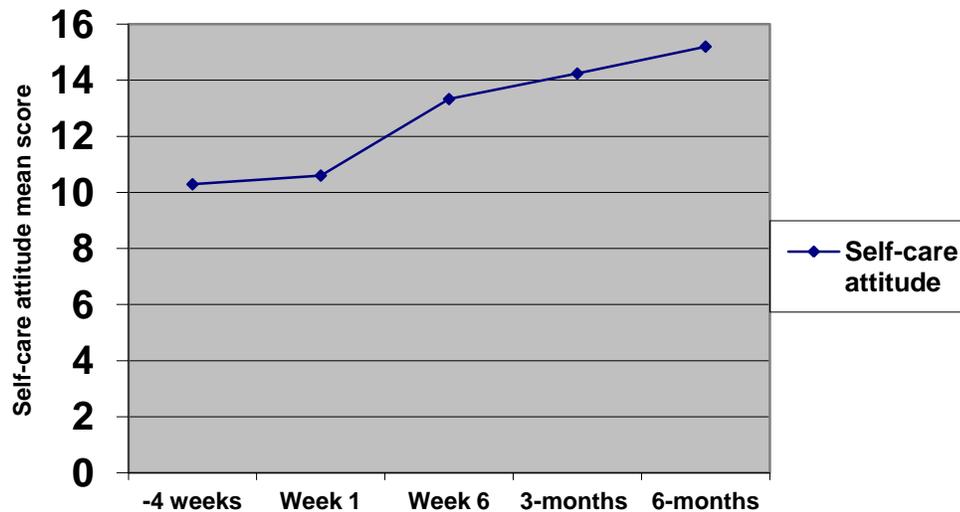
Table 4.21 gives the descriptive analysis of the self-care attitude data, including the mean, standard deviations, and interquartile ranges of pre- and post- changes of patients’ self-care attitude.

Table 4.21: Pre- and post- treatment mean values and standard deviation of self-care attitude as evaluated by the attitude toward back pain self-care orientation questionnaire (SCQ) [Range 5-25, 5 = passive attitude toward self care, 25 = positive attitude toward self care]

	N	Mean	SD	Min	Max	Percentiles		
						25 th	50 th (Median)	75 th
SCQ -4 weeks	55	10.29	3.332	5	18	8.00	11.00	12.00
SCQ week 1	55	10.60	3.609	5	18	8.00	11.00	13.00
SCQ week 6	55	13.33	3.198	8	20	11.00	13.00	15.00
SCQ 3-months	55	14.24	3.702	5	24	12.00	14.00	17.00
SCQ 6-months	55	15.20	4.656	6	26	12.00	15.00	18.00

The mean self-care orientation score increased at each time point, suggesting patients’ self-care attitude gradually improved before, during and after the CBCLBP programme. The mean score at each time point was plotted in a graph (**Figure 4.8**).

Figure 4.8: Graph to show the effect of the CBCLBP programme on patients' attitude towards back pain self-care



[Attitude toward back pain self-care orientation questionnaire (SCQ)
Range 5-25, 5 = passive attitude toward self care, 25 = positive attitude toward self care]

As shown in **Figure 4.8**, the mean self-care attitude mean score increased from -4 weeks to 6-months. The greatest increase was seen between week 1 and week 6, which was immediately after the CBCLBP programme. After completion of the programme, patients' self-care attitude score continued to improve at 3-months and 6-months, but with a slower rate. **Table 4.22** illustrated the examination of significant difference in patients' self-care attitude at each phase.

Table 4.22: To examine the significant difference of patients' attitude toward self-care between each phase using Wilcoxon signed-rank test

Attitude toward back pain self-care questionnaire	-4 week and week 1	Week1 and week 6	Week 6 and 3 months	3 months and 6 months
Mean difference	0.31	2.73	0.91	0.96
Z	-0.695	-4.487	-2.051	-1.606
p- value	0.487	<0.001	0.040	0.108

[Attitude toward back pain self-care orientation questionnaire (SCQ)

Range 5-25]

There was no significant improvement between -4 weeks and week 1 while patients were on waiting list ($Z= 0.695$, $p= 0.487$). Patients' self-care attitude was then statistically significantly improved between week 1 and week 6 ($Z= 4.487$, $p< 0.001$), which was the treatment phase. Their self-care attitude continued to improved significantly between 6 weeks and 3-months ($Z= 2.051$, $p= 0.040$). However, between 3- and 6-months after the completion of the programme, the improvement was not statistically significant ($Z= 1.606$, $p= 0.108$) (Table 4.22)

4.9 Aim 5- To examine the cost of back care per change of ILOC, and the cost of the CBCLBP programme from a provider's, patient and societal perspective

The primary objective is to examine the cost of back care per change of ILOC. In addition to the primary objective, the cost of the six-week CBCLBP programme from a provider's, patient and societal perspective, as well as the longer term (6-months) back care cost for patient and provider are also examined. **Table 4.23** shows the key units that consumed over the course of the study period from the provider, patient and societal perspective.

In order to clearly handle the aims of this question, these results are discussed under the following sub-headings:

1. The cost of a six-week CBCLBP programme from a provider's, patient and societal perspective (**Section 4.9.1**);
2. The cost per change of ILOC as a result of the CBCLBP programme (**Section 4.9.2**), and
3. The longer-term (6-months) cost of back care from a patient and provider's perspective (**Section 4.9.3**).

Table 4.23: Key unit costs used that consumed during the study (Prices, UK £)

Item	Unit	Cost (£)	Reference
GP	Per 11.7 minutes	45	PSSRU (Curtis, 2013)
Prescription pain medication	Per head	8.80	NHS Information Centre and Office for National Statistics (2010-2011)
Specialist physiotherapist (Band 7)	Per hour	58	PSSRU (Curtis, 2013)
Physiotherapist's assistant (Band 3)	Per hour	21	PSSRU (Curtis, 2013)
AWR for employer in the Northwest, UK	Per hour	10.75	Office for National Statistics (03 July 2014)
Value for non-working time (e.g. housework and leisure time)	per hour	6.04	Department for Transport (2014)
Car usage	Per mile	44 pence	The Automobile Association Developments Limited, 2014
Personal Social Services Research Unit (PSSRU) (Curtis, 2013)			

4.9.1 The cost of a six-week CBCLBP programme from a provider's, patient and societal perspective

4.9.1.1 Provider's cost incurred in a six-week CBCLBP programme

Table 4.24: Staffing time and staffing cost to provide the six-week CBCLBP programme

Staffing required to provide the six-week CBCLBP programme	Staffing time	Staffing Costs (£) (per patient)	Staffing Costs (£) (based on 8 patients per group)
One initial GP visit (GP referred to Physiotherapy)	11.7 minutes (£45 per 11.7 minutes consultation)	45	45
One-to-one physiotherapist's assessment and advice prior to the programme	1 hour (£58 per hour consultation)	58	58
Physiotherapist delivering the programme	17.5 hours (£58 per hour; 7 sessions of 2.5 hours each)	1015	127
Physiotherapist's assistant assisting the programme	17.5 hours (£21 per hour; 7 sessions of 2.5 hours each)	367.5	46
Total	36 hours and 11.7 minutes	1485.5	276

As illustrated in **Table 4.24**, the staffing cost for each patient who attended the CBCLBP programme includes a one-to-one GP consultation, a one-to-one

physiotherapist assessment prior to the programme, one physiotherapist and one physiotherapist's assistant who ran the programme. Each programme consisted of eight patients at a time, and each programme included six sessions in the physiotherapy gym and one hydrotherapy therapy session in the pool.

The staffing cost per patient was calculated by the total amount of time of GP, physiotherapist and physiotherapist's assistant involved in providing the six-week CBCLBP programme, multiplied by their hourly or consultation rate (£) accordingly (**Table 4.24**). Since each group consisted of 8 patients on average, this was then divided by eight. This resulted in a total NHS staffing cost of £276 per patient based on treating 8 patients per group.

Table 4.25: Price of gym equipments (from Pattersonmedical.co.uk) and hydrotherapy equipments (from JPLennard Ltd, 2012)

Equipment item	Cost per unit (£)	Number of item	Total cost (£)	Equivalent Annual Cost (EAC) (+VAT)* (£)
Treadmill*	4635	1	4635	1026.57
Cross trainer*	695	1	695	153.93
Trampette*	201.5	2	403	89.26
Pulley weight*	1963	1	1963	434.77
Bike*	495	2	990	219.27
Dumb bell 1kg*	8.49	2	16.98	3.76
Dumb bell 2kg*	12.17	2	24.34	5.39
Dumb bell 3kg*	17.04	2	34.08	7.55
Mat*	21.31	10	213.1	47.2
Pillow	14.99	10	149.9	149.9
Relaxation CD	12	1	12	12
CD player	20	1	20	20
Laptop*	442.14	1	442.14	97.93
Projector*	510.38	1	510.38	113.04
Theraband	4.40	4	17.6	17.6
Gym ball 65cm*	17.41	1	17.41	3.86
Gym ball 75cm*	21.71	1	21.71	4.81
Step*	29.47	2	58.94	13.05
Woggle noodles	5.9	8	47.2	47.2
Kickboard	6.3	8	50.4	50.4
Arm ring	3.67	16	58.72	58.72
Pool ball	7.5	2	15	15
Chlorination machine*	520	1	520	115.17
Chlorine tablets	12.95	2	25.9	25.9
Maintenance	2300	1	2300	2300
Sodium hypochlorate	35.9	4	143.6	143.6
Polyalum chloride	39.13	4	156.52	156.52
Sodium bicarbonate	41.25	4	165	165
Thyosulphate flakes	36.75	4	147	147
Sodium biosulphate	32.62	4	130.48	130.48
Delivery	55	4	220	220
Plumbers	147	1	147	147
Total EAC (£): 6141.88*				
Cost of equipment for the six-week CBCLBP programme per patient (£): 9.82				

*Total [annuitized 3.5*5 years]

Table 4.25 illustrates the equipment costs included both equipments used in the physiotherapy gym and in the pool. The equivalent cost (EAC) was calculated as £6141.88. This was based on five-year life spans of the equipments. Equipment with five-year life spans, used by each patient for two hours per session (six sessions in the gym and one sessions in the pool), resulted in costing the NHS £9.82 per patient for using the equipment during the CBCLBP programme.

No participant reported visit to other NHS services such as GPs, other services or procedure while they were undertaking the CBCLBP programme. Therefore, the total mean provider cost to provide a six-week CBCLBP programme was £285.82 (i.e. staffing cost of £276 plus equipment cost of £9.82).

4.9.1.2 Patient cost incurred in a six-week CBCLBP programme

The characteristics of patient cost that may incur by patient, or companion in the pursuit of the six-week CBCLBP were shown in **Table 4.26**.

Table 4.26: Characteristics of patient cost (i.e. patients' out-of pocket expenses) incurred during the six-week CBCLBP programme

	N (%)
Method of travelling to physiotherapy <ul style="list-style-type: none"> ▪ Car ▪ Bus or Train ▪ Taxi ▪ Walk ▪ Ambulance ▪ Other 	 47 (85%) 5 (9%) 2 (4%) 1 (2%) 0 (0%) 0 (0%)
Car parking fees <ul style="list-style-type: none"> ▪ Yes ▪ No 	 0 (0%) 55 (100%)
Companion <ul style="list-style-type: none"> ▪ Yes ▪ No 	 2 (4%) 53 (96%)
Lost earnings (including patients, family, and partner) whilst at physiotherapy <ul style="list-style-type: none"> ▪ Yes ▪ No 	 2 (4%) 53 (96%)
Reimbursement <ul style="list-style-type: none"> ▪ Yes ▪ No 	 0 (0%) 55 (100%)
Prescription Charges <ul style="list-style-type: none"> ▪ Yes ▪ No 	 0 (0%) 55 (100%)
Other expenses <ul style="list-style-type: none"> ▪ Yes ▪ No 	 2 (4%) 53 (96%)

As shown in **Table 4.26**, the majority of participants were travelled to the physiotherapy department by car (85%). No car parking fees was reported (as the physiotherapy department provided free on-site parking). 96% of the participants (those with paid occupation) reported that there was no lost of earning while undertaking the CBCLBP programme. These costs are tolerated by society rather than patients themselves. No reimbursement and prescription charge during the six-week programme. Only 4% participants reported other expenses were spent. An actual amount reported was calculated.

Table 4.27: Patient cost (i.e. patients' out-of pocket expenses) incurred during the six-week CBCLBP programme

	Out of Pocket Expenses Per Patient (£) Mean ± SD (Range), (N=55)
Travel costs to physiotherapy	4.00 ± 8.25 (0 to 50.75)
Lost earnings whilst at physiotherapy	2.55 ± 13.77 (0 to 90)
Prescription Charges	0
Other expenses	2.55 ± 13.77 (0 to 90)
Total	9.10 ± 3.19 (0 to 90)

Based on the data on **Table 4.26**, patient cost to attend the CBCLBP programme was calculated (**Table 4.27**). The mean patient cost was approximately £9.10 to undertake the six-week CBCLBP programme.

4.9.1.3 Societal cost incurred during a six-week CBCLBP programme

Table 4.28: Societal cost (i.e. value of time lost from work or non-working activities) during the six-week CBCLBP programme

	Patients who lost time from work activities	Patients who lost time from non-working activities
N = (%)	30 (55%)	25 (45%)
	Mean ± SD (Range), (N=30)	Mean ± SD (Range), (N=25)
Total time lost from travel & attending the programme (minutes)	827.8 ± 67.6 (560 to 875)	824.8 ± 52.8 (735 to 870)
Cost of time lost per patient from both travelling and attending the programme (£)	166.1 ± 18.06 (103 to 178)	83.08 ± 5.42 (74 to 88)
Average societal cost per patient (£): 124.59 ± 8.94 (74 to 178)		

Table 4.28 showed the mean societal cost incurred during the six-week CBCLBP programme. The mean value of time lost from work activities was £166.1, and the mean value of time lost from non-working activities was £83.08. The mean societal cost for the CBCLBP programme was approximately £124.59.

Table 4.29: The cost of a six-week CBCLBP programme from a provider's, patient and societal perspectives

Costs to provide a six-week CBCLBP programme	Including	Cost Per Patient (£) Mean ± SD (Range), (N=55)
Provider's cost (£)	Staffing costs, and equipment costs	285.82
Patient cost (£)	Travel costs, lost earning from attending the programme, prescription charge and other expenses	9.10 ± 3.19 (0 to 90)
Societal cost (£)	Value of time lost from travel and from attending the programme	124.59 ± 8.94 (74 to 178)

Table 4.29 summarized the cost of a six-week CBCLBP programme from a provider's, patient and societal perspective. To provide a six-week physiotherapy CBCLBP programme, the mean provider's cost was approximately £285.82 per patient (based on treating 8 patients per group), the mean patient cost was approximately £9.10, and the mean societal cost was approximately £124.59 per patient.

4.9.2 The cost per change of ILOC as a result of the CBCLBP programme

This question was answered by calculating the division of the provider cost by the mean score of change in ILOC between week 1 and week 6 of the programme.

The mean ILOC was 21.36 at week 1, and 26.76 at week 6 [ILOC range 6-36, 6=low ILOC, 36 = high ILOC] (see **Table 4.5**), the mean change score of ILOC was 5.4 points (week 6 post treatment mean score minus week1 pre-treatment mean score).

To calculate the incremental cost/ change of ILOC ratio, this was divided the provider cost (£285.82) by the mean score of change in ILOC (5.4 points). Therefore, the incremental cost of ILOC was approximately £53. i.e. it cost the provider £53 for each point of ILOC improvement.

4.9.3 To determine the longer-term (6-months) cost of back care for patient and provider

This question was answered based on the data collected between question 1 and question 7 of the cost questionnaire (**Appendix 23**), asking patients about GP usage, prescription charge, travel costs and other therapy charges following completion of the CBCLBP up until six months. Societal cost at 6- months was not evaluated.

Table 4.30: Characteristics of healthcare services usage following the completion of the six-week CBCLBP programme

	N (%)
Visit to GP (N=55)	
▪ Yes	14 (25%)
▪ No	41 (75%)
Total number of visit to GP (N=14)	45 (range 0-5)
Prescription pain medication (N=55)	
▪ Yes	15 (27%)
▪ No	40 (73%)
Visits to other therapy (N=55)	
▪ Yes	9 (16%)
▪ No	46 (84%)
Type of therapy (N=9)	
▪ Hydrotherapy	5 (56%)
▪ Physiotherapy	2 (22%)
▪ Acupuncture	2 (22%)
▪ Osteopathy	0 (0%)
▪ Pain clinic	0 (0%)
▪ Other	0 (0%)
No of sessions of other therapy (N=9)	
▪ Hydrotherapy (N=5)	25
▪ Physiotherapy (N=2)	6
▪ Acupuncture (N=2)	12
Type of service of other therapy (N=9)	
▪ NHS (free)	0
▪ Fee-paying (private)	9

As shown in **Table 4.30**, out of the 55 study participants, only 14 patients (25%) visited their GP again during the six months period after the completion of the CBCLBP, and 15 (27%) required prescription pain medication from their GP.

Nine patients (16%) visited other therapy after the CBCLBP programme, this included hydrotherapy (56%), private physiotherapy (22%) and acupuncture (22%). These therapies were indicated as self-funded by patients, thus this was accounted as patients cost.

No participant was reported utilising the NHS Physiotherapy service at 6 months follow up. As a result, the NHS costs following the completion of the programme involved only the GP visits and the prescription pain medication.

Table 4.31: Patient cost (i.e. patients' out-of pocket expenses) incurred during the six months period following the completion of the CBCLBP programme

	Out of Pocket Expenses Per Patient (£) Mean ± SD (Range)
Travel and prescription costs (N=13)	27.25 ± 20.14 (8.05 to 80.05)
Travel and other therapy costs (N=9)	133.4 ± 120.8 (25 to 300)
Total patient cost at 6-month	£160.7

Table 4.31 summarises the mean patient cost incurred six months after completing the CBCLBP. As shown, the mean travel and prescription cost was £**27.25** ± 20.14, and the mean travel and other therapy costs was £**133.4** ± 120.8. Therefore, the mean patient cost was approximately £160.7 six-month following completion of the CBCLBP programme.

Table 4.32: Provider’s cost per patient (i.e. NHS cost) incurred during the six months period following the completion of the CBCLBP programme

	Number of usage after completing the CBCLBP programme (Range)	Total provider costs (£)	Provider costs per patient following the CBCLBP programme (£) Mean ± SD (Range)
GP usage (costs calculated based on £45 per 11.7 minutes consultation) (N=14)	45 (1-10)	2025	144.6 ± 111.9 (45 to 450)
Medication costs (costs calculated based on 8.80 per head from GP) (N=14)	15 (1-2)	132	9.43 ± 2.35 (8.80 to 17.60)
Total provider’s cost following the CBCLBP programme (£): 2157			
Total provider’s cost per patient following the CBCLBP programme (£): 154.1 ± 77.44 (8.05 to 450)			

25% participants reported visit to GP (**Table 4.30**) with a total number of 45 consultations (**Table 4.32**). Where participants indicated that they visited their GP and there was a prescription charge reported in their questionnaire, it was assumed there was a medication cost incurred. The mean provider’s cost six months following the CBCLBP programme was approximately £154.1.

4.9.4 Key findings of economic evaluation

- To provide a six-week physiotherapy CBCLBP programme, the mean provider's cost was approximately £285.82; the mean patient cost was approximately £9.10, and the mean societal cost was approximately £124.59;
- The incremental cost of ILOC was approximately £53. i.e. it costs the provider £53 for every point of ILOC gained; and
- In the six months following the completion of the CBCLBP programme (from week 6 to 6-months), the mean patient cost was approximately £160.7, and the mean provider's cost was approximately £154.1.

4.10 Conclusion

This chapter provides the descriptive and statistical findings drawn from the analysis related to the research questions. Each question was addressed appropriately. The next chapter goes on to discuss the interpretation of the results, including discussion of positive and negative findings of the present study, comparison with previous works and significance of these findings.

CHAPTER 5 DISCUSSION

5.1 Introduction

This chapter revisits the five key aims of the current studies and explains how they are answered. It discusses the key positive and negative findings, and their possible mechanism, in accordance with each individual research question. Whilst this study has confirmed some of the findings of previous studies, it differs from the existing literature as well. Similarities and differences in relation to previous work are highlighted and discussed.

Aims of the study:

1. To assess the effects of the physiotherapy CBCLBP programme on patients' HLOC (**Section 5.3**).
2. To examine the effects of the CBCLBP programme on pain, disability and FAB (**Section 5.4**).
3. To determine if there is any relationship between patients' HLOC and pain, disability and FAB (**Section 5.5**).
4. To examine patients' self-care attitude toward their back pain in terms of their desire in future use of healthcare and prescription pain medication as a result of the programme (**Section 5.6**).
5. To investigate the cost of back care per change of ILOC, as well as the cost of the CBCLBP programme from a provider's, patient and societal perspective (**Section 5.7**).

5.2 Comparison between patients who completed the CBCLBP programme and those who dropped out of the programme

This study provided some significant baseline difference between patients who completed the programme and those who dropped out. This information may be useful for physiotherapists and managers when screening appropriate NSCLBP patients prior to the CBCLBP programme in their physiotherapy service.

Baseline differences between patients who completed the programme and those who dropped out

A total of n= 70 eligible patients with NSCLBP were initially recruited, with n= 55 (79%) completing the study and all outcome assessments. Patients who dropped out of the programme (i.e. patients who were consented for the programme, but they never attended, or only attended the first session of the programme) (n= 15, 21%) were significantly: (a) of poorer employment status; (b) of poorer financial status; and (c) possessing a higher level of ELOC. This latter factor suggests that those who dropped out of the programme were significantly more externally orientated, i.e. held the belief that the responsibility for their health was assigned to other people such as medical professionals and families. This is supported by the literature, which suggests that individuals with higher ELOC are less likely to assume responsibility for their health, and are less likely to engage in behavioural involvement such as self-care and active participation in medical care (Wallston & Wallston, 1982; Koleck et al., 2006).

Comparison to other studies

Dropout from treatment is common problem in CBT management for CLBP (Glombiewski et al., 2010). In the current study, n=15 (21%) consented patients did not attend or only attended the first session of the programme. All remaining patients attended all sessions resulting our study having complete data at each outcome assessment (-4 week, week 1, week 6, 3-months and 6-months) for all the 55 patients. It is suggested that a loss of $\leq 20\%$ follow-up rate is acceptable in RCTs or cohort studies (Fewtrell et al., 2008). With the

present study has no patient dropped out during follow-up, this is considered acceptable and posing no serious threats to validity (Fewtrell et al., 2013). Compared to other high to moderate quality studies investigating NSCLBP patients in physiotherapy rehabilitation, the dropout rate during follow-up is ranging from 16% to 35% (Woby et al., 2004a; Johnson et al., 2007; Critchley et al., 2007; Woby et al., 2008).

According to qualitative and quantitative evidence, there are many reasons for NSLBP patients to dropout in their rehabilitation. Examples include: patients' expectation to be provided a specific diagnosis of NSCLBP (Rhodes et al., 1999; Sloots., 2010), wanted medical treatment to cure their pain (Sloots et al., 2009; Sloots et al., 2010), the idea that exercise does not help or aggravates pain (Mailloux et al., 2006), different views on responsibilities with regard to the rehabilitation (e.g. patients expected more responsibilities to be taken by the clinicians) (Sloots et al., 2009), and a lack of trust in the rehabilitation clinician (Sloots et al., 2010).

A lower attrition found in the present study could at least be partially attributed by the successful change of patients' expectation and beliefs regarding the nature and treatment principle of NSCLBP through the highly-structured programme. The PI and the physiotherapists were acutely aware of the importance of patient skills when delivering the CBCLBP programme (as described in **Figure 3.4**). Being an active listener, caring, confident, competent and acknowledging patients' complaints may establish trust and rapport between physiotherapists and patients, which may then result in a higher uptake and adherence to the CBCLBP programme.

Patients who dropped out of the programme were probably those who failed to change, or not ready to change their expectation and beliefs about the NSCLBP. It must be noted that the group-structured intervention is not universal for all NSCLBP patients, particularly the CBA intervention assumes that individuals are proactive, and places more responsibility on patients and challenges their

expectations about pain management and prognosis (Nordin et al., 2006; Waddell & Burton, 2005). For instance, it may not make much sense, from the patients' perspective, to self-care, or be interested in the CBA component if they hold a higher level of ELOC. Therefore, an alternative such as CBT delivered by trained cognitive-behavioural therapists or one-to-one session given by experienced physiotherapist in CBA can be considered for this subgroup of patients with profile characteristics of poor employment and financial status and high ELOC.

Implication for physiotherapists

On the basis of current findings, physiotherapists could consider using assessment of patients' HLOC as one alternative to reduce dropout rate in their CBCLBP service. More specifically, those with a combination of poorer employment status, poorer financial status and higher ELOC may not be appropriate for a group-structured CBA approach intervention. Physiotherapists could also consider asking questions along the HLOC continuum. Yellow flags assessment questions such as "What do you currently do to help your own back pain?" and "What do you expect and hope to gain from physiotherapists?" are useful starting points to understand patients' perception of control about their NSCLBP prior to referral onto the group intervention.

Generalizability of included patients

Aside from the baseline differences in employment status, financial status and ELOC, there were no other significant baseline differences between those who completed the programme and those who dropped out of the programme.

The current study targeted NSCLBP patients with high FAB because this subgroup of NSCLBP patients is more likely to benefit from psychological approaches such as CBA intervention (Airaksinen et al., 2006; Savigny et al., 2009). This followed the current physiotherapy practice and NICE guidelines in the UK, which state those patients with significant psychological distress (such as high FAB), disability and failure to respond to other conservative treatments

are recommended to be managed by combined active exercises and CBA treatment (Savigny et al., 2009).

5.3 Aim 1- The effect of the CBCLBP programme on HLOC

This is the first study in literature demonstrating that a physiotherapy-led CBCLBP programme is effective in altering patients' HLOC belief.

Main finding:

No significant improvement of HLOC was seen before the programme (Phase A1); significant improvement of HLOC was found immediately after the CBCLBP programme (Phase B), and such improvement was sustained for six months following the programme (Phase A2).

What are the possible reasons why HLOC failed to improve during Phase A1 but improved during Phase B?

1. Effective delivery of self-management

Despite usual physiotherapy care (Phase A1) including giving relevant back care advice, information booklets and home exercise as form of self-management, advice on self-management is not simply a matter of information giving. It is about 'how' they could be effectively delivered (Savigny et al., 2009; Koes et al., 2010). This involves the practitioner offering affective communication (reducing concerns and worry, creating rapport), and cognitive reassurance (change in beliefs, changes in knowledge and understanding, and increased sense of control through education) (Pincus et al., 2013), as offered in the CBCLBP programme. An 18-months prospective study (Harkapaa, 1991) provided moderate evidence that the use of active self-care was significantly associated with high ILOC. It is possible that the CBCLBP programme offered more effective delivery of patients' self-management. When patients are able to self-manage their NSCLBP and its physical and psychological consequences, it may give them an increased sense of responsibility and personal control (ILOC), as opposed to believing in external (ELCO) and chance (CLOC) factors.

2. Biomedical vs Biopsychosocial treatment approach

Treatment modalities employed in individual physiotherapy (such as mobilization and manipulation) are predominantly bio-medically orientated and based on intervening on tissue levels, rather than bio-psychosocially oriented and aimed at altering patients' beliefs as in the CBCLBP programme. Consequently, patients' HLOC belief may not be fully addressed since cognitive factors were not deliberately targeted within the context of usual physiotherapy care. The improvement of HLOC observed in phase B suggested that the 'top-down' approach (**Figure 1.3**), such as CBA is superior compared to the 'bottom-up' approach (such as usual physiotherapy care) in altering patient's HLOC.

3. Physiotherapists' skills and experiences

The challenges for physiotherapists to embed a psychosocial element within physiotherapy practice are well documented (Foster et al., 2011). It may be that (1) physiotherapists' biomedically orientated beliefs may influence their clinical reasoning process (Daykin & Richardson, 2004; Foster et al., 2011), and (2) a much wider range of skills, knowledge and confidence are required when managing relevant psychosocial factors that may be beyond the scope of physiotherapy (Kent et al., 2009; Foster et al., 2011). The PI and the physiotherapists who led the CBCLBP programme were experienced clinicians (with at least 12 years clinical experience, Band 7 or above physiotherapist), who have special interest in NSCLBP. They all have basic CBT training and are highly experienced in NSCLBP and in delivering the CBCLBP programme. This factor, along with other non-specific factors such as a clear treatment rationale, a standardised and highly structured programme, an emphasis on active participation and self-responsibility may at least partially explain why HLOC significantly improved as a result of the CBCLBP programme.

In light of the above, it appears that the combination of (1) an effective delivery of self-management; (2) a biopsychosocial treatment approach treatment; and

(3) experienced physiotherapists in delivering the CBCLBP programme may be the reason for the difference in HLOC between phase A1 and phase B.

What treatment components of the CBCLBP programme may account for the significant improvement of HLOC in Phase B?

It is impossible to isolate the contribution each component of the programme made to the improvement of HLOC. However, based on the HLOC theory, which is about an individuals' belief of self-responsibility and empowerment for their own health (Wallston et al., 1978), the treatment components that are likely to be contributing factors for the improvement of HLOC may have included those:

1. Changing negative beliefs and attitude about pain (Foster et al., 2008);
2. Influencing adoption of coping strategy (Main & Spanwick, 2000; Carroll et al., 2002) and,
3. Self-management skills that empower patients to manage their own pain (Crowe et al., 2010).

1. Changing negative beliefs and attitude about pain

Patients with NSCLBP often hold various beliefs about their pain. For example, the belief that one has little personal control over pain (Crombez et al., 1999; Goubert et al., 2004a), that health professionals should “fix” their pain and being passive to rehabilitation (Kendall, 1997), that pain signifies harm and that one cannot modify one's own experience and that pain will be an enduring part of life in the future (Kendall, 1997).

The CBCLBP programme aims at changing patients' negative beliefs and attitudes. This is achieved directly by various education components such as providing higher level of information about NSCLBP, addressing patients' negative thoughts and beliefs, and anticipating that the key for success is individuals being proactive and that their beliefs and behaviour contribute to improved management (Waddell & Burton, 2005; Nordin et al., 2006).

Patients' negative beliefs and attitudes may also modify indirectly through exposure to graded exercise, pacing, relaxation and techniques for goal setting.

Several studies (of high to moderate risk of bias) have demonstrated that intervention based on CBA leads to modification of patients' beliefs about the nature and treatment of their pain (Coughlin et al., 2000; Walsh & Radcliffe, 2002; Moseley, 2002). Re-conceptualizing these negative beliefs means patients might become more acceptant about their NSCLBP, and hold more beliefs that they have a primary role and responsibility in managing and improving their condition.

2. Self-management skills

Several studies provided moderate quality evidence that physiotherapy delivered CBA intervention improved patients' self-care (Klaber Moffett et al., 1999; Klaber Moffett et al., 2006; Critchley et al., 2007). In the CBCLBP programme of the current study, patients were taught a range of self-management skills such as alternative pain relief, relaxation techniques, physical exercises, relapse management, pacing and goal setting. These self-care skills empower patients to be more autonomous and independent in their daily self-management and future relapses. Additionally, it also gives patients an advantage of maintaining some feeling of control, and enhancing the perception of their own ability to facilitate pain relief (Foster et al., 2010; Main et al., 2010).

This study did not collect qualitative data. Yet, some common themes among participants' informal verbal feedback during the last session of the programme (week 6) may give some insights into which specific aspects of the programme may link to improvement of HLOC beliefs. For instance, some participants reported that attending the course had changed the way they thought about their pain, and their role in the management. Reduction in negative beliefs, addressing unrealistic expectations from health professionals and introducing them to self-management techniques are frequently reported as the main

components that boosted their feeling of personal control and confidence in their ability to self-manage their NSCLBP. This informal feedback from patients gives some credence to support the theoretical assumption that belief modification and self-care components are likely to be attributed to improvement of HLOC beliefs in the present study. However, a future study combining quantitative and qualitative methods will be required to provide more information about the underlying mechanism and patients' perspective to reason why improvement of HLOC had occurred as a result of the programme.

What are the possible explanations for the sustained improvement of HLOC at 6-months (Phase A2)?

The non-significant improvement of HLOC seen in Phase A2 may be explained by the absence of weekly physiotherapy contact and support as offered in Phase B. However, it is still encouraging to see HLOC continued to improve but just at a slower rate up to 6-months. Two possible explanations may contribute to the sustained improvement of HLOC observed in Phase B:

1. Deep learning

It may be that the CBCLBP programme has promoted 'deep learning' of our patients, in which information is retained, understood and applied to problems at hand (Sandberg & Barnard, 1997), rather than 'superficial' learning, in which information is only remembered but not understood or integrated with attitudes and beliefs (Evans & Honour, 1997). 'Deep learning' is facilitated by high motivation of the learner (Sankaran, 2001) and presentation of relevant and personal information (Moreno & Mayer, 2000). Both of which are promoted in the CBCLBP programme, and both of which may have an effect on sustaining improvement of HLOC.

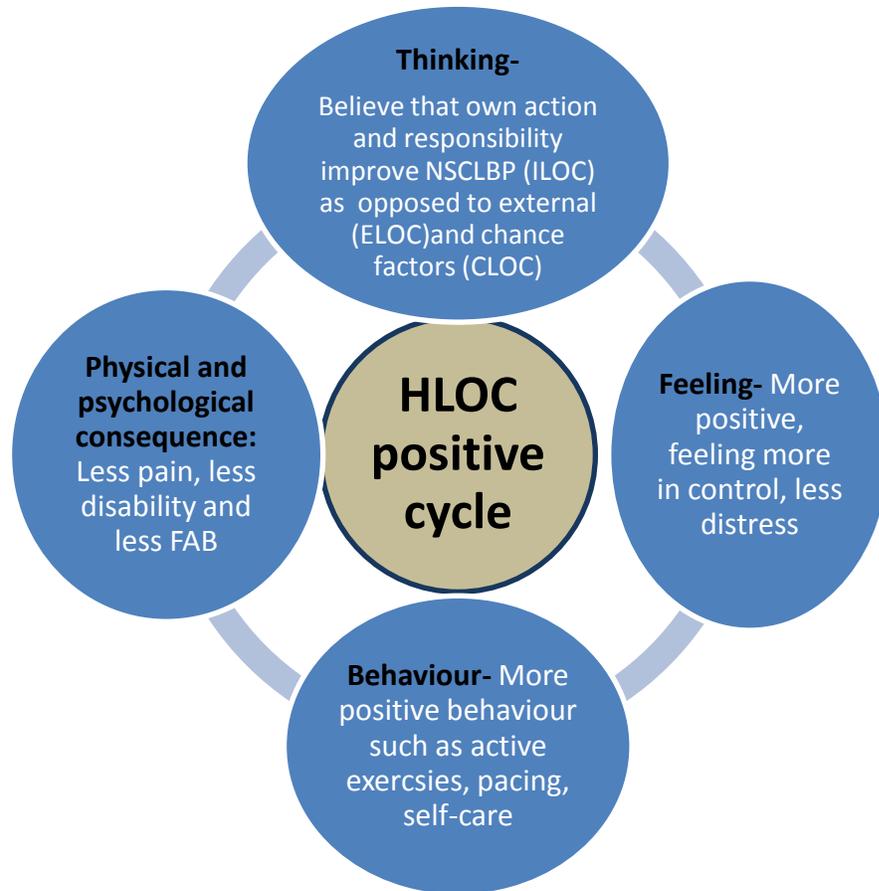
2. Advantages of improved HLOC

According to the literature, there are a number of advantages of holding high level of ILOC, low level of ELOC and low level of CLOC in terms of NSCLBP management. Patients with higher ILOC are more likely to describe their pain and disability as less intense (Sengul et al., 2010), have more effective coping

strategies to deal with pain (Harkapaa et al., 1991), have less FAB at activity (Richard et al., 2011), have better physical functioning (Keedy et al., 2014), have less psychological distress (Crisson & Keefe, 1998), and are more likely to take an active role and engage with exercise programmes (Harkapaa et al., 1991). The combination of these positive physical, psychological and behavioural consequences associated with improved HLOC possibly reinforce and continue to promote an individuals' belief that their improved NSCLBP is attributed to internal factors as opposed to external or chance factors over time. Thus, a sustained improvement of each subscale of HLOC is seen.

For instance, if patients with high ILOC believe that their NSCLBP has improved as a the result of practising daily home exercise, as opposed to a 'techno-fix' from physiotherapists or due to chance, they would probably be more likely to practise them regularly. Taking up daily home exercise not only improves physical (less pain and less disability) and psychological well-being (less distress and more active coping), it also has an advantage that patients feel in control of their own NSCLBP condition, and feel capable of performing daily exercises to preserve their improved NSCLBP condition. Such positive behaviour has an influence on patients inadvertently maintaining the thoughts and beliefs (higher level of ILOC, lower level of ELOC and CLOC), hence creating a positive cycle (see **Figure 5.1**) as proposed by the CBT model (Kerns et al., 2011).

Figure 5.1: Positive cycle of improved HLOC



The implication of this observation is that patients' response to the CBCLBP programme may depend on which HLOC is dominant. From this knowledge, we may deduce that improving HLOC could be one important factor in (1) influencing a more successful uptake of and adherence to the CBCLBP programme, and (2) sustaining the effectiveness of the CBCLBP programme.

ELOC dominant vs ILOC dominant

One important finding is that patients' HLOC changed from being ELOC dominant (1.62 points mean difference between ELOC and ILOC at week 1), to being ILOC dominant (9.27 points mean difference between ILOC and ELOC at week 6 and 12.57 points at 6-months; **Table 4.5** and **Table 4.7**). This means that, because of the CBCLBP programme, patients became more internally orientated (belief that they are responsible for their own back condition), as

opposed to being externally orientated (belief that his/her condition is determined by others or luck/chance) up to 6-months after the programme.

This finding supports the treatment philosophy of the CBA, which attempts to modify patients' beliefs (Vlaeyen et al., 1995c). This finding also supports the recommendation for the management of CLBP (Chou et al., 2007), in which healthcare providers should encourage self-responsibility and give patients an independent and active role in their management (Lorig & Holman, 2003). The present finding showing patients became ILOC dominant at week 6 and 6-months is the reflection of successful implementation of the programme.

Comparison to other studies- validity issues

No direct comparison can be made between this study and from existing evidence because this is the first study examining the effect of a physiotherapy programme on HLOC. However, the present findings support some previous studies, which found intervention with some sort of CBT component leads to change in HLOC beliefs in chronic pain and CLBP (Harkapaa et al., 1991; Coughlin et al., 2000; Rybarczyk et al., 2001; Spinhoven et al., 2004; Klaber Moffett et al., 2006; Keedy et al., 2014).

It must be considered that heterogeneity is among these studies, including variation in interventions, clinical setting, professions who delivered the programme and the reporting of the outcomes. In addition, the average quality of the available evidence is of high to moderate risk of bias. These methodological limitations include heterogeneous group (Klabe r Moffett et al., 2006), selective bias, short follow-up (Keedy et al., 2014; Harkapaa et al., 1991), under-powered sample size (Coughlin et al., 2000); inappropriate outcome measures (Coughlin et al., 2000) and high dropout (Spinhoven et al., 2004). Compared to the current study, which uses appropriate validated outcome measure to assess HLOC, powered sample size, longer follow-up period (6-months) and complete follow-up data (no follow-up dropout), these

methodological strengths mean our findings are likely to have a higher internal validity compared to previous studies.

This current study partly supports the findings of Klaber Moffett et al. (2006), which showed a physiotherapy pain management programme using CBA improved ELOC, but not in both ILOC and CLOC at 6-months. However, it must be noted that the pain management programme employed by Klaber Moffett et al. (2006) was only brief (2-3 hours), whereas the patients' contact time of the CBCLBP programme in the present study was approximately 13 hours. This might imply that the duration of the intervention needs to be sufficient (at least 13 hours) to bring favourable and consistent changes in patients' HLOC beliefs. Another major weakness of study by Klaber Moffett et al. (2006) is that they have included patients with neck pain and back pain of mixed subacute and chronic duration, this may explain why the MHLC is lack of sensitivity to change.

It is acknowledged that the HLOC construct is only one piece of the much wider and more complex psychological context in understanding patients' with NSCLBP. However, considering HLOC beliefs are associated with the clinically important outcomes of NSCLBP (including pain intensity, disability and FAB), and positive health-related behavioural changes (such as better self-care and active coping) that both patients and physiotherapists seek to address in their treatment, improvement of HLOC should be regarded as a successful treatment outcome for physiotherapy.

5.4 Aim 2- To examine the effect of the CBCLBP programme on pain intensity, disability and FAB

Main finding:

No significant improvement of pain intensity, disability and FAB were seen before the programme (Phase A1); significant improvement of all three outcome measures was observed immediately after the CBCLBP programme (Phase B). Such improvement was sustained for six months following the programme (Phase A2).

Why pain intensity, disability and FAB failed to improve during Phase A1, but improved in Phase B?

1. 'Bottom-up' vs 'Top-down' approach

In our study, all NSCLBP patients were with high FAB. Patients with high FAB probably consider pain as more threatening, more catastrophic thoughts, less likely to confront pain problem and be less active in coping (Jackson et al., 2005). Although the usual physiotherapy care attempts to address the sensory and biomedical aspects of pain, it predominantly utilises a 'bottom-up' treatment approach (i.e. intervene pain on tissues levels such as manual therapy, electrotherapy and exercises). This therapeutic approach could be inadequate for NSCLBP patients with high FAB, in which cognitive and behavioural factors are likely to be more an enduring barrier and an important part their pain experience and persistent disability (Chou & Shekelle, 2010; Ramond et al., 2011). This may explain why our patients responded better to a 'top-down' approach (**Figure 1.3**), such as the CBCLBP programme that directly addresses the cognitive and behavioural aspect of pain. The difference between Phase A1 and Phase B illustrates that the 'top-down' treatment approach have more to offer to this sub-group of NSCLBP patients, than the traditional 'bottom-up' treatment model (Moseley, 2003b).

2. Reduction of threatening input

It is documented that the threat value of pain in NSCLBP patients is more likely to be contributed by psychological, behavioural and cognitive realm (such as attitudes and beliefs) rather than the physical one (Moseley, 2003a; Moseley, 2007). Increased threatening input of the brain results in overprotective responses such as: fear, anxiety, negative beliefs, avoidance behaviour and hypersensitivity of pain neuromatrix.

One focus of the CBCLBP programme is to address pain belief and attitude by increasing patients' understanding about pain, and help patients to recognise the complex physical and psychological consequence that drives ongoing pain. This approach may lower the perceived degree of threatening input of the brain, resulting in less pain sensitivity, less fear and better physical performance. In contrast, although manual therapy strategies given during usual physiotherapy care may have an inhibitory effect on nociceptive input which gives short-term pain relief (Vicenzino et al., 1998), such therapeutic approach do not address the non-nociceptive input of pain (cognitive-evaluative) (Moseley, 2003a). In addition, the biomedical oriented treatment approach may reinforce patients' negative belief about their pain such as something is wrong and damage in their tissues. This may in turn activate the threatening input and exaggerate overprotective responses, hence result in lack of improvement across sensory, physical and psychological domains as observed in Phase A1.

3. Multi-dimensional treatment approach

The CBCLBP programme in the current study consisted of various components. This means that the multi-factorial nature of NSCLBP is more fully addressed by the CBCLBP programme than individual physiotherapy. This result is partly consistent with the study by Klaber Moffett et al. (2004), which reported active exercise plus CBT education was more effective than usual GP care at reducing disability at 12-months to patients with subacute CLBP and high FAB.

Although all patients were given basic pain education, self-management advice and home exercise programme during Phase A1, there was no significant

physical and psychological improvement. This may imply that the additional use of CBA education component and supervised graded exercise component introduced in Phase B may have a bigger and possibly a more direct impact on patients' physical and psychological health, than individual physiotherapy care which is without these components.

4. Individual vs Group therapy

The biggest advantage of group therapy is probably helping patients to realise that he or she is not alone, and there are other people who have a similar problem. This often can be a huge belief for patients with NSCLBP when they may face similar issues such as FAB, anxiety and catastrophizing.

Being in a group may also give patients an opportunity to open up and communicate their thoughts and feelings, and to provide mutual support to each other and offer suggestion to problem-solve and deal with a particular problem that patients may not have thought of.

For instance, during the CBCLBP programme, there were group discussions and group problems solving on: identifying and challenging unhelpful thoughts, personal barriers of against physical activities, over-/ under- activity, goal setting, and discussion on group experience of alternative pain control and self-management. Physiotherapists acted as a moderator and facilitator for each theme during the group activities. These exercises in a dynamic and supportive group environment may facilitate patients to change their old way of thinking, feeling and behaving in favour of more positive and productive ways. The advantage of being in group therapy, as opposed to individual therapy, may be one of the contributing factors in explaining the difference between Phase A1 and Phase B.

From the clinical perspective, it is reasonable to suggest that physiotherapists should consider referring those NSCLBP patients with high FAB onto the

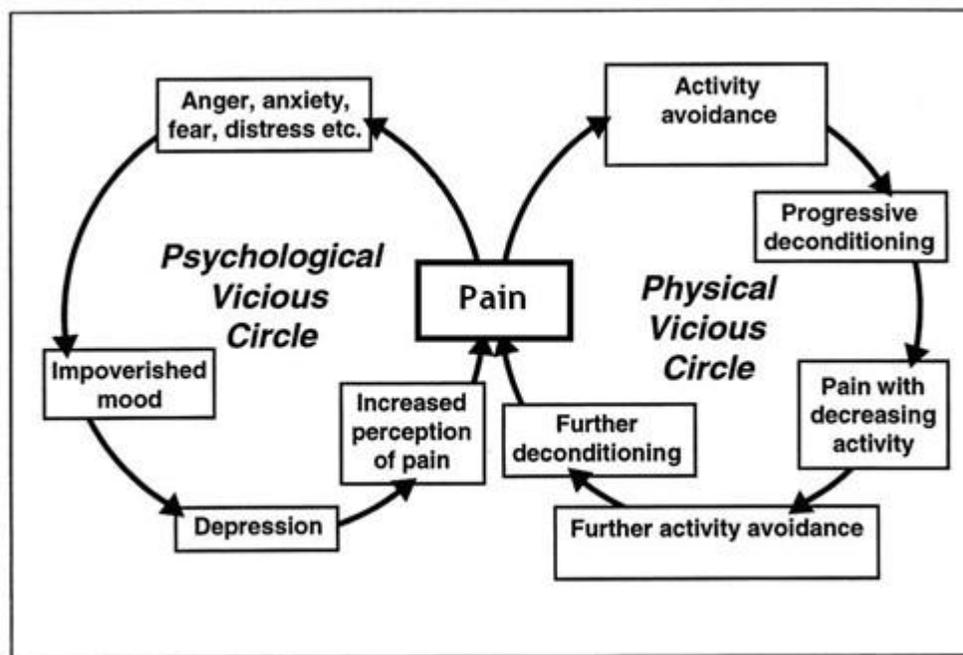
CBCLBP programme as their first-line intervention, as opposed to their last option when patients fail to respond individual physiotherapy.

What treatment components may account for the significant improvement observed in Phase B?

Despite recognizing the importance and benefits of both physical and psychological elements, until now, it is unclear whether clinical improvement is reached by the CBA education itself, or the exercise therapy, or the combination of both (Mannion et al., 2001; Smeets et al., 2006a).

The various treatment components of the CBCLBP programme probably break the vicious physical and psychological cycle as described below (**Figure 5.2**).

Figure 5.2 Physical and Psychological vicious cycle of pain (Newell, 2011)



It is impossible to isolate the contribution that which specific components of the programme made to the improvement of pain, disability and FAB, since it is likely due to the combination of the following components and their effect from a neurophysiological, cognitive/behavioural and physical perspective of pain.

1. From a neurophysiological perspective

The vicious cycle has been found to be broken with pain neuroscience education (Nijs et al., 2011; Moseley, 2004). Studies in patients with NSCLBP have shown that education on pain physiology improves patients' pain-related attitudes and beliefs (Nijs et al., 2011; Moseley, 2004), and is directly associated with better symptomatic and physical outcomes even when there is no opportunity to be physical active (Moseley, 2004; Moseley et al., 2004).

The usual physiotherapy care may include some basic physiology of pain and anatomy of the spine. However, the problem in NSCLBP patients is 'how' to explain the cause of their pain when no obvious anatomic defect or tissue damage can be found. The CBCLBP programme provided high-level of pain physiology information such as explanation of central sensitization, mechanism of acute pain vs chronic pain, and pain neuromatrix. It also clarifies patients' misunderstanding about pain. The complex concept of chronic pain was delivered using patients' lay-language and metaphor based on the book 'Explained Pain' (Butler and Moseley, 2003). For instance, the complex concept of sensitization is explained as a burglar house alarm which set too sharp, which leads to constant 'false' alarming of the house even there is no break-in. The purpose of the house alarm is no longer useful, which in turn may result in unnecessary fear, stress and anxiety- all the factors that amplify the sensitivity of CNS (O'Sullivan, 2005; Woolf, 2011).

The education of pain physiology may alter knowledge about pain states and convince patients that (1) hypersensitivity of CNS rather than local tissue damage is the cause of their presenting symptoms, and (2) that there are many factors that contribute to the maintenance of pain (Gracely et al., 2004). When pain is appraised as less dangerous by the patient, the threatening input to the brain reduces. Positive cognitive and emotional factors (such as less fear, less conscious need for protection, positive coping, realistic beliefs, awareness of pain mechanisms, positive emotions) then modulate pain in a positive way via forebrain (O'Sullivan, 2005; Woolf, 2011) as well as de-activate the pain

neuromatrix (Moseley, 2003a). Hence, lowering sensitivity of CNS (Woolf, 2011) and increasing pain threshold at which subsequent improvement of pain intensity, disability and FAB are seen as a result of the programme.

Patients who have pain want to have a satisfactory explanation for their pain (Ring et al., 2005). In comparison with basic pain education in usual physiotherapy care, it is possible that higher level of pain education provides patients with a physical cause of their ‘non-specific’ pain. A common example might be: abnormal regulation of pain signals within the CNS, which become sensitized. Rather than leaving patients feeling concerned about their ongoing pain, and ‘shop’ to seek a satisfactory explanation for their pain and treatment. When patients acknowledge the complexity of pain, and that the influence of physical, psychological and behavioural factors can be related to the existence of chronic pain, it might motivate them to engage with the CBA education and physical components of the CBCLBP programme, hence allowing for a better physical and psychological outcome.

2. From a cognitive and behavioural perspective

A variety of the CBA education components were used in the current study (**Figure 3.5**). These components were not designed to treat pain and disability directly as in the biomedical model (which assumes individuals are the passive recipients, and expect symptoms to recover by receiving specific therapy such as medication (Nordin et al., 2006). Rather, the CBA treatment philosophy aimed to address the underlying psychological and behavioural factors (such as patients’ belief about pain, passive coping and FAB), hence the associated pain and disability were reduced.

For example, the operant component of the CBCLBP programme such as pacing, goal setting and graded activity management aim to reinforce health behaviour and reduce pain behaviour (Ferster & Skinner, 1957). This enables patients to return to a more active lifestyle, and increases their range and style of active coping. The cognitive component such as explanation of pain physiology, fear-avoidance model, and skills for managing unhelpful patterns

of thinking (for example, belief that one is disabled by pain; or that pain signified damage) may influence patients' adoption of coping strategies, reduce FAB and their psychological impact associated with pain and disability (Beck, 1979b; Walsh & Radcliffe, 2002) The respondent component such as use of relaxation technique helps to reduce stress, pain-related muscular tension and aid sleep (Henschke et al., 2010).

As mentioned, psychological factors including emotions, stress, illness perception, pain cognition and pain behaviour are potential sustaining factors of central sensitization (Curatolo et al., 2006; Diatchenko et al., 2006). The various CBA education components covered in the CBCLBP programme as well as the exercise component, are also likely to directly or indirectly decrease the hypersensitivity of the CNS (Nijs and Van Houdenhove, 2009; Nijs et al., 2009).

3. From a physical perspective

Exercise component

A graded supervised exercise programme (including stretching, postural control, muscle strengthening, core stability exercises and aerobic exercises) and a home exercise programme were used in this study (**Section 3.6.6**). Exercise therapy is shown to improve physical pain and disability (Liddle et al., 2004; Hayden et al., 2005a; Hayden et al., 2005b; Krismer & Van Tulder, 2007), as well as reducing FAB (Mannion et al., 2001), depression and catastrophizing (Smeets et al., 2006b). However, it cannot assume that the observed positive outcome is directly attributable to changes in the musculoskeletal system. In fact, evidence emerged from systematic reviews (Steiger et al., 2012; Airaksinen et al., 2006) and individual study (Renkawitz et al., 2006) did not strongly support the relationship between changes in clinical outcome (pain, disability) and changes in physical function (range of motion, strength and muscular endurance). This may imply that the improvement in pain, disability and FAB observed in Phase B may not be the sole result of musculoskeletal changes of exercise therapy. Rather, it may be other changes elicited by exercise therapy responsible for these self-reported improvements

such as: improvement in self-efficacy, coping strategies and fear-avoidance (Mannion et al., 2001), modification of motor control patterns as a consequences of re-weighting of sensory input (Popa et al., 2007), improvement in motor control impairment resulted in less ongoing abnormal tissue loading and peripherally driven nociceptive sensitization (O'Sullivan, 2005), altered cortical representation of the back (Crombez et al., 1999; Woby et al., 2008) or simply from a positive patient/ therapist relationship/ interaction (Kluber Moffett & Richardson, 1997).

Several systematic reviews of NSCLBP (Krismer & Van Tulder, 2007; Hayden et al., 2005b; Liddle et al., 2004; Van Middelkoop et al., 2011) concluded that exercise therapy only demonstrates modest improvement in pain and function in NSCLBP. The difference observed in Phase A (without CBA component) and Phase B (with CBA component) may suggest that the beneficial effects of exercise therapy are more due to the central effect (i.e. involving cognitive, psychological and neurophysiological (cortical organisation), rather than local (such as muscles and joints) in this subgroup of NSCLBP patients.

Changing patients' beliefs such as FAB (Twomey & Taylor, 2000) and pain perception (Moseley, 2002; Moseley 2004) are associated with better physical performance in CLBP patients. If the ultimate goal of exercise therapy in the CBCLBP programme is to get patients moving again, and be able to confront their fear and avoidance about physical activities, then the benefit of conventional exercise therapy will only be succeeded by supplemented with the CBA intervention in this subgroup of NSCLBP patients. An additional CBA component may be the underlying mechanism to facilitate the physical and psychological effects of exercise, and to achieve more desired symptomatic outcomes.

During the CBCLBP programme, patients were instructed to safely break the fear-avoidance cycle and physical deconditioning by engaging a supervised graded exercise programme. Although exercise therapy directly aims at

improving patients' physical functional ability, patients' experience of completing the prescribed exercises in a paced and graded manner without experiencing undue harm may decrease pain behaviour and reduce their FAB, hence may lead to less pain and less disability, as proposed in the fear-avoidance model (**Figure 2.2**) (Lethem et al., 1983; Vlaeyen & Linton, 2000).

From a neurophysiological perspective, with experiencing no harm in completing exercises in a graded exposure manner means reducing the threat associated with exercises via both nociceptive and non-nociceptive mechanism (Moseley, 2003a). The consequence of these responses is likely to: decrease sensitivity of CNS (Woolf, 2011), de-activate pain neuromatrix (Moseley, 2007) and influence pain modulation (secondary to cognitive and emotional factors) (O'Sullivan, 2005; Zusman, 2002). This in turn increase pain threshold, increase tissue nociceptive tolerance and facilitate the positive cognitive-evaluative factors such as positive coping, positive beliefs and positive emotions.

In addition, with physiotherapists monitored progress weekly and provided appropriate reinforcement for compliance, correction of misperception of pain following exercise and problem-solve barriers to adherence, patients may gain trust in the function of their back, hence adjust their negative cognitions (such as FAB) and appraisals (Mannion et al., 2001), while simultaneously producing benefit in other outcome domains such as pain and disability.

The exercise component of the CBCLBP programme also included a session of Pilates and hydrotherapy. These other choices of exercises may shift patients' emphasis from the 'reversal of physical de-conditioning' to the 'adoption of enjoyable physical exercises'. It may also open up the array of potential choices of different exercises to be carried out, hence allowing patients to consider issues of cost, patients' preferences and access to facilities, which are all important considerations for continued self-care in the future.

Long-term maintenance of benefits from exercise requires patient compliance and active engagement. It has been shown that patients who have less FAB about activity have better compliance with a physical programme (Twomey & Taylor, 2000). Higher level of ILOC is also associated with more engagement in beneficial health behaviours such as regular exercise (Affleck et al., 1987; Burker et al., 2005). In view of this, both increases in ILOC and reduction of FAB reported in the current study may imply that our patients were probably more likely to gain the physical and psychological benefits from exercise and more likely to maintain these benefits in the longer-term. This may partly explain why patients' self-reported pain intensity, disability and FAB continued to improve at 3-months and 6-months follow-up.

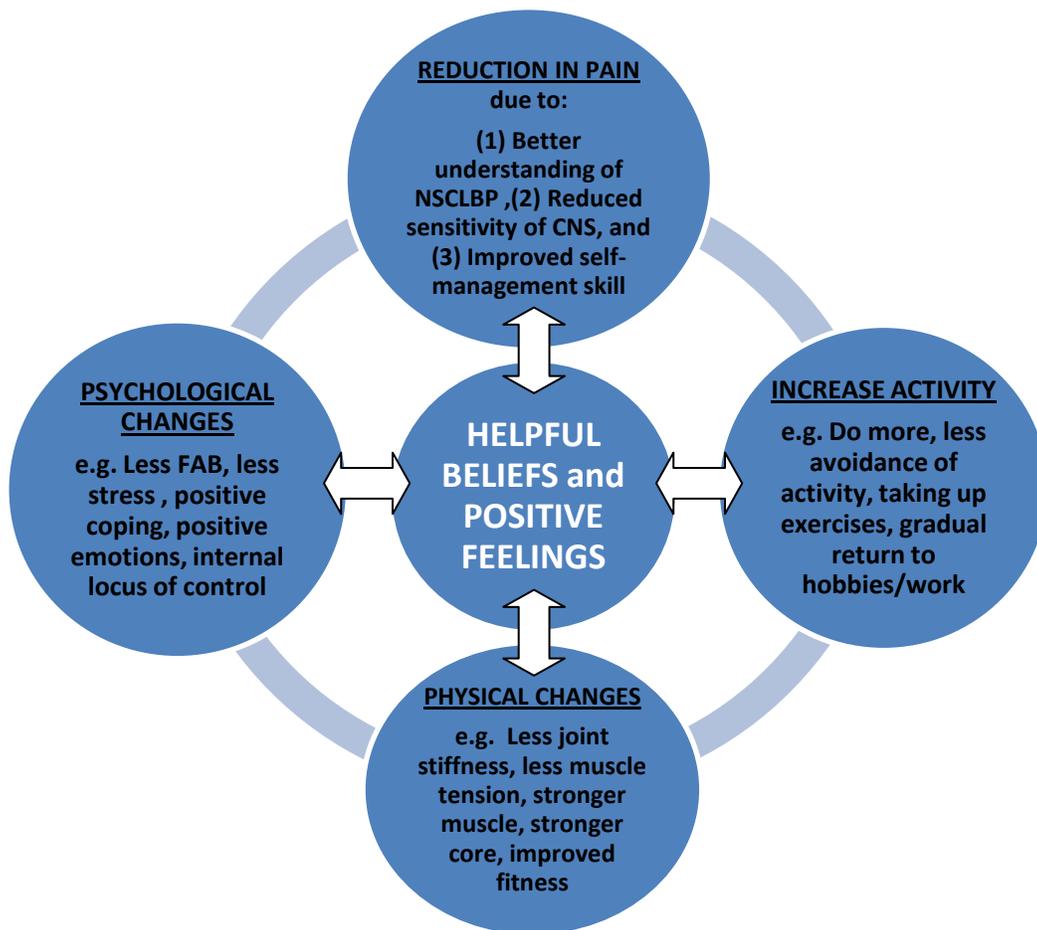
Self-management component

It has been reported that enhancing self-management skills showed modest improvement in pain intensity, disability and FAB, compared to usual care (Moore et al., 2000). When compared to treatments such as physiotherapy, exercise and acupuncture, the effect of self-management was equally or less effective in reducing pain and disability (Oliveira et al., 2012a). A number of self-management techniques (such as information booklet, pain control, relaxation, problem solving, pacing, regular exercise, managing flare-up and relapse prevention) were introduced with the aim of empowering patients to take responsibility and self-care in managing symptoms. By being more knowledgeable about their chronic condition and encouraging patients to take lead in self-management result in positive reinforcement, greater confidence and independence. Having a more positive belief (higher ILOC, lower ELOC, lower CLOC and less FAB) may also aid patients approach to their self-management with a more positive attitude or 'getting on with it' rather than conceived of self-management as a 'fight' and becoming overwhelmed by it. These cognitive, behavioural and emotional responses from effective self-management may improve the physical and psychological consequence of NSCLBP.

What are the possible explanations for non-significant but sustained improvement during Phase B?

Beliefs lie at the heart of the CBA treatment because how patients think and feel about their pain affects what they do about it (Beck, 1979a; Beck, 1979b). Thoughts, beliefs, emotions and behaviours interact with each other and are targeted for improvement using a variety of methods and skills as discussed. The sustained improvement observed at 6-months is likely to be the reflection of a maintenance cycle effect (**Figure 5.3**). The variety of treatment components either change patients' behaviour directly, or change behaviour indirectly by changing their beliefs. When positive behaviour inadvertently reinforces positive beliefs and emotions, this creates the positive cycle which results in the maintenance of improved pain, disability and FAB.

Figure 5.3: Positive cycle in sustaining the improvement of pain intensity, disability and FAB



Between 6 weeks and 3-months

Only disability showed significant further improvement at 3-months, while both pain intensity and FAB did not. This further significant improvement in disability at 3-months perhaps indicates that the various treatment component of the CBCLBP programme is mostly effective in reducing pain-related disability. It is also a reflection that patients are doing more and having better function even with some extent of pain.

The reason for non-significant further improvement in pain intensity and FAB at 3-months may have something to do with the much improved pain intensity and low FAB immediately after the programme (mean VAS= 3.95 and mean TSK= 33.15 at week 6). Given pain is a multi-faceted experience emerging from the dynamic interplay of a patient's physiological state, thoughts, emotions, behaviours and social influences, it is unrealistic to expect patients with NSCLBP to be pain-free and have no maladaptive cognitions such as FAB. The already mild pain intensity and lower FAB at week 6 may be the reason for no further significant improvement at 3-months.

Between 3-months and 6-months

It is unexpected to find that pain intensity showed significant further improvement at between 3-months and 6-months, because the CBCLBP programme did not target pain relief specifically. One possible explanation for this late positive result could be that patients in the study may develop more effective self-care techniques and coping strategies over time, which allows them to minimize the impact of their pain on their daily activities. Beliefs about pain have also been shown to play a significant role in persistence of pain, and how people adapt to it (Pincus & Morley, 2002; Walsh & Radcliffe, 2002). Therefore, it is also possible that patients' negative pain beliefs are successfully modified following participation of the CBCLBP programme and patients become more acceptant about their pain with time, as previously mentioned in the literature (Aldrich et al., 2000; McCracken et al., 1998).

Both disability and FAB showed no further significant reduction between 3-months and 6-months. This may be partly due to the absence of regular physiotherapy contact and support as provided in Phase B. This may also be due to the already low FAB (mean TSK= 32.27) and low disability level (RMQ= 7.76) at 3-months. Hence the potential to further improve disability and FAB at 6-months may be lessened. Study has shown FAB to be present in pain-free people (Houben et al., 2005). Pain-free people in the general population reported pain-related fear comparable to, or only slightly lower, than acute and chronic pain patients (Houben et al., 2005).

Influences of improved HLOC related to sustained improvement at 6-months

In agreement with the present study, evidence suggested that improved HLOC is associated with pain reduction (Sengul et al., 2010), disability (Sengul et al., 2010; Haldorsen et al., 1998), and FAB (on activity) (Richard et al., 2011). Therefore, it is possible that the sustained HLOC improvement seen in Phase A2 may also contribute to the sustained effect of pain intensity, disability and FAB observed in Phase A2.

Comparison to other studies- similarities and differences

In comparison with other physiotherapy studies using comparable outcome measures, with similar interventions and follow-up period, the present study showed 45% reduction in pain intensity (as evaluated by VAS) between week 1 and 6-months (**Table 4.11**), while the study by Johnson et al. (2007) found 42% pain intensity reduction and Critchley et al. (2007) found 29% pain intensity reduction at 6-months in the pain management arm.

In respect of disability, our study demonstrated 35% reduction in disability score (as evaluated by RMQ) between week 1 and 6-months (**Table 4.13**), while the study by Johnson et al. (2007) revealed 39% improvement, and the pain management arm by Critchley et al. (2007) showed 46% reduction in disability score at 6-months.

The present findings achieved similar improvement in pain intensity and disability between week 1 and 6-months when compared to these previous studies. Possible explanation could be due to the similarities between them, including (1) use of validated outcome measures for measuring pain (evaluated by VAS or NRS) and disability (by RMQ); (2) similar baseline pain and disability score of included patients (patients of mild/moderate pain, and moderate level of disability); (3) similar intervention (highly structured programme of similar treatment rationale, content, duration and method of delivery), and (4) led by physiotherapists in a clinical environment. Collectively, this evidence may imply that the physiotherapy CBCLBP programme is effective in reducing pain and disability in this subgroup of patients with a highly-structured programme of 12- 16 hours of duration.

The current study showed a 24% improvement in FAB (as evaluated by TSK) from week 1 to 6-months (**Table 4.15**). Comparing to Lamb et al. (2010), who demonstrated a 48% reduction in FAB (as evaluated by FABQ), the current finding is less favourable comparatively. It is noteworthy that patients in the present study had a high baseline of FAB (mean TSK = 42.3; a cut-off score of ≥ 37 reflect high level of FAB), and investigated patients with NSCLBP only (i.e. at least more than 3-month duration of LBP). In contrast, Lamb et al. (2010) reported a lower baseline FAB value (mean FABQ = 6.3 as evaluated by FABQ 0-24; a cut-off score of ≥ 14 reflect high level of FAB about physical activity) (George et al., 2010), and included both subacute and CLBP patients (minimum of 6 weeks duration of LBP).

It is acknowledged that the TSK and FABQ are different instruments for measuring pain-related fear. However, it has also been shown that both measurements have an adequate concurrent validity (i.e. there is consistent relationship between the scores from the two measurement procedures) (Swinkels-Meewisse et al., 2003b). This gives confidence that both instruments are measuring the same construct (Lundberg et al., 2011). Therefore, it is plausible that the baseline difference of FAB and duration of LBP might

explain a less favourable improvement in the current study when compared to the study by Lamb et al. (2010).

Targeting NSCLBP patients with psychological risk factors

High baseline FAB and longer duration of NSLBP may hamper the potential to improve FAB outcome. A systematic review assessing the influence of FAB on the outcome of various treatments in RCTs in patients with LBP (Wertli et al., 2014b), concluded that those patients with high baseline scores of FAB (as evaluated by TSK and FABQ) had more pain and/ or disability and were less likely to return to work. The greatest treatment efficacy (graded activity and physiotherapy CBA education) was seen when high FAB was addressed in those patients presenting relatively early in their presentation (i.e. LBP less than 6 months duration), but not in those with LBP for more than six months. The present finding shows that patients with high FAB and more than 6-months duration also produce favourable result following the programme. However, since there is no 'low fear' comparison group in the current study, we cannot conclude that the CBCLBP programme targeting patients with high FAB is any more useful than patients with low FAB.

The significant difference between Phase A1 and Phase B suggested that the CBCLBP programme is more effective than usual physiotherapy care in patients with high FAB. This is in contrast with some existing evidence, which concluded that active rehabilitation (physical exercise class with using CBA) has no effect when compared to manual therapy (Hough et al., 2007), and little effect when compared to usual care (Kent & Kjaer, 2012) at reducing activity limitation when targeting NSLBP patient with psychosocial characteristics. However, it must be noted that these studies included a mixed duration of NSLBP population. Acute/sub-acute and chronic LBP patients differ in all physical and most psychological variables (Grotle et al., 2010). Heterogeneity in patient's population may dilute the effect of the CBA active intervention. Inclusion of a homogenous population (i.e. NSCLBP) in this study has

advantages to draw more focused conclusion specific to the characteristics of this challenging subgroup of NSLBP population.

Questioning the current guideline of 100 hours

The total duration of the programme in the current study was approximately 13 hours (i.e. six two-hour sessions CBCLBP programme and one, one hour session of hydrotherapy). This is substantially less than the NICE guideline recommendation, which suggests use of intensive combined exercise and CBA treatment for 100 hours over up to 8 weeks (Savigny et al., 2009). However, such a recommendation from NICE guideline is predominantly based on the findings of only one systematic review on CLBP (Guzmán et al., 2001), in which 10 RCTs were considered. Methodological flaws included: lowering the cut-off point in the assessment of methodology quality, an undue focus on selected clinical outcomes and selected patients sub-group, may also weaken the validity of their conclusion. Therefore, the guideline recommendation of 100 hours drawn from this systematic review (Guzmán et al., 2001) is highly questionable and is high risk of bias.

The guideline of 100 hours over 8 weeks per patient for an NHS physiotherapy outpatient setting is also challenging (i.e. approximately 12.5 hours per week per patient). For instance, many NHS physiotherapy outpatient departments would not be able to provide the guideline value. According to a survey of NHS Physiotherapy waiting times, workforce and caseload conducting between Year 2010 and 2011 in the UK (CSP, 2011), musculoskeletal physiotherapy had the highest caseload among all other physiotherapy outpatient services. The waiting time for the majority of musculoskeletal outpatient service in the UK was 6-8 weeks, the mean patients referrals into musculoskeletal outpatient physiotherapy was 11668 per year, and 32% respondents (outpatient physiotherapy managers) reported that waiting times had increased compared to the previous year (CSP, 2011). Possible reasons for increased waiting time included: staffing related issues, increased referrals, changes in service organisation (e.g. merger) and changes in commissioning/ planning. The low capacity and high demand of the NHS musculoskeletal service under the

current financial climate of the NHS means that the provision of 100 hours over 8 weeks is highly difficult, especially for the big referrer such as NSCLBP.

Findings of the current study, and evidence of previous studies with similar interventions and baseline profiles show that 78 hours (Smeets et al., 2006a); 12 hours (Critchley et al., 2007); 16 hours (Johnson et al., 2007) and 9 hours (Lamb et al., 2010) are adequate durations to demonstrate effectiveness. This raises the question whether the NICE guideline value of 100 hours intensive rehabilitation is necessary for all NSCLBP patients with moderate/ high level of symptoms and psychosocial distress presenting in out-patient physiotherapy?

NICE is currently updating its 2009 guidelines on NSLBP management (Savigny et al., 2009), and has published draft recommendations for public consultation in March 2016. In their draft recommendation on NSLBP and sciatica, the use of combined physical and psychological programme (such as the CBCLBP programme) remains in the recommendation. However, it is no longer specified the required hours for the use of combined physical and psychological programme for any produced effect as stated in its 2009 guideline (Savigny et al., 2009). Based on our present findings and other available evidence, we suggest that treatment hours of approximately 13 hours may be sufficient for producing positive clinical outcomes for this subgroup of NSCLBP patients (i.e. with moderate level of pain, moderate level of disability and high FAB).

Refinement of the NICE guidelines is much needed to illustrate which type of patients may benefit from less intensive rehabilitation and can be treated by physiotherapists, such as the CBCLBP programme, and which type of patients may need 100 hours intensive multi-disciplinary rehabilitation or onward referral to psychologists or cognitive-behavioural therapists. This would further improve clinical decision-making and avoid long treatment hours unnecessarily. Such an idea also concurs with the current NICE draft guideline (March 2016), which adding the recommendation of using risk assessment tool such as the

STarTback tool to inform decision-making about stratified management. However, the NICE guideline draft has just finished the public consultation period in May 2016. Hence any change and update have not yet been published.

5.5 Aim 3- To determine if there is any relationship between patients' HLOC, pain intensity, disability and FAB

This question was answered by examining two relationships: (1) the correlation that existed between changes in HLOC, pain intensity, disability and FAB; and (2) to what extent changes in ILOC, ELOC, CLOC and other variables (i.e. pain and/or disability and/or FAB), can predict changes in pain intensity, disability and FAB (i.e. outcome of interest).

Main findings on the correlation between pain intensity, disability, FAB and HLOC

- A significant relationship was found between reduction of pain intensity, reduction of disability and reduction of FAB. This suggests that these three key clinical elements of NSCLBP were inter-related.
- Increase in ILOC, reduction in ELOC and reduction in CLOC were significantly associated with reduction in pain intensity.
- Increase in ILOC was significantly associated with reduction in disability, but reduction in disability showed no significant relationship with reduction in ELOC and reduction in CLOC.
- Increase in ILOC, reduction in ELOC and reduction in CLOC were significantly associated with reduction in FAB.

5.5.1 Correlation between HLOC, pain intensity, disability and FAB

Correlation between FAB and disability

Reduction of FAB was associated with reduction of disability in this study. A possible explanation could be that the vicious cycle of the fear-avoidance model is broken. i.e. as FAB decreased, threat perception, avoidance behaviour and hypervigilance also decreased, which consequently reduced disability. This

finding lends further support to the fear-avoidance model, which proposed that fear of movement or (re)injury is associated with disability (Vlaeyen et al., 1995a; Vlaeyen & Linton, 2000). This present finding is also in agreement with systematic review (Ramond et al., 2011), and other individual studies, which consistently reported a positive relationship between disability and FAB (Crombez et al., 1999; Thomas et al., 2010; Elfving et al., 2007; Woby et al., 2004b; Grotle et al., 2004).

Interestingly, studies that showed FAB is weakly correlated to disability often included the examination of both FAB and self-efficacy within the same study (Woby et al., 2007a; Pincus et al., 2006; Denison et al., 2004). The discrepancy with these previous work may suggest the possibility that self-efficacy could be a factor that mediating between FAB and disability.

Correlation between pain intensity and disability

In the current study, reduction of pain intensity was related to reduction of disability. This is consistent with a number of studies which reported a positive relationship between pain intensity and disability (Thomas et al., 2010; Bair et al., 2008; Peters et al., 2005; Woby et al., 2004a; Turner et al., 2004). However, there are also other studies reported weak or even non-existing associations between pain and disability (Meyer et al., 2009; Reneman et al., 2007; Waddell et al., 1992; Waddell et al., 1993; Vlaeyen et al., 1995a; Vlaeyen et al., 1995b). There seems to be no common ground to explain the similarities and differences between the current study and previous studies. The relationship between pain and disability is not straight-forward, particularly in NSCLBP patients. The inconsistent finding highlights the complexity between pain and disability. A possible explanation for inconsistent finding could be that LBP is associated with a number of physical, psychological and social factors (Gatchel et al., 2007; Waddell, 1992), which are also associated with disability (Pincus et al., 2002; Waddell & Waddell, 2000). With heterogeneity among studies such as variation in NSLBP population, variation in patients' baseline characteristics

and different study designs, this may distort the relationship between pain intensity and disability.

Another possible explanation could be that there are other factors may mediate the relationship between pain intensity and disability. For instance, it has been shown that employment status (Van den Hout et al., 2001) and ILOC and catastrophizing (Spinhoven et al., 2004; Smeets et al., 2006b) maybe the factor that mediates the relation between pain and disability.

Correlation between FAB and pain intensity

An association was found between reduction of FAB and reduction of pain intensity in this study, suggesting that as FAB decreased, so did the level of pain intensity, and vice versa. Severity of pain is determined by patients subjectively, and patients' evaluation of pain affect the level of pain-related fear that may develop, and hence the behaviour of avoidance of movement (Asmundson et al., 2004). From a neurophysiological perspective, FAB is a negative cognitive factor that can drive and amplify pain through the CNS via the forebrain (Zusman, 2002; O'Sullivan, 2005). Therefore, when FAB reduces, pain intensity may also reduce due to decrease in hypersensitivity marked by central sensitization. From a physical perspective, less FAB may imply less physical de-conditioning and less guarded movements. With stronger stability and increased motor control within the back, it may influence loading of lumbar spine and reduce the production of peripheral nociceptive input (O'Sullivan, 2000; O'Sullivan, 2005), hence pain intensity may reduce.

Previous studies reported a positive relation between FAB and pain intensity (Guclu et al., 2012; George et al., 2001), while some reported a weak or no association between them (Thomas et al., 2010; Crombez et al., 1999; Vlaeyen et al., 1995a; Vlaeyen et al., 1995b; Woby et al., 2004b).

Thomas et al. (2010) had a very similar baseline patient profile (TSK = 46, VAS= 6.04, RMQ= 13.94) as well as that in Crombez et al. (1999) (TSK= 44.4,

VAS= 61.7, RMQ= 14.1) when compared to the present study (TSK= 42.3, VAS= 6.04, RMQ= 11.8). However, both Thomas et al. (2010) and Crombez et al. (1999) found no association between FAB and pain intensity. A possible explanation for this inconsistent finding may be that study by Thomas et al. (2010) and Crombez et al. (1999) were cross-sectional, where measurement of FAB and pain intensity were only taken as a snapshot. In contrast, the current study is longitudinal where correlation between changes of FAB and changes in pain intensity were considered over time. Since repeated measurements were taken, the present results should be more valid than cross-sectional data. The different results may suggest that the pain intensity-FAB association is dynamic, and it could change over time, and with the CBCLBP programme.

Correlation between HLOC and pain intensity

The present study found that improvement of ILOC, ELOC and CLOC were significantly associated with reduction of pain. This indicates that higher level of ILOC, lower level of ELOC and lower level of CLOC are linked with pain reduction. This result is in direct agreement with Sengul et al. (2010), which also reported a relation between pain intensity and ILOC, ELOC and CLOC, and partially consistent with Harkapaa (1991) who found a relationship between pain and ILOC and ELOC.

Compared to the study by Sengul et al. (2010), which suffered from selection bias and between-group variability, the A-B-A design of the current study has more advantage as it is the same group of patients serves as its own control. Hence, our result is likely to have a higher internal validity.

A possible explanation for the relationship between HLOC and pain intensity could be that higher level of ILOC, lower level of ELOC and lower level of CLOC reflect more self-responsibility, and patients beliefs that their own behaviour is more likely to impact their pain, as proposed by the HLOC theory (Wallston et al., 1976). Engaging more positive behaviours (such as regular mild aerobic exercise) reduce the heightened reactivity of the CNS, hence leads

to reduction in pain mediated by central sensitization (Busch et al., 2007). In addition, there is also evident that an individuals' perception of control may have a direct or indirect effect on pain intensity reporting, hence patients may report more intense pain due to their feeling of lack of control and inability to influence the pain sensations (Pellino & Oberst, 1992).

Correlation between HLOC and disability

The correlation between HLOC and disability is weak. Disability is only associated with increased ILOC, but there is no significant relation between reduction of ELOC and CLOC. This finding indicates that disability may be more influenced by internal beliefs, rather than external and chance beliefs. The relation between reduction of disability and increased ILOC may be explained by individuals with higher level of ILOC being more likely to attempt and complete activities, as they believe their own behaviour and responsibility accounts for outcome, as opposed to those who believe in external and chance factors, where passivity and inactivity are more likely to occur. Besides, it was suggested that patients who have higher ILOC have higher self-motivation and more active involvement in healthcare treatment (Wallston & Wallston, 1982). This means that patients with higher ILOC are more likely to benefit from the CBCLBP programme, which aims at reducing disability.

There are only three studies (Harkapaa et al., 1991; Haldorsen et al., 1998; Sengul et al., 2010) in the literature examining the relationship between HLOC and disability in NSCLBP. The present finding is in direct agreement with Haldorsen et al. (1998) and Harkapaa et al. (1991), both also reported disability was related to ILOC only. Sengul et al. (2010) reported ILOC and CLOC were positively correlated with disability in NSCLBP patients, but not with ELOC. The discrepancy of findings between studies may be explained by the heterogeneity of patient baseline characteristics, variation in research design, number of variables included in analysis and statistical methods. Besides, there is variation in methodological quality among studies (of high/ moderate risk of bias), which weaken the validity and strength of support for the HLOC construct.

So far, the emerging evidence seems to support the relationship between ILOC and disability. However, with the limited amount of available evidence, this area warrants further research to support the relationship between HLOC and disability in NSCLBP.

Correlation between HLOC and FAB

An association was found between improvement of ILOC, ELOC and CLOC and reduction of FAB. This is the first study within literature showing that improved HLOC are associated with reduced FAB in patients with NSCLBP.

Richard et al. (2011) reported a correlation between FABs-PA and ILOC and ELOC (but not CLOC). However, the included patients of this study were only workers (mean age of 38.7) with NSLBP who had self-reported at least a day of incapacity due to LBP. Therefore, their findings cannot be generalised to a wider population with NSCLBP presenting in primary care, who are generally older and experienced LBP for more than three months.

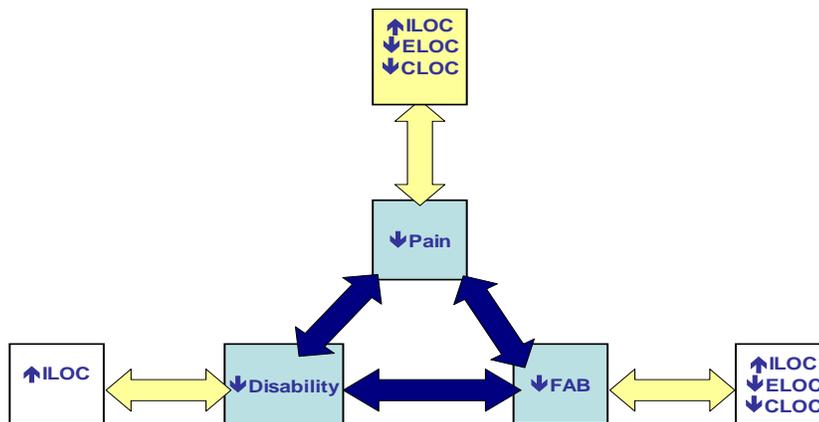
The mechanism underlying this association is unclear and it has not been discussed in the literature. However it could be hypothesised that reduction of FAB has impact on the three responses to fear, which are: (1) psychophysiological (e.g. less muscle reactivity); (2) behavioural (less avoidance behaviour and more active coping); and (3) cognitive elements of fear (e.g. less catastrophizing thoughts) (Leeuw et al., 2006). All these responses may result in internal belief that pain can be controlled by oneself (ILOC), rather than external factors (ELOC and CLOC). The reverse is also true. If patients believe they are the one responsible for their back condition, and that own behaviour determined outcome (as opposed to external factors), they are probably more likely to employ active coping and less likely to avoid activities despite pain, thus resulting in less FAB.

Another possible explanation for this relation can be explained from the neurophysiological perspective. The pain neuromatrix contributes to the experience of pain. But much of the pain neuromatrix are also the areas that

control decision-making, learning, goal-orientation, attention, cognition and emotion (Melzack, 1999). When these areas are colonised by selective attentional focus on pain, particularly individuals with high levels of fear of excessive attention and protection (Keogh et al., 2001; Dehghani et al., 2003), it limits the higher mental processes in the brain such as learning and planning. This is why patients with high FAB are challenging to treat. Patients may find it difficult to comply with treatment advice such as taking self-responsibility, thinking positive and behaving positive, all can influence one's HLOC in a negative manner.

In contrast, lower levels of FAB may orientate attention away and disengaging thoughts from pain. Hence enhancing patients' capacity and learning with therapeutic instructions and advice, which then likely to influence one's HLOC is a positive manner. Therefore, it is reasonable to propose there is a relationship between HLOC and FAB in NSCLBP patients with high FAB.

Figure 5.4: Correlation between reduction in pain intensity, reduction in disability, reduction in FAB and improvement in HLOC subscales



In sum, it is acknowledged that the development and maintenance of NSCLBP is multi-factorial, and it could be due to a complex combination of biological, psychological and social factors (Gatchel et al., 2007). The correlation data of the present study provides evidence on the link between pain, disability, FAB, and HLOC, following the implementation of the CBCLBP programme. As shown in **Figure 5.4**, these variables of NSCLBP interact and correlate with each other.

As discussed in earlier sections, this study extends a previous study that found an association between reduction in pain intensity, reduction in disability and reduction in FAB in NSCLBP.

Both reduction in pain and reduction in FAB were found to be associated with all HLOC subscales whereas disability was associated with increased ILOC. Patients that we see in clinical practice often simultaneously have multiple psychological factors that may impair outcomes. Consideration of the relationship between improvement of HLOC and improvement of pain intensity, disability and FAB enable us to further understand the underlying mechanism of how desired treatment outcomes can be attained.

5.5.2 To determine what extent changes of ILOC, ELOC, CLOC and other variables can predict changes in pain intensity, disability and FAB

5.5.2.1 When pain intensity is the outcome

The present study found that both reduction of FAB and reduction of disability were the significant predictors of reduction in pain intensity (**Table 4.18**). Both variables accounted for an additional 37% of the variance in changes in pain intensity, after adjusting for demographics. Examination of beta weights, however, revealed that reduction in disability ($\beta=0.486$, $p< 0.001$) was a much stronger predictor than FAB ($\beta=0.248$; $p< 0.05$) when pain intensity is the outcome.

A number of mechanisms may explain why reduction in FAB and reduction in disability emerged as significant predictor to reduction in pain intensity. According to the fear-avoidance model (Vlaeyen et al., 1995b; Vlaeyen & Linton, 2000), patients with higher levels of FAB become excessively attentive to their bodily symptoms, and have a tendency to monitor signs of bodily threat periodically. This dysfunctional attentional style to detect potential pain-threatening information is known as hypervigilance. Hypervigilance results in a greater chance of reporting and exacerbating pain sensation and disability levels. Accordingly, it is plausible that reduction in disability and reduction in FAB might reduce patients' hypervigilance, hence reducing their misinterpretation or exaggeration of pain sensation.

Disability means restricted activities. Restricted activities lead to physiological changes such as spinal stiffness, decreased muscle atrophy and strength, loss of fitness and function, decreased co-ordination and balance, and weight gain. These physiological factors are shown to have some impact on chronic low back pain (Verbunt et al., 2003). The stress from FAB is also shown to exacerbate the reactivity of the CNS, leading to increased pain associated with central sensitization (Curatolo et al., 2006). In addition, it has also been reported that pain-related fear is linked with pain and disability through muscular reactivity (Vlaeyen et al., 1999).

Collectively, it is feasible that reduction in disability and reduction in FAB lead to lower level of pain intensity.

This result suggests that employing treatment components that target disability and FAB would potentially achieve better pain outcome in patients with NSCLBP. For example, by educating that pain physiology alters pain beliefs and attitude (Moseley et al., 2004), and in conjunction with physiotherapy, it improves symptomatic and functional outcomes in CLBP (Moseley, 2002; Moseley et al., 2003b). By encouraging patients to complete various type of exercises and functional activities in a graded and paced manner help to reduce pain behaviour (Ferster & Skinner, 1957; Nijs et al., 2011). Stress management, explanation of FAB model and relaxation are likely to decrease pain hypersensitivity of CNS (Nijs and Van Houdenhove., 2009; Nijs et al., 2009).

Rightly, some NSCLBP patients need passive treatment such as hands-on mobilisation and manipulation to facilitate their rehabilitation, especially when they struggle with their pain. However, passive treatment should be minimally used because of their cost, lack of long-term effectiveness and lack of significant impact on functional outcomes and return to work (Chou et al., 2007; Chou & Shekelle, 2010). The message of using self-care techniques, keeping active and paced activities should be emphasized consistently by clinicians and it should be seen as a proactive alternative method to manage pain by NSCLBP patients.

HLOC accounted a non-significant 6% of the variance in pain intensity. All subscales of HLOC (i.e. ILOC, ELOC and CLOC) were found to have no predictive value of reduction in pain intensity, after accounting for demographics, FAB and disability (**Table 4.18**). This finding suggests that change in HLOC has no predictive importance in the reduction of pain intensity. No direct comparison can be made as relevant literature is very limited. Some previous studies used composite assessments to measure patient perception of control, as opposed to MHLC scales. For instance, a cross-sectional study by Woby et al. (2004b) found that patients' perception of ability to decrease pain (as evaluated by CSQ) explained an additional

6% of the variance of pain intensity. A subsequent cross-sectional study by Woby et al. (2007a) demonstrated that a number of cognitive factors (including perceptions of control) accounted for an additional 30% of the variance in pain intensity, however perceptions of control over pain (as evaluated by CSQ) were not a significant predictor to pain intensity. So far, it appears that HLOC beliefs have no significant predictive value in pain intensity. This might suggest that improving patients' HLOC beliefs is unlikely to have a major impact upon pain reduction in patients with NSCLBP.

5.5.2.2 When disability is the outcome

After controlling for demographics, the current study found that reduction in pain intensity and reduction in FAB accounted for an additional 33.1% of the variance in disability. However, only pain intensity ($\beta=0.53$, $p< 0.001$) emerged as a significant predictor of disability (**Table 4.19**). This suggested that pain intensity is a unique predictor relating to reduction of disability as outcome. This is in direct agreement with the two previous cohort studies (of moderate risk of bias) conducted in physiotherapy department, which also reported pain intensity accounted for a relatively large proportion of the variance in disability (Woby et al., 2004a; Woby et al., 2008). Compared to these previous studies, which have a short follow-up period (6-8 weeks), and higher follow-up dropout rate (25-35% dropout in follow-up data), our study may provide a more valid evidence due to a longer follow-up period (6-months) and low attrition bias (completed follow-up data).

Woby et al. (2004a) reported that reduction in pain intensity accounted for an additional 43% of the variance in reduction in disability in a cohort of NSCLBP patients presenting in physiotherapy, while Mannion et al. (2001) found reduction in pain intensity only explained 16% of the variance in reduction in CLBP disability. The inconsistent findings of the predictive relationship between change in pain intensity and change in disability appears to be affected by the baseline levels of disability. Patients recruited in Mannion et al. (2001) reported a comparatively lower level of disability (mean RMQ=7.6), the present study reported moderate levels of disability (mean RMQ=11.8), whereas Woby et al. (2004a) reported a relatively

higher levels of disability (mean=13.1). In view of this, it is possible that baseline values of disability may influence the relation between changes in disability and changes in pain intensity.

Another possible explanation for inconsistent findings of pain predicting disability could be that other factors may mediate the relation between these two constructs. For example, catastrophizing and internal control might be a factor that mediates the relation between pain intensity and disability (Spinhoven et al., 2004; Smeets et al., 2006b). Employment status may also be a factor mediates the relation between pain and disability (Van den Hout et al., 2001). A more recent systematic review reported that self- efficacy, psychological distress and fear may also mediate the relation between pain and disability (Lee et al., 2015). It is acknowledged that these potential mediators may over- or under-estimate the predictive importance of pain intensity in reduction of disability between studies. However, the data of the present study derived from a homogenous cohort of NSCLBP patients, hence the bias due to these potential confounders should not affect the present reporting. Further investigation includes the application of mediation analysis and assessment of the possible effect of uncontrolled confounders using sensitivity analysis would be required to provide understanding of the underlying causal mechanism between pain intensity and disability (Imai et al., 2010).

Despite the present finding suggesting that pain relief may be important in achieving reduction in disability, treatments directly aimed at pain relief are often unsuccessful in patients with NSCLBP (Waddell, 2004), and are contra-indicated to the theoretical approach of CBT based intervention. In fact, it has been suggested that successful management of chronic pain is solely due to patients' acceptance of their pain, rather than a reduction in their pain intensity per se (Aldrich et al., 2000; McCracken, 1998).

Some studies reported the significant predictive importance of FAB in disability (Crombez et al., 1999; Vlaeyen & Linton, 2000; Pincus et al., 2002; Woby et al., 2004a; Meyer et al., 2009), while some trials have found a weak association between FAB and disability (Reneman et al., 2003;

Burton et al., 2004; Pincus et al., 2006; Woby et al., 2007a; Woby et al., 2007b).

In the present study, reduction in FAB did not emerge as a unique predictor of reduction in disability ($P > 0.05$). It is noteworthy that whilst not a significant predictor, there was a significant association between these two variables ($p = 0.013$) (**Table 4.17**). This potentially implies that reduction of FAB might only exert an indirect influence on disability via the effect it has on other cognitive factors. Referring to correlation data, the only cognitive factor that has association with both reduction of FAB and reduction of disability is increase in ILOC (**Figure 5.4**). On this basis, it is possible that increase in ILOC could be the intermediary link between the causal relationship of reduction in FAB and reduction in disability. However, this hypothesis can only be confirmed by applying mediation analysis in future work.

HLOC only explained a further non-significant 0.5% of the variance in disability. All subscales of HLOC were found to have no predictive value to reduction of disability, after accounting for demographics, pain intensity and FAB (**Table 4.19**). This finding suggests that change in HLOC has no impact on the reduction of disability in our patients. A possible explanation could be that disability is a complex and multi-dimensional phenomenon, in which both physiological and a variety of psychosocial factors determine disability. Secondly, HLOC may only exert an indirect influence on disability via the effect it has on other factors, therefore the predictive importance of HLOC have reduced when assessed alongside factors that have a direct effect on disability. For example, pain intensity (Woby et al., 2004a; Van den Hout et al., 2001) and FAB (Crombez et al., 1999; Meyer et al., 2009) have been shown to account for a relatively large proportion of variance in disability.

No existing evidence can be found to make direct comparison regarding the predictive value of HLOC beliefs to change of disability. Some studies reported that perceptions of control (measured by composite measures) showed no predictive value to disability statistically (Woby et al., 2007a;

Mannion et al., 2001). On the other hand, Sengul et al. (2010) found a correlation between disability and both ILOC and CLOC (but not ELOC) in patients with CLBP. A cohort study by Foster et al. (2010) that examined a comprehensive range of psychological variables in patients with both subacute and chronic LBP demonstrated that patients' weak perception of personal control was a significant and strong predictor in LBP disability outcomes at 6-months. However, this study assessed perception of personal control by IPQ-R, which is a composite measure consisting of 12 subscales and 8 patients' illness perception (Moss-Morris et al., 2002). Therefore, the IPQ-R cannot conclude the independent predictive importance of HLOC, as in MHLC. Limited and inconsistent evidence in this area warrants further examination regarding the predictive relationship between changes in HLOC and changes in disability in NSCLBP population. So far, the relation between HLOC and disability appears rather weak.

It is noteworthy that both reduction in pain and reduction in FAB explained an additional 33.1% of the variance in disability, and HLOC explained a further 0.5%, thus indicating that reduction in disability must be influenced by other factors. There is evidence suggesting self-efficacy may be a stronger determinant of disability, than those factors (such as catastrophizing and fear of movement/ (re-) injury) within the fear-avoidance model (Ayre & Tyson, 2001; Denison et al., 2004; Woby et al., 2007b). However, further study will be required to clarify this.

5.5.2.3 When FAB is the outcome

It was found that both reduction in pain intensity and reduction in disability accounted for 17.2% of the variance in FAB. Examination of beta weights, however, showed that only reduction of pain intensity ($\beta=0.325$, $p<0.05$) emerged as a significant predictor to reduction in FAB (**Table 4.20**). This result is in contrast to those observed in a number of other studies, which have shown that FAB has a greater effect on disability than pain intensity (Wideman et al., 2009; Gheldof et al., 2010; Jensen et al., 2010). A possible explanation of this could be that pain is an important reason for avoiding movements in our patients who have a high baseline value of FAB. With reduction in pain intensity, it is probable that patients are more likely to

confront pain problems, develop active coping, which ultimately leads to less FAB (Vlaeyen et al., 1995a). This result implies that adequate pain relief and changing maladaptive pain cognition may be particularly important to address when managing patients with high FAB.

After accounting for demographics, pain intensity and disability, the HLOC showed an additional 31.9% of the variance in reduction in FAB. Among the three subscales of HLOC (i.e. ILOC, ELOC and CLOC), increase in ILOC emerged as a unique predictor related to a reduction in FAB ($\beta = -0.407$, $p < 0.01$) (**Table 4.20**). This suggests that patients' reduction in FAB is largely related to one's internal belief (ILOC), rather than influenced by external orientation belief (i.e. ELOC and CLOC). Furthermore, a much larger proportion of the variance explained by the improvement in HLOC (31.9%) was seen, in comparison to reduction in pain intensity and disability (17.2%), indicating that change in HLOC has a larger effect on reduction in FAB, than change in pain intensity and disability.

This is the first study which shows that HLOC explains a considerable proportion of the variance in reduction in FAB, and it is also the first study which demonstrates that increase in ILOC is significantly predictive of a reduction in FAB.

The underlying mechanism between HLOC and reduction in FAB has not been discussed in the literature. However, existing evidence may explain why improvement of HLOC beliefs leading to reduction in FAB occurred in the present study. It has been suggested that coping strategies significantly improved following multidisciplinary CBT approach pain management (Jensen et al., 2007). Active coping strategies involve taking responsibility for treatment, having a higher level of engagement in beneficial health behaviours, and attempting to function or stay active despite pain. In contrast, passive coping strategies reflect assigning management to an outside source, taking less time to evaluate a problem situation and have a lower engagement in beneficial health behaviours (Brown & Nicassio, 1987).

There is also evidence indicating that there is an association between HLOC and use of coping strategies (Harkapaa et al., 1991). Specifically, individuals with higher levels of ILOC are more likely to employ active coping strategies, whereas ELOC and CLOC beliefs reflect passive coping strategies. In light of the above, it is possible that because patients with ILOC believe their actions and behaviour are responsible for outcome, they are then more likely to engage in active coping and attempts to function, despite pain. This may in turn reduce their avoidance behaviour and FAB. On the other hand, patients with higher external control orientation believe that the responsibility for one's health is assigned to other people, or luck and fate. Consequently, they are more likely to use passive coping, have less attempts to control pain and be more likely to avoid increasing activities. This may then lead to increased FAB.

In addition, it has been suggested that ILOC are related to positive adjustment to illness and less psychological distress in medical populations (Burker et al., 2005). An increased perception of control may also reduce feelings of being threatened and challenged by a stressful situation (Lazarus & Folkman, 1984). For many NSCLBP patients, performing many daily living activities is considered to be stressful. Therefore, it is plausible that patients with higher level of ILOC are more likely to confront pain, and feeling less threatened and less distressed by their pain. According to the fear-avoidance model theory, this "good" coping and confrontational style results in less FAB.

FAB is a known powerful psychological factor in persistent pain and disability in NSCLBP as shown in high quality systematic reviews (Ramond et al., 2011; Chou & Shekelle, 2010). The consequences of high FAB include disability (Crombez et al., 1999; Rainville et al., 2011), exaggerations in pain perception (Lethem et al., 1983; Crombez et al., 1999; Goubert et al., 2004b), decreased performance of physical tasks (Al-Obaidi et al., 2003), passive coping (Lethem et al., 1983), reduced psychological well-being, dependence on medications, and excessive utilization of medical services (Derebery & Tullis, 1983; McGrail Jr et al., 2002). Because of the consequences of high level of FAB, the persistence of it could dampen the

effectiveness of NSCLBP treatment and have a negative impact on both patients and health care providers. Therefore, it would seem beneficial to explore other factors that may anticipate the reduction in FAB, such as higher ILOC as found in the present study. This is supported by Wideman et al. (2013), who challenged the sequential and simplistic fear-avoidance model, and suggested that the fear-avoidance model should be seen as a more complex and dynamic multiple relationship in which other factors are likely to be involved.

From a clinical perspective, this result may suggest that treatment targeted to increase ILOC could facilitate improvement in FAB in NSCLBP patients with high FAB. This is useful information for clinicians working with NSCLBP with high FAB, because this is the sub-group often considered challenging to treat (Rainville et al., 2011). In addition, pain-related fear is a crucial aspect in patients' disability, which needs to be addressed in order to achieve optimal outcomes (Lundberg et al., 2011). Further research is warranted to support the view that ILOC predicts better FAB outcomes and more remains to be learned through future research regarding its underlying mechanism. It is proposed that components modifying various maladaptive pain beliefs and enhancing self-management are likely to have some impact on patients' ILOC beliefs. Clinicians could consider placing more focus on these components (as detailed in **Section 5.3**) to facilitate FAB outcomes in patients with high FAB.

Overall, changes in HLOC accounted for further 6%, 0.5% and 31.9% variance in changes in pain intensity, disability and FAB respectively. This finding demonstrates that HLOC (particularly ILOC) has significant predictive value in reducing FAB, however it shows no significant predictive value to both reduction in pain intensity and reduction in disability. A possible explanation for this could be that both HLOC and FAB are psychological factors (both constructs concerning patients' belief about their pain), while pain intensity and disability are physical factors associated with NSCLBP. This result supports the current understanding of NSCLBP, that when NSLBP becomes chronic, the psychosocial factors are more powerful factors in the development and persistence of NSCLBP and

disability, than the physical factors (Waddell, 2004; Koleck et al., 2006; Bakker et al., 2009). This finding is also in direct agreement with the treatment philosophy of the CBA, where emphasis is placed to address patients' maladaptive belief, feelings and behaviours (Airaksinen et al., 2006; Henschke et al., 2010).

5.6 Aim 4- To examine patients' self-care attitude toward their back pain in terms of their desire in future use of healthcare and prescription pain medication as a result of the CBCLBP programme

Main finding:

No significant improvement of self-care attitude was seen before the programme (Phase A1); significant improvement of self-care attitude was found immediately after the CBCLBP programme (Phase B), and such improvement was sustained for six months following the programme (Phase A2).

What are the possible reasons for patients' self-care attitude failing to improve during Phase A1 but improving significantly during Phase B?

1. Self-management component

Despite usual physiotherapy care (Phase A1), which included a variety of self-management components, none of the strategies were cognitive and behavioural in nature such as relaxation, distraction, personal goal setting and problem solving techniques. This may imply that the cognitive-behavioural elements of self-management in the CBCLBP programme may be important in improving patients' perception of their need for self-management, at least with respect to this subgroup of NSCLBP patients with moderate level of pain, moderate disability and high FAB.

Self-management is concerned with managing the day-to-day impact of NSCLBP. In NSCLBP, functional limitations (i.e. disability level) are more closely associated with cognitive and behavioural aspect of pain, rather than the sensory and biomechanics one in NSCLBP (Campbell & Edwards, 2009; Gatchel et al., 2007). This may suggest that patients' self-care attitude is more likely to be enhanced, by giving cognitive-behavioural elements of self-management in addition to the patients' information and education provided traditionally in one-to-one physiotherapy.

2. Relationship between HLOC and use of self-care

Harkapaa (1991) reported that use of self-care was significantly associated with higher ILOC and lower ELOC. Therefore, it is possible that an increased ILOC and decreased ELOC during Phase B may have something to do with patients being more actively adopted self-management strategies, and patients' perception of need for self-management has improved, hence reflecting on their improved self-care attitude.

3. Patients/ physiotherapist relationship

Self-management involves five key elements: problem-solving, decision-making, resource utilization, forming a patient/healthcare provider relationship, and taking action (Lorig & Holman, 2003). The success of effective self-management therefore depends on the collaboration between patients and healthcare providers (Bodenheimer et al., 2002). Being on a weekly 2-hourly programme for six consecutive weeks may be more effective in helping patients to acquire the problem solving skills and the confidence to self-manage their NSCLBP, than 4 sessions of individual physiotherapy as shown in the current study.

Being in a group may also facilitate the improvement in self-care attitude. A RCT involving 812 patients with arthritis in primary care concluded that the self-management arthritis programme reduced patients' anxiety and improved participants perceived self-efficacy to manage symptoms (Buszewicz et al., 2006). Although this study showed no significant effect on pain, physical functioning or number of GP consultation in primary care, it highlights that a self-management programme delivered in a group can impact on patients' psychological well-being such as anxiety, depression and self-efficacy. With NSCLBP being chronic condition liked arthritis, it is possible that the psychological benefits from being in a group may improve patients' self-attitude towards their back pain.

What treatment components of the CBCLBP programme may contribute to improved self-care attitude?

Improved self-care attitude towards back pain requires (1) change of self-management behaviour and (2) increased individual's ability to self-manage their NSCLBP.

1. Self-management behaviour

Self-management behaviour refers to the actions and thoughts that a patient uses to self-manage their condition (Summers et al., 2014). These behaviours may include: (1) knowledge and ability to control pain using pharmacological and non-pharmacological pain relief; (2) strategies to cope with stress such as relaxation and effective communication with friends, family and health professionals; (3) strategies to maintain a positive outlook and motivation to self-management such as distraction, pacing activities, problem-solving and goal setting and; (4) ability to handle flare-ups such as, plans of action to manage setbacks and equip patients with knowledge to decide when to self-manage, or to seek help appropriately (such as introducing "red flags"). These various physical and CBA activities should not be seen as mutually exclusive as the spectrum of approaches often compliments one another when used simultaneously (Lawn & Schoo, 2010).

2. Increased individual's ability to self-manage their NSCLBP

It was suggested that even individuals who are less motivated and less confident initially, can develop new skills and competencies through supported self-management (Hibbard & Greene, 2013). Supported self-management comes in many forms. It can range from verbal and written education materials, health-professional led physical and psychological intervention, to specifically designed exercise classes and personalised support and advice (Du et al., 2011).

For instance, it has been shown that exercise is one of the most commonly used self-management strategies in NSCLBP patients; however patients are only likely to do exercises that fit in with their lifestyle or make sense to them (Cooper et al., 2009), or the experience of exercise without feeling fear and undue harm (Mannion et al., 2001). This implies that physiotherapists

should be flexible and cater for patients' individual needs, and should not assume a "one size fits all" approach in their treatment. The CBCLBP programme included the opportunity to review home-exercises (**Appendix 13**) and overcome patients' personal physical and psychological barriers which would compromise their self-management tasks. This was well received by patients. Various types of graded exercise such as core stability work, stretching exercise, lightweight and cardiovascular training (**Appendix 14**) were included in the 45 minutes supervised exercise circuits. Pilates and hydrotherapy are particularly welcomed by patients. This study showed that 56% of the participants continued hydrotherapy 6-month following the programme. Collectively, these observations may suggest that some form of 'personalised' approach in home exercise programme and introducing new activity (such as hydrotherapy and Pilates) that differs from patients' normal home exercise routine seems to help facilitating self-care attitude.

Why there is difference between statistical significance and clinical significance during Phase B?

In terms of statistical significance, the effect of the CBCLBP programme has yielded a statistically large improvement of self-care attitude between week 1 and week 6. This finding replicates the positive results of previous studies which also demonstrate the effectiveness of the physiotherapy-led CBA programme in improving self-care (Klaber Moffett et al., 1999; Critchley et al., 2007), and the effectiveness of group-based self-management education programme in primary care (Von Korff et al., 1998; Moore et al., 2000). Despite variations in interventions, patients' characteristics, reporting of the outcomes, involvement of physiotherapist in delivering the programme, and methodological qualities among studies in current literature, this study lends further support to the effectiveness of CBA active rehabilitation in enhancing patients' ability to self-care.

However, in terms of clinical relevancy, the effect of the CBCLBP programme resulted in 20% improvement in self-care attitude, which is not considered to be clinically relevant (MCID= 30%, Ostelo et al, 2008). This means that the treatment effect size for self-care attitude that occurred in

Phase B is unlikely to be clinically important to patients. This finding was unexpected, due to the goal of the CBCLBP programme is to empower patients to take responsibility for their pain management. Keedy et al (2014) found that NSCLBP patients have significantly higher ILOC but no improvement in ELOC (for medical professionals) following an intensive two-week MI programme. This may suggest that it is possible for patients to experience increased ILOC, but not necessarily abandon their external expectancies related to the future desire of using healthcare and prescription medication. Despite an increase in ILOC and decrease in ELOC during Phase B, this finding may exemplify a case in which increase in ILOC and decrease in ELOC does not imply better self-care attitude perceived by patients, at least with respect to their desire in future healthcare and prescription usage.

Another possible explanation could be the limitation of the SCQ, which was the outcome measure used for assessing patients' self-care attitude. The majority of the outcome measures (VAS, RMQ and TSK) are well-known and have well-documented reliability and validity. In comparison, the SCQ has not been as well studied, and has less well documented psychometric properties.

Firstly, the SCQ demonstrates moderate internal consistency reliabilities ($\alpha=0.51-0.61$), and it was shown to predict future use of health care for back pain and/ or future use of prescription pain medications in two different samples (Saunders et al., 1999). This means that all the five-items of the SCQ deal with patients' self-care attitude. However, it must be noted that a measure is only reliable for use with a particular population (Roach, 2006). Since the SCQ is developed and validated mainly based on patients with NSCLBP (Von Korff et al., 1998; Saunders et al., 1999; Moore et al., 2000), it is possible that the SCQ lacks sensitivity when assessing NSCLBP with high FAB specifically as in the present study.

Secondly, it may be the responsiveness of the SCQ, which refers a measure's ability to accurately detect changes when it has occurred (Beaton et al., 2001). A number of factors may influence the responsiveness of a

measure; for instance, patients were rated on a 5-point scale of the SCQ, whether they strongly agreed, agreed, were neutral, disagreed or strongly disagreed with the five-items statements. The stated capacity of patients may improve or decline within the responses [‘strongly agreed’ or ‘agreed’] or [‘strongly disagreed’ or ‘disagreed’], because these responses do not give enough boundaries, and large changes in patients’ subjective perception on self-care attitude are required to change categories. Thus, the SCQ may be less responsive because the scoring of some of the five items of the SCQ is unlikely to change in response to the CBCLBP programme.

What are the possible reasons for the sustained improvement in self-care attitude during Phase A2?

1. Developed self-management that fits one’s life

Self-management behaviours develop over time, based on both incremental learning from experience and evaluation of actions (Ong et al., 2011). Audulv et al. (2012: 331) identified four phases of self-management over time:

- ‘Seeking effective self-management strategies
- Considering costs and benefits
- Creating routines and plans of action
- Negotiating self-management that fit’s one life’

The final phase is of particular interest to explain the sustained improvement in self-care attitudes. Once patients had identified self-management strategies that worked for them, a final phase of adjustment occurred in order to fit with patients’ day-to-day lives. Over time (even after completion of the CBCLBP programme), patient may embed some of the self-management behaviours into their lives, and that likely become a routine. Patients may learn, adapt, modify the self-management skills, which make them feel more confident and motivated towards their self-care that suits their individual needs, thus feeling less desire to visit health care services and use prescription pain medications.

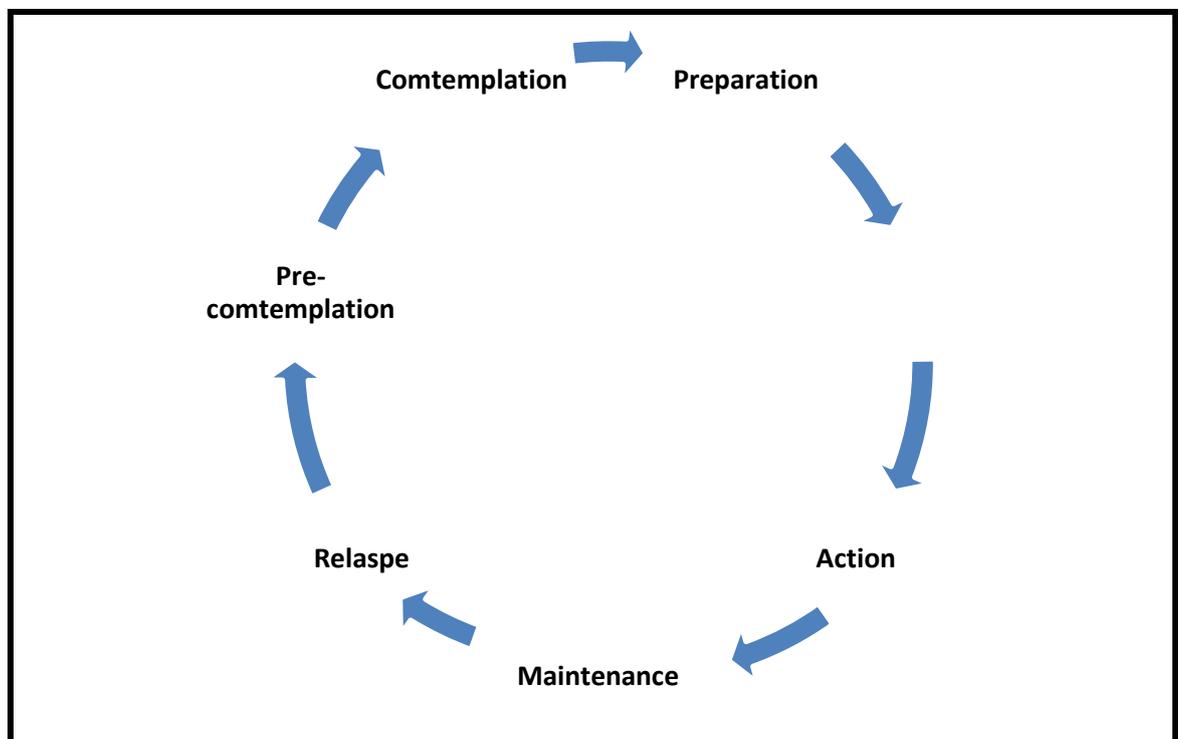
2. Stages of behavioural change

Maintenance of effective self-management only succeeds if the patient is motivated and ready to make behavioral or life-style changes. Five stages of behavioural changes have been identified across multiple studies including smoking cessation, exercise and diet (Prochaska & DiClemente, 1983; Prochaska et al., 1991).

Five stages of change (Kerns et al., 1997) (**Figure 5.5**):

1. **Precontemplation**- the stage where individuals have little interest in changing specific behavior;
2. **Contemplation**- the stage where individuals think about behavioural change but unlikely to make that change soon;
3. **Preparation**- the stage where individuals actively consider behavioural change and prepare for the change;
4. **Action**- the stage where individuals actively work toward changing their behavior;
5. **Maintenance** – the stage where individuals maintain changes in behaviour.

Figure 5.5: Cycle of change (Kerns et al., 1997)



The CBA perspective in NSCLBP is entirely consistent with this theoretical framework. The CBCLBP programme proceeded through a series of phases that begin with helping patients to reconceptualise negative thoughts and feelings and encourage change in beliefs and commitment to change to enhance their self-care ability. This is followed by a set of CBA skills practice (such as cognitive restructuring, relaxation, pacing activities and exercises) that help promote and maintain changes in self-management. For instance, patients may have no interest to take up daily exercise when they first attended the CBCLBP programme (Pre-contemplation). With the various CBA components and supervised exercise in the programme, patients may start considering daily exercise (Contemplation), take active steps to change such as joining the gym and living in a more active lifestyle (Action) and finally attempt to maintain those changes such as attending gym regularly and living healthy (Maintenance).

As shown, relapse is part of the cycle. It was reported that maintenance of health behavioural changes (such as smoking cessation) may take individual at least six times to achieve long-term changes (Prochaska & DiClemente, 1983; Prochaska et al., 1991). Patients in the CBCLBP programme were reassured that relapse is a natural part of the cycle, and episode of relapse should be viewed as a positive learning experience (i.e. why relapse and how to address it), then re-entering the cycle with better preparation. The sustained improvement in self-care at 6-months is likely due to patients were in the 'maintenance' stage.

Advantages of improved self-care attitude

The findings of the present study demonstrated that with this subgroup of NSCLBP patients (with moderate pain, moderate disability and high FAB), the CBCLBP programme is more effective in improving their back pain self-care attitudes (in terms of future use of healthcare and/or prescription pain medications), than usual physiotherapy at 6-week and 6-months.

The sustained 6-months improvement in self-care attitude results in a number of advantages to both patients and healthcare providers. First, a more active self-care attitude implies that patients showed less desire to utilise healthcare and prescription pain medications (as evaluated by SCQ)

following the programme. This leads to reduced associated costs for healthcare services and healthcare usage, which give social and economic benefits. Second, when patients were able to treat themselves without excessive or unnecessary reliance on professional care and/ or prescription medications, it gives them the feeling of being in personal control. This is supported by the increased ILOC and decreased ELOC found in the current study during Phase B and Phase A2. From the patient's perspective, being able to manage day-to-day impact of the condition, and to perform functional activities including work and hobbies has both physical and psychosocial benefits.

Informal feedback from patients which may give alternative explanation for sustained self-care ability

Interestingly, the informal feedback from many participants reported that their brief return visits for follow-up assessment at 3-months and 6-months as part of the study provided them with motivation and reassurance to continue self-care. This is congruent with some qualitative studies, which also show that participants expressed their wish for follow-up following discharge to support self-management of CLBP (Cooper et al., 2009; Liddle et al., 2007). Telephone review services have been used for patients with acute LBP whilst they were awaiting physiotherapy appointments (Taylor et al., 2002), therefore it may be worthwhile exploring its use in supporting NSCLBP patients' self-care following discharge from the CBCLBP programme in future work. Alternatively, further work could be considered to study if telephone, group-based or electronic [Skype] follow-up would facilitate continued ability to self-care in NSCLBP patients following participation of the CBCLBP programme.

Promoting self-care is an important objective in the CBCLBP programme. A UK policy document has emphasized the importance of self-management of long-term conditions (Department of Health, 2006), in which patients are encouraged to take an active role for continued self-care. Consequently, one of the measures of successful treatment outcome is whether patients take over their self-management, and if they are able to rely less on professional care and/ or prescription medications as reported in current study.

5.7 Aim 5- The cost per change of ILOC as a result of the CBCLBP programme

The primary objective was to examine the cost of back care per change of ILOC. In addition, the cost of the six-week CBCLBP programme from a provider's, patient and societal perspective as well as the longer term (6-month) back care cost for patient and provider were examined.

5.7.1 The cost of a six-week CBCLBP programme from a provider's, patient and societal perspective

From a provider's perspective, the total cost to the NHS of providing a six-week, 7-session of 2 hours [14 hours] CBCLBP programme was £285.82 per patient (based on treating 8 patients per group), the mean patient cost was £9.10, and the mean societal cost was £124.59 (**Table 4.29**).

Provider's cost for the physiotherapist-delivered programme comparison to other studies

There are no published studies evaluating the cost of a six-week physiotherapy CBCLBP programme. There are also only a limited number of economic studies of physiotherapy CBA active rehabilitation within the literature. Therefore, the PI can only make comparison with studies of similar intervention, treatment rationale and patient population that included economic evaluation. These previous studies concluded that the physiotherapist-delivered CBA intervention is less costly than individual physiotherapy (Critchley et al., 2007); spinal stabilisation class (Critchley et al., 2007), and other active treatments for LBP (Lamb et al., 2010). **Figure 5.6** summarized the comparison of provider cost between the present study and previous studies.

Figure 5.6: Comparing the provider’s cost with previous studies

Study	Patients’ characteristics	Total treatment time	Delivered by	Provider costs per patient	Provider costs per hour
Current study	NSCLBP patients with moderate pain, moderate disability and high FAB	14 hours (8 patients per group)	Band 7 or above physiotherapist and band 4 physiotherapy assistant	£285.82	£20.42
Critchley et al. (2007)	NSCLBP with moderate pain and moderate disability	12 hours (unclear of number of patients per group)	Senior physiotherapist with at least two years clinical experience and physiotherapy assistant	£165	£13.75
Lamb et al. (2010)	Subacute and chronic NSLBP patients with moderate pain, moderate disability and lower FAB	9 hours (8 patients per group)	Physiotherapist, nurse, psychologist and occupational therapist	£187	£20.78

As shown, the current study has almost the same provider’s cost per hour as the study by Lamb et al. (2010). i.e. it costs the provider approximately £20 per hour to provide a CBA active rehabilitation programme. In comparison, Critchley et al. (2007) has the lowest provider’s cost per hour (£13.75). A possible explanation for the difference could be that the current study included a session of hydrotherapy in our CBCLBP programme, which is relatively more expensive than the physiotherapy gym and equipment that were predominantly used by Critchley et al. (2007). Another possible explanation could be the cost of staffing. The programme of Lamb et al. (2010) was delivered by multi-disciplinary members, whereas the present study was delivered by Band 7 or above musculoskeletal specialist physiotherapists with at least 10 years’ clinical experience. The pain management programme by Critchley et al. (2007) was delivered by senior physiotherapists (unclear of banding) with at least two years’ experience, which possibly cost less. In addition, it may have something to do with the number of patients per class. Provider’s cost is calculated based on the number of patients per class, the higher the number of patients per class, the

lower cost it is likely to be. Critchley et al. (2007) was unclear about the number of patients per class in their pain management programme, whereas the present study and Lamb et al. (2010) both were based on 8 patients per class. Finally, inflation should be considered, since these previous studies (Critchley et al., 2007; Lamb et al., 2010) were conducted more than six years ago. An average inflation in the U.K. has been fluctuated between 0.05% and 4.48% in the last ten years (Worldwide inflation data, 2010), which likely to have a direct impact on cost difference between studies.

How to keep cost down? CBCLBP programme vs Individual Physiotherapy

The provider's cost of £285.82 per patient is based on 8 participants per class. However, this cost would be increased if there are less than eight patients being treated. For instance, if there are only 4 patients per group, the provider's cost would be raised to £458.46 per patient. This study did not compare the cost between group-based treatments to individual physiotherapy treatment. By taking an example of the normal practice in Stockport NHS physiotherapy, a band 7 physiotherapists (costs £58 per hour, (Curtis, 2013)) averagely treats a NSCLBP patient individually for 6 hours from referral to discharge, this works out physiotherapy staffing cost of £348 per patient. This implies that group-structured treatment will only be less costly than individual physiotherapy if each programme takes up to 6-8 patients per group. This highlights the importance of careful selection and appropriate referral to the group-structured CBA intervention. Clinical decision-making for the CBA programme referral can be aided by NICE guideline recommendation and use of validated screening tools such as STarTback (Hill et al., 2011). Consideration of patients' preference for the programme was also shown to be clinically important in reduction in pain and disability (Johnson et al., 2007). Therefore, good communication and to understand patients' preference prior to referral should also be considered.

Group-structured and CBA treatment is not for every patient. For example, some patients simply prefer not being treated in a group, or those with multiple problems or having difficulties in understanding English language may find group-based intervention unsuitable. CBA intervention challenges

patients' beliefs and behaviours about their back pain, and emphasizes self-responsibility and self-care. Therefore, if patients do not prefer group-based treatment, or do not engage with the general goal of the CBA rehabilitation, they are probably more likely to fail to attend the CBA based group intervention. This consequently leads to higher provider's cost due to attrition and small group size.

It was recommended by The British Pain Society (2013) that the appropriate group size for the CBA programme should aim to have 8-12 participants. This is not only for economic benefit for the provider. But an appropriate group size can be useful for group influence such as maximizing the opportunity to draw on the experiences of group members, providing a natural social environment to address cognitive and behavioural change, and help normalizing pain experience. If the group size is too small or large, it may weaken the potentially useful group influence (The British Pain Society, 2013).

Mean patient cost attending the programme

The mean patient cost during the programme was £9.10, which includes travel costs, lost wages, prescription costs and other out-of-pocket expenses incurred during the six-week programme. No direct comparison can be made within literature. The mean patient cost of £9.10 means a low financial burden to patient.

An explanation for low travel cost could be the easy access and central location of the physiotherapy department, which is located in the town centre. Besides, 85% of the study participants travelled by car, and the car parking of the physiotherapy department is free of charge, with plenty of spaces. Therefore, there is no car parking fees incurred and no stress in looking for a car parking space. A well-conducted transport study showed that there is a strong link between transport or transport related factors and missed NHS appointment (Hamilton & Gourlay, 2002). The ease of access and low travel cost for patients may have an indirect impact on their attendance.

Only 4% participants reported lost wages to attend the CBCLBP programme. This could be explained by offering participants three available class times to choose from, so that they could attend the programme without direct personal financial sacrifice (62% patients were working). No prescription charges were reported, and only 4% reported other costs incurred when undertaking the six-week programme. This demonstrates a low utilisation of other health services during the CBCLBP programme, possibly because patients feel that they are able to cope better with their NSCLBP and they establish more positive outlook towards their self-management when having regular physiotherapy contact during the programme.

Mean societal cost

The mean societal cost was £124.59 per patient during the programme. This includes the value of time lost to travel and time spent in the physiotherapy department. The AWR for employer in the Northwest UK is £10.75 per hour (Office for National Statistics, 2014). To reflect the employers' cost, this rate was uplifted by 13.8% to reflect employers' National Insurance and superannuation contributions (HM Revenue and Customs, 2014). On the other hand, the value for non-working time (e.g. housework and leisure time) was multiplied by £6.04 (Department for Transport, 2014).

The present findings showed that the mean societal cost due to lost time from work (£166) was almost double compared to the mean societal cost due to lost time from non-working time (£83). An explanation for this result could be that 96% of participants with paid occupation responded as making arrangement such as "time off without loss of pay" or "annual leave" to attend the programme (**Table 4.26**). This cost is tolerated by society rather than patients themselves, which is more beneficial from the patients' cost perspective.

Compared to some LBP economic surveys conducted in the context of Germany primary care, Becker et al. (2010) reported that the mean societal cost per patient per year was €936 (£743) in a sample of 451 CLBP patients. A large cost survey of LBP (N=5650) by Wenig et al. (2009) reported that

the mean societal cost was €1322 (£1049) per patient per year in Germany. In the present study, with the mean societal of £124.6 per patient for the six-week programme in primary care, it can be annualised to the mean societal cost of £1080 per patient per year. This is similar to the findings by Wenig et al. (2009), but it is more expensive than the report by Becker et al. (2010). A possible explanation could be that in the survey by Becker et al. (2010), over 50% of the CLBP patients only used drugs as form of CLBP management and only 4% of them participated in a rehabilitation programme in the survey. This may consequently reduce the indirect cost such as taking time off from work for appointment, travel and lost productivity. The inconsistent findings can also due to the differences in patients' characteristics, treatments received by patients, and structure of healthcare systems in different countries.

5.7.2 The cost per change of ILOC as a result of the CBCLBP programme

The ILOC was used to measure the incremental cost-effectiveness of the CLBP programme. We found it costs the provider £53 for every unit of improvement of ILOC.

This is the first study which has reported the cost per change of ILOC, providing a bench mark for future studies. However, the potential benefit of improvement of ILOC is evident in this study, including (a) Improvement in ILOC is found to be significantly associated with improvement in pain intensity, disability and FAB in this study and (b) improvement in ILOC was shown to be a significant predictor to reduction in FAB.

Other studies reported in the literature have also demonstrated evidence of the benefits of improving ILOC in NSCLBP. For example, ILOC was positively correlated to quality of life (Sengul et al, 2010), active coping strategies (Harkapaa et al, 1991), less psychological distress (Crisson and Keefe, 1998), information seeking and prediction of better outcome (Main and Waddell, 1991). Given that an incremental cost of ILOC of £53 may potentially gain the aforementioned clinical benefit, this may provide a

useful and alternative way for managers and clinicians to consider the cost-effectiveness of the CBCLBP programme.

To put our finding of cost per change of ILOC into context, Hollinghurst et al. (2008) conducted a cost effectiveness analysis to compare the cost to the NHS with the primary outcome of the RMQ and the number of days free of pain. A total of 579 patients with NSCLBP in primary care who randomised into: exercise, six sessions of massage, and six sessions of Alexander technique, as single and combined intervention. Their findings revealed that: (1) Incremental costs to the NHS of every point reduction in disability score were: £61 per point on disability score by exercise alone; £64 per point by Alexander techniques plus exercise, and £448 per point by massage alone; (2) Incremental costs to the NHS of additional pain-free day were: £9 per additional pain-free day by exercise, £43 per additional pain-free day by combined Alexander techniques and exercise, and £26 by massage alone. With an incremental cost to the NHS of every point of improvement in ILOC of £53, it seems to be a good value option for the provider comparatively.

During the planning of the economic evaluation of this study, it was suggested that the use of EQ-5D would be a useful outcome measure. However, the PI was concerned about the risk of respondent fatigue (Lavrakas, 2008). If EQ-5D was included, each participant would have a total of seven questionnaires to complete. This may have resulted in reluctance by participants to complete the outcome measures, which may have led to poor response rate and poor data quality (Lavrakas, 2008). In addition, the PI felt that it is important for clinicians and policy makers to consider a range of outcomes when drawing conclusions about the cost effectiveness of an intervention (Coast, 2004). Therefore, the cost per ILOC was chosen.

The PI acknowledged that the use of EQ-5D to calculate quality of life adjusted years (QALYs) will be a better option than ILOC in order to provide data that can be compared across studies. The EQ-5D instrument is recommended by Department of Health (2010) and the CSP (Jette et al.,

2009) to assess cost effectiveness in relation to musculoskeletal physiotherapy outpatient services. It is also widely used in many existing studies. The current study can be replicated by using EQ-5D so that a standardised and direct comparison with other studies and other treatments for NSCLBP can be made.

5.7.3 The longer-term (6-months) cost of back care from a patient and provider's perspective

NSCLBP is a chronic condition that often results in ongoing providers' and patients' costs. This highlights the importance of evaluating the economic impact in a longer term as a result of the CBCLBP programme. In the 6-months period following completion of the CBCLBP programme, the mean patient's cost was £160.7 (including prescription charge, travel costs and therapy charge) (**Table 4.31**), and the total mean provider's cost (including GP visits and any utilisation of NHS service) per patient was £154.1 (**Table 4.32**).

Hollingshurst et al. (2008) reported the mean provider's cost for patients' normal GP care (when patients received no active NHS treatment for their LBP) was £55 per year, and the mean patient cost at one-year was £375, with £170 (45%) of this relating to expenditure on private therapies. To compare these data to our mean provider's cost (£308) and patient cost (£321) at one-year (by doubling our six-month figures), the provision of the CBCLBP programme is much more expensive for the provider, however it is cheaper for patients' out of pocket expenses at one-year if patients received the CBCLBP programme.

It must be noted that there may be other potential cost in long-term (> 1-year) if patients did not receive appropriate treatment. For instance, it was suggested that the total UK low back pain related cost, including private care and societal cost such as loss of productivity are between 4.7- 10 times more than NHS cost (Koes et al., 2001). While commissioners and managers are actively seeking evidence for clinical and cost effectiveness for NSCLBP treatments, the financial burden of NSCLBP is far more complex due to its high societal cost, patient cost and potential provider's

cost in long-term. The saving for providers, patients and the society are likely to be greater over time by implementing appropriate treatments.

Mean patient cost at 6-months: comparison with other studies

Critchley et al. (2007) reported the total mean patient cost from baseline to 6-months was £70.49 following participation of a physiotherapy-led CBT rehabilitation, whereas the total mean patient cost of current study was £160.70 at 6-month. When comparing the baseline between two studies, pain intensity and disability scores were very similar (VAS= 59mm and RMQ= 11.5 (Critchley et al., 2007), VAS= 60.4mm and RMQ= 11.5(current study)). The duration of both programmes also had similar content and similar treatment duration. Travel cost is unlikely to be the reason of a higher mean patient cost found in our study. This is because the present study took place in Stockport, which is cheaper to travel, whereas study by Critchley et al. (2007) was in London, which is more expensive for patient to travel.

One explanation for higher mean patient costs in the present study could be that all those nine patients (only 9 out of 55 patients went for other therapy 6-months following the CBCLBP programme) self-funded their therapy (**Table 4.30**). Interestingly, the majority of the patient cost (£133.4 out of £160.7) was spent on “travel and other therapy”, rather than “travel and prescription costs”. Besides, amongst “type of other therapy”, 56% of patients opted for self-funded hydrotherapy, 22% private physiotherapy and 22% self-funded acupuncture (**Table 4.30**). This observation implies that despite patients in the present study reviewing higher mean patient cost than Critchley et al. (2007), the majority of patient chose proactive treatment (i.e. hydrotherapy) to continue self-care, rather than opting for passive treatments such as private physiotherapy and acupuncture. It was found that use of self-care was significantly associated with high ILOC and low ELOC (Harkapaa, 1991). It is possible that the steady increase in ILOC and decrease in ELOC found in the present study may partly explain the increase in self-care attitude at 6-months following the CBCLBP programme.

Mean provider cost at 6-months: compared with other studies

Lamb et al. (2010) reported that mean provider cost at one year was £234.51 per patient in their advice plus CBT intervention group. Klaber Moffett et al. (1999) reported mean provider cost was £334.95 per patient at one year in their exercise and CBT group. Both of these studies examined patients with a mix of subacute and chronic LBP, and only reported provider cost at one-year. This present study reported £154.1 for six months period in NSCLBP patients following the CBCLBP programme. Direct comparison with other studies is difficult due to difference in LBP population being studied, economic evaluation design, clinical setting and follow-up period. There is also evidence to suggest that age, gender, social class and employments are also determinants of utilisation of primary care services (Field & Briggs, 2001). However, if it is doubled the six-month mean provider cost of the present study, it gives £308.2 at one-year which is similar to those reported by Klaber Moffett et al. (1999).

Healthcare utilization at 6-months

Patients with CLBP are likely to seek care (Mortimer et al., 2003; IJzelenberg & Burdorf, 2004), and more likely to use health care services (Carey et al., 1995; Carey et al., 1996; Von Korff et al., 2007). In the six months after completing the CBCLBP programme, 25% participants re-visited their GP, 27% required prescriptive pain medication, no participants reported use of NHS therapy services (including physiotherapy and secondary care), and 22% reported private physiotherapy services (**Table 4.30**).

Lamb et al. (2010) studying patients with subacute and chronic LBP, reported 50% of participants re-visited their GP at least once during follow-up, 19% used NHS physiotherapy and 23% private back pain services. As shown, our finding of NHS utilization is comparatively much lower than the study by Lamb et al. (2010). The different findings may be explained by the different employment status between the two studies. A higher rate of GP consultation is shown to be associated with unemployment (Carr-Hill et al., 1996; Field & Briggs, 2001). Lamb et al. (2010) reported 9% of participants were unable to work because of back pain and 7% unable to work due to

other illness. In the present study, 2% were on sick leave, 6% were unemployed due to back pain and no participant was unemployed due to other illness (**Table 4.1**). Unemployment implies a life event of change, and such change may cause stress, increased tendency to sick role behaviour and increased perception by patients that there is a need and benefit to consult their doctors (Westin, 1993). The lower unemployment rate (62% were employed and currently working) in this study could at least be the reason for less GPs consultation at 6-months. It is acknowledged that other factors such as cultural difference, physical and psychological health, social security needs and financial and family hardship may also affect GP consultation (Westin, 1993; Carr-Hill et al., 1996; Field & Briggs, 2001). However, they are not always easy to disentangle in research due to its complexity and the consideration of these factors is beyond the scope of present study.

Another explanation for the lower healthcare utilization in current study may be related to the significant improvement in ELOC. It has been suggested that higher consultation is associated with externalised beliefs regarding pain management in LBP patients (Wallston & Wallston., 1982; Waxman et al., 1998). In the present study, significant reduction in ELOC was observed at week 6 and 3-months; a slow but non-significant reduction in ELOC continued until 6-months (**Table 4.8**). Although the correlation between healthcare utilization and ELOC was not examined in this study, these two factors may be associated, as suggested in the literature (Wallston & Wallston, 1982; Waxman et al., 1998).

84% of the participants did not consult other therapy following the CBCLBP programme at 6-months. This can be seen as a reflection that participants are self-managing satisfactorily (**Table 4.30**). 16% of the participants visited other therapy following completion of the programme, yet all were self-funded. Of the different therapies patients visited during the six-month period, hydrotherapy appears to be the most popular (56%); private physiotherapy and acupuncture accounted for 22% and 22%, respectively. It is unclear why so many patients opted for hydrotherapy following the CBCLBP programme. A RCT concluded that hydrotherapy

produced better improvement in disability and quality of life in patients with CLBP than physiotherapy home-based exercise (Umit et al., 2009). It is also noteworthy that informal feedback from patients found hydrotherapy particularly enjoyable, and beneficial to their NSCLBP condition both physically and psychologically; and many of them saw it as part of their self-management rather than a therapeutic treatment. A great interest opting for hydrotherapy following the CBCLBP programme suggests that patients became more independent about their future self-management and they developed their own preferred self-care strategies which is healthy, proactive and fun.

With the demand for evidence-based practice in physiotherapy, combined with the need for the best use of both public and private resources, policymakers and commissioners understandably require physiotherapists to demonstrate their service and expertise are efficacious and effective, and supported by evidence. The present findings provide a benchmark for the cost of a six-week physiotherapy CBCLBP programme from a provider and patient perspective in both short-term and longer term (6-months). It also included the societal cost per patient to attend the programme. It must be noted that careful selection when referring NSCLBP patients onto group-based intervention is important in keeping the provider cost down. The low healthcare utilisation six months following the programme could be seen as a reflection of how successfully the various components of the CBCLBP programme have been achieved.

CHAPTER 6 SUMMARY, RECOMMENDATIONS AND CONCLUSIONS

6.1 Introduction

Despite a large body of studies supporting the positive effect of the CBA active rehabilitation in NSCLBP, there is limited evidence for the effectiveness of CBA treatment targeting NSCLBP patients with psychosocial risk factors such as high FAB. Besides, the overall quality of existing evidence relating to this field is poor, with the majority associated with mixed duration of NSLBP patients. Therefore, this study focussed on NSCLBP patients characterized with high FAB, which is a challenging subgroup of LBP patients for primary physiotherapists encountered in clinical practice.

Only a limited number of studies have investigated the effects of CBA treatment on HLOC, and the association between HLOC and the key clinical elements of NSCLBP. Existing evidence is overall low in quality. These studies do not allow us to determine the potential importance of HLOC in the physiotherapy management of NSCLBP. On the basis of HLOC concerns of individuals' beliefs about self-responsibility, and whether one's actions and behaviour may influence outcomes (Wallston & Wallston, 1982), HLOC may be a contributing factor or underlying mechanism of how desired outcomes can be achieved. Therefore, this study has chosen HLOC as the primary outcome and examined its relationship with other NSCLBP co-variables.

The majority of LBP patients are seen in primary care, and the cost is substantial (Becker et al., 2010). It is important that a treatment achieves 'value for money' in the current financial climate. Therefore, a cost study was also included in this study, with the aim of providing a benchmark to managers and policy-makers when allocating their limited budget and resources. This final chapter presents a summary of the findings, recommendations, strengths, limitations, key learning and conclusions drawn from the present thesis.

6.2 Summary- Aims and key findings of the study

Aims of the study were to:

1. Assess the effects of the physiotherapy CBCLBP programme on patients' HLOC.
2. Examine the effects of the CBCLBP programme on pain, disability and FAB.
3. Determine if there is any relationship between patients' HLOC and pain, disability and FAB.
4. Examine patients' self-care attitude toward their back pain in terms of their desire in future use of healthcare and prescription pain medication as a result of the programme.
5. Investigate the cost of back care per change of ILOC, and the cost of the CBCLBP programme from a provider's, patient and societal perspective.

Key findings of the study

1. The physiotherapy CBCLBP programme has significantly improved patients' HLOC, with such improvement being sustained for six months.
2. The physiotherapy CBCLBP programme has significantly improved patients' pain intensity, disability and FAB, with such improvement being sustained for six months.
3. **(i)** A significant relationship was found between reduction of pain intensity, reduction of disability and reduction of FAB.
(ii) Increase in ILOC was significantly associated with reduction in pain intensity, disability and FAB.
(iii) Reduction in ELOC and reduction in CLOC were both significantly associated with reduction in pain intensity and FAB, but they had no significant relationship with reduction in disability.
(iv) All subscales of HLOC (i.e. ILOC, ELOC and CLOC) were found to have no predictive value of reduction in pain intensity and reduction in disability, after accounting for demographics and other co-variables.

(v) Increase in ILOC has emerged as the unique and significant predictor of reduction in FAB, after accounting for demographics and other co-variables.

4. The physiotherapy CBCLBP programme has significantly improved patients' self-care attitude towards back pain, with such improvement being sustained for six months.
5. (i) To provide a six-week physiotherapy-led CBCLBP programme, the mean provider cost was approximately £285.82; the mean patient cost was approximately £9.10, and the mean societal cost was approximately £124.59;
(ii) The incremental cost of ILOC was approximately £53. i.e. it costs the provider £53 for every point of ILOC gained; and
(iii) In the six months following the completion of the CBCLBP programme, the mean patient cost was approximately £160.7, and the mean provider cost was approximately £154.1.

6.3 Strengths and weaknesses of the study

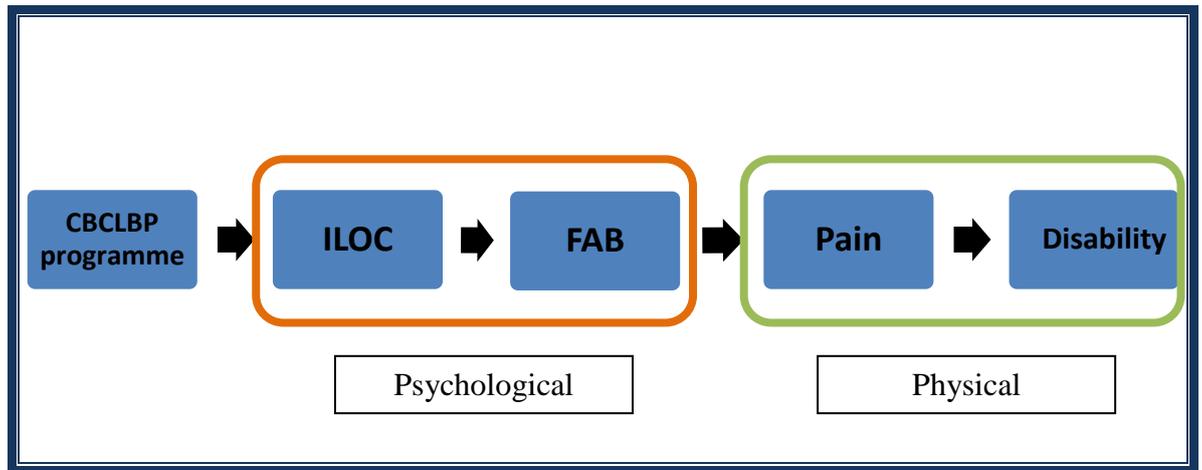
6.3.1 The innovations and benefits of the study

This is the first study to examine the effects of a physiotherapy led CBCLBP programme on HLOC in NSCLBP patients. There are a limited number of studies in the literature evaluating interventions with a CBA component on HLOC in NSCLBP. Evidence consistently supported the positive effect of CBA intervention on HLOC. However, the quality of evidence was generally poor. Methodological limitations of previous relevant studies include: (1) short follow-up period (< 3-months) (Keedy et al., 2014; Harkapaa et al., 1991); (2) use of heterogenous group of back pain patients (Klaber Moffett et al., 2006; Rybarczyk et al., 2001); and (3) incomplete follow-up data (Keedy et al., 2014; Rybarczyk et al., 2001). The present study is likely to provide more valid findings than these previous works because of the use of a homogenous group of patients (NSCLBP with high FAB), a longer follow-up period (6-months) and complete follow-up data were obtained.

This study is also the first that has shown increase in ILOC was the unique and significant predictor of reduction in FAB. Again, evidence in this line is limited. There is only low to moderate quality evidence to support the relationship between HLOC and NSCLBP variables. Many methodological criteria regarding internal and external validity of these previous studies were not fulfilled. Besides, the majority of them conducted cross-sectional correlation, thus preventing directional conclusions of causality between HLOC and NSCLBP outcomes. The present study has an advantage that it includes a predictive component, to determine causality.

The following chain (**Figure 6.1**) is proposed to summarise the predictive relationship of increase of ILOC, reduction in FAB, reduction in pain intensity and reduction in disability, following the CBCLBP programme.

Figure 6.1: The predictive relationship of an increase of ILOC, reduction in FAB, reduction in pain intensity and reduction in disability.



As shown in **Figure 6.1**, this study found that the CBCLBP programme was effective in enhancing ILOC; increase of ILOC predicting reduction of FAB; reduction in FAB predicting lower pain intensity, and lower pain intensity predicting lower disability.

The CBCLBP programme may directly improve these physical and psychological outcomes (as shown in **Section 5.3** and **Section 5.4**). However, it is also possible that the physical outcomes (pain intensity and disability) improved via the intermediate link of psychological improvement (i.e. increase of ILOC and reduction in FAB). The sequential and directional relationship as seen in **Figure 6.1** highlight the importance of improving patients' ILOC and FAB, and they could be the underlying factors influencing patients' responses to pain and disability. An important message here is that unless the psychological aspects are taken care of first (such as ILOC and FAB), the physical components (pain intensity and disability) may not be addressed and followed.

This finding is entirely consistent with the treatment philosophy of the CBA, where the emphasis is to address patients' maladaptive beliefs, feelings and behaviours (Airaksinen et al., 2006; Henschke et al., 2010).

The new findings of this thesis provide an increased understanding of HLOC in relation to the key clinical elements of NSCLBP. It adds new knowledge to the current evidence that increased ILOC predicts better FAB outcome in NSCLBP. This may be particularly beneficial from a clinical perspective. Intervention strategies can be extended to the development of a sense of personal control over pain, whilst simultaneously eliminating fear-avoidance mechanisms and improving overall physical function (which we already knew). HLOC may be one important underlying factor to help achieve the desired treatment outcomes in NSCLBP patients with high FAB. Clinicians could consider addressing patients' HLOC more fully and more specifically during their physiotherapy CBA rehabilitation (see **Section 6.5.1 Implication for practice**).

No previous work has examined the effectiveness of CBA treatment targeting only NSCLBP patients with psychosocial risk factors such as high FAB. This is another major advantage of the present study, which concluded that the CBCLBP programme was more effective than usual physiotherapy care at reducing pain, disability, FAB, and improving HLOC and self-care attitude in NSCLBP patients with high FAB. This has highlighted that the CBCLBP programme is more appropriate for this subgroup of patients in improving the physical and psychological aspects of their NSCLBP. This finding is beneficial for both clinicians and policy-makers during clinical reasoning and design of patients' care pathway. This may also prompt appropriate treatment for appropriate patients, so that unnecessary waste of time and resources maybe saved for the patient, provider and the society.

6.3.2 Strength of the study

Strength relating to methodological quality

1. Strength of A-B-A design: high in internal validity

The use of A-B-A design offers a number of strengths in terms of validity of the present findings. Firstly, it studies the same group of patients under treatment and no treatment condition, and having the same group of patients acts as its' own control (Engel & Schutt, 2012). Therefore, this inherently reduces most threats to internal validity that may have been caused by

sampling bias and between-group variability. Secondly, the use of same subject design means there is no need for randomization and allocation concealment. Therefore, selection bias reduces and this consequently increases the internal validity. Thirdly, replicating the CBCLBP programme over the course of study period to patients of different baseline characteristics enhances external validity (Kazdin, 2010). These advantages strengthen the internal and external validity of the findings. It allows the PI to make confident statements that changes in outcome measures between phases are due to the effect of the CBCLBP programme but not some other factors.

A desirable quality of baseline data is stability, because this implies that data displays limited variability (Byiers et al., 2012). With stable baseline data (Phase A1 and Phase A2) and with three baseline data points (-4 weeks, 3-months and 6-months) as in this current study, stability has been achieved and an appropriate basis has been formed for comparison. Therefore, any change of trend over the study period is likely to be attributed to the effect of the CBCLBP programme (Phase B), and any trend observed in the absence of the programme is likely to be the continuation of treatment effect (Byiers et al., 2012). This ‘good’ quality baseline data strengthens the validity of the present findings about the effect of the CBCLBP programme on HLOC and other outcome measures.

2. Good generalizability

This study also has good generalizability. The PI believes that the results of the present study are applicable to the population of NSCLBP patients with high FAB presenting for primary physiotherapy. This is because: (a) participants were recruited from Stockport, with a variety of socio-economic classes from a range of rural and urban, affluent and deprived areas of Stockport; (b) the baseline characteristic differences between those who completed the programme and those who dropped out of the programme only presented significant differences in employment status, financial status and ELOC. But aside from these differences, there are no other significant differences between them. This suggests that data of the present study is derived from patients who were representative of the original sample,

indicating the results of good generalizability; (c) baseline profile of the included patients is appropriate for the CBA active rehabilitation in accordance to clinical guidelines (Savigny et al., 2009), and therefore the generalizability of the current findings for clinical practice is probably high; (d) this study was conducted within the context of an existing intervention (i.e. the CBCLBP programme) in a busy primary NHS physiotherapy department with no extra resource or research manpower. The PI had to consider and manage practical issues such as time, resource and other clinical caseload. All physiotherapists involved in the study were experienced physiotherapists with no additional research training. Therefore, the programme and the current findings could easily be replicated in any primary physiotherapy department as it is a reflection of real-life practice, and (e) the CBCLBP programme was not exclusive for research purpose due to political and ethical considerations. Patients attending the CBCLBP programme during the study period were a mix of research participants and non-participants. Thus, the present findings are more likely to reflect reality and natural interaction of patients and physiotherapists compared to evidence emerged from an RCT research environment. Because of its practice-based nature, it may be beneficial when implementing the current findings in future clinical practice (Chan & Clough, 2010).

3. Low attrition

Another important strength of the present study is its low attrition bias. Although CBT treatment for CLBP tends to have high attrition (Glombiewski et al., 2010), all participants in this study managed to complete the CBCLBP programme (25% attended five out of six sessions; 75% attended all six sessions). In addition, the response rate at each follow-up evaluation (week 6, 3-months and 6-months) was 100%. From a patients' perspective, completion of the programme enables participants to optimize benefits from the programme components. From a research perspective, complete outcome data allowed the PI to have all necessary pre- and post-treatment data for statistical analysis and adequate reporting, which in turn strengthens the validity of the findings. An explanation of excellent attendance could be that the PI was able to offer participants three available classes of different times each week, which enabled participants to attend

the programme without compromising work or family life. The PI also offered patients to complete their questionnaires either via face-to-face appointment at their convenient time (including out-of-hour) or by post, which gives participants the flexibility and availability to respond to their questionnaires. This suggests that one key for low attrition is to offer flexible timetable of the programme.

Another possible explanation for low attrition could be that patients were motivated, and had a realistic expectation of the CBCLBP programme. The PI regularly stressed the importance to all physiotherapists in the physiotherapy department that each potential referred patients should be thoroughly explained the nature of the CBCLBP programme (alongside written information), and showing willingness to take part. So, those who decided to attend the programme were probably less likely to drop-out because they had a good understanding and correct expectation of the programme.

4. Care taken to reduce methodological limitations

Despite being a single-handed researcher and clinician in a busy NHS physiotherapy department, the PI has taken every possible measure to ensure methodological quality of this study. Methodological strength of this study includes:

- Pilot study on the first five eligible patients (who were not included in the study);
- Adequate powered sample size based on powered calculation;
- Use of strict selection criteria and investigation of a homogenous group of subjects (i.e. patients with NSCLBP with high level of FAB);
- The use of A-B-A same study design that strengthen the internal validity of findings;
- Use of a wide range of relevant outcome measures of high validity and reliability, which capture the main domains of NSCLBP, and are important to both patients and clinicians;
- The application of highly-structured and standardized intervention;

- Standardized manner of data collection consistently throughout the study period;
- A reasonable length of follow-up period;
- Low attrition bias due to completed outcome data at all time-points;
- Application of appropriate statistical analysis;
- Careful interpretation of the data;
- Good generalizability for clinical practice.

Based on the Cochrane Bias Methods Group's recommendation for risk of bias assessment (Higgins et al., 2011), it is reasonable to state the evidence which emerged from this current study is valid, is of good methodological quality.

Strength relating to impact on practice

1. The CBCLBP programme is more clinically effective than usual care

This current study challenges the effectiveness of individual physiotherapy in improving NSCLBP outcomes. Prior to the CBCLBP programme (Phase A), patients had an average of four sessions of individual physiotherapy treatment (such as joint mobilisation, manipulation, written home exercise programme, and back pain information booklet). However, patients showed no significant improvement in all outcomes. During the programme (Phase B), all outcomes improved significantly, with a sustained effect to 6-months. This implies that the CBCLBP programme is more effective than the usual individual physiotherapy care, at least with respect to this subgroup of NSCLBP patients with high FAB. This is an important take home message for clinicians, because many physiotherapists still regard the CBCLBP programme as a last resort when treating NSCLBP patients.

2. Questioning guideline recommendation of 100 hours treatment time

This study challenges the guideline value of 100 hours over up to 8 weeks in the delivery of active exercise CBA rehabilitation (Savigny et al., 2009). The total duration of the CBCLBP programme in present study is approximately 14 hours over 6 weeks, which demonstrates significant clinical improvement in this subgroup of NSCLBP patients with moderate pain, moderate disability and high FAB presenting for primary physiotherapy. Currently, there is no consensus about the duration,

frequency and intensity of the programme in clinical practice. Further work and refinement of NICE guidelines is needed to determine a more concrete reference regarding the intensity and duration of the programme, and “what works for whom” to avoid long treatment hours unnecessarily.

3. Reinforced clinical effectiveness of physiotherapy CBA programme at low provider cost

This study lends further support to previous physiotherapy studies of high quality in terms of clinical effectiveness and costs (Critchley et al., 2007; Johnson et al., 2007; Lamb et al., 2010). The present study demonstrates that the physiotherapy CBCLBP programme is clinically effective and has a sustained effect at 6-months on the key clinical elements of NSCLBP. Further, it costs less for the provider to provide a six-week CBCLBP programme (£285.82 per patient based on 6-8 patients per group), compared to individual physiotherapy (£348 per patient based on the routine 6 hours physiotherapist’ time from receipt of referral to discharge from the service). In addition, the CBCLBP programme is ran by experienced physiotherapists alone with CBA training. There is no involvement of pain consultants, cognitive-behavioural therapists, other multi-disciplinary members and ongoing secondary care referral. This consequently cuts cost for the health service and optimises the use of health resources. This is positive for the physiotherapy profession, particularly NHS physiotherapists who are under constant pressure to prove their treatment can be clinically effective, as well as an inexpensive treatment to the provider.

6.3.3 Weakness of the study

1. Weakness of A-B-A design compared to RCT

Despite the various methodological strengths of the same-subject A-B-A design over the between-subjects design such as the RCT (see **Section 6.3.2 Strength of the study**), it is acknowledged that the same-subject design also has its weaknesses when compared to the between-subjects design. First, subject dropout is more problematic in the same-subject design (Nunn, 1998). In the between-subjects design, there will be at least twice as many participants than the same-subject design, since there will be two or more arms of participants. A fundamental inferential statistics principle is that: as

the number of subjects increases, the power increases and the probability of type II error reduces. In contrast, there is only single group of patients in the same-subject design. If the smaller sample size reduces due to dropout, statistical power of the experiment reduces, and the probability of type II error also increases. The loss of one patient has double the impact and a higher probability of committing type II error.

Secondly, although all research designs are susceptible to some extent of carryover effect (practice and fatigue effect), the same-subject design is particularly susceptible since participants are subjected to both control and treatment condition (Gonzalez, 2009). Either participants will become more accomplished through practice and experience, having a positive effect of their self-reported score, or they will experience fatigue from taking the same tests, having a negative effect of their self-reported scores. These factors may skew the results and weaken the validity of the findings. A between-subject design does not induce a carryover effect because each participant is only subjected to a single condition, either being part of the treatment or control condition.

Another disadvantage of the same-subject A-B-A design is its inability to deal with treatments that have irreversible effects on patients (Cunningham et al., 2013). For example, the same-subject design would not be appropriate to examine the efficacy of an invasive brain surgery. Once a patient had surgery, it is likely to lead to irreversible change. The same-subject design does not permit the ability to detect changes in variables between treatment (e.g. brain surgery) and no-treatment condition (post brain surgery). On the other hand, because a between-subjects design compares treatment and control condition, thus it has an advantage to be used in treatments that have irreversible effects. However, such limitation should not corrupt the findings of the present study since the CBCLBP programme is unlikely to produce irreversible effect on a complex chronic condition such as NSCLBP.

Finally, the same-subject design can be ethically problematic, for not providing alternative treatment, as opposed to a between-subjects design, where alternative is available for study participants. However, this should

not be an ethical concern for our participants because the CBCLBP programme is a recommended second-line physiotherapy treatment in accordance with evidence-based guidelines for NSCLBP (Savigny et al., 2009; Chou et al., 2009; Koes et al., 2010).

2. Clinician-researcher dual role

Experimenter bias

The main limitation of the present study is that the PI acted as both researcher and clinician. Due to limited staff resources, it was necessary that the PI took the dual role of the researcher and clinician. The PI was involved in gaining all informed consents, carried out the majority of the treatment, and collected all data at 3-months and 6-months follow-up. This may have potentially introduced experimenter bias effect as the PI was aware of the hypothesis being tested, and may potentially have had a set of expectations and predictions about the treatment outcome (Burns, 1997).

Expectancy and Hawthorne effect

The PI's personal belief and enthusiasm for the CBCLBP programme may have influenced patient's attitude and behaviour, hence may influence patient's pain and disability reporting. Patients may also have a tendency to work harder and give better reporting because they knew they are under study, and were being investigated (i.e. Hawthorne effect) (Earl-Slater, 2002). Both the Hawthorne effect and the PI personal belief for the programme are known to affect the outcome of the treatment (Klaber Moffett & Richardson, 1997). This is referred to as the expectancy effect. Expectancy has direct effects on cognitions and indirect effects on behaviour (Bootzin, 1985). Both the patients and the health professionals' enthusiasm play an important role in positive outcome to treatment (Petrie & Hazleman, 1984; Klaber Moffett & Richardson, 1997).

Halo effect

The PI is an experienced clinician specializing in treating patients with NSCLBP delivering the CBCLBP programme for over twelve years. The quality of the communications, the delivery of the education, and the interaction between the PI and patients is likely to be positive and pleasant for patients. The consistent clinical input from a single relatively

experienced and approachable physiotherapist with a special interest in NSCLBP may result in halo effect (Nisbett & Wilson, 1977). Such factor may have an influence on the outcome of treatment particularly on reporting of pain, disability and perceived control (Klaber Moffett & Richardson, 1997).

These potential biases would have reduced the validity of the findings. Therefore, it would have been preferable for the PI to have acted as an independent researcher, with no input into treatment and data collection. This may have enabled a better approximation of objectivity (the so-called 'Archimedean point') and would have increased the chances that our results can be generalised. However, this was not possible in the current study.

A major advantage of being a dual role of clinician-researcher is that it enables the development of a stronger relationship between patients and the PI, which may facilitate treatment attendance, the follow-up process and minimize the potential for loss to follow up. By having the PI collect 3-month and 6-month data also helped ensure data quality, and minimize missing data. These factors may explain low attrition and no missing data during the study.

3. Potential mediators

This study aims at examining specific variable(s) predicting outcome of interests. However, it is acknowledged that these direct causal associations may be mediated by other factors, which is beyond the remit of the current study. For example, self-efficacy, psychological distress and fear may mediate the relation between pain and disability (Lee et al., 2015). Future work using mediation analysis is needed to study the mechanism underlying these associations, and to determine whether any specific factors play an intermediate role that explains how the predictor variable(s) leads to improvement of clinical outcomes.

4. Selection bias

According to the inclusion criteria of the CBCLBP programme, participants had to be positively opted-in to the programme, and had to be motivated to change behaviours. Since our patients already showed self-motivation when

they entered the CBCLBP, and all managed to complete the programme and the 3-months and 6-months follow-up, there is a high possibility that patients in the current study may represent a motivated subgroup. This may result in selection bias which may explain the favourable outcome in this study (Higgins et al., 2011).

5. Lack of qualitative data

Unfortunately, this study did not collect qualitative data of why and how patients' various pain beliefs may change over time in the context of their physiotherapy treatment experience. The current study can be replicated by using a mixed qualitative and quantitative method. Over the course of the study period, the PI had many informal verbal feedbacks from the participants about their experience and beliefs about pain. Their views added much richness in addition to the quantitative findings. The subjective experience of patients may help: (1) explain the positive outcomes of the current study from the patients' perspective; (2) understand the underlying mechanism of why and how the CBCLBP programme works; and (3) identify specific treatment components that can be targeted to improve treatment outcome.

For example, reduction in negative beliefs, addressing unrealistic expectations from health professionals and a variety of self-management skills, are frequently reported by patients (informal feedback during the programme) as important components that boost their ILOC beliefs. Pain education and explanation of sensitization were also well-received by patients. Many said understanding pain was the turning point for them to become more engaged and empowered in their own NSCLBP management. This information gives some insights into the underlying mechanism between changes in ILOC and specific aspects of the programme. Therefore, it is recommended that a mixed qualitative (for example, the use of focus group and semi-structured interviews) and quantitative method can be used in future studies, because each method is capable of providing valuable information and are complimentary to each other (Hicks, 2009).

6. Possible confounding variables

Confounding variables were not controlled for, such as advice and other treatments received prior to the programme, and six months after the programme, which may influence treatment outcomes. However, these confounders are difficult and impractical to control. Besides, it is unethical to stop patients seeking advice and/or other treatments before and after their CBCLBP programme. Other factors, such as patients' expectations to treatment and various biopsychosocial factors may also affect their response to self-reported outcomes over the study period. Importantly however, in either case a potential influence on outcomes should not corrupt the main findings of this present study because we have the same group of patients serves as its own control. Hence the change of trend over the study period is likely due to the effect of the CBCLBP programme.

7. Follow-up and single site

The follow-up period was six months. Considering NSCLBP is a chronic condition, a longer follow-up period would have been ideal to give more relevance to the data, which could give more validity to the findings. However, a follow-up period over more than six months was impractical and challenging for a single-handed PI. Besides, the period between completion of the CBCLBP programme and end of study period (six month) should be long enough to eliminate preservation or performance bias.

The current study was conducted in single site, which has several advantages over multi-centres such as: (a) it is logistically easier; (b) it is cheaper; (c) it does not require prolonged negotiations on study protocol and ethics approval;(d) it simplifies data collection; (e) it is likely to deal with less heterogeneous patient population, hence diminishes confounding factors. However, it must be noted that the most shortcomings of single-site studies is their limited external validity (Bellomo et al., 2009). This is because conducting a study in a single clinical environment may not be generalizable to a broader population of NSCLBP patients with high FAB. Besides, it tends to give a more dramatic and larger treatment effect size, compared to multi-centres study (Bellomo et al., 2009). The PI has made attempts to determine external validity of the findings by comparing other

previous published studies. Further larger, multi-centred with a longer follow-up period will be valuable to confirm the present findings.

8. Limitation of the cost study

Unfortunately we did not include EQ-5D questionnaire, which would have allowed us to calculate cost per QALY. We also did not collect costs during Phase A1 because the cost study was newly introduced several months after patient recruitment. The economic analysis could be improved by using the use of EQ-5D. It is acknowledged that ILOC is an unusual choice of cost study outcome measure, and its use would not allow direct comparison of cost effectiveness with other NSCLBP treatments. This is a drawback of the present cost study. However, as previously mentioned, the PI was concerned about the risk of respondent fatigue, which may have led to poor response rate and poor data quality (Lavrakas, 2008). In addition, the PI reasoned that HLOC is the primary outcome measure and the main interest of the present study. Therefore, the cost per ILOC was chosen. Replication of the current study could be improved by using the EQ-5D to calculate QALYs, thus a standardised and direct comparison with other studies and other treatments for NSCLBP can be made, which is of great importance for the provider and policy decision-maker. However, it could also be argued that it is important for clinicians and policy-makers to consider a range of relevant outcomes (such as HLOC) when making decisions about how to spend their limited healthcare resources.

Another limitation of the cost study is the reliance on patients to recall the amount of healthcare utilisation of all types, travel and loss of productivity. It is possible that inaccurate or biased recall reduce the validity of the cost data.

6.4 Key learning from the research

Belief is at the heart of chronic back pain, i.e. how people think and feel about their pain affects what they do about it. Every patient's pain experience is unique. The journey of this research started as very impersonal, with a belief that an 'all-round' clinician should be play a proactive and reflective role in relation to our skills and patient's care. Not

only being ‘research-minded’, but becoming actively involved in carrying out research and implementing evidence in our professional practice.

The research questions of the current study are based on clinical observation and experience. It occurred to the PI that a patient’s belief of who is responsible and who has control over their back condition makes a difference in their treatment outcome. For instance, those patients who believe their actions and own responsibility will improve their NSCLBP outcome generally do better than those who feel disempowered. Some patients believe it is the physiotherapist’s responsibility to fix their back condition. Some patients believe their back pain is just a matter of bad luck or fate, and have very little control over it. This study has confirmed that HLOC does have a relationship with patients’ main complaint of NSCLBP such as pain, functional limitation and avoidance of movement. This learning has extended our understanding of HLOC in relation to NSCLBP, and HLOC can be an important consideration during the design and delivery of the physiotherapy CBCLBP programme.

Managing patients with NSCLBP can be challenging, yet highly rewarding at times. Appropriate referral of the right patients at the right time enhances the chance of successful outcomes. It is the treating clinicians’ role to decide what dominant factors within the complex context of the biopsychosocial framework may drive their patients’ NSCLBP and the associated physical and psychological consequences.

Often at the start of the programme (session 1), at least one patient may question why someone in pain will engage with treatment that is aimed at their thoughts, beliefs and behaviours. This may be unsurprising as most patients have *real* pain, but not just *think* they have pain. Over the study period, the PI realised that the explanation of pain physiology, pain neuromatrix and sensitization model of the programme is a powerful ice breaker, as it gives patient a physical cause of their ‘non-specific’ pain, rather than ‘it is all in the head’. Hence patients are more willing to engage with the various components of the programme. Several RCTs and individual studies have already investigated the efficacy of higher level of

pain education in LBP with promising evidence (Moseley, 2002; Moseley, 2003a; Moseley, 2004; Moseley et al., 2004; Ryan et al., 2010). The effect of the CBA and combined exercise rehabilitation seems to be complimented by the effect of higher level of pain physiology education. An interesting area to look at in a future study is to see whether the addition of higher level of pain education to usual physiotherapy care may improve patients' NSCLBP outcome. There is evidence to suggest that health professionals who had formal training in pain science education performed much better than those who were untrained (Moseley et al., 2003c). All the physiotherapists who delivered usual physiotherapy care did not have formal or professional training in pain science, as opposed to those who delivered the CBCLBP programme. This may highlight the need for pain science training in all musculoskeletal physiotherapists working in the pain field, or consider making it a core competence training.

Dissemination, publication and implementation

Implementation of research evidence can be challenging in musculoskeletal physiotherapy practice. Barriers may include: (1) organisational barriers such as limited time, resource and support, and (2) cultural barriers within the profession such as peer resistance, reluctance of changing established practice and changing work culture (Chan & Clough, 2010). However, there are ways to help bridge the gap between research evidence and clinical practice.

Future plans to disseminate and implement the current findings include: (1) presenting the current findings in a user-friendly manner and making it relevant, practicable and applicable for clinicians and commissioners (Chan & Clough, 2010), (2) involvement in patients' care pathway design, (3) publishing in appropriate journals, (4) presenting in musculoskeletal physiotherapy and pain conferences, and (5) sharing findings with appropriate personnel in clinical interest groups via social media. It is of great personal interest to the PI to conduct further clinical research in the future, help bridging clinical expertise and research evidence to improve quality of patients' care in physiotherapy.

6.5 Implications and recommendations

6.5.1 Implication for practice

1. The CBCLBP programme should be considered as first-line treatment

Despite calls from clinical guidelines recommendation (Savigny et al., 2009) and a large body of existing evidence, many physiotherapists in clinical practice still view the CBA active rehabilitation (such as the CBCLBP programme) as a last resort for their NSCLBP patients. There are a number of possible explanations for this. For instance, this may be due to the physiotherapists' biomedical orientated pain beliefs which may influence their clinical reasoning process (Daykin & Richardson, 2004; Foster & Delitto, 2011). A study in the UK reported that healthcare providers' beliefs influence their judgement and clinical decision about what treatments are given to patients with CLBP (Corbett et al., 2009). In addition, patients often hold certain expectations and pre-conceptions about their physiotherapy treatment (Hills & Kitchen, 2007), which consequently may interfere with the clinician's choice of treatment. Several physiotherapy studies have reported that patients are more satisfied with a hands-on treatment approach, compared to active rehabilitation programme (Hay et al., 2005; Klaber Moffett et al., 2006). However, passively treating patients unnecessarily may over-medicalise their NSCLBP condition, and reinforce passive coping (Waddell, 2004).

The study concluded that the CBCLBP programme has a bigger and possibly more direct physical and psychological impact on this subgroup of NSCLBP patients with high FAB, than usual physiotherapy care. This could be the CBA education and the multi-dimensional nature of the CBCLBP programme, is more adequately and appropriately address the complexity of NSCLBP. It is also likely to have something to do with the positive group influence and the interaction with others who face similar problems. This finding has an important clinical implication for physiotherapists: that the CBCLBP programme should be employed more regularly in this subgroup of NSCLBP patients. The PI highly recommends that the CBCLBP programme should be seen as a first-line treatment by physiotherapists, rather than a last resort.

2. Careful patient's selection to attain low attrition

A high attrition rate of group-based intervention, particularly the CBA intervention for NSCLBP patients is a common problem in clinical practice. The current findings imply that the assessment of HLOC may be a useful screening tool to aid appropriate referral onto the group-based CBA active rehabilitation. The present findings show that those patients who had a combination of poor employment status, poor financial status and high ELOC are significantly more likely to drop out of the programme (i.e. patients who were consented for the programme, but they never attended or only attended the first session of the programme). These patients may still be beneficial from the treatment philosophy and components of the CBCLBP programme. However, group therapy may not be the preferred treatment for them. Clinicians should acknowledge this and consider referring these patients for CBT or providing one-to-one physiotherapy CBA treatment where appropriate.

Clinicians could consider using MHLC scale, 'yellow-flag' interview questions along the HLOC continuum, in conjunction with a validated screening tool such as STarTback tool (Hill et al., 2011) in order to match patients more closely to appropriate treatment with less likelihood of drop-out. Careful selection of right patients for the right treatment is not only important for patients in terms of receiving appropriate back care, it is also important for clinicians in terms of clinical decision-making and unnecessary waste of service capacity. In addition, appropriate referral means more likelihood of low attrition, which in turn would be more economical from the provider's perspective. Attrition can be minimised by implementing a number of classes of different times (for instance, the late afternoon class of the CBCLBP was very popular and patient friendly) in order to suit individual patients' needs.

3. Low cost option for the provider

This study reports the provider costs of the six-week CBCLBP programme (£285.82 per patient), which is lower than individual physiotherapy (£474) (Critchley et al., 2007), spinal stabilization class (£379) (Critchley et al., 2007), GP best care plus exercise (£486) (UK BEAM Trial Team, 2004b),

and GP best care plus manipulation (£541) (U.K. Beam Trial Team, 2004b). This study provides a benchmark to provider and policy-maker, in which the CBCLBP programme is likely to be a low cost treatment option. However, as previously mentioned, appropriate referral and low attrition are keys to keeping the cost down. Therefore, it is important that clinicians carefully select appropriate patients on to the group-based treatment, and explain to patients clearly the nature of the programme, so that a realistic patients' expectation is set.

4. Treatment approach to target ILOC

Key findings that may be useful in improving existing practice include:

- Increase in ILOC is significantly correlated to reduction in pain intensity, reduction in disability and reduction in FAB;
- Improvement in HLOC beliefs accounts for a considerable proportion of the variance (31.9%) in reduction in FAB, whereas there is no significant predictive importance to both reduction in pain intensity and disability
- An increase in ILOC is a unique predictor to reduction in FAB, which means improvement of ILOC exerts a significant influence upon reduction of FAB.

On the basis of these findings, it would seem reasonable to suggest that improvement in ILOC should be seen as an important cognitive factor to target in the physiotherapy rehabilitation programme. For instance, clinicians may inform patients of the potential impact of their level of ILOC versus ELOC on the uptake of, and responses to CBCLBP programme and self-management tasks.

Patients could also be provided with the research findings, such as those in the current study to increase their understanding regarding the influence of HLOC beliefs toward the key clinical elements of NSCLBP. In addition, an introduction of the influence of internal/external beliefs on feelings and behaviours, and addressing patients' external and/ or chance beliefs may also be useful in enhancing feelings of personal control. Raising patients' awareness of the role of HLOC may promote more engagement in

rehabilitation and active health behaviour, which is important for rehabilitation outcome.

The present finding that ILOC has a significant predictive importance to reduction in FAB would seem beneficial for clinicians as one alternative to improve FAB outcome. In current practice, treatment components designed to reduce FAB such as pacing activities, graded exposure to exercise and fear-avoidance model are well-recognised by physiotherapists specializing in NSCLBP. On the basis of the current findings, it is recommended that clinicians could consider targeting treatment components that enhance ILOC to optimise FAB outcomes in patients with high levels of FAB. Based on the treatment philosophy, it is proposed that modification of pain beliefs and the variety of self-management skills may be of particular importance in enhancing ILOC. This is because both these components have an impact on improving an individual's belief that their own actions and behaviours attribute to outcome and their NSCLBP, which also gives them an advantage of maintaining some feeling of control. There is an association between ILOC and active coping (Harkapaa et al., 1991). Individuals with a higher level of ILOC are more likely to use active coping strategies, which means they are more likely to develop effective problem-solving and functions despite pain, which may in turn lead to less avoidance of behaviour and FAB.

5. Impact on physiotherapy practice locally

The positive results of this present study have prompted the physiotherapy department in Stockport to make several changes to improve practice: (1) a new back pain triage clinic was set up. This aims to assess NSCLBP patients promptly so that they can refer for appropriate treatment. Patients were triaged using the STarT back screening tool and the TSK. Physiotherapists were also encouraged to use the MHLC scale and 'yellow flags' questions relating to HLOC; (2) A new patients' care pathway was re-designed with the CBCLBP programme is considered as a first-line treatment for NSCLBP patients with high FAB; (3) Education components were re-designed, with the emphasis on improving ILOC. Components such as pain education, inform patients of potential benefits of increased LIOC

versus ELOC and CLOC and self-management skills of cognitive-behavioural elements were emphasized. Education components were also facilitated by videos and quiz to enhance patients' ILOC with regard to engagement in the CBCLBP programme, and (4) there were several in-service training sessions for physiotherapists in the Trust, so that clinicians were aware the study findings, the current state of knowledge and their further training needs.

6.5.2 Implication for research

1. This study produces favourable results for patients with high FAB. This may suggest that the CBT based intervention produces better outcome in patients with high FAB. Replication of the current study by including a high, medium and low FAB group in future work would be useful to see if clinical outcomes following the CBCLBP programme, and the predictive relationship between HLOC and other variables would be different from the present results. The differentiation of psychological profile of patients would help to refine management guidelines on which type of patients may mostly benefit the CBCLBP programme. In addition, further examination of the predictive value of HLOC in relation to other key variables in NSCLBP would help to establish if HLOC would (or would not) have predictive importance in patients of different levels of FAB.
2. This study should be replicated with the addition of qualitative research to explore both patients' and practitioners' beliefs and attitudes about their NSCLBP treatment, and how these influence their health and practice behaviour. The qualitative data from both patients and practitioners might help to: (1) understand the response and action from their perspectives and personal experiences; (2) explain the positive and negative findings observed in the current study, hence increase the comprehensiveness of the present findings, and (3) create openness and give opportunity to both patients and practitioners to expand their response or new dimensions of the research topic that may not be considered by the P.I.
3. It is acknowledged that examining HLOC alone only offers a small piece of the picture in terms of predicting outcome for NSCLBP patients following the CBCLBP. Some authors (Oberle, 1991; Luszczynska & Schwarzer, 2005), and the developers of the MHLC scales (Wallston et al., 1978) mentioned the importance of assessing the influence of other variables in addition to HLOC. For example, self-efficacy maybe a stronger predictor of health behaviour changes than HLOC (Luszczynska & Schwarzer, 2005). Self-efficacy refers to an

individuals' beliefs regarding their confidence and ability to perform a particular behaviour (Bandura, 1977). Therefore, it is possible that the prognostic importance of ILOC found in the current study would be different if self-efficacy is included. Replication of the current study with the inclusion of self-efficacy is recommended in order to further examine the role of HLOC in NSCLBP patients.

4. The effect of the CBCLBP programme seems to be complimented by the effect of higher level of pain physiology education. Having a deeper understanding of chronic pain may be an important part of rehabilitation for NSCLBP patients. An interesting area to look at in a future study is to see whether the addition of higher level of pain education to usual physiotherapy care (having musculoskeletal physiotherapists to have extra pain neuroscience training) may improve patients' NSCLBP outcome.

6.6 Conclusion

Belief is a powerful driving force in one's behaviour. HLOC, which refers to a person's belief over their health conditions and a person's perception of who is responsible for his or her health condition (Wallston and Wallston, 1982), is a significant concept. This is because HLOC has a meaningful relationship with health attitude, behaviours, coping styles and the clinically important outcomes of NSCLBP, which are all the key components in attaining successful treatment outcomes of the CBCLBP programme.

This study supports the positive effects of a physiotherapy CBCLBP programme, both clinically and economically in the short-term (6-week) and the intermediate term (6-month). It also offers evidences that HLOC may provide helpful constructs in facilitating appropriate referrals and improving treatment outcomes in NSCLBP patients with high levels of FAB.

This study highlights that improvement in ILOC has a significant relationship with the key elements of NSCLBP including pain intensity, disability and FAB. In particular, increased ILOC was found to be significantly predictive of reduction in FAB at 6-months, however it shows

no significant predictive value to both reduction in pain intensity and reduction in disability. A possible explanation of this could be that both HLOC and FAB are psychological factors (both constructs concerning patients' belief about their pain), whilst pain intensity and disability are physical factors associated with NSCLBP. This result supports the current understanding of NSCLBP, that when NSLBP becomes chronic, the psychosocial factors are more powerful factors in the development and persistence of NSCLBP and disability, than the physical factors (Waddell, 2004; Koleck et al., 2006; Bakker et al., 2009). This finding is also in direct agreement with the treatment philosophy of the CBA, where emphasis is placed to address patients' maladaptive belief, feelings and behaviours (Airaksinen et al., 2006; Henschke et al., 2010).

From a clinical perspective, it would seem reasonable to suggest that improvement in ILOC could be seen as a potentially important cognitive factor to target in physiotherapy rehabilitation programmes as an alternative pathway to optimising FAB outcome. Treatment components that are likely to enhance ILOC (such as patient education about potential impact of levels of internal versus external HLOC, addressing unhelpful external and chance orientated beliefs, high level of pain education, pain belief modification, adoption of active coping and self-management skills) could be considered to add to and be emphasized in the existing programme. These components can also be considered to integrate in physiotherapists' training competence. This may be particularly beneficial for NSCLBP patients with high levels of FAB.

From a research perspective, these findings provide new knowledge and extend the current limited evidence regarding the role of HLOC in NSCLBP. Specifically, the findings demonstrate that HLOC beliefs are modifiable by a physiotherapy intervention underpinned by CBA principles. HLOC is associated with the key clinical elements of NSCLBP and has significant predictive importance in improving FAB outcomes. It is acknowledged that HLOC is only one piece of the much wider and complex psychological context in understanding NSCLBP. However, these findings may provide a new dimension for both researchers and clinicians when

addressing treatment effectiveness and prognosis of NSCLBP. Evidence in this aspect of care remains very limited. Further research is needed to support these relationships and the role of HLOC in NSCLBP management.

6.7 Key messages

- Physiotherapy departments should routinely consider the CBCLBP program as a first-line intervention in patients with NSCLBP, rather than regarding it as a last resort as is currently frequently the case.
- Careful selection, appropriate patient referral and offering flexible timetables of programme are likely to be keys for low attrition and keeping costs down from the provider's perspective.
- Belief is the main driving force for behaviour. Assessment of HLOC and addressing HLOC can be integrated into the existing physiotherapy CBCLBP programme to improve treatment outcomes and optimise self-care.
- Increased in ILOC predicts better FAB outcomes. Education content that enable patients to understand the impact of internal versus external beliefs in relation to NSCLBP management, high level of pain education, modification of pain belief, and self-management skills of cognitive-behavioural elements, may potentially enhance patients' ILOC, hence improving FAB outcomes.

APPENDIX 1: NRES (Bristol) ethics approval letter for the current study 12/SW/0197



Health Research Authority

NRES Committee South West - Central Bristol

Whitefriars
Level 3, Block B
Lewin's Mead
Bristol BS1 2NT
Email: ubh-tr.SouthWest3@nhs.net

Telephone: 0117342 1329
Facsimile: 0171 3420445

29 June 2012

Ms Sharon Ho Yi Chan
Advanced Musculoskeletal Physiotherapist Specialist & Doctorate Student
Stockport NHS Foundation Trust
Physiotherapy Department, 1/F Kingsgate House
Wellington Road North
Stockport, Cheshire
SK4 1LW

Dear Ms Chan,

Study title: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?
REC reference: 12/SW/0197
Protocol number: 1143

Thank you for your letter of 29 June 2012, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

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.

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:

1. Please change the phrase 'health locus', located in the Participant Information Sheet, into layman's language.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

A Research Ethics Committee established by the Health Research Authority

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.

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).

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. Confirmation should also be provided to host organisations together with relevant documentation.

Approved documents

The documents reviewed and approved by the Committee are:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Summary/Synopsis	1	14 February 2012
Response to Request for Further Information		29 June 2012
Referees or other scientific critique report	MMU RD1 Letter	16 February 2012
Referees or other scientific critique report	MMU Ethics Approval letter	23 March 2012
REC application		12 June 2012
Questionnaire: Form C of the Multidimensional Health Locus of Control	Validated	
Questionnaire: The TSK Questionnaire	Validated	
Questionnaire: The Roland-Morris Low Back Pain and Disability Questionnaire	Validated	
Questionnaire: The Visual Analogue Scale for Pain	Validated	
Questionnaire: Attitudes Toward Back Pain Self-Care Questionnaire	Validated	
Protocol	1	14 February 2012
Participant Information Sheet	2	28 June 2012
Participant Consent Form	2	26 June 2012
Letter of invitation to participant	1	22 May 2012
Letter from Sponsor	MMU	17 May 2012
Investigator CV	Sharon Chan	01 May 2012
Investigator CV	Dr Goodwin	01 February 2012
Investigator CV	Dr Wibberley	01 February 2012
GP/Consultant Information Sheets	1	14 February 2012
GP/Consultant Information Sheets	Letter to inform that their patient is participating: Version 1	14 February 2012

Evidence of insurance or indemnity	MMU	17 May 2012
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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.

Further information is available at National Research Ethics Service website > After Review

12/SW/0197	Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project

Yours sincerely,



Dr Pamela Cairns
Chair

Email: ubh-tr.SouthWest3@nhs.net

Enclosures: *After ethical review – guidance for researchers*

Copy to: *Mr Melaku Wolde-Michael*
Ms Jan Smith, Stockport NHS Foundation Trust

APPENDIX 2: MMU ethics approval letter

MANCHESTER METROPOLITAN UNIVERSITY
FACULTY OF HEALTH, PSYCHOLOGY AND SOCIAL CARE

M E M O R A N D U M

FACULTY ACADEMIC ETHICS COMMITTEE



To: Ms Ho Yi Sharon Chan (08988758)

From: Prof Carol Haigh

cc Emma Reilly

Date: 23 March 2012

Subject: Ethics Application 1143

Title: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Thank you for your application for ethical approval.

The Faculty Academic Ethics Committee review process has recommended approval of your ethics application.

Approval has been granted on the condition that ethical approval must be obtained from IRAS prior to embarking on the project.

We wish you every success with your project.

A handwritten signature in black ink, appearing to read "Carol Haigh" and "Jois Stansfield".

Prof Carol Haigh and Prof Jois Stansfield
Chair and Deputy Chair
Faculty Academic Ethics Committee



17 May 2012

For the attention of
NHS Research Ethics Committee

Dear Sirs

Project title: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Chief Investigator: Dr Peter Goodwin

Re questions A35 and A36 - indemnity and/or compensation in the event of negligent or non-negligent harm

I refer to the above application to your Committee, and specifically to the work to be carried out by Ho Yi Sharon Chan as part of her studies at our University.

I confirm that the insurance policies in place at Manchester Metropolitan University will cover claims for negligence arising from the conduct of the University's normal business, which includes research carried out by staff, and by undergraduate and postgraduate students as part of their course. This does not extend to clinical negligence.

No arrangements have been made to provide indemnity and/or compensation in the event of claims for non-negligent harm arising from this study.

Yours faithfully

A handwritten signature in blue ink, appearing to read 'J Cunningham'.

J Cunningham
Director of Finance

All Saints Building
All Saints
Manchester
M15 6BH
United Kingdom

Telephone
+44 (0)161-247

Fax
+44 (0)161-247

E-mail

@mmu.ac.uk



INVESTOR IN PEOPLE



Manchester Metropolitan University

University exchange: +44 (0)161-247 2000 Minicom: +44 (0)161-247 6520 Website: www.mmu.ac.uk

APPENDIX 2a: MMU Sponsorship letter

Student and Academic Services

Research, Enterprise and Development

17 May 2012

For the attention of
NHS Research Ethics Committee



Manchester
Metropolitan
University

Dear Sir/Madam,

Project Title: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Academic supervisor: Dr Peter Goodwin

I am pleased to confirm that Manchester Metropolitan University will take on the role of academic sponsor, as outlined in the Research Governance Framework for Health and Social Care, for the above study. The role of the sponsor covers:

- Assuring the scientific quality of proposed research;
- Ensuring the projects are appropriately managed and monitored;
- Promoting a quality research culture through training and the academic environment;
- Ensuring researchers understand and comply with procedures associated with their research;
- Ensuring researchers are suitably qualified to undertake the proposed research;
- Promoting maximum dissemination of research findings;
- Ensuring research ethics committee approval is obtained.

I can also confirm that Manchester Metropolitan University will act as academic sponsor for the above study as we have fulfilled the necessary requirements outlined and agree to take on the responsibility for the conduct of the study to its conclusion. Please note that this does not extend to duty of care for patients.

Yours faithfully

Professor David Raper
Director of Research and Enterprise

Ormond Building
Lower Ormond Street
Manchester
M15 6BX
United Kingdom

Telephone
+44 (0)161-247

Fax
+44 (0)161-247 6823

Email
@mmu.ac.uk

Website
www.mmu.ac.uk/sas



Manchester Metropolitan University

University exchange: +44 (0)161-247 2000 Minicom: +44 (0)161-247 6520 Website: www.mmu.ac.uk

APPENDIX 3: R&D Stockport approval letter

Stockport 
NHS Foundation Trust

Sharon Chan
Specialist physiotherapist
Physiotherapy Department
1/F Kingsgate House
Wellington Road North
Stockport
SK4 1LW

Research & Development Office
F08, Pinewood House
Stepping Hill Hospital
Poplar Grove
Stockport
SK2 7JE

Tel: 0161 419 5801 / 5814
E-mail: jan.smith@stockport.nhs.uk

6 August 2012

Dear Sharon,

Research Office Reference Number: 2012020
Project Title: CBCLBP Programme- Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?
REC number: 12/SW/0197

I write to advise that NHS permission has been granted for the above research to be conducted at Stockport NHS Foundation Trust, with effect from the date of this letter. NHS permission has been granted on the basis described in the application form, protocol and supporting documentation. Permission is only granted for the activities for which a favourable opinion has been given by the Research Ethics Committee.

I acknowledge that Manchester Metropolitan University has accepted the role of Research Governance Sponsor for this study. Please ensure you are fully familiar with your responsibilities as outlined in the research protocol.

Permission is granted subject to the attached terms. Please ensure you and all members of the research team are familiar with these terms before commencing your research. You are required to sign a copy of this letter and return to this office, to confirm your understanding and acceptance of these terms.

I would like to take this opportunity to wish you well with your research and if I can be of further assistance, please do not hesitate to contact me.

Yours sincerely,



Jan Smith
Research & Development Manager

cc: Angela Gabbidon

I have read, understood and agree to comply with the Terms of Approval attached to this Permission letter:

Name:

Signature Date

Your Health. Our Priority.

NHS Permission letter v4.1 16.05.12

Documents Reviewed	Version No. / Reference	Date
Protocol	Not version controlled	
Participant Information Sheet	V.3	17/07/2012
Consent Form	V.2	26/06/2012
GP and Physiotherapist Information Sheet	V.1	14/02/2012
GP and Physiotherapist Letter	V.1	14/02/2012
Questionnaire- Form C	V.1	21/05/2012
Questionnaire- TSK	V.1	21/05/2012
Questionnaire- VAS	V.1	21/05/2012
Questionnaire- Attitudes towards back pain self-care	V.1	21/05/2012
Questionnaire- Rowland-Morris	V.1	21/05/2012
Ethics approval letter	12/SW/0197	01/08/2012

NHS Permission letter v4.1 16.05.12

Terms of NHS Permission:-

- The unique Research Office Reference Number for the project must be quoted in all correspondence with the Research Office
- All research undertaken under this permission must be conducted in line with guidance given within the Research Governance Framework (DH 2005), ICH GCP (clinical trials) and Trust policies and procedures, available in the Documents section, and Research Governance page of the Research & Development microsite
- The Research Office must be informed as soon as possible of
 - The actual start date of the project
 - Any changes to the protocol throughout the course of the project
 - Any amendments sent to the MHRA and/or Research Ethics Committee
 - Any changes to the management of the project
 - Any changes to the local research team
 - Any extensions to the project, and associated additional funding, if applicable
 - The actual end dates, recruitment and final, of the project
- The Research Office must be given a minimum three months' notice, in writing, if the Chief or Principal Investigator is intending to leave the employment of the Trust
- The Research Office must be advised immediately if the Chief or Principal Investigator is unable to continue to fulfil his/her duties as CI/PI for other reason e.g. long-term sickness
- Any evidence of fraud and/or misconduct in research must be immediately brought to the attention of the Research Office
- All amendments, including changes to the local research team, must be submitted in accordance with guidance in IRAS and notified to the Research Office
- All substantial amendments must be notified to the Research Office to check whether R&D permission of the research at site is affected, before implementation
- For Clinical Trials of Investigational Medicinal Products, the Research Office must be notified of all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) relating to Trust patients/participants. A copy of official notification to the regulatory bodies (Sponsor, NRES, MHRA as applicable) should be supplied by post, email or fax, number 419 4967
- The research Sponsor, Chief Investigator or local Principal Investigator may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The Research Office must be notified immediately that such measures have been taken, the reasons why and the plan for further action.
- Copies of annual progress and end of study reports must be provided to the Research Office as soon as available.
- The Trust is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. All research taking place on Trust premises is subject to the Trust monitoring/audit programme. Investigators are required to make themselves available for any monitoring/audit visit, on a mutually agreed date
- Investigators are required to complete and submit any self-assessment or other request for information that may be issued by the Research Office from time to time

Failure to comply with any of the above may result in withdrawal of Research Office approval for the project and the immediate cessation of the research. Persistent failure to comply may result in disciplinary action

NHS Permission letter v4.1 16.05.12



PARTICIPANT INFORMATION SHEET

RESEARCH TITLE: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

CHIEF INVESTIGATOR:

Sharon Chan

Doctoral student and musculoskeletal specialist
Physiotherapy Department, Stockport NHS Foundation Trust
1/F Kingsgate House
Wellington Road North
Stockport SK4 1LW
Work contact telephone number: +44 (0)161 4265445/ 5446
sharon.chan1@nhs.net

Please note that this study is being completed as part of the Professional Doctorate qualification.

INVITATION: You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

PART 1

WHAT IS THE PURPOSE OF THE STUDY?

The aim of this study is to investigate how a cognitive-behavioural chronic low back pain programme may alter patients' "locus of control", i.e. the extent to which patient's believe they can control their own health. Such psychosocial factor is important for attaining successful treatment outcome and improving the prognosis of chronic low back pain. This study aims to improve the management of those patients with chronic low back pain. The outcome of this study will provide appropriate evidence to establish the importance (or not) of the health locus of control in the back rehabilitation programme,

and thus enable effective and evidence-based interventions to be developed in this field of physiotherapy practice.

WHY I HAVE BEEN INVITED?

You have been invited to participate because you are eligible to this study. For this research, we would like to include at least 60 patients, who have low back pain with or without leg pain, for more than three months, and with no serious pathology.

Inclusion criteria: patients with low back pain for more than 3 months with or without leg pain, aged over 18 years, with disability and distress primarily caused by chronic low back pain, as perceived by patient and assessor, with Tampa Scale of Kinesiophobia (TSK) score more than 37 (indicating patient shows fear of movement and associated avoidance behaviour) and able to give consent.

Exclusion criteria: patients who are diagnosed with serious spinal pathology such as malignancy and vertebral fracture, acute herniated disc with nerve root entrapment, unstable spondylolisthesis, TSK score less than 37, health conditions that prevented them from exercising safely, language problems, age less than 18 years, and patients unwilling to participate the programme.

DO I HAVE TO TAKE PART?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect the standard care that you receive.

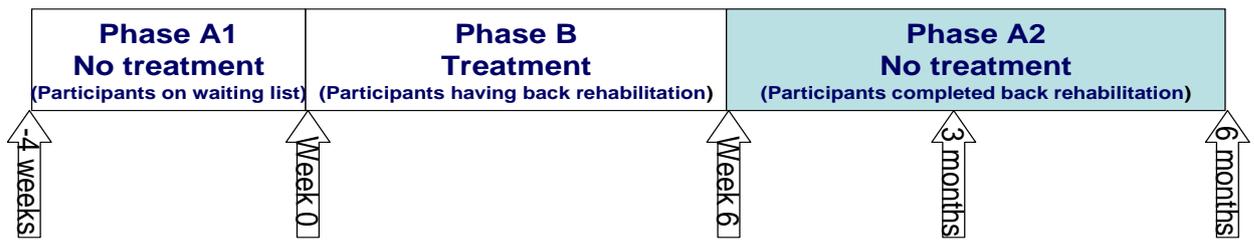
WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you do decide to take part, you will undergo the routine cognitive-behavioural chronic low back pain rehabilitation programme, which is the normal care provided by the physiotherapy department, Stockport NHS Trust for patients with chronic low back pain, however there will be an addition of completing some questionnaires before and after the programme. The back rehabilitation programme has been in place for a number of years in the physiotherapy department in line with the UK guidelines; it is based on best available evidence and current best practice in the UK.

To summarise: Whether you decide to take part in the research or not, you will still receive the same exact programme as in normal care, the only difference is that participants in the study will be asked to complete some questionnaires. If you decide not to take part, you will simply undergo the same routine back rehabilitation programme as planned.

The back rehabilitation programme is a 6-week (two hours weekly) programme consisting of exercise and education. If you do decide to take part, you will be asked to complete some additional questionnaires relevant to your chronic low back pain condition. The questionnaires will take about 20 minutes to complete at baseline (4 weeks prior to the programme), at the beginning of the programme (week 0), at completion (week 6) and at 3-months and 6-months follow-up. Please refer to the diagram below:

Diagram to illustrate the study design



Outcome measures will be taken at:

- - 4 weeks (Baseline)
- Week 0 (Before treatment)
- Week 6 (After treatment)
- 3 months after completing treatment
- 6 months after completing treatment

The programme is based on the best available evidence, which aim to promote positive coping strategies, improve general function, and enhance your confidence in self-care. Through the programme, a variety of issues including mechanisms of chronic pain, anatomy and diagnosis, techniques for activity management, pacing, goal setting, stress management, relaxation, challenging negative thoughts and behaviours, lifestyle changes such as graded exercises, weight reduction return to normal activities and hobbies, acceptance of chronic back pain condition, problem solving and developing coping skills will be addressed. In addition to the education component, you will also exercise as a group including core stability work, stretching exercise, cardiovascular exercise circuit, aqua aerobics and Pilates.

WILL MY EXPENSES BE COVERED FOR TAKING PART IN THIS STUDY?

No, your travel expenses will not be covered by the research team. Your attendance to the back rehabilitation programme is no different from patients who attend the ordinary NHS physiotherapy appointment, except we will ask you to fill in some questionnaires 4 weeks and immediately prior the programme, and at 3-months and 6-months follow-up.

WHAT DO I HAVE TO DO?

You will be asked to try your best to attend all the six sessions of the programme in order to gain the maximum benefit from it. If you decide to take part in this study, you will also be asked to complete and return the questionnaires at each evaluation (see diagram). Your completed questionnaire is very important for the data analysis of the research.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

There are no disadvantages and risks from taking part. All the subject recruitment, assessment and the rehabilitation programme will take place at the physiotherapy department, Kingsgate House, Stockport NHS Foundation Trust, where Health and Safety at Work Act (1974) is operated all the time.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

We cannot promise that this study will help you, however the back rehabilitation programme to be delivered in this study represents current recommendation by UK guidelines and it is a well-established service in the physiotherapy department. Therefore, you would learn strategies that are based on best available evidence and current best practice in the UK.

Through the programme, a variety of topics will be addressed and will be targeted including pain beliefs, fear avoidance behaviours, sense of personal control, your thoughts, feelings and coping strategies. Therefore, there will be intended benefit to improve your confidence and positivity in self- management skills, the sense of personal control over your chronic back problem and your confidence and fitness on exercising by taking part in this study.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Once you have completed the six-week back rehabilitation programme and the 6-months follow up questionnaires, you would be discharged from the physiotherapy service, as in normal practice and in compliance with the departmental policy. However, if there is any reason you would like to access the physiotherapy service when the research study stops, you could consult the research physiotherapists and/or your General Practitioners (GPs).

WHAT IF THERE IS A PROBLEM?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

PART 2:

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes we get new information about the treatment being studied. If this happens, we will tell you and discuss whether you would like to continue in the study. If you decide not to carry on, we will make arrangements for your care to continue in the physiotherapy service. If you decide to continue with the study, we may ask you to sign an agreement outlining the discussion.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You have full right to withdraw from the study at any time without giving any reason. If you decide to withdraw, please inform the Chief Investigator at the earliest possible opportunity. If you withdraw, it may be beneficial to use your data already collected up to the point of withdrawal but all other data will be destroyed. The data that have been collected will only be retrieved and analysed using the subject identification number assigned to your data set, and your anonymity will be maintained at all times.

WHAT IF THERE IS A PROBLEM?

Because of our strict safety policy, we do not anticipate that you will be harmed in any way by taking part in this study. If you have any concern about any aspect of this study,

you should ask to speak to the Chief Investigator, Sharon Chan, who will do the best to answer your question. Please ring 0161 4265445 or e-mail on sharon.chan1@nhs.net. If you remain unhappy and wish to complain formally, you can follow the NHS Stockport Complaints Procedure by contacting the Complaints Department on 0161 4265888 or via e-mail on Compliants.email@nhsstockport.nhs.uk

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

To ensure anonymity, all data collected will be kept strictly confidential and anonymous. You will be given an identification number known only to the Chief Investigator and the research physiotherapy team. No one will be able to access your personal data and trial data, except the Chief Investigator, your General Practitioner (GP) and the member of the direct care team in physiotherapy. Data will be stored, using identification number, on a password secure computer within the physiotherapy department, and hard copies will be kept in the locked cabinet within the department. The Chief Investigator will use the trial data appropriately and publish findings where optimal use can be made of them such as journal publication, disseminating findings to practice and implementing changes for more effective practice, also for general public in an understanding manner. Once the results are reported, it will not be possible to identify individual persons.

When the research data are no longer required for the conduct of data analysis after the study has ended, the hard copies and the electronic data will be destroyed and disposed of by the Chief Investigator securely, as adhere The Records Management: NHS Code of Practice (2006) guidelines.

WILL MY GENERAL PRACTITIONER/ FAMILY DOCTOR (GP) BE INFORMED MY PARTICIPATION OF THE STUDY?

Your General Practitioner (GP) will be notified of your participation in the study, and we would seek your consent to do so. The information to be exchanged between the Chief Investigator and your General Practitioner (GP) is no different from that which physiotherapists would normally send to your GP following your treatment in the NHS Stockport physiotherapy service.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results obtained will used as part of the Doctoral dissertation. It will be published as a scientific article in peer reviewed journals and will also be presented at professional conferences. You are welcome to obtain a copy of the publication by contacting the Chief Investigator You will not be able to be identified from the publication.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

This research is organised by the Chief Investigator, Sharon Chan, along with the research supervisor team, Dr. Peter Goodwin and Dr Christopher Wibberley from the Faculty of Health, Psychology and Social Care, Manchester Metropolitan University. No funding is required as the intervention and manpower used in this study are part of the ordinary NHS Stockport physiotherapy practice and patients' routine care.

WHO HAS REVIEWED THE STUDY?

This study has reviewed and approved by the Research Ethics Committee of the Manchester Metropolitan University, the National Research Ethics Committee (NREC)

and the NHS. The ethical approval process is carried by an independent group of professionals to protect your safety, rights, wellbeing and dignity.

FURTHER INFORMATION AND CONTACT DETAILS

When you have completed the back rehabilitation programme, time will be allowed for you to ask questions about the research. For further information about this research project, please contact the Chief Investigator.

WHAT IF THERE IS A QUERY?

If you have a concern about any aspect of your participation or any other queries, please raise this with the Chief Investigator, Sharon Chan, or contact the research supervisors Dr Peter Goodwin and Dr Christopher Wibberley of the Manchester Metropolitan University.

If you would like some independent advice about this research project, you can contact the research supervisors Dr Peter Goodwin and Dr Christopher Wibberley or the Patient Advice Liaison Service (PALS) in Stockport, Contact details are as followed:

Patient Advice Liaison Service (PALS) Stockport telephone number: 0161 4265631
www.nhsstockport.nhs.uk/PALS.aspx

Director of Study:

Dr. Peter Goodwin

Faculty of Health, Psychology & Social Care, Elizabeth Gaskell Campus
Manchester Metropolitan University

Hathersage Road, M13 OJA

p.goodwin@mmu.ac.uk 0161 2472941

Supervisor of Study:

Dr. Christopher Wibberley

Faculty of Health, Psychology & Social Care, Elizabeth Gaskell Campus
Manchester Metropolitan University

Hathersage Road, M13 OJA

c.wibberley@mmu.ac.uk 0161 2472522

Please keep this information sheet safe so that if you decide to participate, you can refer to it at any time. If you take part in this study, you will also be given a signed consent form to keep.

Thank you for taking time to read this information and considering this study

APPENDIX 5: Informed consent letter



Study Number: REC reference: 12/SW/0197 R&D: 2012020
Centre: Physiotherapy Department, Kingsgate House
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Name of Researcher (Chief Investigator): Sharon Chan

Please initial box

1. I confirm that I have read and understand the information sheet dated 17.07.12 (version 3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the sponsor of the trial (Manchester Metropolitan University) and responsible persons authorised by the sponsor, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study.

5. I agree to take part in the above study.

Name of Patient

Date

Signature

Name of Person
taking consent (Chief Investigator)

Date

Signature

When completed: 1 for participant; 1 (original) for researcher site file; 1 to be kept in medical notes.

APPENDIX 6: Letter to inform GPs/physiotherapists that their patients entered the study



Dear Doctor/ Colleagues,

RE: Patient's name.....Date of Birth.....

With the above named patient's agreement and consent, I am writing to inform you that the above named patient is eligible and agreed to participate in the research study, which aims to investigate if a cognitive-behavioural chronic low back pain programme may alter patients' locus of control, and its associated impact on clinical outcomes. This study has been reviewed and approved by the Research Ethics Committee of the Manchester Metropolitan University, the National Research Ethics Committee (NREC) with reference number.....and the NHS.

Interventions used in this study represent current best available evidence. Participants will have full rights to withdraw anytime during the study without giving any reason, yet they will still receive the same high standard of care.

Please do not hesitate to contact me on 0161 4265445 or via e-mail on sharon.chan1@nhs.net if you have any question about my research study.

Many thanks

Kind regards

Sharon Chan
Chief Investigator & Musculoskeletal Specialist

APPENDIX 7: Letter to inform GPs/physiotherapists about the study



INFORMATION FOR GPs and Physiotherapists

RESEARCH TITLE: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Dear Doctor/ Colleagues,

I am conducting a research study as part of the Doctorate qualification. The aim of this study is to investigate how a cognitive-behavioural chronic low back pain programme may alter patients' health locus of control, and its associated impact on clinical outcomes.

The current back rehabilitation programme run by the physiotherapy service represents the recommendation by the UK guidelines. For the purpose of this study, the intervention will still be based on the best available evidence, but particular attention will be paid to target patient's belief, fear avoidance behaviours, internal focus of control and positive coping strategies. This research aims to provide an improved form of management for patients with chronic back pain. There will therefore be benefits to those patients who participate and a potential improvement in the care of patients following this study.

You can refer your patient with chronic low back pain into the physiotherapy service following the usual pathway and those who are interested in learning more about how to self-manage their back pain condition, and who fulfil the inclusion/ exclusion criteria (see enclosed attachment) will be invited to participate in the study. Eligible patients will be given an information leaflet and a full verbal explanation about the study. They will also be given at least a week to consider whether to take part. Informed consent will be obtained prior to the entry. With the patient's agreement and consent, you will be informed of any patient you referred who agreed to participate in this study.

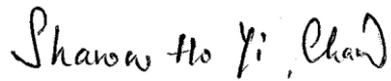
Patients who agreed to take part in this study will be invited to attend a 6-week (two hours/ week) programme consisting of exercise and education. Patients will not be disadvantaged compared to standard care, except we will ask him/ her to fill in some questionnaires 4 weeks prior the programme and at 3-month and 6-month follow-up.

This study has been reviewed and approved by the Research Ethics Committee of the Manchester Metropolitan University, the National Research Ethics Committee (NREC) with reference number 12/SW/0197 and the NHS. Please do not hesitate to contact me

on 0161 426 5445 or via e-mail on sharon.chan1@nhs.net if you have any questions about my research study.

Many thanks

Kind regards



Sharon Chan
Chief Investigator & Musculoskeletal Specialist

Inclusion & exclusion criteria of the chronic low back pain study

Inclusion criteria will be:

- Patients with low back pain >3 months with or without leg pain
- Age >18years
- Disability and distress primarily caused by CLBP, as perceived by patient and assessor, Tampa Scale of Kinesiophobia (TSK) score >37 (indicating patient shows fear of movement and associated avoidance behaviour)
- Able to give consent

Exclusion criteria will be:

- Patients who are diagnosed with serious spinal pathology such as malignancy and vertebral fracture, acute herniated disc with nerve root entrapment, unstable spondylolisthesis
- TSK score < 37
- Health conditions that prevented them from exercising safely
- Language problems
- Age <18
- Patients unwilling to participate the programme

Departmental Protocol

Inclusion & exclusion criteria of the Back Rehabilitation Programme

Inclusion criteria will be:

- Patients with non-specific low back pain >3 months with or without leg pain
- Age >18years
- Disability and distress primarily caused by CLBP, as perceived by patient and assessor
- Patients medically fit to take part in the exercise programme
- Able to give consent

Exclusion criteria will be:

- Evidence of red flags indicating serious pathology
- Patient is not medically fit to participate in an exercise programme
- Patients who are diagnosed with serious or specific spinal pathology such as malignancy, vertebral fracture, spinal stenosis, acute herniated disc with nerve root entrapment, rheumatoid arthritis, unstable spondylolisthesis
- Health conditions that prevented them from exercising safely
- Language problems
- Age <18
- Patients who are demonstrating psychological distress, both pain and non-pain related, which is beyond the scope of the physiotherapy-led back pain rehabilitation.
- Patients unwilling to participate the programme

Appendix 9: Invitation letter to eligible participants



Date.....

Dear potential research participant,

Invitation to the study of chronic low back pain

You are being invited to take part in a research study on chronic low back pain. Following the initial assessment with physiotherapist, you are identified as a possible participant of this study.

Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the **Participant's Information Sheet** attached carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Part 1 tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more details information about the conduct of the study.

The aim of this study is to investigate how a cognitive-behavioural chronic low back pain programme may alter patients' health locus of control, and its associated impact on clinical outcome. This study will help develop a more effective rehabilitation programme to improve the management of those patients with chronic low back pain.

It is up to you to decide whether or not to take part. If you do decide to take part, you will be asked to keep the attached Participant's Information Sheet and asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect the standard care that you receive.

If you have any questions or problems, please contact me on 0161 4265445 or via e-mail on sharon.chan1@nhs.net.

Yours sincerely

Sharon Chan

Chief Investigator, Doctorate student and musculoskeletal specialist

SESSION 1

Overview of basic anatomy and function of the spine

Common diagnosis of back pain and clarify any misunderstanding of diagnostic language

Explain primary and secondary “suffering” - physical, mental and emotional reaction to pain

Introduce Fear-avoidance model and explain its detrimental effect

Emphasis on Pain ≠ harm

Teach home exercises

Mat work and exercise circuit in the gym

SESSION 2

Quick recap on session 1 and question

Introducing cognitive restructuring technique such as imagery and attention diversion

Difference between acute and chronic pain

Explaining pain- Pain gate theory, pain neuromatrix, sensitization

Relationship between pain and inactivity

Alternative pain control

Importance of staying active

Cycle of change

Importance of improved self-management

Mat work and exercise circuit in the gym

SESSION 3

Quick recap on session 2 and question

Relationship between thinking, feeling and behaviour

Introduce helpful and unhelpful cycle

Relationship between pain and stress

Explore other causes of pain

Stress and relaxation

Relaxation practise - diaphragmatic breathing exercises technique, three minutes breathing space and relaxation CD (20 minutes)

Mat work and exercise circuit in the gym

SESSION 4

Quick recap on session 3 and question

Relationship between pain and poor posture

Posture - sitting, standing and lying

Safe moving and lifting technique

Sleep - pillow and mattress

Reinforce technique of postural stretches

Pilates

Body Scan CD (20 minutes)

SESSION 5

Quick recap on session 4 and question

Activity management and 3Ps (Planning, Pacing and Prioritizing) technique

Work out tolerance level

Personal goal setting - SMART goal

Role of exercise

Rules for exercising

Benefit of exercise

Mat work and exercise circuit in the gym

SESSION 6

Quick recap on session 5 and question

Future self-management and flare-up plan

Top tips for future management and lifestyle change

Information on PARIS – exercise prescription scheme

Hydrotherapy- introduction and arrange session of hydrotherapy

Feedback from patients- what and how the CBCLBP programme beneficial them

Question time

Mat work and exercise circuit in the gym

After SESSION 6

Hydrotherapy session (as allocated)



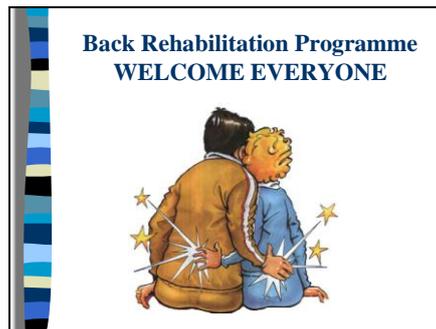
Appendix 11: Patients' written information and education materials of the CBCLBP programme (week 1 to week 6)

Session 1

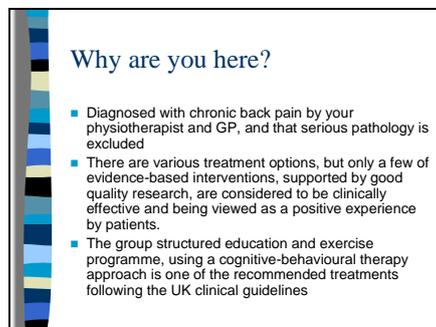
Slide 1



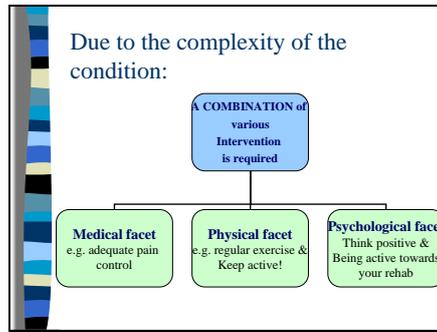
Slide 2



Slide 3



Slide 4



Slide 5

- What will the programme involve?
- All based on best available evidence and current best practice in the UK
 - 6 sessions of exercise and education based on cognitive-behavioural principle
 - Relaxation session
 - Hydrotherapy (optional)
 - Combination of listening, talking, discussing & sharing experience

Slide 6

- In the education sessions, you'll learn about:
- Mechanism of chronic pain, anatomy and diagnosis
 - Activity management and pacing
 - Benefit of exercise
 - Personal goal setting
 - Pain control- medicine & alternative pain relief
 - Stress management and relaxation technique- breathing exercise and relaxation CDs
 - Healthy lifestyle- getting active, trim and healthy!
 - Postural, Lifting & handling workshop
 - Develop coping skills and self- help techniques
 - Promote positive attitude and sense of control over your chronic back pain condition

Slide 7



In the exercise sessions:

- Mat work- core stability and stretching exercise
- Cardiovascular exercise circuit in the gym
- Pilates
- Hydrotherapy (optional on Week 7)

Slide 8



Objectives of the programme:

- ↑ Understanding of chronic pain and acceptance of the condition
- ↑ Understanding of anatomy
- ↑ Physical fitness, endurance & flexibility
- Help you return to normal activities & hobbies
- Learn relaxation skills & stress reduction
- Learn good posture & safe lifting technique
- Learn alternative methods of pain relief
- Feel more confident to self- manage your back condition
- Feel more in control & positive about the outlook of it

Slide 9

ICE BREAKER



*•Speak to the person who is sitting next to you
•Tell each other 3 things about yourself,
EXCEPT your low back pain!*

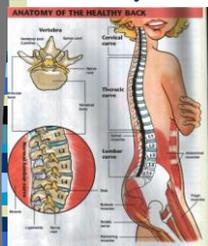
Slide 10

Content of session 1

- Basic anatomy and function of the spine
- Common diagnosis of back pain
- Explain primary & secondary "suffering"- physical, mental and emotional reaction to pain or fear avoidance
- Pain ⇌ Harm

Slide 11

Anatomy of a healthy spine



- Consists of 33 vertebrae lying in 5 region
- 7 cervical vertebrae
- 12 thoracic vertebrae
- 5 lumbar vertebrae
- 5 fused vertebrae-sacrum
- 4 fused vertebrae-coccyx

Slide 12

Structures in the spine

- Vertebrae
- Intervertebral disc
- Spinal cord
- Spinal nerves
- Ligaments
- Muscles



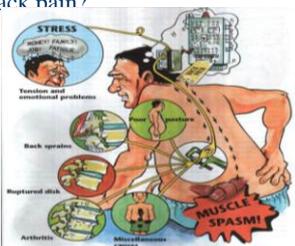
Slide 13

Function of the spine

- One of the strongest part of the body
- Supports the weight of your upper body & transfers weight to your lower limbs
- Vertebral bodies & discs allow strength & flexibility
- Reinforced by strong ligaments & powerful muscles
- Protects the spinal cord

Slide 14

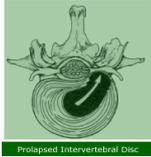
What are the common causes of low back pain?



Slide 15

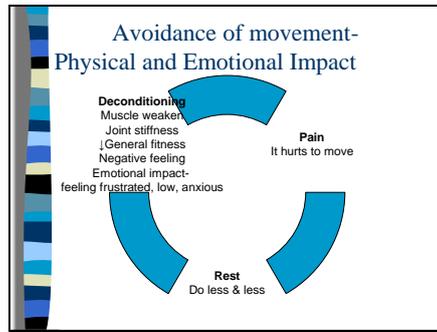
Common cause of back pain

- Osteoarthritis
- Degenerative disease/ Wear and tear
- Spondylosis
- Slipped disc/ Bulging disc
- Nerve root irritation/ trapped nerve. E.g. sciatica
- Osteoporosis
- Habitual poor posture
- Tension & emotional Stress
- **The majority of back pain is mechanical in nature, & NOT due to serious disease.**

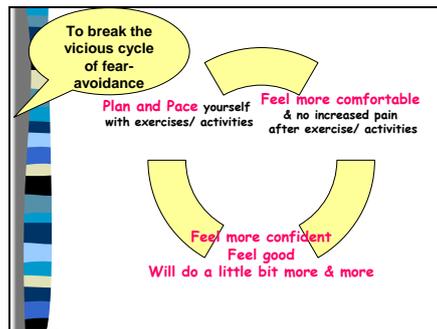


Prolapsed Intervertebral Disc

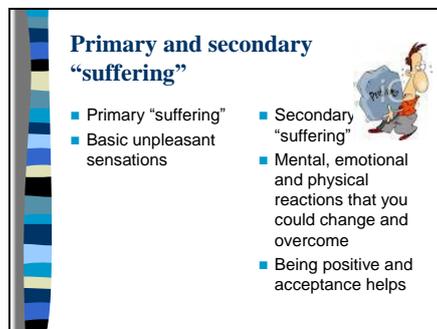
Slide 16



Slide 17



Slide 18



Slide 19

Positive Notes



- *You may not be able to get rid of the basic unpleasant sensations, but it is within your control to help the secondary mental, emotional and physical reactions*
- *The coming sessions will discuss what might help overcome and address these reactions*

Slide 20

Tips of the day

Pain ☒ Harm

Hurt ☒ Harm

Slide 21

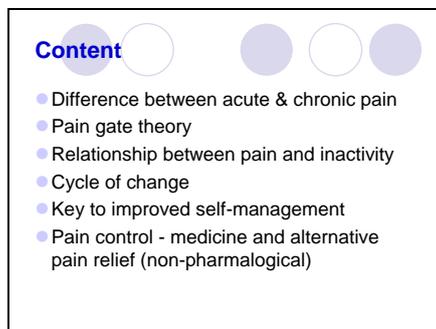
Tips of the day

- *Being positive and acceptance helps overcome the secondary "suffering"- they are within your control and you could make changes!*

Appendix 11
Session 2
Slide 1



Slide 2



Slide 3



Slide 4

Pain is.....

- **Personal** - very individual & subjective
- **Difficult to define**
- **A sensory experience**: unpleasant, sharp, dull aching pain
- **An emotional experience**: depressed, worried, frustrating
- **Two types of pain: Acute & Chronic**
- **May or may not be caused by physical damage**

Slide 5

Acute Pain

- Presence of inflammatory sign
- Pain, redness, swelling, heat & loss of function
- Indicating body damage
- A warning sign to protect your body - useful!!
- Short lasting < 3 months

Slide 6

Example of acute pain-
Sprained ankle



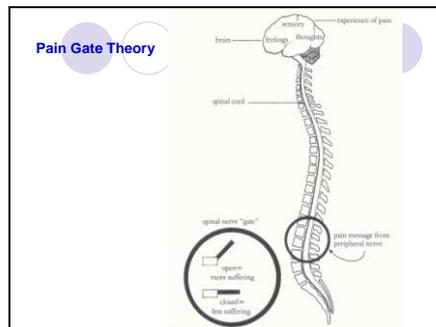
- Structures in the ankle damaged
- Signals to the brain → stop walking to prevent further damage
- Allows body to heal

Slide 7

How do we feel pain?

- Pain transmitted through the nervous system
- Changes in the body are detected by sensors
- Stretch or pressure → message to spinal cord and brain → which tells body to stop
- Series of connections called gates
- Gate open = pain messages get through
- Gate closed = pain message is stopped

Slide 8



Slide 9

Chronic Pain

- May be primary diagnosis e.g. OA/disc protrusion
- Chronic pain = the pain receptors become over sensitised
- Body has healed *but* pain gate remains open
- Problem with the pain processing circuit not the tissues.
- E.g. phantom limb pain, post op pain

Slide 10

KEY to recovery from Chronic Back Pain

- **Acceptance** - understand primary pain (not going to go away completely) and the secondary "suffering" (which is within your control and you can change them!).
- **Adjustment** - pacing activities, modifying activities
- Identify your **personal barriers/resistance**

Slide 11

Secondary "suffering"/ experience

- Fear
- Feeling low and depressed
- Feeling stressed
- Frustrated
- Lack of sleep
- Worried about job
- Family issues/ pressure

***DISCUSS** - Identify if you may have any secondary "suffering" and how you might overcome them?*

Slide 12

Things that OPEN the pain gate

- Emotional stress
- Fear
- Anger, worry, tension
- Low mood
- Thinking about pain
- Inability to cope
- Boredom due to minimal involvement in life activities
- Maladaptive attitudes
- Being deconditioned (stiff joints, tight muscles, low muscle tone)

These secondary "experiences" something you can control and change

Slide 13

Things that CLOSE the pain gate

- Application of Heat or Ice
- Relaxation
- Medication
- Appropriate activity level- exercise & stretching
- Avoiding excessive emotions
- Making time to focus on positive emotions (keep a gratitude journal for example)
- Managing stress properly
- Distraction away from Pain
- Increased Social Activities
- Practicing Positive Attitude
- Appropriate Exercise
- Increased Positive Life Activities
- Healthy Eating
- Refraining from Unhealthy Habits
- Having a communicative outlet to share thoughts and feelings

These are also things you could actively do and within your control

Slide 14

What can I do??



- Exercise has been shown to help physically and psychologically
- Being fit & healthy makes you feel good too!

Slide 15

DISCUSS - why you may be afraid to move?

*What are the potential barriers that may stop you moving/exercising?
Physical or emotional barriers?
How may you overcome these barriers?*

Slide 16

How may you overcome these barriers?

- Adequate pain control
- Pace yourself - *do what you feel comfortable and gradually increase the amount of activities in your own pace*
- Keep positive & be confident of yourself
- Make time for it
- Reward yourself
- Do something fun and enjoyable!
- Exercise with others



Slide 17

Pain ∇ Harm

Some post exercise soreness for a day or two is NORMAL if your joints are a bit stiff and muscles a bit weak. Don't Panic!

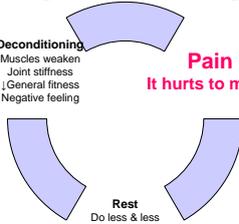
Slide 18

Avoidance of movement

Deconditioning
Muscles weaken
Joint stiffness
↓ General fitness
Negative feeling

Pain
It hurts to move

Rest
Do less & less



Slide 19

Adequate Pain Control is important to allow you to start exercising!
Medicine & management of chronic pain



Slide 20

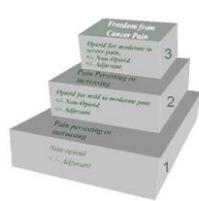
Medicine

- Adequate pain relief is essential for successful rehabilitation
- Analgesics have a variety of side-effects & interactions with other drugs.
- ✓ Patients should always be referred to the **GP/pharmacist** if medication needs changing

Slide 21

The WHO (World Health Organisation) 3 steps Analgesic Ladder (1986)

WHO's Pain Relief Ladder



3
2
1

Slide 22

Commonly prescribed analgesia -
Paracetamol

- **Indication:** mild to moderate pain. 1st line treatment for Osteoarthritis
- **Additional information:** many over the counter medications e.g. Lemsip, which patients can buy themselves, contain paracetamol, this should NOT be taken with paracetamol.

Slide 23

Commonly prescribed analgesia -
mild opioids

- **Indication:** moderate to severe pain. Or patients who have an inadequate response to "step 1" analgesics
- **Example:** codeine, dihydrocodeine, tramadol
- **Additional information:** often combined with paracetamol e.g. Co-codamol, Co-dydramol, Tramoxet

Slide 24

Commonly prescribed analgesia -
NSAIDs - Ibuprofen, Naproxen, Diclofenac (Voltarol)

- **Indication:** mild to moderate pain. Commonly used for back pain & other musculoskeletal disorders. E.g. arthritis, bone pain, inflammatory pain
- **Additional information:** always take the tablets with food

Slide 25

Commonly prescribed analgesia -
low dose anti-depressants

- **Indication:** nerve pain, night pain, relaxation and help sleeping
- **Examples:** Amitriptylline, nortriptylline, imipramine, clomipramine
- **Problem:** tend to make people drowsy#

Anti-epileptic drugs

- **Indications:** Epilepsy & nerve pain
- **Example:** Gabapentin, Pregabalin

Slide 26

Commonly prescribed analgesia -
Skeletal muscle relaxants

- **Indication:** acute pain, severe muscle spasm
- **Example:** Diazepam, Temazepam, Nitrazepam
- **Additional Information:** can be useful in extreme cases of muscle spasm during flare up, and should limit intake to a few days only, then reduce gradually

Slide 27

Tips on pain control

- **If you reduce your medication at a controlled rate, it is unlikely to increase your pain levels, and you may even feel better in yourself**
- **Using other pain management skills can help you to reduce pain medication**
- **Ideas of alternative pain relief?**

Slide 28

**Non-Pharmalogical pain relief-
Discuss in group**

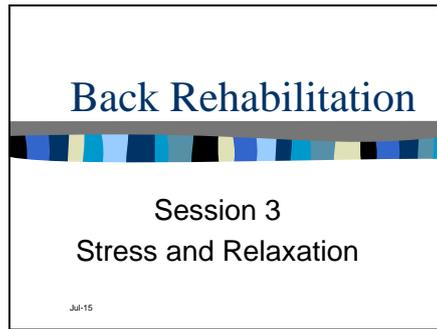
- Heat/Cold
- Physiotherapy
- Osteopathy/Chiropractic treatment
- Acupuncture
- TENS
- Reflexology, massage, Reiki
- Relaxation techniques

Slide 29

Tips of the day

- **Acceptance** - understand primary pain (not going to go away completely) and the secondary "suffering" (which is within your control and you can change!).
- **POSITIVE thinking, feeling and behaviour**
- **Adjustment** - pacing activities, modifying activities
- Identify your **personal barriers/resistance**, and try to overcome them
- **Distraction of pain**

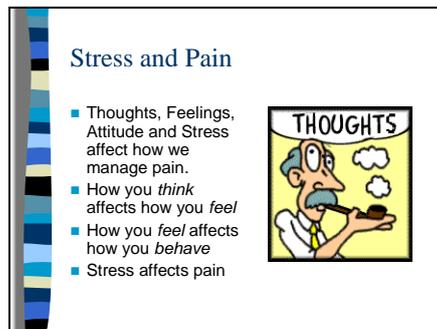
Appendix 11
Session 3
Slide 1



Slide 2



Slide 3



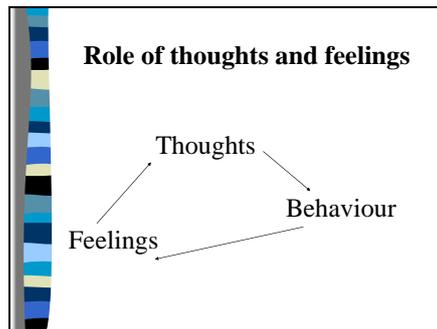
Slide 4



Things that OPEN the pain gate

- Stress
- Fear
- Anger
- Low mood
- Thinking about pain
- Inability to cope
- Being deconditioned (stiff joints, tight muscles, low muscle tone)

Slide 5



Slide 6



Thinking negatively

- Extreme thoughts
- Black and White thinking
- Unhelpful thoughts
- Negative thoughts

How does pain feel when we're in a bad mood?

Slide 7

**Negative thoughts =
BEHAVIOUR changes**

- Reduced activities
- Avoid activities
- Become deconditioned
- Pain increases

This will have a detrimental affect on pain

Slide 8

Unhelpful cycle

The diagram features a central yellow sad face icon with a blue border. Four arrows point from the icon to the following text:

- Do less & less
Withdrawn from activities
- Thinking becomes negative "I can't cope"
- Feel low & negative

Slide 9

Helpful cycle

The diagram features a central yellow happy face icon with a blue border. Four arrows point from the icon to the following text:

- Feel positive & believe that you can control it better
- I can cope as long as I pace & plan
- Feeling good
Sense of achievement and personal control
Feel confident

Slide 10

Stress <=> Pain

Stress Response

- ↑ Heart rate
- ↑ Breathing rate, more shallow
- ↑ Muscle tension
- Sweat
- Butterflies in your tummy



The illustration shows a woman with a pink top and yellow hair, looking stressed. She has a red heart on her forehead and is holding a pink flower. Below her is a smaller illustration of a person with a large, tangled mass of lines representing stress or pain in their stomach area.

Slide 11

Stress response

- ***However stress response can be constructive and non-constructive.***
 - **Stress response - Constructive Vs Non-constructive**

Slide 12

Constructive	Non-Constructive
 <ul style="list-style-type: none">■ Flight or Fight■ Prepares us for danger■ Useful■ Short duration 	 <ul style="list-style-type: none">■ Occurs in response to normal every day activities■ Habit forming■ Not useful■ Build up of tension = person becomes unaware of the stress

Slide 13

How do you cope with stress?



Take five and relax!

Slide 14

Why Relax?

- Lowers stress levels
- Breaks cycle of stress = ↑ pain
- ↓ Muscular tension



Slide 15

Diaphragmatic Breathing

Deep breathing technique

Uses the sheaf of muscle between lungs and stomach

Combats shallow & rapid breathing

Slide 16

How to do it?

- Comfortable and relaxed position
- Hands over your ribcage
- Breathe in through the nose trying to expand ribcage laterally
- Breathe out feel ribcage drop
- Equal movement of both sides
- Practice no more than 4 a day



Slide 17

Three minutes breathing space



- A "three minute breathing space" is a "pause" from activity, where you stop doing everything and simply be quiet for three minutes
- Easy to do at regular intervals throughout the day. E.g. once every hour
- Can be quite powerful - makes you feel calmer and more relaxed

Slide 18

Three minutes breathing space- How to do?



1. Sit/lie down in a comfortable position, with your eyes closed
2. Focus on your natural even breathing, and allow yourself to feel the gentle movements of your ribs as you breathe
3. Try to take your attention to the area with muscle tension and pain, and let your muscle tension and pain soften on your out breath
4. You can also be aware of what you are feeling emotionally, and what sort of thoughts are passing through your mind
5. Remain aware of your breathing as well as your sensations, feelings and thoughts for three minutes, you will probably become more "centred", calm, and relax

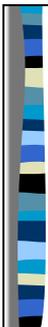
Slide 19



Why practice breathing techniques?

- Promotes a natural even movement of breath
- Strengthens the nervous system
- Relaxes the body
- Supplies body with O²
- Improves circulation to the abdominal muscles by its massaging action
- Breaks cycle of pain = stress

Slide 20



But if you are stressed....

- Increased tension
- Hyperventilated breathing
- Tense up abdominal muscles, and use more accessory muscles. So your diaphragm is not at its optimal function
- More energy is required to "breathe"
- Reduced oxygen supply to the body

Slide 21



CBT (Cognitive Behavioural Therapy)

Talking therapy which helps people understand the links between your symptoms, thoughts and feelings, behaviour and how this affects your life.

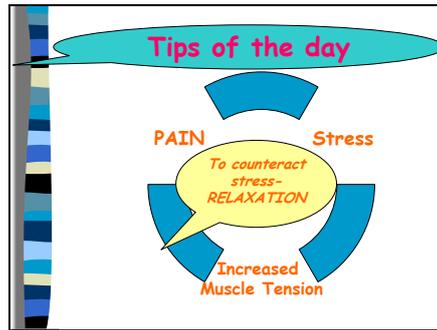
- There are group and 1:1 sessions which may be of interest to you, which we can discuss towards the end of the programme.

Slide 22

Learning to reduce stress and relax, and combined with exercise can relieve back pain

It can start you on the road to a happier and healthier lifestyle!

Slide 23



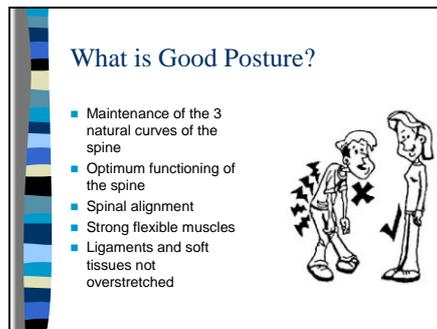
Appendix 11
Session 4
Slide 1



Slide 2



Slide 3

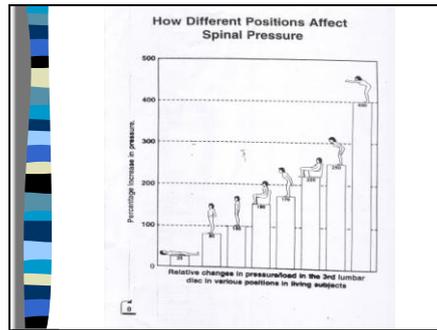


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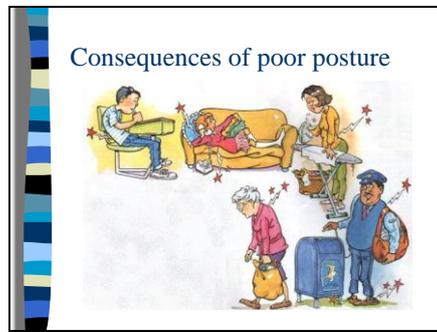
Why good posture is important for people with back pain?

- When your spine is at the normal “S” shaped curvature, the muscles work the most efficiently without getting painful & tired. Also the ligaments and other soft tissues are at their optimum length, and they are not overstretched.
- GOOD Posture - ↓PAIN & muscle tension

Slide 5



Slide 6



Slide 7

Consequences of poor posture

- Worsens back pain
- Accelerate degenerative changes
- ↑ Risk of injury
- Tight & imbalanced muscles
- ↑ Stiffness = ↓ functioning of spine
- Weakened intervertebral discs
- Could lead to "Dowager's hump"

Slide 8

Causes of poor posture



Slide 9

Posture that works

- Good standing, sitting & sleeping
- Good posture in motion
- Postural exercises
- Regular stretches
- Mini breaks & "Active" rest

Slide 13



Posture checklist - Everyday activities

- Emptying the washing machine
- Gardening
- Doing the dishes
- Cleaning
- D.I.Y around the house

Any other activities?

Slide 14

To learn good posture may feel strange at first



But you'll be surprised at how quickly it becomes a comfortable habit, and how good it looks and feels.

Slide 15



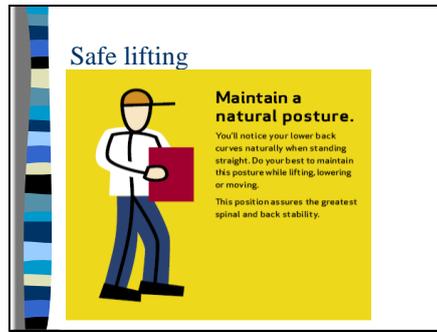
Lifting

Back injuries can result from poor lifting

Bad lifting

- Bending over the load
- Twisting
- Holding object at arms length
- Not using the large leg & buttock muscles

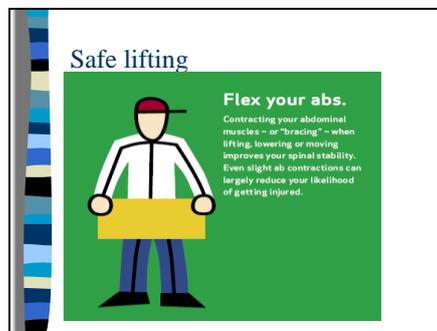
Slide 16



Slide 17



Slide 18



Slide 19

Safe lifting



Don't do the twist.
Twisting decreases the stability of your back and increases your likelihood of injury. Pivot with your feet to turn, rather than twisting your body.

Slide 20

How to lift properly

- Get a firm footing
- Bend your knees
- Tighten stomach muscles
- Lift with your legs
- Keep the load close
- Keep your back straight

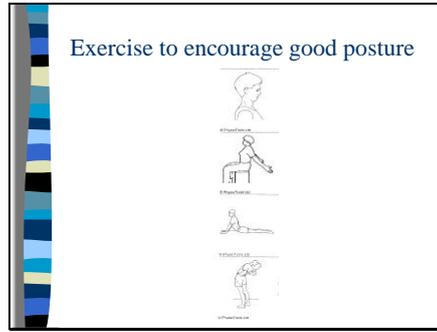
Slide 21

Regular stretches

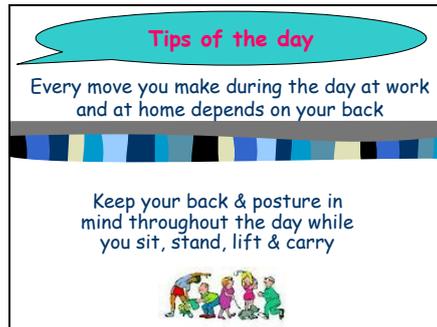
- Get up and stretch regularly, every 20-30 minutes.
- This can reduce accumulated tension and allow you to feel more relax.



Slide 22



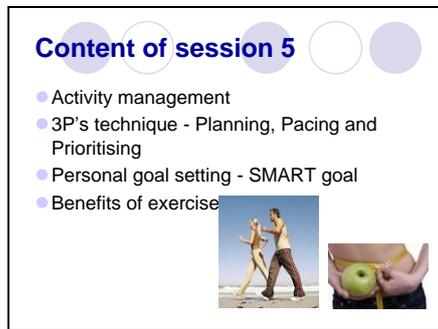
Slide 23



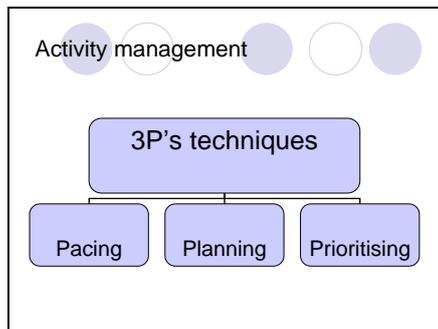
Appendix 11
Session 5
Slide 1



Slide 2



Slide 3



Slide 4

Purpose of 3P's management

- 3P's enables you to avoid over-activity/ under activity
- Take back control over your life & stop pain controlling you

Under-activity
E.g. prolonged rest & medication

Over-activity
Increased pain

Slide 5

Activity cycle

- *Good day- Do too much. Bad day- suffering*

Activity level

Time

Good day

Bad day

Aim to gradually increase activity level in the future

Aim to level out the curve

Basic daily activities

Slide 6

To increase the consistency of activity level:

- 3P's – Pacing, Planning, Prioritizing
- Work out your tolerance level

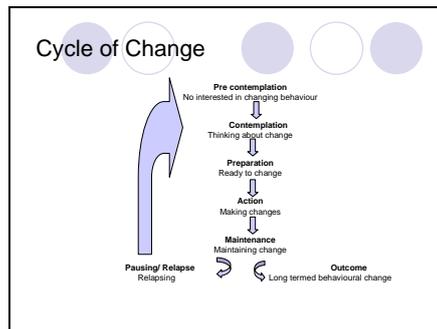
Slide 7

Tolerance level

- **What is tolerance level?**
- *It is how much can be done at the moment without over-doing it.*
- **How to set your baseline tolerance?**
- **Worksheet in your education pack**

	Good Day (mins)	Bad Day (mins)	Baseline tolerance = (Good days+ bad days)/ 2
Sitting			
Standing			
Walking			

Slide 8



Slide 9

Healthy Stockport

Healthy Stockport:
Free confidential local support service to help you make lifestyle changes e.g. smoking cessation, weight loss.
Contact: 0161 426 5085
www.healthystockport.co.uk

Slide 10

Goal Setting
SMART GOAL

- S - Specific
- M - Measurable
- A - Achievable
- R - Realistic
- T - Time- specific



Slide 11

Personal SMART goal

- GOAL:
- Homework - Set a SMART goal

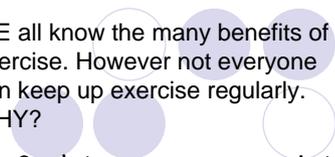
Week 1	
Week 2	
Week 3	
Week 4	
Week 5	
Week 6	

Slide 12

BENEFITS OF EXERCISE

WE all know the many benefits of exercise. However not everyone can keep up exercise regularly.
WHY?

So what are your reasons against exercise?



Slide 13

Reasons against exercise

- **FEAR & Increase PAIN!**
- Laziness
- Lack of motivation & time
- Work & family commitments
- Lack of confidence, not sure what is safe to do

ANY OTHER BARRIERS?

Slide 14

Deconditioning & lack of exercise can lead to.....

- ↓ Activity level & weight gain
- ↓ Physical fitness & ↓ endurance
- ↑ Joint stiffness & weaken muscles
- Weak bones
- Depression/↑ risk of depression
- Low energy & ↑ tiredness
- Poor sleep
- ↓ Ability to cope stress
- ↑ Sensitivity of pain receptors
- ↑ **PAIN**



Slide 15

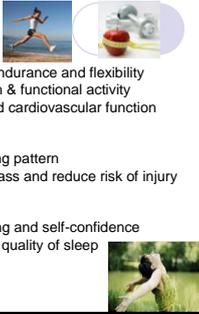
TO ADDRESS THESE PROBLEMS, exercise has shown to have a beneficial effect - both physical & psychological aspects

Pain ↗ Harm

Slide 16

Benefits of exercise

- ✓ Improved muscle strength, endurance and flexibility
- ✓ Improvement of co-ordination & functional activity
- ✓ Increased general fitness and cardiovascular function
- ✓ Improved circulation
- ✓ Increased level of energy
- ✓ Improved balance and walking pattern
- ✓ Potential increase in bone mass and reduce risk of injury
- ✓ Weight loss
- ✓ Reduction in levels of stress
- ✓ Increased feeling of well-being and self-confidence
- ✓ Potential improvement in the quality of sleep
- ✓ **Reduction in pain**



Slide 17

Tips to start exercising!!

- ❖ Set simple & achievable goals
- ❖ Pace yourself
- ❖ Add variety to prevent boredom
- ❖ Exercise with others
- ❖ Be flexible
- ❖ Track your progress
- ❖ Reward yourself
- ❖ Exercise prescription - PARIS scheme



Slide 18

Any Questions?



Appendix 11
Session 6
Slide 1



Back Rehabilitation

Session 6



Small text at bottom left: J&J 15

Slide 2

Content

- Management of flare up
 - Relapse plan
- Future management
- Continuity following back rehabilitation - **PARIS**
- To fill in: Post assessment questionnaire & evaluation form
- Certificate



Slide 3

Managing setbacks

- Relapse is the nature of back pain
- Self-management skills would help to:
 - ✓ ↓ Duration of bad days
 - ✓ ↓ Frequency of bad phrase
 - ✓ ↓ Severity of pain
 - ✓ Feel more in control



Slide 4

Flare up plan

- **DON'T PANIC & STAY POSITIVE**
- Painkillers & NSAIDs
- Heat/Ice
- Regular change of position & stretches
- Keep active but ↓ amount of activity, then gradually ↑ as pain get easier
- 3P's - Pace, Plan & Prioritise
- Relaxation
- Positive thinking - you can manage it!



Slide 5

Warning signs

- Having severe pain that gets worse over several weeks instead of better
- Feel generally unwell with back pain
- Difficulty passing urine or controlling urine
- Numbness around your back passage or genitals
- Numbness, pins & needles or weakness in both legs
- Unsteadiness on your feet

These symptoms are very RARE. Don't let that list worry you too much!



Slide 6

How to look after your back in day-to-day activities?

BACK OWNER'S MAINTENANCE GUIDE

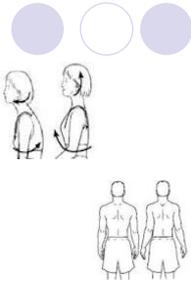


- Maintain your back's three natural curves by being consciously aware of your posture and correcting it.
- Avoid excessive one-sided work at all times.
- Help reduce strain on your back when lifting your weight down and by exercising regularly to build strong supporting muscles.
- Lift with your legs—not your back—by squatting and bending your knees. Hold the object as close to your body as possible. Do not twist.
- Change positions frequently during the day. Break up tasks such as driving for a long period of time into shorter segments.
- Sleep on a firm mattress, either on your back or your side.
- Do not bend straight over, back or over to pick up something, even if it is a light object—don't lift or carry anything heavier than you can manage with ease.
- Avoid lifts over your shoulder or a level or over it.
- Don't slouch or bend forward when sitting or driving.
- Use your driver's seat as much as possible if you have a powered back seat.
- Check with your doctor's office if you have any further questions.
- Stay fit and trim. Exercise regularly. Working and exercising are excellent ways to work out.

Slide 7

Regular stretches

- Get up and stretch regularly, every 20-30 minutes
- Micro-breaks in between work, especially after prolonged position
- Look at ergonomic design at work



The slide features a title 'Regular stretches' in blue. Below it are three decorative circles: a solid purple one, a white one with a purple outline, and another solid purple one. To the right of the text are two line drawings of a person's head and neck in different positions, and two line drawings of a person's torso and back in different positions.

Slide 8

Relaxing/ sleeping

- Make sure your mattress is firm enough so that your spine is well-supported.



The slide features a title 'Relaxing/ sleeping' in blue. Below it are three decorative circles: a solid purple one, a white one with a purple outline, and another solid purple one. To the right of the text is an illustration of a mattress with a star above it, set against a blue background with a crescent moon.

Slide 9

Heat

- A good way to reduce pain, joint stiffness and relax your muscles
- Hot water bottle, wheat pack, hot shower or bath
- Pleasantly warm
- 15-20 minutes



The slide features a title 'Heat' in blue. Below it are three decorative circles: a solid purple one, a white one with a purple outline, and another solid purple one. To the right of the text are two illustrations: a hot water bottle and a person taking a hot shower.

Slide 10

Keep fit and active

- Keeping active, physically fit & trim will help you avoid back pain.
- You can reduce your risk of back pain by improving the strength and flexibility of the muscles supporting your spine.



Slide 11

Safe lifting

Maintain a natural posture.

You'll notice your lower back curves naturally when standing straight. Do your best to maintain this posture while lifting, lowering or moving.

This position assures the greatest spinal and back stability.



Slide 12

Safe lifting

Don't do the twist.

Twisting decreases the stability of your back and increases your likelihood of injury. Pivot with your feet to turn, rather than twisting your body.



Slide 13

Referrals:



- Healthy Stockport- helps you to make lifestyle changes e.g. smoking cessation, weight loss
- Cognitive Behavioural Therapy (CBT) referral- may help if you have anxiety, stress and depression as a result of chronic pain
- PARIS scheme: Physical activity referral in Stockport. Referral to gym to continue with exercise

Slide 14

Remember:



- Back pain is common, it's rarely due to serious disease & the long - term outlook is good☺
- Hurt ≠ Harm
- Bed rest more than a day or two is usually bad for you. Staying active will help you get better faster. The sooner you get going, the faster you will get better
- Regular exercise & staying fit helps general health & your back
- You have to get on with your life. Don't let your back take over

Slide 15

Any Question?



- Well done & we hope you enjoyed the course!!
- All the very best to you!

Slide 16

Future activity: What now?

- Lifestyle change - taking up exercise, pacing activities
- 3P's & activity management
- Goal setting
- Stay active & fit
- Be positive
- Practise relaxation
- Don't panic when flare - up
- Take up exercise - PARIS scheme, aqua aerobics, pilates, walking.



A positive attitude will get you anywhere !

Slide 17

Certificate & Evaluation form



Homework 1

Personal SMART goal

GOAL:

WEEK 1	
WEEK 2	
WEEK 3	
WEEK 4	
WEEK 5	
WEEK 6	

Homework 2:

TOLERANCE LEVEL WORK SHEET

Most people find prolonged sitting, standing or walking aggravates their back pain. Pacing involves gradually increasing the tolerance for a particular task, therefore work out a tolerance level or time limit at standing, sitting and walking are helpful.

What is tolerance level?

It is how much can be done at the moment without overdoing.

How to set your baseline tolerance?

Write down how long you can sit, stand and walk for a good day, then do the same for a bad day. Then work out the average between those two values, hence you got your baseline tolerance (the maximum time you will do that activity). This could ensure you don't overdo on a good day.

	Good Day	Bad Day	Tolerance level = (Good day + bad Day) / 2
Sitting			
Standing			
Walking			

Suggestion:

- ❖ *You could use of timer initially to help stick to your tolerance level.*
- ❖ *Once you happy with the baseline tolerance level, you can gradually increase your tolerance level by effective pacing.*

Managing Setback- What I would do?

Strategy	During acute flare-up Day 1- 3	Day 3 onward
1		
2		
3		
4		
5		
6		

STOCKPORT NHS TRUST PHYSIOTHERAPY SERVICE

BACK REHABILITATION PROGRAMME

*Getting started with
your home exercises &
postural stretches
everyday*

Getting started

Establish your baseline repetition i.e. the number of times you can do an exercise without overdoing it. It is very important to set your baseline at an easily achievable level to help you gain confidence and reduce 'fear' of exercising e.g. each exercise is performed 10 times, hold the stretch for 5 seconds (twice a day)

Consider using 15-20 minutes of **heat** treatment such as a hot water bottle, wheat pack, hot shower/bath, on your back before you do your home exercises. Or try taking some **painkillers** beforehand if appropriate. The heat helps to relax the muscle tension and reduce the pain, and it will help you to perform your exercises more effectively and comfortably

When you carry out the stretching exercises remember **the 3 "S" - "S" Slow, "S" Sustained and "S" Steady.**

Move **slowly** into the stretch position.

Sustain (hold) the stretch for a slow count of 5 seconds. You will feel some stretching sensation but that is entirely normal. Please ensure that you do these exercises within your comfortable range.

Steadily release the stretch and return to the start position. The physiotherapist will demonstrate and advise you about the correct technique of the exercise

Progressing

Progress by gradually building the length of time you hold each stretch up to 20 seconds. You can also gradually build up the number of repetitions

Set yourself exercise targets each week - they can be general, e.g. "work up to 19 repetitions of each exercise by the end of the week".

Record your achievements daily on the chart provided so you can see your progress and gain confidence

Reward yourself for sticking to your plan - treat yourself if you managed to stick to your exercise plan, you deserve it. Use rewards after an exercise session, at the end of the week or at the end of the month.

Physical activity is good for everybody and too much rest can lead to stiffness in your muscles and joints. Research shows that exercise is the most important way that you can help yourself if you have back pain. Exercise might make your back feel a bit sore at first but it doesn't cause any harm - so don't let it put you off! Start off slowly and gradually increase the amount of exercise you do. Also **make your exercise enjoyable!** Over time, your back will get stronger, more flexible and this should reduce pain and **help to make you feel like you can manage more with your back pain condition.**

HOME EXERCISE PROGRAMME

Lying on your back with knees bent and arms by your side.

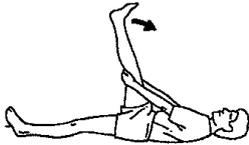
Tighten your stomach muscles and press the small of your back against the floor letting your bottom rise. Hold 5 secs. - relax.



Repeat ___ times.

© PhysioTools Ltd

Lying on your back. Lift your leg towards your chest. Place your hands behind the knee.



Gently pull your leg towards your chest. Feel the stretch behind your thigh. Hold ___ secs.

Repeat ___ times.

© PhysioTools Ltd

Lying on your back with knees bent and feet on the floor.

Lift your pelvis and lower back (gradually vertebra by vertebra) off the floor. Hold the position. Lower down slowly returning to starting position.



Repeat ___ times.

© PhysioTools Ltd

Lying with your knees bent and feet on the floor. Lift your knees towards your chest.

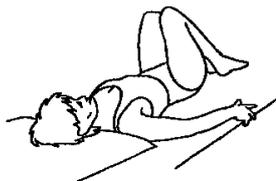
Place your hands behind both knees and draw them towards your chest. Hold ___ secs.



Repeat ___ times.

© PhysioTools Ltd

Lying on your back with knees together and bent.



Slowly roll your knees from side to side keeping your upper trunk still.

Repeat ___ times.

© PhysioTools Ltd



Stand straight with feet apart.

Support your back with your hands while bending your back as far backwards as possible. Keep your knees straight during the exercise.

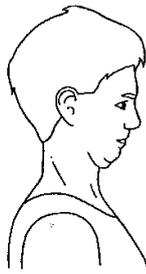
Repeat ___ times.

Postural stretches

Maintaining good upright posture is crucial when you experience back pain. Poor posture affects the soft tissues supporting your back and that will increase your pain, and may also lead to muscle tightness and weakness, stiff joints and deconditioning.

Try to maintain good posture when sitting, standing and walking. It may feel a bit strange to start with, but you will be amazed how quickly your body adapts to good posture and how good you look!

Practise the following postural stretches regularly throughout the day e.g. 3 repetitions of each stretch every hour.

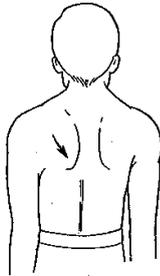


Sitting straight-backed.

Pull your chin in, keeping your neck and back straight (not tipping your head forwards). Hold at the end position and feel the stretch in your neck.

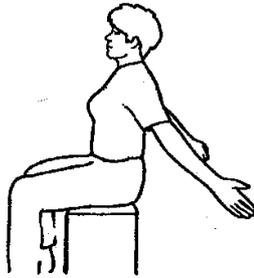
Repeat ___ times.

© PhysioTools Ltd



1. Assume upright posture with shoulders relaxed
2. Move ___ shoulder blade down and toward opposite hip
3. Hold ___ seconds
4. ___ repetitions, ___ times per day

© The Saunders Group Inc.



Sit with your back straight and feet firmly on the floor.

Pull your shoulder blades together while turning your thumbs and hands outwards.

Repeat ___ times.

© PhysioTools Ltd



Stand straight with feet apart.

Support your back with your hands while bending your back as far backwards as possible. Keep your knees straight during the exercise.

Repeat ___ times.



Stand with back to the wall. Have feet hip distance apart and a few cms away from the wall.

Place hand in the small of your back. You should only be able to slide your hand in to the space behind your lower back. Not your whole arm.

Pull your shoulder blades back and down (imagine you're tucking your shoulders into your back pockets)

Ensure the back of your head is touching the wall and try to lengthen the back of your neck.

Monitor & record your home exercise progress

Date:

How many times have you done each exercise today?

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Pelvic tilting							
Hamstrings stretch							
Bridging							
Knees to chest stretch							
Knees roll side-to-side							
Back extension in standing							

Appendix 14: Exercise circuit sheet of the CBCLBP programme

CBCLBP programme exercise circuit sheet

Name: D.O.B:/...../..... NHS No.:

Number of week	Week: Date:	Week: Date:	Week: Date:
1. Cross Trainer (minutes)			
2. Exercise bike (minutes)			
3. Trampet (minutes)			
4. Lunge (reps)			
5. Wall press up (reps)			
6. Wall slide with small gym ball (reps)			
7. Gym Ball - in sitting & straighten your knee (reps)			
8. Rowing with pulley (reps and weight)			
9. Treadmill (minutes/speed)			
10. Core stability: a) half bridge in lying (reps) b) four-point kneeling (reps)	a) b)	a) b)	a) b)
Comments			
Physiotherapist's Signature:			

Appendix 15: Hydrotherapy Exercise

1. Walking forwards, sideways, backwards, walking with high knees.
2. Holding Woggle float at either end walk forward and place one end of float into water arm stretched forwards, pull it towards you as you step and reach out with opposite side and do the same , continue walking.
3. Stood with feet shoulder width apart and flat on the floor, arms resting on float, rotate left and right.
4. Stood with feet flat and shoulder width apart, holding float by your side with elbow straight, bend down to side of float and slowly up, repeat on both sides.
5. Feet shoulder width apart maintain good back posture, hold woggle towards middle in both hands and push into the water with the ends out of the water and bring out slowly, repeat and keep straight back.
6. As above half submerge float, keep submerged and slowly rotate left and right keeping feet flat on floor.
7. Keep feet slightly apart, arms by your side. Lean sideways sliding your hand down the outside of your leg and then straighten and repeat the same movement to the other side. Repeat 10 times to each side.
8. Stand sideways to the rail holding on with one hand, feet at the side of pool, lean your hips in towards the centre of the pool. Hold for 5 seconds then straighten. Repeat 5 times then turn and do the same with the other side.
9. Facing the rail hold on with both hands standing with feet away from the wall. Drop your back into a hollow bringing pelvis towards wall and arch back and then return to your start position. Repeat 10 times.
10. Facing rail hold on with both hands and walk feet up wall, bend your knees and curl your back to wall and then straighten out knees and arms and stretch out, repeat 10 times.
11. Holding square float in two hands keep good back posture, feet hip width apart push float out and back against the water, maintain upright position.
13. Rest float on surface of water hands flat on float and arms extended out in front, push float into water to submerge it slowly and then slowly bring up.
14. Position as above bend knees and stick bum out as if to sit down then straighten up, repeat squats.

15. Stood with good posture hold float out to side in one hand, bring under water in front of you and swap hands bring float out of water on other side and then lift above your head, swap hands again and bring down back into the water, repeat going both ways.
16. Stand sideways with your right leg straight and your foot pulled up towards you. Swing the right leg forwards and backwards 10 times. Repeat with the left leg.
17. Stand sideways and draw big circles round with your right leg in front and then behind you, repeat 10 times then do with left leg
18. With back against wall hold onto rail and put a float under your feet, move legs from side to side.

Appendix 16: Pilates

Back Rehabilitation Pilates Class:

Date and Time:

Physiotherapist/Pilates Instructor:

Patient Name:

DOB:

NHS No:

The above named patient attended an 'Introductory Pilates for LBP' session at Kingsgate House as part of the back rehabilitation programme. The following 'ticked' exercises show the programme that was followed under the supervision and guidance of a Qualified APPI Pilates Instructor.

Stand, find neutral spine position, 'centre set', Pelvic triangle and Trans-Abs

Warm-Up:

- Marching/ walking series
- Mermaid in Standing
- Foot Series
- Side Plié
- Dumb waiter
- Cx Retractions/Rot/SF
- Roll down

Main Body:

4-Point kneeling...

- Thread the needle
- Cat stretch
- Superman

Prone...

- Swimming
- Breast Stroke
- Swan Dive

Side Lying...

- Clam
- Side Kick
- Arm Opening

Supine...

- Scissors
- Hip twist
- Shoulder Bridge
- 100's
- Abdo Prep

Stretches / cool down:

- Gluteal stretch
- Mermaid stretch
- Spine stretch
- Re-cap Posture in standing

Physiotherapist Signature:.....

Appendix 17: Primary outcome measure: Form C of MHLC (measure of HLOC)

Participant Study Identification Number:

DATE.....

Form C of the Multidimensional Health Locus of Control Scale

Instructions: Each item below is a belief statement about your medical condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer **EVERY ITEM** and that you circle **ONLY ONE** number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

		1=STRONGLY DISAGREE (SD)		2=MODERATELY DISAGREE (MD)		3=SLIGHTLY DISAGREE (D)		4=SLIGHTLY AGREE (A)		5=MODERATELY AGREE (MA)		6=STRONGLY AGREE (SA)	
		SD	MD	D	A	MA	SA						
1	If my condition worsens, it is my own behavior which determines how soon I will feel better again.	1	2	3	4	5	6						
2	As to my condition, what will be will be.	1	2	3	4	5	6						
3	If I see my doctor regularly, I am less likely to have problems with my condition.	1	2	3	4	5	6						
4	Most things that affect my condition happen to me by chance.	1	2	3	4	5	6						
5	Whenever my condition worsens, I should consult a medically trained professional.	1	2	3	4	5	6						
6	I am directly responsible for my condition getting better or worse.	1	2	3	4	5	6						
7	Other people play a big role in whether my condition improves, stays the same, or gets worse.	1	2	3	4	5	6						
8	Whatever goes wrong with my condition is my own fault.	1	2	3	4	5	6						
9	Luck plays a big part in determining how my condition improves.	1	2	3	4	5	6						
10	In order for my condition to improve, it is up to other people to see that the right things happen.	1	2	3	4	5	6						
11	Whatever improvement occurs with my condition is largely a matter of good fortune.	1	2	3	4	5	6						
12	The main thing which affects my condition is what I myself do.	1	2	3	4	5	6						
13	I deserve the credit when my condition improves and the blame when it gets worse.	1	2	3	4	5	6						
14	Following doctor's orders to the letter is the best way to keep my condition from getting any worse.	1	2	3	4	5	6						
15	If my condition worsens, it's a matter of fate.	1	2	3	4	5	6						
16	If I am lucky, my condition will get better.	1	2	3	4	5	6						
17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself.	1	2	3	4	5	6						
18	The type of help I receive from other people determines how soon my condition improves.	1	2	3	4	5	6						

Appendix 18: Secondary outcome measure 1: VAS (measure of pain intensity)

The Visual Analogue Scale (VAS) for pain

Participant Study Identification Number:

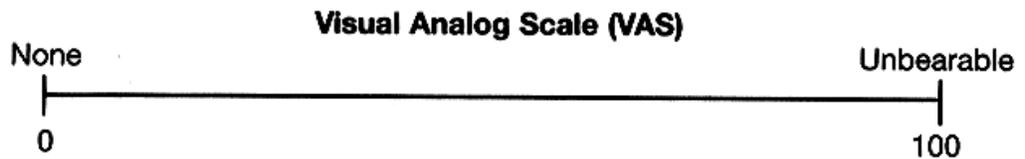
.....

DATE.....

This scale lets us know the level of your pain today. Please place a mark on the line below which best describe your pain TODAY.

B1. Visual analog scale

Mark below on the scale from 0 to 100 your level of pain discomfort with 0 being None and 100 being unbearable.



Appendix 19: Secondary outcome measure 2: RMQ (measure of disability)

The Roland-Morris Low Back Pain and Disability Questionnaire

Participant Study Identification Number:

DATE.....

Below are some of the comments which people have used to describe themselves. Read the list, think of yourself TODAY, mark the box with either 1 (True) or 0 (False), whichever describes you TODAY.

0 = False 1 = True

1. I stay at home most of the time because of my back pain.	
2. I change position frequently to try and get myself comfortable.	
3. I walk more slowly than usual because of my back pain.	
4. Because of my back, I am not doing the jobs I usually do around the house.	
5. Because of my back, I use a handrail to get upstairs.	
6. Because of my back, I lie down to rest more often.	
7. Because of my back, I have to hold on to something to get out of an easy chair.	
8. Because of my back, I try to get other people to do things for me.	
9. I get dressed more slowly than usual because of my back.	
10. Because of my back, I try not to bend or kneel down.	
11. I find it difficult to get out of a chair because of my back.	
12. I am in pain almost all the time.	
13. I only stand up for short periods of time because of my back.	
14. I find it difficult to turn over in bed because of my back.	
15. My appetite is not very good because of my back.	
16. I have trouble putting on my socks/tights because of the pain in my back.	
17. I only walk short distances because of my back pain.	
18. I sleep less well because of my back pain.	
19. Because of my back trouble, I get dressed with help from someone else.	
20. I sit down for most of the day, because of my back.	
21. I avoid heavy jobs around the house because of my back.	
22. Because of my back, I am more irritable than usual.	
23. Because of my back I go upstairs more slowly.	
24. I stay in bed most of the time because of my back.	

Appendix 20: Secondary outcome measure 3: TSK (measure of FAB)

The TSK Questionnaire

Participant Study Identification Number:

DATE.....

This section lets us know how you are dealing with the back pain.

Please circle the number most appropriate for each statement.

	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
1. I am afraid that I might injure myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong.	1	2	3	4
4. My pain would probably be relieved if I were to exercise.	1	2	3	4
5. People are not taking my medical condition seriously enough.	1	2	3	4
6. My accident/back problem has put my body at risk for the rest of my life.	1	2	3	4
7. Pain always means I have injured my body.	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous.	1	2	3	4
9. I am afraid that I might injure myself accidentally.	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	1	2	3	4
11. I would not have this much pain if there wasn't something potentially dangerous going on in my body.	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I do not injure myself.	1	2	3	4
14. It is really not safe for a person with a condition like mine to be physically active.	1	2	3	4
15. I cannot do all the things normal people do, because it is too easy for me to get injured.	1	2	3	4
16. Even though something is causing me a lot of pain, I do not think it is actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain.	1	2	3	4

Appendix 21: Secondary outcome measure 4: SCQ (measure of attitudes toward back pain self-care)

Attitudes Toward Back Pain Self- Care Questionnaire (Von Korff et al, 1998)

Participant Study Identification Number: **DATE**.....

Below is a five-item Self- Care Orientation Scale to assess people attitudes toward self-care for back pain. Please read carefully and indicate on a five-point scale (1-5 points for each item) whether you strongly agree, agree, neutral, disagree or strongly disagree with the following statements:

	Strongly agree 1	Agree 2	Neutral 3	Disagree 4	Strongly disagree 5
1. For your back pain problem, prescription pain relievers are necessary to control the pain when it is really bad.					
2. Your back problem requires ongoing attention and advice from a physician.					
3. You have found that things you do on your own are more helpful than medical treatments.					
4. You feel able to care for your back problem on your own.					
5. You would avoid using prescription medicines for your back pain, even if it were severe.					

Appendix 22: Participants' outcome measures collection booklet



RESEARCH TITLE: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Data Collection Booklet

Participant study number		
Back rehab class- which group & Name of physiotherapist		
		<i>Tick if Completed ✓</i>
Date of Consent taken		
Date of assessment: 4 weeks prior to back rehab		
Date of assessment: Week 1		
Date of assessment: Week 6		
Date of assessment: 3 months		
Date of assessment: 6 months		



RESEARCH TITLE: Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

DATA COLLECTION BOOKLET

Data Collection on
-4 weeks, week 1, week 6, 3 months or 6 months
Please tick as appropriate

Date completed:

Participant Study Identification Number:
DATE.....(Week.....)

1. Form C of the Multidimensional Health Locus of Control Scale (Wallston et al, 1978)

Instructions: Each item below is a belief statement about your medical condition with which you may agree or disagree. Beside each statement is a scale which ranges from strongly disagree (1) to strongly agree (6). For each item we would like you to circle the number that represents the extent to which you agree or disagree with that statement. The more you agree with a statement, the higher will be the number you circle. The more you disagree with a statement, the lower will be the number you circle. Please make sure that you answer **EVERY ITEM** and that you circle **ONLY ONE** number per item. This is a measure of your personal beliefs; obviously, there are no right or wrong answers.

		SD	MD	D	A	MA	SA
1	If my condition worsens, it is my own behavior which determines how soon I will feel better again.	1	2	3	4	5	6
2	As to my condition, what will be will be.	1	2	3	4	5	6
3	If I see my doctor regularly, I am less likely to have problems with my condition.	1	2	3	4	5	6
4	Most things that affect my condition happen to me by chance.	1	2	3	4	5	6
5	Whenever my condition worsens, I should consult a medically trained professional.	1	2	3	4	5	6
6	I am directly responsible for my condition getting better or worse.	1	2	3	4	5	6
7	Other people play a big role in whether my condition improves, stays the same, or gets worse.	1	2	3	4	5	6
8	Whatever goes wrong with my condition is my own fault.	1	2	3	4	5	6
9	Luck plays a big part in determining how my condition improves.	1	2	3	4	5	6
10	In order for my condition to improve, it is up to other people to see that the right things happen.	1	2	3	4	5	6
11	Whatever improvement occurs with my condition is largely a matter of good fortune.	1	2	3	4	5	6
12	The main thing which affects my condition is what I myself do.	1	2	3	4	5	6
13	I deserve the credit when my condition improves and the blame when it gets worse.	1	2	3	4	5	6
14	Following doctor's orders to the letter is the best way to keep my condition from getting any worse.	1	2	3	4	5	6
15	If my condition worsens, it's a matter of fate.	1	2	3	4	5	6
16	If I am lucky, my condition will get better.	1	2	3	4	5	6
17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself.	1	2	3	4	5	6
18	The type of help I receive from other people determines how soon my condition improves.	1	2	3	4	5	6

2. The Visual Analogue Scale (VAS) for pain

Participant Study Identification Number:

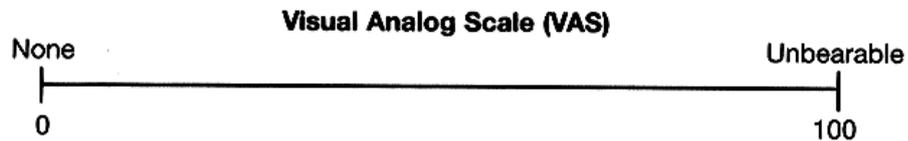
.....

DATE.....(Week.....)

This scale lets us know the level of your pain today. Please place a mark on the line below which best describe your pain TODAY.

B1. Visual analog scale

Mark below on the scale from 0 to 100 your level of pain discomfort with 0 being None and 100 being unbearable.



3. The Roland-Morris Low Back Pain and Disability Questionnaire

Participant Study Identification Number:

DATE.....(Week...)

Below are some of the comments which people have used to describe themselves. Read the list, think of yourself TODAY, mark the box with either 1 (True) or 0 (False), whichever describes you TODAY.

0 = False 1 = True

1. I stay at home most of the time because of my back pain.	
2. I change position frequently to try and get myself comfortable.	
3. I walk more slowly than usual because of my back pain.	
4. Because of my back, I am not doing the jobs I usually do around the house.	
5. Because of my back, I use a handrail to get upstairs.	
6. Because of my back, I lie down to rest more often.	
7. Because of my back, I have to hold on to something to get out of an easy chair.	
8. Because of my back, I try to get other people to do things for me.	
9. I get dressed more slowly than usual because of my back.	
10. Because of my back, I try not to bend or kneel down.	
11. I find it difficult to get out of a chair because of my back.	
12. I am in pain almost all the time.	
13. I only stand up for short periods of time because of my back.	
14. I find it difficult to turn over in bed because of my back.	
15. My appetite is not very good because of my back.	
16. I have trouble putting on my socks/tights because of the pain in my back.	
17. I only walk short distances because of my back pain.	
18. I sleep less well because of my back pain.	
19. Because of my back trouble, I get dressed with help from someone else.	
20. I sit down for most of the day, because of my back.	
21. I avoid heavy jobs around the house because of my back.	
22. Because of my back, I am more irritable than usual.	
23. Because of my back I go upstairs more slowly.	
24. I stay in bed most of the time because of my back.	

4. The TSK Questionnaire

Participant Study Identification Number:

DATE.....(Week....)

This section lets us know how you are dealing with the back pain.

Please circle the number most appropriate for each statement.

	Strongly Disagree	Somewhat Disagree	Somewhat Agree	Strongly Agree
1. I am afraid that I might injure myself if I exercise	1	2	3	4
2. If I were to try to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong.	1	2	3	4
4. My pain would probably be relieved if I were to exercise.	1	2	3	4
5. People are not taking my medical condition seriously enough.	1	2	3	4
6. My accident/back problem has put my body at risk for the rest of my life.	1	2	3	4
7. Pain always means I have injured my body.	1	2	3	4
8. Just because something aggravates my pain does not mean it is dangerous.	1	2	3	4
9. I am afraid that I might injure myself accidentally.	1	2	3	4
10. Simply being careful that I do not make any unnecessary movements is the safest thing I can do to prevent my pain from worsening.	1	2	3	4
11. I would not have this much pain if there wasn't something potentially dangerous going on in my body.	1	2	3	4
12. Although my condition is painful, I would be better off if I were physically active	1	2	3	4
13. Pain lets me know when to stop exercising so that I do not injure myself.	1	2	3	4
14. It is really not safe for a person with a condition like mine to be physically active.	1	2	3	4
15. I cannot do all the things normal people do, because it is too easy for me to get injured.	1	2	3	4
16. Even though something is causing me a lot of pain, I do not think it is actually dangerous	1	2	3	4
17. No one should have to exercise when he/she is in pain.	1	2	3	4

5. Attitudes Toward Back Pain Self- Care Questionnaire (Von Korff et al, 1998)

Participant Study Identification Number:
 DATE.....(Week.....)

Below is a five-item Self- Care Orientation Scale to assess people attitudes toward self-care for back pain. Please read carefully and indicate on a five-point scale (1-5 points for each item) whether you strongly agree, agree, neutral, disagree or strongly disagree with the following statements:

	Strongly agree 1	Agree 2	Neutral 3	Disagree 4	Strongly disagree 5
1. For your back pain problem, prescription pain relievers are necessary to control the pain when it is really bad.					
2. Your back problem requires ongoing attention and advice from a physician.					
3. You have found that things you do on your own are more helpful than medical treatments.					
4. You feel able to care for your back problem on your own.					
5. You would avoid using prescription medicines for your back pain, even if it were severe.					

Appendix 23: Cost questionnaire



Study Title:

Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control

Patient Cost Of Back Care Questionnaire

Participant study number :.....

We are interested in what it has cost you to attend the back rehabilitation programme. We are interested in travel costs, prescription charges, loss of pay and possibly other therapy charges up to six months after the completion of the back rehabilitation programme.

The information you provide will be treated in complete confidence and will not affect the service you receive. Thank you for your help.

We would like you to think about the 6-month period after your back rehabilitation classes. Please tick the appropriate box:

1. Have you visited your GP in the 6 months since attending your back rehabilitation classes?

Yes No

2. If YES, how many times?

3. How much did you spend on travel and prescription charges in total?

£ _____

4. Have you had any other type of treatment (other than GP visits) for your low back pain in the 6 months since completing your back rehabilitation classes?

Yes No

5. If YES what type of treatment was it?

6. How many sessions did you attend?

7. How much did you spend on travel and therapy charges in total?

£_____

We would like you to think about the journey you made to attend your back rehabilitation programme:

8. How did you travel to and from the hospital? (You may tick more than one box, if appropriate)

	Car	Bus or train	Taxi	Walk	Ambulance	Other
Journey to Hospital	<input type="checkbox"/>					
Journey From Hospital	<input type="checkbox"/>					

9. If you ticked 'Other' Please specify:

.....

10. If you ticked 'bus or train', or 'taxi', please indicate the approximate return fare:

£.....

11. Were you eligible for reimbursement for the costs you incurred in attending the classes?

Yes No

12. How long was the journey from home to hospital? Please give the approximate time.
from door to door:

..... hoursminutes

13. Approximately, how far did you travel from home to the hospital?

..... miles

14. If you came by car, how much have you had to pay for parking?

£.....

15. Did someone accompany you to the hospital?

Yes No

16. If you were accompanied, did your companion also have an appointment at the hospital?

Yes No

17. What would you (and your companion, if relevant) normally have been doing had you not had to visit the hospital? *(Please tick the appropriate boxes).*

	Self	Companion
Paid Occupation		
Looking after children, other relatives, friends		
Other (please describe)		

18. If you have ticked 'Paid Occupation' above, please indicate what arrangements you made to be absent from work. *(Please tick the appropriate boxes).*

	Self	Companion
Annual Leave		
Hours rearranged		
Time off <u>without</u> loss of pay		
Time off <u>with</u> loss of pay		
Other (please describe)		

19. If you have ticked 'Time off with Loss of Pay', please indicate the approximate sum you have lost.

£.....

20. Were there any other costs involved in visiting the hospital that have not been covered above? If so, please give details.

.....

21. What was the total cost incurred by these other expenses?

£.....

22. Please give the total time, in minutes, spent at the physiotherapy department when attending the back rehabilitation classes (excluding travelling time).

.....minutes

THANK YOU FOR COMPLETING THE QUESTIONNAIRE

Appendix 24: NRES amendment approval letter for economic evaluation and cost questionnaire



Research & Development Office
F08, Pinewood House
Stepping Hill Hospital
Poplar Grove
Stockport
SK2 7JE

Sharon Chan
Specialist Physiotherapist
Stockport NHS Foundation Trust
1st Floor, Kingsgate House
Wellington Road North
Stockport
SK4 1LW

Tel: 0161 419 5801 / 5814

E-mail: research.development@stockport.nhs.uk

27 March 2013

Dear Sharon,

Notification of Acceptance of Amendment and Continued NHS Permission
Research Office Reference Number: 2012020

Project Title: CBCLBP Programme - Does a cognitive-behavioural chronic low back pain programme alter patients' health locus of control?

Amendment No.: 1

Thank you for submitting documentation related to the above amendment.

I have reviewed the documentation and I am pleased to confirm that this amendment does not affect the Research Office permission previously given. The amendment may therefore be implemented at this site under the existing NHS Permission. Please note that you may only implement changes that were described in the amendment notice or letter (as listed below).

You are reminded of your responsibilities under the Research Governance Framework (2005), a copy of which is available at

http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/AtoZ/Researchgovernance/DH_4002112

Yours sincerely,

Jan Smith
Research & Development Manager

Documents Reviewed	Version No. / Reference	Date
Notice of amendment		15.03.13
Ethics approval letter	Amendment number: 1	26.03.13
Protocol	2	06.03.13
Patient cost of back care questionnaire	1	06.03.13

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