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What effects does a physiotherapy-led group intervention using Interactive Behavioural Modification Therapy (IBMT) have for people with chronic musculoskeletal pain?

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A thesis submitted in fulfilment of the requirements of the Manchester Metropolitan University for the degree of Masters of Science by Research

Department of Health Professions  
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2015

## Declaration

I declare that that this dissertation, submitted in accordance with the requirements of the Manchester Metropolitan University for the degree of Masters of Science by research is all my own work, has not been submitted before to any other institution and that any previous work used in this dissertation, whether published or unpublished, has been acknowledged and referenced.

If awarded the degree, I give permission for my dissertation to be available for reading in the library, for outside loan and for photocopying.

Signed

Date

## Abstract

### **Background**

Chronic pain can be disabling. It is a major cause of morbidity and increased usage of healthcare services. The effects of a physiotherapy led-programme using Interactive Behavioural modification therapy (IBMT) with a 3-month follow-up for patients with musculoskeletal pain is unknown.

### **Aims**

To examine pre to post and medium term (3 months) effects of a physiotherapy-led programme, the Functional Rehabilitation programme (FRP), for patients with chronic musculoskeletal pain, in terms of fear of movement, disability, self-efficacy, depression and physical function.

### **Design**

The study included two phases. Phase one was a preliminary retrospective study using data from 278 patients. Phase two used a prospective pre-experimental medium-term follow-up study design with 53 participants. The FRP programme was delivered over a 5-week period, each group had between 8 and 10 participants. Both phases were undertaken at Fairfield General Hospital outpatient physiotherapy department, Pennine Acute NHS Hospitals Trust.

### **Outcome measures**

Primary outcome was Tampa scale of Kinesiophobia (TSK), secondary measures included; Roland Morris Disability Questionnaire (RMDQ), Pain disability questionnaire (PDQ), pain self-efficacy questionnaire (PSEQ) and the Hospital anxiety and depression scale (HADS). In addition physical function tests included speed and distance of walking and step up repetition.

### **Results**

Improvements were observed in all outcome measures. Minimal clinical important difference (MCID) was reached in those measures with recognised levels (TSK and RMDQ) and were sustained at 3-month follow-up. In addition, depression scores reduced to

within normal level (0-7). There was no statistically significant difference in outcomes between condition types.

### **Conclusions**

A physiotherapy-led group intervention using a psychologically informed approach produced positive changes in reducing fear relating to movement, pain-related disability, depression and anxiety in a mixed chronic pain aetiology group. There was no statistically significant difference in outcomes between low back pain and multi-site pain. Future studies should look at a longer term follow-up with an RCT design of the impact of physiotherapist's management.

In relation to the growing problem of managing increasing numbers of people with chronic pain, this study adds to the growing body of evidence of how physiotherapist's could take a lead role in chronic pain management. This would help to address the current shortage of skilled professionals to deliver pain management and expand the professions repertoire. Further, it adds weight on previous research carried out by physiotherapists which has focussed on chronic low back pain to this study's mixed chronic pain cohort.

### **Keywords**

Chronic musculoskeletal pain; fear; disability; self-efficacy; Psychology; Physiotherapy; group-treatment.

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## Output and Dissemination

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## Abbreviations

AfC	Agenda for Change
AMED	Allied and Complementary Medicine Database
ANOVA	Analysis of Variance
ARMA	Arthritis Musculoskeletal Alliance
BPA	Best Practice Advice
BPS	British Pain Society
CASP	Critical Appraisal Skills Programme
CBI	Cognitive Behavioural Intervention
CBT	Cognitive Behavioural Therapy
CINAHL	Cumulative Index to Nursing & Allied Health Literature
CSAG	Clinical Standards Advisory Group
CSQ-24	Coping Strategies Questionnaire 24
CWP	Chronic Widespread Pain
ESCAPE	Enabling Self-management through Exercise
FRP	Functional Rehabilitation Programme
GNP	Gross National Product
HADS	Hospital Anxiety and Depression Scale
IASP	International Association for the Study of Pain
IBMT	Interactive Behavioural Modification Therapy
LBP	Low Back Pain
LVCF	Last Value Carried Forward
MCID	Minimal Clinical Important Difference
MSK	Musculoskeletal
NHS	National Health Service
NICE	National Institute for Clinical Excellence
OAK	Osteoarthritis of the Knee self-management programme
PDQ	Pain Disability Questionnaire
PEDro	Physiotherapy Evidence Database
PMP	Pain Management Programme
PSEQ	Pain Self-Efficacy Questionnaire
QALY	Quality-Adjusted Life Years
RCT	Randomised Controlled Trial
RMDQ	Roland Morris Disability Questionnaire
SBST	Keele STaRT Back Screening Tool
SSE	Spinal Stabilisation Exercises
TENS	Transcutaneous Electrical Nerve Stimulation
TSK	Tampa Scale of Kinesiophobia
UK BEAM	Back Exercise and Manipulation trial
VAS	Visual Analogue Scale
WOMAC	Western Ontario and McMaster Universities Index

# 1 Introduction

Sir Liam Donaldson, the Chief Medical Officer, in 2009, reported that the growing prevalence of chronic pain was a 'ticking time bomb' for the National Health Service (Donaldson, 2009). This has been further endorsed by the International Association for the Study of Pain (IASP) in 2015, reporting that the intractable nature of chronic pain is a community problem in terms of health and economic implications for the individuals and their families and society. Chronic pain is recognised as amongst the 10 worst conditions for years lived with disability, according to the 2010 Global Burden of Diseases study (Murray et al. 2013). Chronic pain is a complex phenomenon. People are affected by both the symptoms of pain and the impact that pain has on their lives. In 2005, only 14% of people suffering with chronic pain reported seeing a pain specialist. Access to integrated pain services was found to be a problem recognised in the chief medical officer's report (Donaldson, 2009). However, (Nicholas, 2015) suggests that the problem lies not solely with access to pain services but the treatments on offer. He discusses the key to effective chronic pain management is firstly acceptance and an understanding from the sufferer that they have a major role to play in their own self-management. Secondly, he suggests that health providers need to recognise that some people seeking help with chronic pain require good quality pain management from non-pain specialist services. This, he argues would address the concern about growing demand and access to pain services. Sowden (2006) suggests that physiotherapists are in an enviable position to help address this workforce shortage and take a lead role in the management of people with chronic pain. Currently, physiotherapists are the lead clinicians for management of chronic low back pain. Nicholas (2015) outlines, the effect of physiotherapy-led interventions in delivering pain management for people with chronic musculoskeletal pain needs to be explored before the profession can develop its role and lead policy change in this area.

## 1.1 Pain definition

Blyth et al. (2010, cited in Croft et al. 2010) state that pain is frequent and accompanies the human experience. It is a universally shared experience. Despite this, defining what pain is has been challenging. The most widely used definition of

pain is defined by the International Association for the Study of Pain (IASP) in 1994 (online: no page number) as;

“An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage”

Despite pain being a universally shared experience, the reality is that it is a private event and expressed to others as a series of behaviours e.g. taking pain relief medication, seeking help, grimacing and changing movement patterns (Linton and Shaw, 2011). The IASP broad definition relates to acute pain, cancer pain and chronic non-cancer pain. It recognises that pain is an experience and highlights the sensory and emotional aspects of pain in addition to acknowledging that pain can be present with either actual or potential tissue damage. Despite this definition, pain is usually described in terms of acute or chronic. Acute or nociceptive pain is generally accepted as being recent onset, limited duration (under 12 weeks), with a causal relationship with injury or disease and with limited, if any, psychological factors (Duarte, 1997).

One of the fundamental aims of medicine and health care is to help relieve pain and the suffering which accompanies pain. Despite this aim, the challenge of managing pain that persists beyond acute pain and becomes chronic, is elusive.

## 1.2 Chronic pain and its epidemiology

The British Pain Society (BPS) 2013, defines chronic pain as:

“Chronic pain is continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery” (online: no page number)

This limited definition focuses solely on the time aspect of pain and fails short to describe the magnitude of the problems associated with chronic pain.

In Western industrialised countries, musculoskeletal (MSK) chronic pain is a major and growing public health concern with over 20% of the adult population reporting chronic pain as a problem (Nicholas, 2015). The majority of patients with chronic pain also have increased disability and mental health disturbances compared to patients without chronic pain. Croft et al. (2010) reported that the consequences of untreated

chronic pain are not only to the individual but also for healthcare providers and the wider economy e.g. loss of earning due to sick leave.

It is difficult to establish an accurate figure of patients living with chronic pain in the United Kingdom (UK). In the UK, recent estimates indicate the prevalence of chronic pain affects between 7.8 and 10 million people, depending on the source. The National Pain Audit (2012) reported that 7.8 million people in the UK are suffering with chronic pain, whereas the British Pain Society report (2014) estimate approximately 10 million; (over 10% of the UK population). The incidence of low back pain alone is thought to affect over 17 million people in the UK, with a further 3.5 million each year reporting their first episode of which 3.1 million still report persistent symptoms at 1 year, (The Arthritis Musculoskeletal Alliance (ARMA) guidelines (2004). Despite wide variation in the incidence of pain in several studies, chronic pain represents a major public health problem that requires a change to current pain management delivery (Nicholas, 2015). The declaration of Montreal in 2010 was adopted at the end of the world congress for pain and stated that access to pain management was a fundamental human right as a response to the increasing prevalence of chronic pain. In 2012, The Department of Health in the UK acknowledged this growing problem and recognised chronic pain as a long-term condition. The English Pain Summit report (2012) set one of their primary objectives to make chronic pain a “high street” disease; recognisable and with timely access to treatment, care and education. More recently in a clinical update for the management of pain for IASP (Nicholas, 2015) has called for urgent action to broaden the scope of who can deliver pain management services to cope with the demand. This calls for a review of current guidelines and service provision.

#### 1.2.1 Economic cost

Chronic pain has far reaching consequences for the individual but also to society in terms of the cost of health care and wider economy effects (The English Pain Summit, 2012).

Foster et al. (2010), report that 1.6 million adults in the UK report low back pain per year and out of those people who consult their GP with low back pain typically 60-80% continue to experience pain and disability at 12 months post-consultation.

Critchley et al. (2007) reported the annual expenditure to the National Health Service (NHS) on low back pain alone was estimated at £1.1 billion. The ARMA guidelines for low back pain (2004) break the cost down into £141 million in GP consultations, a further £512 million in hospital care and private health care costs of £565 million, which brings the total to nearer £1.6 billion a year. The Royal College of General Practitioners in 2014 endorsed this figure, suggesting that patients with chronic pain consult their family doctors 5 times more frequently than those without chronic pain. In addition to the direct healthcare costs in the UK, musculoskeletal pain is the commonest cause for incapacity with around 25% of people who are not working citing pain as the main reason. Low Back Pain (LBP) is cited in nearly half of those absent from work with MSK pain (Johnstone et al. 2002). Between 1994 and 1995, 116 million workdays were lost due to low back pain with an estimated cost of £10,668 million in production and informal care costs (Hansen et al. 2010). The total costs to the UK economy are estimated to be 1-2% of the Gross National Product (GNP) (ARMA guidelines 2004).

### 1.3 Aetiology

Chronic pain is recognised as multi-faceted in terms of the effects it has on both the sufferer, family and society. There have been advances in identifying risk factors and understanding the pathological processes involved in the development of chronic pain. Psychological, social and behavioural risk factors have been found to be stronger predictors of chronic pain than physical risk factors i.e. structural changes or pathology (Swinkels-Meewisse et al. 2003). However, despite awareness of these risk markers, the causal relationship of these factors to the incidence of pain has not been well established. In this thesis, an overview of the risk factors for chronic pain are discussed.

#### 1.3.1 Socio-demographic factors associated with pain

##### 1.3.1.1 Gender

Being female is a well-established risk factor for developing chronic pain (Blyth et al. 2010, cited in Croft et al. 2010). Lombana and Vidal (2012) suggest that hormonal changes that occur during the monthly cycle in females may account for some of the variability in pain tolerance. They suggest higher oestrogen levels in the first part of the cycle have a protective pain mechanism and during this part of the cycle there is



little difference between reporting of pain from noxious stimuli between men and women. When oestrogen levels fall (getting lower) there is a marked difference with women reporting more pain at lower thresholds, in addition to a higher level of pain intensity from noxious stimuli (Riley et al. 1998). However (Gran, 2003), in a systematic review of the epidemiology of pain, summarising the results of several studies showed that there was no link between hormonal changes and pain perception.

Furthermore, (Fillingim et al. 2009) report the findings of a study looking at the prevalence of chronic musculoskeletal pain and found that across 17 countries there was a higher prevalence amongst females; 45% compared to 31% for males. This is further supported in (Blyth et al. 2010, cited in Croft et al. 2010) who report that females are more likely to report multiple areas of pain, lower pain threshold and a greater severity of pain intensity. In addition, Fibromyalgia, a widespread chronic pain state characterised by multiple trigger areas of pain, is more likely to be diagnosed in females than in males. Lombana and Vidal (2012) suggest that the social role expectation between the sexes accounts for some of the difference; females are more often linked to “the more sensitive side of mankind” and additionally they are also more likely to seek medical advice for pain symptoms. Gran (2003) suggested that the difference in pain perception between the sexes was a combination of biological, psychological and social factors. However, the exact mechanism(s) and the pathway that affects individuals is not fully known. Benign Joint hypermobility (BJH) is a musculoskeletal disorder known to have a higher incidence in females (Larsen et al. 1987). It is reported to affect more than 30% of the adult population and in addition to a female dominance is also more prevalent in Asian and African populations (Graham, 2001). People with BJHS may present with early osteoarthritis, subluxation or dislocation of peripheral joints, tendinopathy or bursitis (Smith et al. 2014). The association of chronic pain and psychological distress with BJH has also been well documented (Graham, 2001; Smith et al. 2014).

#### *1.3.1.2 Socioeconomic*

McBeth and Jones (2007) suggest that socioeconomic factors including low educational attainment, low income and unemployment are all associated with an

increased prevalence of chronic pain. The mechanism of the association between these factors is not clear. However (Croft et al. 2010) suggest that there may be a link between pain and socioeconomic factors based on the influence of lifestyle choices including smoking, participating in physical activity and dietary choices. Lionel (2014) suggests that individuals with a higher educational level find more time to engage in physical activity and perceive they have more control over their health choices and in general this reflects in a healthier lifestyle. Coleman et al. (2012) report the outcomes of an osteoarthritis self-management programme as being potentially influenced by the participant's socioeconomic status. They describe a large number of participants were from higher socioeconomic areas and in part they suggested this was due to the self-enrolment recruitment process utilised in the study. They reported that using this recruitment process potentially attracted participants who were more predisposed to use self-management strategies anyway. The authors report previous problems trying to recruit patients from lower socioeconomic groups and acknowledge this needs to be addressed in future studies.

- 1.3.2 Clinical and psychological factors associated with pain – age and co-morbidities
- Several studies have reported that the prevalence of chronic pain is consistently associated with older age (McBeth and Jones 2007; Croft et al. 2010; Van Hecke et al. 2013). For 16-34 the incidence of those reporting chronic pain is reported as 15% in men and 18% in women. This increases to 53% in men and 59% in women of those aged 75 and above (Craig and Mindell, 2011). The prevalence of osteoarthritis, is also known to increase with age. Physiological processes that occur in osteoarthritis involve both structural changes and potential nociception stimulation of the bone, capsule, ligaments and surrounding muscle system. Bennell et al. (2012) state that despite these known physiological changes the correlation between structural changes and pain severity is not well correlated. Harding et al. (1994) suggest that because of the weak correlation between structural changes and pain severity, a uni-dimensional medical model of diagnosis and treatment does not fit. In addition, Arthritis Research UK (2013) in their public health document, suggest that four out of five people with osteoarthritis have at least one other long-term condition which impacts on their general health and well-being. Pain is also a symptom that can be associated with other long-term medical conditions such as diabetes, coronary heart

disease and osteoporosis. The number of people living with one or more long-term conditions is increasing. Currently, 58% of those aged 60 and over live with one long-term condition, in addition the likelihood of living with multiple long-term conditions increases with age (Coleman et al. 2012). Van Hecke et al. (2013) reported people were more than twice as likely to die from ischaemic heart disease or respiratory disease if they reported suffering with chronic pain. They suggested this link might be related to lower physical activity levels in people with chronic pain.

#### 1.4 Psychological risk factors for chronic pain

Psychological problems are potential risk factors for the progression of pain from mild to disabling chronic pain. The factors thought to play a significant role in development of chronic pain are poor coping strategies, beliefs, distress and depressive mood. These factors, if present and not adequately treated are also thought to have deleterious impact on outcome following intervention (Foster et al. 2010).

##### 1.4.1 Depression and catastrophizing

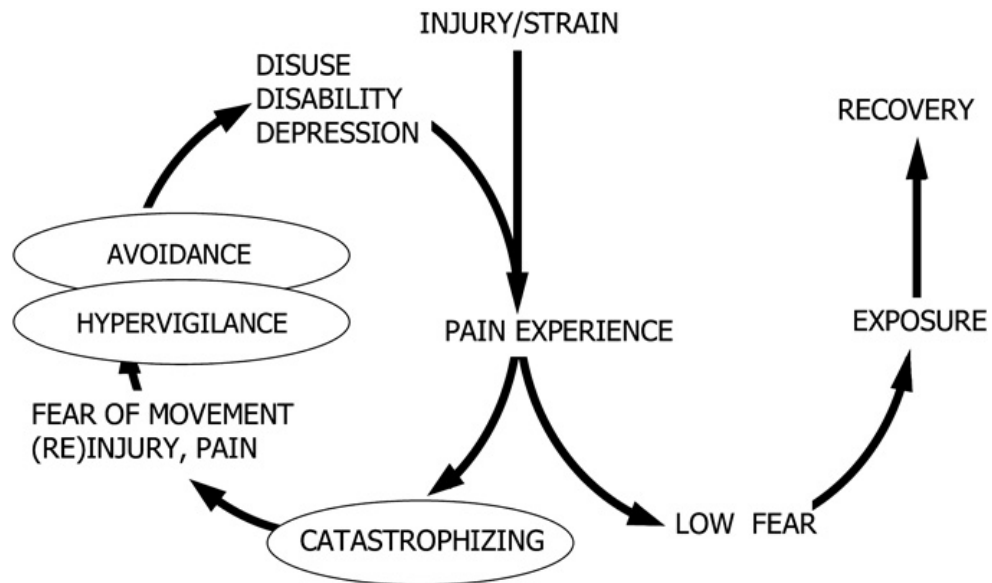
Linton et al. (2011) report that a large number of patients who suffer with musculoskeletal pain are also depressed. Arthritis Research UK (2013) suggest that two thirds of patients with osteoarthritis report having symptoms of depression and those living with persistent pain are four times more likely to exhibit elevated level of depression. Van Hecke et al. (2013) suggest that whilst the association of depression and pain is well established, the definitive cause is unclear and is likely to be bi-directional, i.e. both central and behavioural. Additionally, the presence of depression is widely reported as a significant risk factor for poor outcome following intervention (Woby et al. 2008; Linton and Shaw, 2011). This is surprising considering that the theory of increasing physical activity and self-efficacy, the cornerstone of pain management would be associated with reduced depression (Linton et al. 2011). Sowden et al. (2006) suggests that psychological distress such as depression can interfere with an individual's ability to engage with intervention and therefore this may be a reason for poorer outcome. They suggest that pain management programmes which include CBT, a well-established treatment for depression, may have better outcomes compared to physiotherapy-led approaches as found in (Hay et

al. 2005; Woby et al. 2008; Hill et al. 2011). Catastrophic thinking styles, which can be associated with depression in patients with chronic pain can also impact on treatment adherence if not addressed (Linton and Shaw, 2011). Pain catastrophizing is described as a magnification of the threat of a noxious stimulus, seeing the worst possible scenario from activities and an inability to regulate pain-related negative thoughts (Quartana et al. 2009).

#### 1.4.2 Fear avoidance and Pain Beliefs

This has been one of the most influential models in the explanation of psychological factors in the development and maintenance of chronic pain (Roelofs et al. 2004). The model suggests that if patients interpret chronic pain as a threatening stimulus (pain catastrophizing) then this may lead to fear which can result in two responses; confrontation or avoidance. Confrontation is closely linked to self-efficacy and is considered to be an active adaptive strategy that long-term results in reduced fear and increased daily functioning (de Moraes Vieira et al. 2013). The alternative response is the adoption of avoidance behaviour. Avoidance behaviours may be to limit movement or activities in anticipation of increasing pain combined with the meaning for the increased pain; fear of making their symptoms worse, or fear of causing further damage. Ultimately, the use of avoidance behaviour as the primary pain coping strategy results in deconditioning, lower pain tolerance, reduced functioning, increased fear and depression (Linton and Shaw, 2011). Fear avoidance behaviours are also closely related to certain beliefs about activity restriction, i.e. “pain is a sign to stop what you are doing” or “hurt equals harm” which are associated with the development of long-term pain and disability (Linton and Shaw, 2011).

Figure 1 - The fear avoidance cycle of chronic pain taken from (Vlaeyen and Linton. 2012)



#### 1.4.3 Self-efficacy

The concept of self-efficacy is important in the management of any individual who has a long-term condition including persistent pain (Sowden et al. 2006). It has been reported across several studies that patients who exhibit fear avoidance beliefs also report higher pain intensity and greater levels of disability (Woby et al. 2005; Nicholas et al. 2007; Hill et al. 2011). The concept was originally described by Bandura in 1977, as confidence in one's own ability to carry out an activity and how much effort and how long they will persist in the face of obstacles and aversive experiences (Nicholas et al. 2007). Jackson et al. (2014) in relation to pain, suggests that self-efficacy affects the adoption of active behaviours to control and manage pain symptoms. Foster et al. (2010) found self-efficacy to be one of the strongest predictors of outcome in a cohort of patients with low back pain from primary care. They reported that low self-efficacy was associated with passive coping strategies, e.g. inactivity. An improvement in an individual's self-efficacy is a realistic benchmark to be aiming for with any chronic long term condition (Perry et al. 2013). The idea of living well despite having obstacles might be how people with chronic long term conditions who don't seek health care intervention function and live well. The development of the pain self-efficacy questionnaire by (Nicholas et al. 2007) suggests that the measure can be used as both a screening tool and an outcome measure. The study also suggests that post treatment scores on the pain self-efficacy scale may be

predictive of a person's ability to make long lasting behavioural changes and self-manage, or whether they are at risk of relapsing. If this suggestion is replicated in further research studies then this would potentially be a useful prognostic indicator in clinical practice. Furthermore, it could also be important for service design, to identify those patients who may benefit from follow-up or further support following an intervention to reduce the impact of re-lapse and prevent re-referral back into the health-care system.

#### 1.5 UK Chronic Pain management guidance

The British Pain Society published their revised guidelines on Pain Management Programmes (PMP) for adults with non-cancer chronic pain in 2013. For a pain management programme to be recognised by the BPS it has to be delivered by an inter-disciplinary team, be based on Cognitive Behavioural Principles (CBT) and be time-intensive with a minimum of 36 hours or 12 half-days extending to intensive residential programmes for complex cases in tertiary centres. This type of programme requires a team of different health care professionals (clinician intense), and is also time and cost intense. The majority are found in secondary and tertiary care settings. Although this management option is considered to be a 'gold standard', the cost implication and the accessibility of such an approach requires consideration. The BPS has recently worked with the Royal College of General Practitioners to devise pain-centred care pathways from primary through to tertiary care with an emphasis on biopsychosocial interventions at each stage. The role of the physiotherapist within the BPS PMP is clearly defined as being limited to the exercise and movement aspect of the programme and it is clear that consideration of a PMP being delivered by one profession is considered neither desirable nor efficacious.

##### 1.5.1 CBT

The role of psychological risks factors and their effect on chronicity of pain is well established in the research (Foster et al. 2010; Morley et al. 2013). The use of psychological interventions as a treatment strategy for chronic pain is recognised as being central in a holistic approach and integral to the revised 2013 British Pain Society guidelines for the management of chronic pain.

CBT is one of the most recognised psychological treatment interventions for chronic pain. The development of CBT was a synthesis of work of Wilbert Fordyce, a psychologist, and Aaron Temkin Beck, a psychiatrist (Ehde et al. 2014). Fordyce's work in the 1970s looked at the role of learning theory and behavioural principles and how these related to pain behaviours in those suffering with chronic pain. He identified that pain behaviours could be modified by social and environmental factors (Ehde et al. 2014). In 1979, Beck developed cognitive behavioural therapy for depression after identifying patients in his care had characteristic thought processes which affected their function and behaviour (Brunner, 2013). The role of cognitions and how this affected mood, anxiety and behaviour stimulated interest in combining the two therapies for the treatment of chronic pain. CBT has over the last three decades evolved to become a mainstream treatment option for chronic pain. It is recognised as central to the BPS 2013 pain management programmes.

CBT is not a standard treatment technique rather it is a skill-based approach that the individual works through with the therapist in order to develop strategies to manage their own problems. Common CBT strategies include the use of relaxation, mindfulness and relaxed breathing along with techniques which include challenging automatic negative thoughts and developing adaptive responses to threatening situations (Nash et al. 2013). CBT also uses exercise as an integral behavioural skill. The main goals of CBT in chronic pain management are to improve function, self-efficacy and pain relief whilst alleviating psychological distress (Ehde et al. 2014).

Despite the endorsement by the BPS and recognition in the UK Map of Medicine pathways for chronic pain (Morley, 2010) argues that the nature of CBT makes conducting 'gold standard' randomised control trials to establish its effect is challenging. Furthermore, he suggests that even defining what CBT is can be problematic. Despite these unresolved issues (Ehde et al. 2014) argue that CBT lacks the associated risks of other interventions used for treatment of chronic pain, including medication, surgery, and injection therapies In support of this (Harding et al. 1994) suggests that traditional medicine offers people living with chronic pain very little in the way of useful or permanent solutions for their condition. In contrast, CBT

guides the individual to enable them to develop positive coping strategies and use self-management principles.

#### 1.5.2 UK low back pain guidelines

There are national guidelines that influence practice relating to management of people with low back pain; these are Clinical Standards Advisory Group (CSAG) on low back pain: CSAG (1994); Arthritis Musculoskeletal Alliance (ARMA) 2004; The National Institute for Clinical Excellence (NICE) 2009; The Keele STaRT back tool (Hill et al.2011) and the (Map of Medicine low back pain pathways, 2012).

CSAG (1994) relates to the diagnostic triage into three distinct groups for people presenting with low back pain; simple low back pain 80-85%; nerve root pain 5-10%; and potential serious spinal pathology 1-2%. In 2004, ARMA published their standards of care for people with low back pain, which suggested referral for multi-disciplinary group CBT if pain persisted beyond 12 weeks. This recommendation was reinforced by NICE who published recommendations for the management of non-specific low back pain in May 2009. This guideline relates to the treatment that people who have persistent non-specific low back pain can expect from the NHS in England and Wales to help them manage their pain. It is currently under review and the revised guidelines are expected to be published in 2016. This has been further reinforced by the recently published Map of Medicine pathways for low back pain (2014). In addition to the recommendation for early referral on to pain management services, the pathways use the Keele STaRT Back Screening Tool (SBST). The SBST is a 9-item prognostic screening tool designed to be used in general practice with patients presenting with low back pain. The SBST was designed to aid clinicians identify risks factors both biomedical and psychosocial. The SBST score stratifies patients into three groups; low, medium and high risk of developing chronicity. The score is used to direct clinicians to a matched treatment package; specific physiotherapy management for each SBST group. The SBST represents the most significant change to management of low back pain in the last 10 years and also outlines the role of psychologically informed physiotherapy management for people at high risk due to psycho-social factors.



## 1.6 Psychologically-informed practice and Physiotherapy management of chronic pain

Linton and Shaw (2011) report that whilst 63% of physiotherapists were aware of the impact of psychological factors in chronic pain, only 43% had knowledge about how to utilise these in their management. They argue that whilst physiotherapists are well placed to manage chronic pain, to be the therapist of choice will require a philosophical shift in clinical practice. The majority of Physiotherapists use a biomedical perspective where treatment focuses on the musculoskeletal origin of the 'pain,' and a look at the other contextual factors that impact on the pain. The identification of psychological factors with the use of "yellow flag" questions during clinical assessments is crucial to enable an effective management plan. The concept of the flag system is widely used in practice and was based on the work of (Linton et al. 1999). There are two categories of flags, clinical and psycho-social. Clinical flags are red and more recently orange has been added. Red flags are potential signs of serious pathology that require urgent attention and pathways exist within health care establishments to deal with these presentations. More recently orange flags have been introduced to distinguish psychiatric or serious mental health conditions from milder problems commonly associated with musculoskeletal chronic pain, as discussed earlier. Psycho-social flags are referred to as yellow; while blue and black relate to occupational factors. Yellow flags, along with red, are the most commonly utilised by physiotherapists and aid identification of psycho-social risk factors. They include questions on beliefs, behaviours, family support, work, fear and coping strategies. The identification of yellow flags should form the basis of management, i.e. if beliefs about pain are an obstacle then reconceptualising pain to reassure and explain and techniques such as graded exposure to get patients re-engaged with activity should be utilised (See Appendix 5 - Flag indicators on page 132).

There is a growing evidence base for physiotherapists delivering this type of CBT approach or working in a more psychologically-informed way in the management of chronic pain. The focus has been on the management of low back pain, with clinically significant effects (Critchley et al. 2007; Hill et al. 2011; Lamb et al. 2012). This is explored in chapter 3. Although chronic low back pain remains the largest single musculoskeletal condition for seeking healthcare intervention, pain-related disability

and sick absence from work, it does not cover all conditions where chronic pain is a symptom. There is now a need for health professions like physiotherapy to expand the research base into other areas of chronic pain management, e.g. fibromyalgia and chronic widespread pain. Despite recognition that costly secondary and tertiary centre pain management care is appropriate for those people who have complex presentations, serious consideration should be given to the effectiveness in terms of cost, clinical outcome and patient satisfaction of interventions based on a CBT approach delivered by non-psychology professions in a variety of settings (Nicholas, 2015).

### 1.7 Summary

Chronic pain is recognised as a growing worldwide problem that has multiple known risks factors and associations with other chronic diseases. Nicholas (2015) calls for a fundamental change in the model of health care provision for chronic pain. In 2013, in the UK, NHS England in the report “Everyone Counts Planning for Patients 2014/15-2018/19”, emphasise that the demand on healthcare is changing and this will pose significant challenges to how services are funded and delivered. The report also outlines how meeting these challenges will mean that services will have to be innovative to meet these growing demands.

There is a gap in the literature and in current UK guidelines of clinical and cost effectiveness of quality services that do not use intensive multidisciplinary approaches. There is promising evidence that physiotherapists using CBT or working in a psychologically informed way can effectively manage patients who have chronic low back pain with psychosocial factors. However the evidence of physiotherapy-led management of other chronic pain conditions is lacking. Arguably the techniques used in CBT are also commonly utilised by physiotherapists in their clinical practice, for example exercise therapy, pacing, goal setting, problem solving and therefore there is scope that with additional under or postgraduate training physiotherapist can be innovative and transform their services to meet the growing need of healthcare provision. Harding et al. (1994) supports this view but with the caution that despite the techniques appearing to be the same the method of delivery is quite different and would require a significant shift in training to achieve effectiveness. In

chapter 2 the current available evidence of physiotherapists using CBT or psychologically informed practice is explored.

This study was undertaken to investigate the short- and medium-term effects of a physiotherapy-led group intervention for the management of patients who presented to an outpatient physiotherapy department with chronic musculoskeletal pain interfering with different aspects of their life. This study was conducted in two phases; the preliminary phase was a retrospective study investigating current physiotherapy-led service provision of patients with chronic pain and will be discussed on page 51. The main prospective phase of the study will be discussed on page 51.

## 2 Literature Review

A comprehensive review was undertaken to evaluate the current literature on physiotherapy-led group management of adults with chronic musculoskeletal pain, delivered using principles that are recognised as part of a cognitive behavioural approach, i.e., pacing, goal setting, graded activity, etc.

### 2.1 Search Strategy

AMED, MEDLINE, CINAHL, ScienceDirect, and SCOPUS were included in the search strategy and all were searched from 1985 to present. Hand searching was performed on the reference articles found to be relevant. The Cochrane controlled Registers were also searched for relevant trials and reviews.

### 2.2 Search terms

The following keywords were used to search each of the databases. Each term (keyword) was searched separately, then individual searches were combined. See Appendix 1 – Results for the database search carried out on 23/03/2015 on page 118.

Physiotherap\* OR Physical therap\* “CBT” OR “CBT approach” OR “cog behav ther” OR behav\* ther\*; “chronic pain” OR “persistent pain” OR “low back pain”; “group therapy” OR group OR programme\* OR class OR “group treatment”

### 2.3 Inclusion and exclusion criteria

All search lists from each database were screened and Table 2.1 shows the inclusion criteria for the studies that were included in the final literature review. Studies were excluded if pain was acute or was not musculoskeletal in origin. Studies that examined using specific passive treatment modalities i.e. acupuncture, TENS or those delivering interventions as an in-patient were also excluded. Finally those studies that involved under 18s and those with a recognised history of sexual or physical abuse were also excluded. Many of the studies identified in the initial database search strategy were those where the group intervention was not solely delivered by a physiotherapist but involved a multi- or inter-disciplinary team. After applying the criteria, a total of eleven studies were included in this literature review.

#### 2.3.1 Quality assessment

The PEDro scale (see Appendix 2 - PEDro scale

on page 119) was used to review and score the methodological quality of RCT studies with a cut-off score of 6 and above showing acceptable quality (Maher et al. 2003). Those studies that were reported on as non-randomised, cohort or observational studies were reviewed using the Critical Appraisal Skills Programme (CASP) 2014 (see Appendix 3 - CASP tool for cohort studies on page 121). A summary of the papers included in the literature review can be found in Appendix 4 - Summary of papers in literature review with PEDro scale on page 127.

*Table 2.1 - Inclusion criteria for study selection*

<b>Criteria</b>	<b>Description</b>
Design	Full reports in a peer-reviewed Journal Randomised, non-randomised and observational studies English language
Participants	Adults over 18 with: Chronic musculoskeletal pain from any origin, i.e. osteoarthritis, low back pain, fibromyalgia
Intervention	Treatment intervention that included evidence of an educational, exercise and a self-management element within cognitive behavioural principles. <ul style="list-style-type: none"> <li>• Delivered by a physiotherapist in a group format OR</li> <li>• Delivered on an individual basis by a physiotherapist</li> </ul>
Outcome measures	No studies were excluded based on outcome measure
Comparisons	No studies were excluded based on no comparison group

#### 2.4 Summary of the papers included for this literature review

This review has identified a changing perspective within the research relating to physiotherapy and pain management. There is a clear development in the literature from research involving a biomedical perspective to a newer psychologically informed physiotherapy practice.

## 2.5 Research with physiotherapy from a biomedical model

Physiotherapy research for musculoskeletal chronic conditions has focussed on the area of low back pain management. Physiotherapy is traditionally seen as a core treatment for low back pain. This is supported by the Clinical Standards advisory guidelines (CSAG) 1994; European guidelines (2004) for acute and chronic low back pain; National Institute of Clinical Excellence (NICE) guidelines for the management of low back pain (2009); and more recently in the (Map of Medicine pathways guidance for low back pain, 2014).

### 2.5.1 Randomised Control/Pragmatic trials for low back pain comparing manual therapy and psychosocial interventions

The UK BEAM (Back Exercise And Manipulation) Trial 2004, was a large-scale, randomised control study that compared physical treatments for low back pain, best care advice in general practice and an exercise class; “back to fitness” based on cognitive behavioural principles. The trial scored 8 on the Pedro scale. The trial’s main aim was to determine the effectiveness of manipulation for low back pain and to determine whether the location (NHS or private premises) affected the outcome. At the time of this trial, the predominant guidelines for the management of low back pain in the UK were the Royal College of General Practitioners (RCGP,) 1999, (Wadell et al. 1999) who advocated manipulation as a first line treatment option for acute and sub-acute low back pain, alongside advice to stay active and avoid bed rest.

The cohort of 1170 patients were constrained in the respect of both age (18-65) years and existing medical co-morbidities. In addition, the duration of time the participants had had back pain was unclear and therefore it is difficult to state if they had acute, sub-acute or chronic pain. The symptom requirement for the inclusion in the study was the presence of continuous pain for 20 out of the last 28 days. However, this could have been the participants’ first ever episode of pain or equally they could have had long-standing pain. The relevance of this criterion may relate to resolution of symptoms and degree of psychosocial factors present. The exclusion criteria of specific co-morbidities were, e.g. osteoporosis, anticoagulant therapy and steroid therapy. These were necessary because of the contraindications associated with manipulation, the study’s treatment modality. Similarly (Cecchi et al. 2010) explored the efficacy of a back school intervention compared to other physical

treatments defined as; spinal manipulation delivered by a physician and individual physiotherapy, including exercise, passive mobilisations and soft tissue work. This study used an Italian cohort of 210 participants with chronic, non-specific low back pain. The study scored 9 on the Pedro scale. Although not explicitly stated, the description of where the participants were recruited from was likely to be a secondary care setting. Interestingly, despite investigating the effects of manipulation on low back pain too, they had a broader inclusion criteria and didn't exclude any medical comorbidities or age. The mean (SD) age of the participants was 58.1 (SD+/- 12.2). All of the participants had standard spinal radiographs and a further ninety had CT or MRI scans. This may have been in respect of excluding spinal bony pathology, however, this is not explicitly stated by the authors. The UK based studies (UK BEAM trial 2004; Critchley et al. 2007), would not have been able to provide this level of investigation as RCGP guidelines 1999 do not advocate radiograph or similar investigations for non-specific low back pain (Waddell et al. 1999).

In contrast, Critchley et al. (2007) used a broader inclusion criteria for their UK cohort of 212 patients recruited from primary care with chronic low back pain. They used a randomised pragmatic study design to investigate the clinical- and cost-effectiveness of three types of physiotherapy over an 18-month time period. The study scored only 6 on the Pedro scale which is the cut-off for acceptable methodological quality. Participants were referred to a UK hospital physiotherapy department from either primary or secondary care sources.

Treatment arm one was individual physiotherapy (IP) this was delivered to a maximum dosage of six hours, in 30-minute appointments over 12 sessions. The actual treatment in the physiotherapy arm was left to the physiotherapists' discretion so could have contained a combination of manual, electrotherapy and exercise therapy.

Treatment arm two was spinal stabilisation exercises (SSE). Each patient was assessed and given an individual programme. This was carried out in a group setting with a maximum of eight patients supervised by a physiotherapist and assistant to a maximum of 12 hours, over 8-sessions of 90-minute duration. The third treatment

arm was a pain management programme (PMP), delivered in a group format by a physiotherapist and an assistant. A cognitive behavioural approach was used, to the same sessions and times as treatment arm two.

The premise of the study was similar to the (UK BEAM trial, 2004); the effect of physical treatment compared to spinal stabilisation exercises and a pain management class, all delivered by physiotherapists. The nature of the physiotherapy treatment was left to the discretion of the clinician, therefore modification of techniques could have been employed in respect of existing co-morbidities. Critchley et al. (2007) and (Cecchi et al. 2010) studies came after the release of the European guidelines for the management of acute and chronic low back pain (2004). This suggests that, whilst there was reasonable evidence for manual therapy, there was insufficient evidence about specific spinal exercises and cognitive behavioural approaches (CBA).

#### 2.5.2 Interventions

The manipulation intervention was eight 20-minute sessions performed by a physiotherapist, osteopath or chiropractor over a 12-week period in the (UK BEAM trial, 2004). The exact type and number of manipulations delivered in each session was unknown. This has been challenged as a criticism to their intervention, (Vogel et al. 2005). The “back to fitness” class was equally poor in description of content. The study reported that the participants were invited to attend up to eight sessions of 60-minutes over 4-8 weeks, suggesting that it was left up to the participant whether or how many to attend. The team suggest that this could have affected the findings, reporting that, whilst 92% of those receiving manipulation treatment had what they defined as “basic minimum treatment,” only 63% of those randomised to the “back to fitness” group. This potentially jeopardises the generalisability of the results and is a threat to external validity. In contrast (Cecchi et al. 2010) reported a high retention of 210 participants for their back school intervention with only 2 lost at 12-month follow-up. Whilst their study has similarities with the (UK BEAM trial, 2004) the difference with their back school intervention was that the class had structure to each session and participants were expected to attend. It was delivered by two physiotherapists in fifteen, 1-hour sessions over 3 weeks. However, the description of the intervention suggests that it was ‘traditional’ in content rather than a CBA with



the emphasis on pathology, anatomy and ergonomics in the first 5 sessions, and then exercise and relaxation in the last 10 sessions. Critchley et al. (2007) also reported a reproducible structure for their pain management class intervention delivered by physiotherapists, and yet, like the (UK BEAM trial, 2004), they still reported a higher than average attrition rate of 33% for the pain management intervention compared to 25% for the other two study interventions.

### 2.5.3 Findings

UK BEAM trial (2004), Hay et al. (2005), Critchley et al. (2007) and Cecchi et al. (2010), all used the Roland Morris Disability Questionnaire (RMDQ, 0-24; 0=no pain-related disability, and 24= total pain-related disability) as their primary outcome measure. This outcome measure is widely used in research trials and has been validated for both sub-acute and chronic low back pain populations. A wide range of secondary outcome measures were included for each of the trials, attempting to capture the multi-factorial nature of pain.

Baseline data for the (UK BEAM Trial, 2004) and (Cecchi et al. 2010) was similar for all treatment arms. In contrast (Critchley et al. 2007) reported that their baseline data was similar for all three arms, however, a visual check of the data suggests that the PMP arm were less likely to be in full-time work and more likely to be receiving benefits, resulting in an apparently lower number of days off work at baseline. The SSE arm also reported higher baseline pain related disability with RMDQ; 12.8 compared to 11.1 in the individual arm and 11.5 in the pain management group. This group also reported higher pain intensity as measured on the visual analogue scale (VAS 0-100; 0=no pain and 100= worse pain) 67 compared to individual 60 and pain management 59. The UK BEAM trial (2004) study started with an RMDQ score of 9 for all treatment arms whilst (Cecchi et al. 2010) reported no statistically significant differences of 8.4 in their spinal manipulation group, 9.5 in their back school and 9.7 in the individual physiotherapy group, although this was not reported as statistically different.

There was a 25% attrition rate across all three treatment arms, with the lowest retention in the PMP arm at 67%. The authors report that because of the wait to attend the pain management programme, some participants sought other treatment.

The authors do not make it clear as to whether these participants were excluded from the study or that this was given as a reason for them dropping out. This would clearly affect the results if the participants were allowed to continue with the study whilst receiving additional treatments.

The studies were all powered to detect clinically relevant changes in their primary outcome measure RMDQ (UK BEAM trial 2004; Critchley et al. 2007) by 2.5 (Cecchi et al. 2010) by 2 points, respectively. These scores are consistent with other studies as representing a clinically meaningful reduction (Woby et al. 2008; Lamb et al. 2012).

The UK BEAM trial (2004) reported a mean within-group drop in RMDQ of 3.3 at 3 months and 3.5 at 12 months across all treatment arms, accordingly. The manipulation plus exercise sustained the largest changes at both 3-months (1.9) and 12 months (1.3), whilst the exercise group alone had the smallest changes and these were only seen at 3-months (1.4). Critchley et al. (2007) showed no statistically significant difference between-groups in terms of patient reported outcome measures; pain related disability, pain intensity, quality of life or work limitation. Despite the lack of statistical difference between-groups, within-group changes had a mean RMDQ reduction of over 5 points and this was sustained to long-term follow-up of 18 months, which is clinically and statistically relevant. In contrast (Cecchi et al. 2010) reported a statistically significant ( $p < 0.001$ ) between-group change score between their treatment interventions. They also reported large within-group changes for RMDQ and pain medication use; spinal manipulation RMDQ reducing by 6.7; individual physiotherapy; 4.4 and back school; 3.7. Additionally they reported a reduction in the use of pain medication and the frequency of further episodes of low back pain. Conversely a statistically significant difference ( $p < 0.001$ ) was observed at 12 months for those participants in the spinal manipulation arm seeking further treatment. This suggests that manipulation increased the need for further treatment. This is not a desirable outcome for any chronic condition. The aim of treatment for those with chronic conditions is to equip the patient with skills to enable them to self-manage their condition not create reliance on healthcare providers. Despite reporting smaller changes with drop in RMDQ the (UK BEAM trial, 2004) reported that their combined manipulation and exercise arm also produced a not statistically

significant reduction in back pain beliefs and fear avoidance, which is potentially more relevant to long term pain and self-management.

When considering these studies the large variation of results need to be considered with caution. Both (Critchley et al. 2007) and (Cecchi et al. 2010) had relatively smaller sample sizes, 212 and 210 respectively, therefore, they were possibly underpowered compared to the (UK BEAM trial, 2004). In addition, both had higher starting means of RMDQ which arguably requires a larger reduction compared to a lower starting mean. The Cecchi et al. (2010) cohort suggests recruitment from a secondary care source and is therefore not easily compared to either (UK BEAM trial 2004; Critchley et al. 2007), both of whom recruited from primary care sources in the UK, although with different inclusion criteria.

#### 2.5.4 Cost effectiveness of the trials

In view of the major social and economic loss associated with low back pain economic analyses are common to determine cost-effectiveness of interventions. The quality-adjusted life years (QALY) is used to assess the value for money of an intervention in terms of disease burden, including both the quality and the quantity of life lived (Van de Roer et al. 2008). Both the (UK BEAM trial 2004; Critchley et al. 2007) report economic analysis of their studies. From a quality-adjusted life years (QALY) perspective (Critchley et al. 2007) reported that if health commissioners were willing to pay £30,000 per extra QALY then there would be approximately a 65% chance of PMP being cost effective and a 35% chance for individual physiotherapy. The pain management (PMP) arm had lower overall direct medical costs at £174. This was measured in visits to a general practitioner, consultant, investigations and medication (£174), individual physiotherapy (IP) cost £473 and spinal stabilisation (SSE) arm (£382). This reduced figure may have been affected by the high attrition rate in the PMP arm (33%): according to the Pedro scale less than 85% compliance can affect results. The UK BEAM trial (2004) reported lower overall costs: £195 for manipulation, £140 for exercise, and £125 for combined treatment. The UK BEAM trial (2004) report £10,000 for each extra QALY which, even taking into consideration the time difference between the two studies, is a significant difference. The authors

acknowledge that their cost estimation was lower than the 2004 UK recommendations.

## 2.6 Research reflecting the changing role of Physiotherapists delivering psychosocial interventions in a primary lead role

The preceding research has shown some evidence of physiotherapists using a CBA moving away from a biomedical perspective by starting to examine the efficacy of pain management rather than pain relief. It could be argued that the dominance of the British Pain Society and the publication of their guidelines for pain management programmes in 2007, and revised in 2013 have limited the exploration of pain management delivery outside of their gold standard interdisciplinary team delivery. However, in the next section of this literature review, the emerging role of psychologically informed physiotherapy practice and the emergence of physiotherapists as leads rather than working as part of an interdisciplinary team is explored. The context of this change in research strategy is on the recognition of a growing number of people suffering with chronic long-term conditions and the need for clinically and financially effective strategies that can be accessed by the majority of the population. Nicolas (2015) supports this change as a potentially sustainable answer to the growing problem faced by health systems worldwide. The following studies may reflect the change in significance of the psychosocial interventions delivered by physiotherapists, initially with low back pain participants but with development involving different chronic conditions.

### 2.6.1 Pain management approach in non-group interventions – Overview

Hay et al. (2005) used an RCT design comparing physiotherapists delivering a brief pain management intervention to individual physiotherapy for a UK cohort of 400 participants with sub-acute low back pain recruited from general practice. Similarly (Van de Roer et al. 2008) used an RCT design for a cohort of Dutch participants with non-specific low back pain to compare individual physiotherapy and a group training protocol based on exercise and behavioural therapy. Whilst Hill et al. (2011) looked at individual physiotherapy delivery for participants with low back pain, their treatment was targeted to psychosocial risk factors. Their study showed a significant system change in current UK practice. From their published work on the Keele STaRT back screening tool (SBST). The SBST is a 9-item prognostic screening tool designed to

be used in general practice with patients presenting with low back pain. The SBST was designed to aid clinicians identify risks factors including both biomedical and psychosocial. The SBST score stratifies patients into three groups; low, medium and high risk of developing chronicity. The score is used to direct clinicians to a matched treatment package; specific physiotherapy management for each SBST group. The 'high' risk group receives the pain management approach or 'psychologically informed physiotherapy practice'. The study used an RCT design to compare the stratified physiotherapy care based on the SBST to current best practice care.

Although (Hay et al. 2005) and (Van de Roer et al. 2008) both compared a pain management intervention with individual physiotherapy, the difference in inclusion criteria and dosage is significantly large. Hay et al. (2005) used up to six sessions with a maximum of 2 hours and 45 minutes for both interventions reflective of a typical UK NHS setting. Van de Roer et al. (2008) used 30 sessions for their intensive group training and left the individual physiotherapy to the clinicians' discretion, for a mean number of 13 sessions. This high number of sessions is possibly typical of service delivery in the Netherlands and is reflective of health insurance systems. This is a significant threat to the generalizability and external validity of the results to other clinical settings.

In contrast (Hill et al. 2011) compared the outcome of physiotherapy intervention based on a prognostic screening tool using a broad inclusion criteria; low back pain for any duration, minimum age 18, no upper age limit and only excluded those with serious co-morbidities. In this literature review, only (Woby et al. 2008) and (Lamb et al. 2012) included psychosocial markers in their inclusion criteria. However (Hill et al. 2011) went beyond identifying these issues by targeting the physiotherapy management based on the psychosocial factors. Participants were randomised to either targeted or non-targeted treatment (best current practice). In the targeted treatment group the SBST was used. Those scoring 'low' risk were given a one-off, 30-minute assessment, watched a 15-minute educational video and were provided with the back book (Roland et al. 2002) and a list of community based exercise groups, but no further treatment. The 'medium' risk group was defined as having predominantly physical prognostic indicators without high levels of psychosocial distress. This group

received standardised physiotherapy targeting symptoms and function of up to six 30-minute sessions (mean number was 3.7 sessions). This intervention appears to be the closest to the interventions described in (Hay et al. 2005; Critchley et al. 2007; Van de Roer et al. 2008). The 'high' risk group had high levels of psychosocial indicators, e.g. anxiety and fear. They received six, one-hour sessions of a psychologically-informed physiotherapy intervention. This was alongside function and symptom relief. The control arm of (Hill et al. 2011) non-targeted treatment (best current practice), was referral for physiotherapy treatment based on the clinical findings of the initial assessment by a physiotherapist blinded to the SBST.

Their findings on referral patterns for further treatment in the best current practice arm broadly suggest that physiotherapists were more likely to refer low risk participants; 50%, whilst 40% in the medium group and 33% in the high risk groups were not referred on for further physiotherapy treatment. This finding in itself has implications for physiotherapy practice and could suggest that physiotherapists are either not identifying psychosocial factors or are potentially not confident about their own skills to manage this cohort. Conversely, those with low risk are being potentially over-treated or over-medicalised (Hill et al. 2011).

#### 2.6.2 Psychosocial outcomes

Hay et al. (2005) used RMDQ as the primary outcome measures and powered the study to detect a 2-point difference between groups. Secondary outcome measures included validated measures for depression (Zung), fear (Tampa scale of kinesiophobia; TSK) and subscales of the Coping strategies questionnaire (CS). Despite the cohort having sub-acute low back pain the mean starting RMDQ was 13.8 which suggests a more disabled cohort than (UK BEAM trial 2004; Critchley et al. 2007; Lamb et al. 2008), which were studies specifically looking at a chronic low back pain. They also reported a high baseline mean TSK of 40. There was only a 0.8 change between-groups in RMDQ at both 3 and 12-months. However, there were large within-group changes for both the IP and the BPM on the RMDQ at 3 and 12-months of 7.8 and 8.8. The interesting change which was unaccounted for in the (Hay et al. 2005) study was an increase in TSK score in both groups from 40.7 to 46.7 and 45.5, respectively. This suggests the participants had a reduction in disability but an

increase in fear of movement, which might impact on participants' ability to adopt active strategies, including exercise adherence. A 4-point score change is suggested to be clinically significant on the TSK score (Woby et al. 2007). Van de Roer et al. (2008), reported a similar choice of primary and secondary outcome measure selection. They powered their study to detect a 3-point difference in RMDQ at 12-months. Baseline data was different in (van de Roer et al. 2008): the individual physiotherapy group were more likely to be non-European immigrants, not in paid work and with a higher percentage of constant symptoms, 37% compared to 43%. Despite the level of intensiveness of (van de Roer et al. 2008), the results show only a clinical significant change in reported pain intensity on the numerical rating scale (NRS) at 26 weeks. There were within-group RMDQ changes of 4.9 and 5, but no between-group changes in primary or secondary outcomes. Hill et al. (2011) also used RMDQ as their primary outcome measure with two hypotheses; to detect a 2.5 difference between-groups for medium- and high-risk at 12 months at 5% significance level, and to detect an overall between-groups change of 1 at each time point (0, 4 and 12-months). They accounted for a 25% dropout rate and recruited 850 participants. Secondary outcome measures included TSK, EuroQol, Pain self-efficacy (PSEQ), HAD and SF-12. Baseline data was similar for the control and treatment arm for each risk group, but was different between-groups, i.e. low and high, as expected. The reduction in RMDQ was larger in the intervention group compared to the control and statistically significant for both at 4 and 12-months; mean difference 1.81 intervention and 1.06 control. The within-group changes were also significant 'low' risk 1.06; 'medium' risk 5.3 and 'high' 6.8 when compared to other large scale RCT; (UK BEAM trial 2004; Lamb et al. 2012). Although (Hay et al. 2005) reported a large within-group change for both interventions, their cohort increased on the secondary outcome measures and showed no between-group differences. As discussed earlier the difference in referral for further physiotherapy treatment in the control group may have accounted for differences in 'medium' and 'high' risk SBST group effect; mean 'medium' group-control reduction 3.4 compared to 5.3 in the intervention group. The 'high' risk group showed a similar reduction of 4.4 compared to 6.8 in the intervention group. Total cost of the intensive group intervention was £732 compared to individual physiotherapy at £385. These costs were significantly more

than the previous studies reviewed. No costing was available for (Hay et al. 2005) however in light of the known maximum dosage the costs would be substantially less.

2.6.3 Group-based pain management approaches with low back pain participants Johnson et al. (2007), used an RCT design to investigate the effectiveness of a 16-hour cognitive behavioural intervention delivered by physiotherapists compared to best practice advice delivered via a postal educational pack for the control group. The study selected a cohort of UK patients with persistent disabling low back pain. An interesting selection procedure was used; all patients who consulted their GP with low back pain and who met the inclusion criteria were given a study information sheet and those who gave consent were contacted 3-months after their GP appointment to determine whether they were still reporting persistent disabling low back pain. The term persistent and disabling were defined as RMDQ >5 and Visual Analogue Scale (VAS; 0-100mm; 0=no pain) >20mm. Similarly (Lamb et al. 2012) in an RCT to investigate the effectiveness of a 9-hour cognitive behavioural intervention compared to best practice advice used a psychosocial factor in the inclusion criteria. They selected a cohort of UK patients with 'moderately troublesome' sub-acute to chronic low back pain recruited directly from general practice databases. There is little detail in the report how 'troublesome' was assessed, unlike (Johnson et al. 2007), and indeed how 'moderately' troublesome is distinguished from 'minimally' or 'extremely' troublesome. This suggests they were attempting to identify a specific cohort of patients with low back pain. This is in contrast to, (UK BEAM trial 2004; Critchley et al. 2007; Cecchi et al. 2010), who did not have any psycho-social inclusion criteria on their cohort. Johnson et al. (2007) used a similar age range, 18-65, as (UK BEAM trial, 2004; Critchley et al. 2007; Cecchi et al. 2010), however (Lamb et al. 2012) only specified a lower age limit of 18, similar to (Hill et al. 2011). The choice to limit the age range is interesting as there were no contraindications for manual therapy to consider and there is a potential that the results may not be generalizable to clinical practice which manages a larger age spectrum. A potential justification for limiting age range would have been if the study had looked specifically at the impact of persistent disabling low back pain on work outcomes, however this is not the case in (Johnson et al. 2007).



Johnson et al. (2007) used a CBA for their 16-hour group intervention which was delivered by two physiotherapists. Each group had between 4 and 10 participants and consisted of eight 2-hour sessions over a six week period. Lamb et al. (2012) used a smaller CBA for their 9-hour group intervention, delivered by one health care professional including physiotherapists, nurses or occupational therapists. Each group started with 8 participants and consisted of an initial assessment followed by six 1.5-hour sessions over a six week period. Additionally, both studies also defined treatment compliance of initial assessment and 3 subsequent sessions in (Lamb et al. 2012) and half (4) of the group sessions (Johnson et al. 2007).

Both studies reported on the additional training and measurement of competence to deliver the intervention and ensure treatment fidelity. Lamb et al. (2012) outlined their training package as comprising two classroom days and an assessment with an adapted competence tool. In addition the researchers randomly selected sessions to either audiotape or observe. In contrast (Johnson et al. 2007) described a training package of 4 classroom days followed by purposive sampling of audio-recorded sessions that were reviewed and rated by two external, independent examiners for compliance to cognitive behavioural principles. Despite ensuring that all physiotherapists were assessed, they reported that some therapists found difficulty in adopting the communication style required for a CBA. This may have accounted for only 63% being deemed as compliant with the intervention delivery. The random selection method used in (Lamb et al. 2012) resulted in only 57% being evaluated for their delivery of the CBI. In addition (Lamb et al. 2012) commented on observed sessions. There was variation ranging from 63-83% for compliance with CBT core elements which further jeopardises treatment fidelity. Both studies have identified possible issues with delivery of CBI by non-psychology professionals. This could be a potential barrier to expansion of such type of interventions away from specialist delivery as reported by (Nicholas, 2015).

Both studies used randomisation technique from an independent unit, and allocated participants to either the intervention plus best practice advice (BPA+CBI) or the control arm; best practice advice alone (BPA). Johnson et al. (2007) mailed an educational package which contained nine leaflets and an audio-cassette covering

different self-management strategies suitable for low back pain. The intervention arm received the same educational package in addition to attending a 16-hour physiotherapy-led CBI group. In Lamb et al. (2012) the BPA arm consisted of a single 10-15 minute session with a trained health professional delivering advice about staying active. This was supported by The Back Book (Burton et al. 1999). The intervention arm (BPA + CBI) consisted of the same 10-15 minute BPA session and the 9-hour CBI group.

#### 2.6.4 Outcome measures and findings

Johnson et al. (2007) powered their study to detect a 3-point between-group change on RMDQ and a 12mm change on visual analogue scale (VAS), both of which were used as their primary outcome measures. A total of 234 participants were recruited; significantly more than the 84 per arm that was stated in their power calculation. The secondary outcome measure was health quality of life measured with the EuroQoL. Lamb et al. (2012) used a sample size of 701 calculated on a 2:1 (test: control) treatment allocation allowed for a 25% attrition. They aimed to detect a between-group difference at 12-months of 1.8 on the primary outcome measure; RMDQ with 90% power and 5% significance. The 12-month follow up data was adequately powered with a loss of only 10% for both arms. The study looked at a range of secondary outcome measures including the disability and pain subscales of the Modified Von Korfff, the EuroQol and self-rated benefit (only included on extended follow-up).

Johnson et al. (2007) had a non-significant change of 0.6 points on RMDQ between-groups at 15 months. They reported a within-group mean change of 3.8 at 12 months for the CBI arm, compared to 2.9 for the control. Additionally, they asked participants about treatment preference prior to randomisation and found clinically significant differences on outcomes based on these preferences at 9 and 15 months only; 49% CBI; 8% control; 49% no preference. This raises an interesting aspect of patient-centred care around choice as well as the role of expectations and beliefs about what will help. Linton and Shaw (2011) discussed how the beliefs we have about pain and its management can have a considerable impact on our experience of pain and can

drive coping behaviours. They also suggest that such beliefs and expectations are a good predictor of treatment outcome and this is supported in (Johnson et al. 2007).

Lamb et al. (2012) reported a within-groups statistically significant difference in reduced disability on the RMDQ for both arms of the study at each time point measured; 3, 6, 12 months and extended follow-up, but there was no significance between-groups. The BPA had a mean reduction on RMDQ of 1.1-1.6 points and the BPA plus CBI reduced by 2.2 – 2.9 across the time periods measured.

They have reported an extended follow-up period, mean 34 months (range 20-50 months) and reported a larger attrition than expected, 51% in the BPA and 40% in the BPA + CBI group. The larger than expected loss at follow-up potentially effects the generalisability of the results from the extended follow-up. This loss of power compromises the generalisability of the findings as there are few studies which have examined follow-up beyond 12-18 months. This is important information for researchers and health care providers when seeking evidence about interventions for chronic long-term conditions.

However, despite the potentially positive results for extended follow-up the attrition rate is significant. The authors commented on the scores for responders and non-responders at baseline being no different but we do not know that this is the same case at extended follow-up as no comparable analysis was undertaken. Furthermore, there may be characteristics about those who chose to respond and those who didn't. Any economic analysis based on further health care use in terms of days off work, hospital and GP visits should be viewed with caution as only 55% of the total participants had responded and this might affect the external validity of the findings. Despite this the 12-month results show positive evidence that a relatively low-cost group intervention for a varied cohort of low back pain patients can be provided by health care professionals including physiotherapists, not working in an interdisciplinary team and still produce the same results as studies driven by a biomedical perspective (UK BEAM trial, 2004; Critchley et al. 2007; Cecchi et al. 2010).

It would have been useful for (Lamb et al. 2012) to have reported on the differences in outcomes between the different health professionals delivering the group. Particularly in view of (Johnson et al. 2007) who suggested that some of the physiotherapists struggled with the communication style that delivery required. This would be a relevant area for further research.

## 2.7 Non-RCT study design of psychologically based interventions by physiotherapists

Woby et al. (2008) was different from the previously discussed studies as it used a non-experimental pre-to post-study design. The study investigated the efficacy of a 17.5 hour physiotherapist-led programme for patients presenting with chronic low back pain. The intervention was called 'Work back to Life', a group based approach using cognitive behavioural principles, but which the authors named Interactive Behavioural Modification Therapy (IBMT). Patients were referred to 'work back to life' following assessment by the hospital-based physiotherapy team. The group was delivered by two physiotherapists trained in the delivery of IBMT in a group with between 8-12 patients. The primary outcome measure was the RMDQ and a range of secondary self-reported outcome measures were used including those measuring cognitive processes, i.e. fear of movement with the Tampa Scale of Kinesiophobia (TSK 17-64, 17=no fear of movement or re-injury and 64= complete fear of movement or re-injury), depression with the Hospital Anxiety and Depression scale (0-21, 0-7=normal, 8-10 mild depression, 11-15 moderate depression and 16-21 severe) in addition to pain intensity (Visual Analogue Scale; VAS, 0= no pain, 10=worst pain).

The inclusion criteria explicitly required that participants were showing psycho-social factors e.g. yellow flags, in addition to having chronic pain. This criterion is in direct contrast to the (UK BEAM 2004; Critchley et al. 2007; Cecchi et al. 2010) studies where the criteria were broader. The criteria used were similar but more explicit than in (van de Roer et al. 2008; Lamb et al. 2012). However, the criteria were based on the referring physiotherapists' judgement of psychosocial factors which (Hill et al. 2011) highlighted can be flawed. It should be noted that the STaRT back screening tool was not in use at the time of (Woby et al. 2008).

In view of the acknowledgement that the cohort in (Woby et al. 2008) study is chronic and had more psychosocial factors, it would be expected that the baseline data would be significantly different to the earlier studies discussed. However the baseline RMDQ of 11.6 for (Woby et al. 2008) was not significantly different to (Critchley et al. 2007) at 11.1, but was significantly different to (Lamb et al. 2012), 9.1. Conversely, it is feasible that in this case the physiotherapy team might have identified more of the patients they assessed as suitable due to the effect of being part of a research study; the opposite finding to (Hill et al. 2011).

Results pre- to post-group showed a mean reduction of 3.2 points, with a moderate effect size of 0.56 on the RMDQ. A change on the RMDQ of 2.5 is considered to be a Minimum Clinically Important Difference (MCID) (Critchley et al. 2007; Hansen et al. 2010). Although the (Woby et al. 2008) study produced above the MCID on the RMDQ (Hansen et al. 2010; Murphy et al. 2013) suggest this is typical of a study looking at short term clinical benefits and that it is at this stage large differences are expected to be detected. In addition to the pain disability changes, the study also reported a mean reduced change of 5 on the TSK scale with a large effect size of 0.71.

There are significant potential areas where bias could have been introduced in this study. Firstly selection bias; there were no specific details about how participants were recruited and there is a suggestion that the study used retrospective data rather than recruitment in a prospective manner. Selection bias is also a potential threat to the validity of the results as it was unclear as to when, where and by whom the baseline and post intervention data was collected. There was no blinding of patients to the treatment as there was no comparison group. In addition, the authors suggest that the study is potentially underpowered with no power calculation to set sample size. Therefore, whilst the results from this study appear promising and favourable for the physiotherapy-led IBMT intervention they should be treated with caution. The SBST was not in existence during the (Woby et al. 2008) study, it would have been interesting to combine the SBST with a group intervention approach as this consistently produced better and more cost-effective service delivery with similar clinical outcomes when compared to individual therapy or best advice practice, (Critchley et al. 2007; Lamb et al. 2012). Murphy et al. (2013) has proposed

a protocol looking at using the SBST and matching the score to group-based rather than individual treatment. No further information was available on the outcome of the study but it will possibly have implications for current UK practice, as well as adding to the body of evidence.

#### 2.7.1 Summary

Despite the criticism about the study design used in (Woby et al. 2008), the study could be considered to represent a realistic representation of service delivery i.e. a broad range of medical conditions and age ranges. Arguably conditions found in an RCT, pragmatic or otherwise, are not necessarily desirable or the results necessarily transferable to a clinical setting (Jessep et al. 2009).

This review has identified that there is an expanding body of evidence using high-quality RCT designs of physiotherapists using cognitive behavioural principles to deliver pain management interventions, working in a new, psychologically-informed way. However, the studies discussed have all exclusively investigated participants with low back pain only. Whilst it is acknowledged that low back pain is the most common musculoskeletal pain and accounts for nearly 50% of those off work with pain (Johnstone et al. 2002), there are other non-spinal conditions which routinely present in physiotherapy departments with chronic pain. There is a scarcity of research that examined physiotherapy management of non-spinal conditions using the psychosocial approaches. The final section of the review will focus on the available research in non-spinal conditions to gain insight into the efficacy of interventions.

#### 2.8 Randomised Control/Pragmatic trials for osteoarthritis with physiotherapists using psychosocial interventions

Two RCT designs have examined group interventions by physiotherapists for participants with chronic knee pain. Jessep et al. (2009) used a pragmatic randomised control study design to compare outpatient physiotherapy with an integrated rehabilitation intervention (ESCAPE) for a small UK cohort of 64 patients from general practice with chronic knee joint pain. The study cohort included people with chronic knee joint pain over the age of 50, (mean age 67), defined as having clinical osteoarthritis based on their presentation and history. In addition the study included

those with stable co-morbidities including those with pain in other areas including back, neck and upper limb pain. The study was therefore inadvertently looking at the effect of the control and the intervention on a mixed condition/presentation of chronic pain. Coleman et al. (2012) used a similar, broad inclusion criteria, but in contrast with (Jessep et al. 2009), had a large age range; 18 – no upper age limit. They used an RCT design evaluating a self-management programme for osteoarthritis of the knee (OAK) compared to a waiting list control for an Australian cohort of 146 participants. The choice of such an age range is interesting as the incidence of osteoarthritis is associated with ageing. Hedari (2011), states that 10% of females and 13% of men over the age of 60 will have symptomatic osteoarthritis (Zhang et al. 2010) suggest in their cohort a figure closer to 19% in >45. The incidence of osteoarthritis in the 18-45 is uncommon. Inadvertently by lowering the age range inclusion the study could have potentially recruited participants complaining of chronic knee pain without the clinical features of osteoarthritis. Despite this, the mean age for the study was 65 years. Participants were recruited both from their family doctors (general practitioners) and self-referral in response to adverts in the local media. This threatens the external validity of the findings and was reflected in a difference between-groups of 62% in the high socioeconomic index by postcode. It could be argued that this finding reflects the participants who were recruited from adverts were already more likely to respond to a self-management approach because of self-enrolment (Coleman et al. 2012). The baseline data was different for each group, which may have effect on the outcomes of the study.

#### 2.8.1 Interventions

In Jessep et al. (2009) the outpatient physiotherapy was delivered to the clinician's choice of usual care up to a maximum of 10 sessions. The treatment intervention was delivered for 1-hour over 10 sessions held twice a week in a community centre with a 4-month review. The treatment intervention is described as a collaborative approach challenging people's beliefs, enabling self-management, developing active coping strategies with problem solving skills and planning, in addition to exercise. Interestingly, the intervention could be described as using strategies and skills commonly found in a cognitive behavioural approach, though this is not specified. There is recognition that the skills used in ESCAPE are commonly utilised by

physiotherapists in their daily practice; goal setting, problem solving, and graded approaches, but have recently become synonymous with cognitive behavioural therapy practice. OAK in (Coleman et al. 2012) was delivered by two health professionals over six 2.5-hour sessions using a CBA with exercise. This study utilised other health professionals, in addition to physiotherapists, to deliver the programme as in (Lamb et al. 2012), therefore there is potential that two physiotherapists could have delivered the group together, justifying the inclusion in this review. The control arm of the study was a delayed start of six months before participants could go on the OAK programme, which was effectively a waiting list control.

#### 2.8.2 Outcomes and findings

The primary outcome measure in (Jessep et al. 2009) was the function subscale of the Western Ontario and McMaster Universities Index (WOMAC). The WOMAC has been widely used and is a validated measure for osteoarthritis. It comprises 24 items in 3 subscales for symptoms associated with the osteoarthritis; WOMAC-pain (0-20, 0=no pain 20= worse pain), WOMAC-function (0-68, 0=no loss of function, 68=complete loss of function) and WOMAC-stiffness (0-8, 0=no stiffness, 8=complete stiffness). The study used WOMAC-pain, The Hospital Anxiety and Depression Scale and two non-validated measures; the aggregated functional performance time of four daily activities and exercise-related health beliefs and self-efficacy. Coleman et al. (2012) used WOMAC and the short form 36 (SF36), a quality of life measure over eight domains covering emotional and physical bases, as their primary outcome measures. They also included a range of secondary functional measures, including muscle strength and range of movement.

Jessep et al. (2009) results revealed that both the control and treatment intervention produced more than the minimal clinical improvement difference (MCID) on the primary outcome measure of over 38% for both groups and that this was sustained at 12 month follow-up. White et al. (2010) reports the MCID for the WOMAC between 17- 26% from baseline. Interestingly, levels of anxiety increased, but not with statistical significance, for both the control and treatment groups by 1 point. This was not discussed and did not seem to correlate with changes in self-efficacy or increased healthcare utilisation.



However the results should be viewed with caution; first, the cohort was relatively well at baseline; quality of life (EQ-5d – 0.73, 100=best health and 0=worst health), low level of depression and anxiety (mean 3 and 4, 0-7=normal), high functioning (WOMAC-function 15.9, 0=no loss of function). The study excluded those who were unwilling or unable to exercise or unable to walk more than 100 metres. Interestingly, the reason for unable and unwilling to exercise is not elaborated on. There can be many reasons people are unable to exercise, one of which may be fear which is associated in those with chronic pain, as described in chapter 1. Second, the sample size was small; only 64 patients were recruited with a drop-out rate of 25%. The authors acknowledge this limitation and state it was designed as a feasibility study to provide preliminary data. A further additional bias was the acknowledgment that there was no attempt to stop other treatment being given during the study period. This continued at the GP's discretion. Although this is acknowledged as a potential bias, this is a realistic position of what happens in everyday clinical practice.

Coleman et al. (2012) reported problems with their final results because of the last value carried forward (LVCF) analysis used. In the waiting list control group they had a higher than expected drop out at 8 weeks of 88% (64 started the trial and only 8 responded at 8 weeks and 14 at 6 months). Unexpectedly, the responders increased in the control group at 6-month follow-up but because LVCF was used, it appeared that the control group results were stable across time points for both pain and function. The authors argue that this is unlikely to be the case because of the nature of osteoarthritis where deterioration in symptoms and function is more likely to be noted with passing time. However, we do not know the reasons; the authors suggest that a Hawthorne effect might be an answer, as well as the interaction between responders at the assessment time point with a health care professionals. The results did show an improvement in the OAK group in function at 8 weeks and at 6 months with both primary outcome measures. WOMAC-function improved by 38% within-group for OAK group, similar to (Jessep et al. 2009). However, this reduced to only 14% improvement at 6-month follow-up. The authors commented on this effect being expected after an intervention and the natural deterioration associated with

the chronicity of the condition. However (Jessep et al. 2009) sustained changes in both improved in physical function and reduced pain at 12-month in a similar cohort.

### 2.8.3 Outcome and discussion

Overall, the findings for (Jessep et al. 2009) were in support of (Critchley et al. 2007). Neither intervention was superior to the other but the group intervention was more cost effective, both in term of delivery (£63.67 compared to control £130.77) and in overall costs including further health care usage (GP, consultant visits and medication costs; £319.77 compared to £582.57). Critchley et al. (2007) suggests that their study adds support for physiotherapy delivery of a pain management approach for chronic low back pain in a group setting. Furthermore, the authors suggest that even a 50% shift in the management of patients referred with chronic low back pain to physiotherapy could result in savings for the NHS of £126 million per year (2003-2004 prices). The additional recognition of the intervention being described as a behaviour-changing intervention being delivered by physiotherapists adds further evidence for the role of physiotherapists in chronic pain management. There are a number of issues relating to both internal and external validity to draw any generalizable conclusions from (Coleman et al. 2012).

### 2.9 Summary of the literature review

The studies that have been included in this literature review offer evidence that physiotherapists are making significant contributions to the development of practice within the management of chronic pain. It provides evidence that physiotherapists can manage a cohort of patients with chronic pain using techniques that are not considered traditional, i.e. graded exposure, psychological coping skills, in contrast to treatment techniques traditionally associated with physiotherapists; manual and electrotherapy. The studies included have looked at both management in a group and individually (UK BEAM trial 2004; Critchley et al. 2007; Cecchi et al. 2010) and have reported positive clinical changes that in some studies were sustained to long term follow-up (Jessep et al. 2009; Lamb et al. 2012). Interestingly, the studies that have included an economic analysis, regardless of their approach, put strong cases forward for both group (Critchley et al. 2007) and individual delivery (Hill et al. 2011) being both clinically and cost effective.

The focus of the research to date has been on the management of low back pain. Nicholas (2015) reports that low back pain is the leading cause of disability but despite this the vast majority of treatments achieve no more than 20% reduction in pain levels. The impact of our ageing society and the associated increased incidence and prevalence of chronic joint problems will potentially result in an increase number of people living with chronic pain. However, pain is a complex multi-factorial problem that cannot always simply be related to pathology as discussed in Chapter 1.

The challenge for health care providers including physiotherapists is how to manage this growing number of multi-site pain presentations. This literature review has established that there is no existing evidence about physiotherapist-led management of chronic musculoskeletal pain in a group setting using a cognitive behavioural approach. Group management of people with mixed condition types/pathologies with psycho-social factors are found exclusively in specialist interdisciplinary pain clinic settings where physiotherapists are part of the team but do not deliver the entire pain management programme. The focus of this research is about the management of chronic pain by physiotherapists in a group setting. A pre-experimental longitudinal study design was proposed to evaluate the efficacy of an existing service in a clinical setting and produce preliminary evidence. Nicholas (2015) supports increasing the research evidence of non-psychologists delivering pain management skills to enable more people to be able to access services.

#### 2.10 Study aims

1. To explore the efficacy of a physiotherapist-led, group-based intervention for patients with chronic musculoskeletal (CMSK) disorders to reduce fear avoidance, disability, depression and increase in self-efficacy at pre to post 5 weeks intervention.
2. To explore the medium-term benefits of the group-based intervention on the same outcomes at 3-month follow-up and to investigate differences between outcomes in terms of condition type and referral sources.

### 3 Phase 1 Preliminary Study

#### 3.1 Introduction

In chapter 1, the growing problem of chronic pain was discussed in terms of consequences for the sufferer's health and well-being, and the impact to society in terms of direct healthcare costs and lost work days. Nicholas (2015) calls for a review of the delivery of pain management services to keep up with this growing crisis. Physiotherapists work with people who have a wide variety of conditions and across age groups. They are potentially in a unique position to be involved in developing and delivering accessible pain services across healthcare boundaries (Sullivan, 2008). The cost implications for inter-disciplinary services also requires consideration. The British pain society, in the revised 2013 PMP guidelines, state that they are cost effective in terms of further healthcare usage, i.e. fewer GP appointments, less pain medication and reducing accident and emergency attendance, but there is a growing body of evidence to suggest some uni-disciplinary approaches can also have this effect (Hill et al. 2011; Woby et al. 2008). The recent economic downturn in the UK has resulted in a re-evaluation of priorities for public spending. Research is needed to define clinically based criteria for patients who may benefit from inter-disciplinary interventions and those who could be managed in effective but lower cost interventions.

In response to this growing problem for patients with chronic pain a physiotherapy-led group intervention was developed at Fairfield Hospital in Bury, Lancashire, based on the work of (Woby et al. 2008). The original work examined physiotherapists delivering a 17.5-hour group programme, 5 sessions of 3.5 hours, for people with chronic low back pain based on strategies identified from a cognitive behavioural approach. The term 'Interactive Behavioural Modification Therapy' (IBMT) was devised to identify the intervention as being in the spirit of, but different to, cognitive behavioural therapy. The cohort recruited for (Woby et al. 2008) were all chronic low back patients with psycho-social indicators. The study reported significant reductions and moderate treatment effect sizes in disability, fear of movement, catastrophizing and depression. The group at Fairfield Hospital in Bury has developed the service to

include patients with chronic musculoskeletal (MSK) pain from conditions other than low back pain.

The primary aim of this present retrospective study was to evaluate the outcome of a physiotherapy-led functional restoration programme for patients with persistent musculoskeletal pain in an outpatient setting in terms of change scores on patient reported outcome measures (PROMS). The secondary objectives are to provide evidence of physiotherapy-led management of a mixed aetiology pain cohort and to determine the sample size for the phase two prospective study.

### 3.2 Design

This preliminary study was a retrospective service review of clinical data collected after a 15-hour physiotherapy-led programme for patients with chronic musculoskeletal pain who attended between January 2011 and December 2013. Patients were included if they had completed 3 or more sessions of the programme. In some cases, data was found to be missing; possibly from error or the patient may have not attended the final session for data collection. All patients attended a physiotherapy-led group intervention called the Functional Rehabilitation Programme (FRP). The purpose of this programme is for participants to develop self-management strategies including pacing, managing exacerbations of pain, setback planning, stress management and knowledge about pain neurophysiology. The principles are then practically applied through the movement/exercise component of the programme.

Approval for the study was granted by the Research and Development department of The Pennine Acute NHS Hospitals Trust. R&D Reference: 13RECNA20 (see Appendix 14 - NHS permission letter for preliminary study on page 143).

### 3.3 Patients

Patients were referred to FRP following assessment by outpatient physiotherapists from Pennine NHS Acute Hospitals Trust. The original source of the physiotherapy referral were predominantly from General Practitioners, and secondary care services including orthopaedic, rheumatology and pain. Patients typically had chronic MSK pain which had been present for longer than a 3-month period and were displaying psychosocial signs/behaviour. This was identified by the physiotherapists using

yellow flag questions during their assessments. These typically included; fear of movement, avoidance of everyday activities, unhelpful beliefs about pain, catastrophizing about their conditions and using passive coping strategies. Patients were included in this study if they were enrolled on the Functional Rehabilitation Programme between the review dates, January 2011 to December 2013, and if they had completed at least three sessions. Patients were referred onto the programme by their physiotherapists.

#### 3.4 Physiotherapy-led pain management group intervention (FRP)

The programme consists of 15-hours of group contact delivered by two Agenda for change band 7 physiotherapists in five, 3-hour sessions which was (delivered) over a 5-week period. Sessions are delivered in an interactive and collaborative way to engage the patients as they develop new coping strategies. Specifically, the programme comprises interactive educational components, with exercise and goal-setting principles covering topics recommended by the British Pain Society (BPS) as useful coping strategies for managing chronic MSK pain. The exercise session runs on each week and involves a circuit of 12 stations including resistance, cardiovascular and proprioceptive components. Patients are asked to stay on each station for 1 minute and then move on to the next station. The emphasis during the exercise session is pacing whilst addressing patients fear and concerns relating to physical activity and movement. Each week has a different topic including the de-conditioning effects of persistent pain, pacing, flare up management/setback planning and long term maintenance. Throughout the programme there are three educational sessions entitled 'Making Sense of Pain' which covers pain mechanisms, neurophysiology and factors that influence the pain experience. This section is designed to explore the patient's current pain knowledge and challenge unhelpful pain beliefs. There are also strong links with our third sector partners in local community services including a talk by the expert patient programme co-ordinator on the final session, in addition to direct referral pathways to health trainer services and exercise on prescription schemes.

### 3.5 Assessment Procedure

Patient demographics were recorded on the patient's physiotherapy case notes. Patients completed three patient-reported outcome measure before starting the programme and at the end of the programme.

#### 3.5.1 Fear of movement

The Tampa Scale of Kinesiophobia (TSK, score range 17-64; 17=no fear related behaviour and 64= total fear of movement), is a 17-item questionnaire for assessing pain-related fear of movement and re-injury. Fear of movement has been shown to be a strong predictor of chronic disability in patients with chronic pain, and also can be a barrier to exercise and activity. The TSK is both a validated and reliable measure in a persistent pain population (Burwinkle et al. 2005). A minimum of a 4-point change score is suggested to be clinically meaningful post intervention (Woby et al. 2005).

The secondary outcome measures included;

#### 3.5.2 Pain-related disability for low back pain (RMDQ)

The Roland Morris Disability Questionnaire (RMDQ, 0-24; 0=no pain-related disability, and 24= total pain-related disability), is a 24-item self-report questionnaire relating to low back pain. This measure is widely used in research for different low back pain populations and displays good levels of reliability and internal validity (Hansen et al. 2010; Woby et al. 2008; Critchley et al. 2007). The above studies report reductions of between 1.8 and 4 points as being indicative of a clinically-meaningful change.

#### 3.5.3 Pain-related disability for multi-site pain (PDQ)

If subjects presented with multi-site or widespread pain they completed the Pain Disability Questionnaire (PDQ, 0-150; 0=optimal function, 150=total disability), which is a generic disability questionnaire validated for use with a chronic musculoskeletal population. Categories for severity have been defined for the PDQ; 0-70 mild/moderate disability, 71-100, severe disability and 101-150 extreme disability (Gatchel et al. 2006). There are no Minimally Clinical Difference (MCID) scores currently established for the PDQ.

Finally, the patients completed the catastrophizing subscale of the Coping Strategies Questionnaire 24 (CSQ24). The CSQ24 is a shortened version of the Coping Strategies

Questionnaire and includes 24-items and four factors; Catastrophizing, Diversion, Reinterpreting, and Cognitive Coping (Harland et al. 2003). This tool was found to be a stable assessment tool in patients with chronic low back pain (Harland et al. 2013). However it has not currently not been validated for other chronic pain conditions. There are no MCID scores currently established for the CSQ24, however, a reduction in the catastrophizing score pre- to post-intervention suggests an improvement in coping styles.

### 3.6 Patient comments

A locally devised feedback form was given to the patients at the end of the programme and they were asked to complete it anonymously. Areas discussed were around session and exercise content, which sessions were most and least helpful. In addition patients were invited to make general comments on their experience of attending the programme and ideas for improvements.

### 3.7 Data analysis

Data was analysed in stages using SPSS. Firstly, baseline data including demographic and patient-reported outcome measures were evaluated using descriptive analysis such as frequency, mean and median. Secondly, the pre- to post-intervention scores on the patient reported outcome measures (continuous variables) were computed to determine if there were changes. Parametric paired t-test was used for variables which were normally distributed or non-parametric equivalent Mann-Whitney U test for non-normally distributed data. Effect sizes were also calculated to provide an indication of the size of change on each of the variables. Effect sizes were defined by Cohen as 0.20 small; 0.50 moderate and >0.8 as large (Lakens, 2013). Finally the data was split into condition types; low back pain and chronic widespread pain including fibromyalgia and the change score difference for TSK and CSQ-Cat were computed pre- to post-intervention. A Mann-Whitney U test was run to determine if there were differences in change scores between the two different condition types (low back pain and widespread pain). Significance was set at  $p < 0.05$ .

### 3.8 Results

Between January 2011 and December 2013 a total of 278 people were referred onto the FRP programme. Of these 278, 132 (47%) either did not start the programme or



failed to complete a minimum of 3 sessions and therefore complete data sets were not recorded. There was no additional information on the patient records to account for the reasons for not starting or completing the programme. Table 3.1 shows the demographic characteristics and source of referral for participants who attended (n=154) and those who did not attend (n=129).

*Table 3.1 - Baseline demographic data for patients who completed the programme and those who did not complete*

Characteristic	Number	
	Attendees n=154	Non-attendees n=129
Age Mean (SD)	51.06 (14.04)	47.02 (23.94)
Range	21 – 90	19 – 71
Gender, n	n%	n%
Female	106 (68.8)	94 (72.9)
Male	48 (31.2)	35 (27.1)
Condition type, n (%)		
Low back pain	85 (55.2)	82 (63.5)
Fibromyalgia/widespread pain	69 (44.8)	47 (36.5)
Employment status		
Working	34 (22.1)	30 (23.3)
Not working	76 (49.4)	70 (54.3)
Retired	32 (20.8)	12 (9.3)
Missing data	12 (7.8)	17 (13.2)
Source of referral, n (%)		
Primary care	75 (48.7)	65 (50.4)
Secondary care	68 (44.2)	55 (42.6)
Missing data	11 (7.1)	9 (7.0)

Those who attended had a mean age of 51, were predominantly female, not working and condition type was fairly equal between low back pain (55.2%) and chronic widespread pain (44.8%). There were more patients with low back pain who did not attend the programme (63.5%). A chi-square test for association was conducted between attendance of the programme (completed and not completed) and condition type, gender and referral source. All expected cell frequencies were greater

than five. There was no statistically significant association between attendance status and condition type,  $\chi^2(1) = 0.58$ ,  $p = 0.446$ ; gender  $\chi^2(1) = 0.55$ ,  $p = 0.458$ ; or referral source  $\chi^2(1) = 0.78$ ,  $p = 0.077$ . Demographic characteristics for those who did not complete the programme were similar to those who attended, with the exception that they were younger with a mean age of 47. A Mann-Whitney U test was run to determine if there were differences in age between those who completed the programme and those who did not complete. Distributions of age for both groups were similar, as assessed by visual inspection. Median age was statistically significantly higher in those who completed (51) years than in those who did not complete (44) years,  $U = 6523$ ,  $z = -3.488$ ,  $p = 0.001$ .

#### 3.8.1 Fear of movement – (TSK)

A paired-samples t-test was used to determine whether there was a statistically significant mean difference between the pre to post intervention scores in Table 3.2. Data are mean  $\pm$  standard deviation, unless otherwise stated. There were no outliers detected, for TSK as assessed by inspection of a boxplot. The assumption of normality was not violated, as assessed by Shapiro-Wilk's test ( $p = 0.44$ ).

Table 3.2 shows the participants' fear of movement reduced following the physiotherapy group from  $(39.94 \pm 0.83)$  to  $(34.17 \pm 8.32)$ , a statistically and clinically significant reduction of  $-5.77$  (95% CI, 4.56 to 6.98),  $t(152) = 9.44$ ,  $p < 0.001$ , and moderate effect size calculated by Cohen's  $d = 0.69$ .

Table 3.2 - Pre to post-intervention scores with paired t-test analysis and effect size

Outcome Measure	Pre-group mean (SD)	Post-group mean (SD)	Mean difference	t-test	CI 95%	p-value	Cohen's d
Tampa Scale of Kinesiophobia (TSK) n=152	39.94 (8.38)	34.17 (8.32)	5.77	9.43	4.56 - 6.97	<0.001	0.69
Roland Morris Disability Questionnaire (RMDQ) n=81	12.80 (5.11)	8.38 (5.00)	4.51	7.51	3.31 - 5.70	<0.001	0.88
Pain Disability Questionnaire (PDQ)	91.73 (23.70)	81.13 (27.72)	9.25	3.60	4.10 - 14.40	<0.001	0.39
Coping Strategies Questionnaire Catastrophizing (CSQ-Cat)	15.13	12.27	2.85	4.74	1.66 - 4.04	<0.001	0.39

### 3.8.2 Pain-related disability low back pain (RMDQ)

There were two outliers detected. These were not extreme and were therefore left in the analysis. The assumption of normality was not violated, Shapiro-Wilk's test ( $p = 0.126$ ). A reduction in pain was observed in patients with low back pain in pain-related disability from  $(12.81 \pm 5.09)$  to  $(8.31 \pm 4.94)$ , a statistically and clinically significant reduction of 4.51 (95% CI, 3.31 to 5.70),  $t(81) = 7.51$   $p < 0.001$ ,  $d = 0.83$ .

### 3.8.3 Pain-related disability (PDQ)

There were no outliers detected and the assumption of normality was not violated, Shapiro-Wilk's test ( $p = 0.500$ ). A reduction was observed in patients with non-spinal pain/widespread pain in pain-related disability from  $(91.16 \pm 23.44)$  to  $(81.91 \pm 27.28)$ , a statistically significant reduction of 9.25 (95% CI, 4.105 to 14.40),  $t(55) = 3.60$   $p < 0.001$ ,  $d = 0.35$ .

### 3.8.4 Catastrophizing (CSQ-Cat)

There were multiple outliers and normality was violated, Shapiro-Wilk's test ( $p = 0.02$ ), therefore a non-parametric Wilcoxon signed-rank test was run. There was a statistically significant median decrease (3.00) from baseline (16.00) to post group (12.00),  $z = -4.51$ ,  $p < 0.001$ ,  $d = 0.39$ . Although catastrophizing as measured by the

CSQ24 reduced post intervention, because of the lack of MCID for the CSQ24 it is difficult to evaluate the scale of this change.

### 3.9 Analysis of outcome measures between condition types

The data for TSK and CSQ-Cat difference scores had multiple outliers and were not normally distributed therefore a Mann-Whitney U test was run to determine if there were differences in scores between patients with low back and chronic widespread pain. Only the TSK and CSQ-Cat were analysed as both condition groups completed different disability measures, (RMDQ and PDQ). Distributions of the TSK and CSQ-Cat difference scores were similar, as assessed by visual inspection. Median TSK and CSQ-Cat scores for low back pain (-6.00; -3.00) and chronic widespread pain (-4.00; -3.00) were not statistically significantly different, TSK;  $U = 3,106$ ,  $z = 0.928$ ,  $p = 0.35$ ; CSQ-Cat;  $U = 2,776$ ,  $z = 0.37$ ,  $p = 0.70$ .

### 3.10 Qualitative feedback from patients post-programme

Patients were asked to complete an informal locally devised feedback form following the completion of the programme and this was completed anonymously. Descriptive thematic analysis was performed (Cresswell and Clark, 2011). The majority of comments fell into the following broad themes; support from other patients, staff delivery of the programme, content of the programme and lifestyle changes. The following are comments from each theme described above;

Analysis of the comments revealed that patients were positive about their experience of the group. The majority of comments fell into the following broad themes; support from other patients, staff delivery of the programme, content of the programme and lifestyle changes. The following are comments from each theme described above;

#### **Support from other patients:**

*"I didn't feel like I was on my own"*

*"I couldn't get over how many other people were living with pain. I thought it was only me"*

*"I have made some real friends and we are going to meet up again to support each other"*

### **Support from staff;**

*"The delivery was done in a fun friendly way and I felt I could ask anything"*

*"I felt believed for the first time and the staff made it feel like it was real and wasn't all in my head"*

*"We were able to laugh even though we were talking about serious problems it made it easier somehow"*

*"The staff were friendly, approachable and enthusiastic"*

*"I've been to physio lots of time before but didn't get anywhere. I felt this time I was really listened to and believed and that means a lot – thank you"*

### **Content of the programme;**

*"I enjoyed the exercises, I never thought I'd say that but I did!!"*

*"I felt I have learnt new ways to help me manage the pain. I particularly liked the explain pain talks it made sense"*

*"I liked the way we weren't talked at. We could all chip in and say what we thought and agree and disagree. I've stopped saying I can't thanks to the pacing session"*

*"For me the relaxation sessions were the best. I didn't realise how my breathing had changed and how I was holding myself so stiffly"*

*"To know that I wasn't causing more harm that was the most important information and I have found that since then I've tried more things, things I wouldn't have done before and my pain isn't worse"*

### **Lifestyle changes;**

*"I've stopped saying I can't to everything"*

*"I've started to park further away from the shops and use the stairs for more exercise"*

*"I've stopped saying yes to everything. I'm talking to family and explaining to them how I need to pace"*

*"I've joined a gym and I'm planning on going to Zumba"*

*“I’ve dug my Wii fit out of the attic and started using it: little and often; that’s the way”*

*“I feel more confident now. I had a big black cloud over me and nothing was helping, pills weren’t touching it. I’m doing more now and the pain is no worse so that must mean I’m getting fitter or something”*

### 3.11 Summary of Key findings from Phase 1

The physiotherapy-led intervention produced clinically and statistically significant short term (pre to post) changes in low back pain related disability (RMDQ) and fear of movement in a cohort of patients with chronic MSK pain.

Improvements were also observed in pain-related disability for widespread pain (PDQ) and for catastrophizing. Due to the lack of MCID established for these outcome measures it is unclear as to whether the change scores observed were clinically significant however both were statistically significant  $p < 0.001$ .

No difference in scores (TSK and Cat-A only) were observed between condition types (low back pain and widespread pain) suggesting that a physiotherapy-led intervention with a mixed aetiology group can produce positive changes. This observation may have potential clinical significance, but would be worth testing in a larger cohort of patients. Chapter 2 highlighted that most physiotherapy research in chronic pain group management has focused on either classes/groups for low back pain or osteoarthritis but not a mixed aetiology chronic pain group.

Finally, although informal, qualitative responses from participants from the group appear to support changes observed on the patient reported outcome measures in relation to behaviour and lifestyle changes.

### 3.12 Discussion

The results from this service evaluation provide preliminary support for physiotherapy-led group management for patients with persistent pain from different conditions. The group achieved this by firstly integrating an interactive self-management approach in an environment that supports behavioural exploration of movements/activities. Secondly by raising knowledge and awareness about other coping strategies that can be used to manage long-term conditions.

The overall findings of this service evaluation suggest that the physiotherapist-led group produced changes in reducing fear-related movement and pain-disability in a cohort of patients with persistent MSK pain including widespread, multi-site pain and fibromyalgia (44.8%) and low back pain (55.2%). Whilst the results are similar to those obtained by (Woby et al. 2008), these results are potentially important as they have shown no significant differences in fear-related movement (0.354) or catastrophizing outcomes (0.708) between the two condition types. The results suggest that different condition types do as well as in a mixed group setting as in a chronic low back pain-only group (Woby et al. 2008). This finding has capacity implications for service design in that diverse pain condition types could be managed in one group and this could potentially be both a clinical and cost-effective approach. It is recognised that the patient comments reported here were not collected or analysed using recognised qualitative research methodologies. Nonetheless there appeared to be a positive validation of the physiotherapy-led service and comments relating to changes in behaviour and lifestyle seemed to correlate with improvements in outcome measures. This finding is supported by (Lamb et al. 2012) who included semi-structured interviews as part of their mixed methodology study exploring participant's views on non-psychology led pain management groups.

### 3.13 Limitations

This retrospective review only captured a limited view of the multi-faceted nature of persistent pain. The current evaluation is limited to disability and two constructs of fear; fear of movement and catastrophizing. It has been suggested that a reliance on patient self-reported measures may be a limitation in a persistent pain population as patients may exaggerate or minimise their reports of pain and suffering on self-report measures (Wells Federman et al. 2002). However, the authors suggest that if this is indeed the case then it is reasonable to assume that they may be consistent with this over- or under-reporting. Gatchel et al. (2006) supports their use and discusses how self-report measures have become essential elements of assessing the effectiveness of musculoskeletal treatment. Harding et al. (1994), developed a battery of physical function tests to assess and evaluate physical aspects of a pain management intervention and this could arguably be used to enhance the patient

self-report measures. A further limitation with this current service provision is the lack of follow-up provision. The service evaluated in this preliminary study was set up to discharge patients on completion of the programme and therefore only the immediate pre- to post-effects are known for this intervention. It is recognised, both by the British Pain Society (2013) and in the Map of Medicine pathways for chronic pain (2012), that provision of a follow-up or review is essential for services managing long-term conditions to offer supported self-management. In addition, the high percentage (47%) of people who did not start or complete the group has clinical implications for the service and requires a review of the process of how and why physiotherapists refer patients into the group.

### 3.14 Conclusion

Despite the limitations of this service review, it offers encouraging support to the current service providers and has potential implications for the physiotherapy-led management of patients with persistent pain in a mixed aetiology group.

Following the findings from this service evaluation, a prospective research study was proposed to evaluate the pre- to post-intervention changes with a 3-month follow-up. The study will also evaluate a broader range of dimensions in the self-report measures to capture the multi-faceted nature of chronic pain and include physical function tests to measure physical performance. The findings from this preliminary study were used for the power calculation of the phase two prospective study.



## 4 Methodology

### 4.1 Study design

The study used a pre-experimental medium term follow-up study design. The reasons for selecting the study design were varied including whether the efficacy of treatment gained can be sustained (Lamb et al. 2012). From the literature review there appeared to be a growing body of evidence for physiotherapy-led group-management of specific conditions, i.e. low back pain and osteoarthritis. However there was no research to support physiotherapy-led group management of patients reporting chronic pain as a limiting factor in daily activities in different conditions. However (Nicholas, 2015) suggests that to meet the needs of the growing number of people with chronic pain a range of health professionals in non-specialist services will need to be able to deliver pain management skills effectively. This study design was considered to be an appropriate choice to investigate the effects of an intervention in clinical, everyday practice (Murphy et al. 2013). This study set out to establish whether current service provision at Pennine Acute NHS Hospitals produces changes in terms of patient-reported outcome measures for a group of people with mixed chronic pain presentations, i.e. low back pain, and multi-joint or chronic widespread pain. The current service is based on the work of (Woby et al. 2008), however their work exclusively explored patients with chronic low back pain. The current study examined the effect of a similar intervention on a mixed chronic pain group. Sim and Wright (2000), state that the disadvantages of a pre-experimental study design include both internal and external validity. Internal validity relates to the extent to which the results can be attributed to the intervention being studied whilst external validity relates to the generalizability of the results (Creswell and Clark, 2011). Another factor that influenced study design was that there was no funding granted to provide administrative support, nor staff for the organisation to conduct a randomised controlled trial. The time frame for completion of the prospective phase of the study was an additional extraneous factor. In addition as part of the development of the prospective study design an initial preliminary retrospective service evaluation was performed and this is reported in Phase 1 Preliminary Study on page 51.

## 4.2 Setting

A physiotherapy musculoskeletal outpatient department within a hospital in Bury, Lancashire.

### 4.2.1 Participants

Patients who presented to the outpatient physiotherapy departments of Pennine Acute NHS trust with chronic musculoskeletal pain (present for 3 months or longer) and with signs of psychosocial factors were identified by a physiotherapist during their assessment using yellow flag questions (Kendall et al. 1997; Nicholas et al. 2011).

### 4.2.2 Eligibility criteria

The intervention is designed for an adult population aged 18 years and over with no upper age limit. This minimum age limit is in keeping with other research studies that examined patients with chronic pain (Critchley et al. 2007; Woby et al. 2008; Hansen et al. 2010). However, a few studies have included an upper age limit of 65 (UK BEAM trial 2004; Critchley et al. 2007). However, as this study explored a routine service provision and in acknowledgment of prevalence of chronic pain increases, an upper age limit was not set as an exclusion criteria (Hill et al. 2011; Lamb et al. 2012).

All participants reported a current history of chronic pain from a musculoskeletal disorder, with a duration of more than three months and that they were seeking treatment for. During the initial physiotherapy assessment, each participant was screened for 'red flags'; signs of potential serious pathology. Any evidence of red flags were appropriately referred on for further investigation through the appropriate hospital pathways, (see Appendix 5 - Flag indicators on page 132).

Participants were asked to commit to all five sessions with an explanation that each session covered a different aspect of pain management and that each session, rather than being a stand-alone topic, built from the previous weeks. Hansen et al. (2010), who investigated the effect of a CBT approach for chronic low back pain by a single profession, suggested that attendance of 5.5 hours out of a possible 10 hours was a pragmatic decision of compliance with their study intervention. This study defined compliance as attendance of at least 3 sessions, 9 hours out of a possible 15 hours.

Participants required having adequate command of spoken English to allow full participation in the group discussions. This was in line with similar studies of this type of intervention (Critchley et al. 2007; Murphy et al. 2013). There are examples of studies investigating a similar cohort that excluded participants if they could not read or write in English (Nicholas et al. 2013; Broderick et al. 2014). As this study looked at an existing service, provision was made to accommodate this.

#### 4.2.3 Exclusion criteria

Participants were excluded from the study if they had already completed a pain management programme. This was an attempt to prevent previous exposure to a cognitive behavioural or pain management approach being an extraneous variable that may affect the findings of the study (Lamb et al. 2012). In addition it was felt that if a participant had already been through this type of intervention previously, the reasons for further referral needed to be explored and other management options discussed (Hansen et al. 2010).

It is recognised that having one long-term condition increases the risk of developing multiple long-term conditions, although it is unclear as to the causative link (Long Term Condition Compendium Third Edition 2012). Participants were excluded if they had unstable co-existing pathologies which prevented full participation in the group activities whether this was the exercise or group discussions. Examples of exclusion included unstable angina, recent myocardial infarction, severe chronic obstructive pulmonary disease and severe mental illness. The hospital provides specific group and individual interventions for these conditions. These exclusions were also supported in similar cohorts (Critchley et al. 2007; Woby et al. 2008), and also in cohorts with more complex presentations in specialist centres (Nicholas et al. 2013; Amris et al. 2014).

### 4.3 Study procedures

#### 4.3.1 Recruitment phase

Patients were identified as potential participants by the physiotherapists working in the MSK outpatient team. The physiotherapists were a representative team of mixed grades from junior, agenda for change (AfC) band 5, to clinical specialist level AfC band 8. The team were aware of the study protocol. The intervention in the study

was an existing service that the physiotherapy team were already aware of and used for patients with chronic MSK pain. If they identified during their initial assessment that the patient had a history of chronic MSK pain present for longer than three months, displaying psycho-social factors and meeting the inclusion criteria they were considered for the study. Psycho-social factors were identified using yellow flag questions. This recruitment process is reflective of routine clinical practice and is in keeping with the study design by (Woby et al. 2008) that employed a similar recruitment process.

#### 4.3.2 Consent phase

Following the initial assessment, if a patient was identified as suitable for the group intervention study then the physiotherapist discussed the study with the patient and provided a study invitation letter, a participant information sheet and a consent form, (see Appendix 15 - Participant study consent form, Appendix 16 - Participant study invitation letter & Appendix 17 - Participant study information sheet on pages 144 - 146). The physiotherapist responded to the patient's questions directly and they also invited the patients to contact the principal researcher if they had any further queries about participating in the study. The patients were asked to return the consent form in the envelope provided or return the form to the first session of the group. This ensured that all patients had a minimum of 48 hours to make an informed decision about participating in the study. Potential participants were aware that if they did not want to participate in the study that they could still attend the group intervention as this was an established service offered for this client group and that their non-participation in the study would not affect their treatment.

#### 4.3.3 Baseline Assessment

During the first session of the intervention all participants who had consented completed four patient-reported outcome measures and a physical function test (see Appendix 8 - Study physical function tests on page 136). The questionnaires were administered and scored independently by an outpatient physiotherapist who was not involved in the study. The physical function test was recorded during the first session by the second group physiotherapist and not the principal researcher. The physical function test was performed in a set order for all participants both at

baseline and post intervention. The test started with the timed 20 metre walk test, then the 5 minute walk, followed by the 1 minute timed step up test (see Appendix 8 - Study physical function tests on page 136). Data was transferred from patient physiotherapy records to an anonymised data collection sheet. Participant identification was by unique study code and this was not kept alongside the patient consent form or patient treatment records. Data collection sheets were kept in a secure filing cabinet in the physiotherapy department. Demographic data was collected including age, gender, work status, ethnicity, referral source and condition type. All data was recorded following the baseline assessments, on an SPSS worksheet. Following completion of baseline assessments each participant met with one of the physiotherapists facilitating the group for an individual review. The review lasted for 10 minutes and covered what the patients' expectations/concerns were for the group, if anything had changed since they were last seen in physiotherapy and if there were any reasons why they could not attend all the group sessions. This review was recorded on a separate sheet and attached to the patients' physiotherapy record and was not included on the study data extraction form.

#### 4.4 Intervention

All participants completed a physiotherapist-led group intervention called the Functional Rehabilitation Programme (FRP). The programme is similar in structure to the group intervention in (Woby et al. 2008), which looked at the intervention for a cohort of participants with chronic low back pain. This intervention has been described as using an 'Interactive behavioural modification therapy' (IBMT) which is based on the main principles of cognitive behavioural therapy but not delivered by a trained CBT therapist. This type of intervention has also been described in (Critchley et al. 2007) and (Jessep et al. 2009). FRP has been adapted from this initial work to treat patients with a range of chronic musculoskeletal condition including low back pain and widespread chronic pain. The intervention was delivered by two AfC band 7 physiotherapists both trained in the delivery of IBMT.

Specifically, participants attended five sessions; once a week for 3 hours. Sessions were delivered in an interactive and collaborative way to engage the participants as they developed new coping strategies. The content of the programme comprised an

aerobic exercise component, group discussion, problem solving and making sense of pain education. Patients worked towards identifying a value-based goal that was set by the end of the group and reviewed at 3-month follow up.

The core content of the programme covered topics recommended by the British Pain Society (in their revised guidelines for adult pain management programmes 2013), as useful coping strategies for managing chronic pain. These included exercise, pacing, graded activity, flare-up and setback planning, maintaining change, explaining pain processes and on-discharge access to community based resources/support (see Appendix 6 - Programme timetable on page 134).

The exercise component included a combination of stretching and a mixed circuit (see Appendix 7 - Exercise component for study intervention on page 135). The stretching exercises were demonstrated by the physiotherapist in the first session and the group worked through them together. Patients were expected to continue with these exercises at home, and for the next 4 sessions they completed the stretching exercises unsupervised in the group. The rationale for this was to increase patients' ownership of the exercises and to move away from 'correction of movement' that could potentially increase fear of movement and the fear of harm by doing the exercise incorrectly. It also helped to reduce reliance on the physiotherapist and provide a better and more realistic transition to future community or home based exercise. This rationale was supported in the Long-term condition compendium 2013 about patients taking ownership of their long-term condition. The circuit was completed on session's two to five. There were 12 stations in total and the exercises used were a combination of balance, co-ordination and resistance exercises as well as incorporating movements or positions that patients may have been actively avoiding due to fear, e.g. getting on or off the floor. Amris et al. (2014) used similar functional movements as their primary outcome measure and they demonstrated that following a group intervention ease of movement improved despite no change on patient-reported outcome measures. Mosley et al. (2004) demonstrated that forward flexion in patients with chronic low back pain improved following a 3-hour session and homework of explaining pain neurophysiology,

despite not showing any significant changes on the RMDQ which was similar to (Amris et al. 2014).

#### 4.5 Final assessment

All participants completed the same patient-reported questionnaires from session one and repeated the physical function tests. Each participant met with one of the group physiotherapists individually to discuss their experience of the group and their plans on leaving the group in relation to use of community-based services and what strategies they were going to use in their flare-up plan. The Map of Medicine guidelines (2013) advocate patient reviews as part of their pathways for chronic widespread pain and low back pain.

#### 4.6 Follow-up and end of trial

Following completion of the group, participants who gave consent to be included in the study were given a date to return for a group follow-up session which lasted for 2 hours. At the follow-up all participants completed the patient-reported outcome measures from session 1 and 5, repeated physical function test and were asked about the use of community services, and use of coping strategies in their flare up plan. The group discussed barriers to change they had encountered after they had finished the intervention, what progress they have made with their goals and any experience of changed behaviour. This was an informal and qualitative discussion without a structured questionnaire. Hansen et al. (2010), stated in their study of a CBT approach that unless participants had been asked to keep a detailed diary of all expenses and visits a full cost and health care utilisation projection was impossible. The scope of further health care utilisation was beyond the scope of this current study. All participants were discharged after the follow-up session.

#### 4.7 Outcome assessments

Measuring clinical outcomes is important for any treatment intervention (Dworkin et al. 2005) and an increasingly important aspect of any musculoskeletal research (Gatchel, 2006). The multi-factorial nature of chronic pain and the range of interventions used for treatment makes the decision on what and how to measure challenging. Change in chronic pain status cannot be assessed in the same way as disease processes that can be evaluated using biomedical procedures e.g.

erythrocyte sedimentation rate to measure inflammation in rheumatoid arthritis or a blood pressure reading in hypertension. The interaction between the different multifactorial components in chronic pain is complex and calls for a range of observed and patient-reported outcome measures to be utilised (Anagnostis et al. 2003). The following outcome measures were selected to attempt to capture the range and depth of the effect of chronic musculoskeletal pain and to quantify the effect a physiotherapy-led intervention has on the different dimensions measured.

#### 4.7.1 Primary outcome measure and power calculation

The primary outcome measure was the Tampa Scale of Kinesiophobia (TSK). One of the primary aims of this study was to investigate the effectiveness of physiotherapists delivering a psycho-social intervention for a mixed chronic pain cohort. There is a large body of research exploring the relationship between fear of movement and the maintenance of pain and disability (Vlaeyen et al. 1995; Roelofs et al. 2004; Burwinkle et al. 2005). This is further supported by the fear avoidance model of pain discussed in chapter 1. The role of physiotherapists in interdisciplinary pain management programmes is primarily with the exercise and movement component delivery (Sullivan et al. 2010). Therefore the choice of TSK was considered appropriate to look at a cognitive factor associated with movement, rather than solely physical parameters of increasing exercise.

The TSK is a 17-item questionnaire for assessing pain-related fear of movement (kinesiophobia). Each item is scored on a 4-point scale ranging from “totally agree” to “totally disagree”, the scores are added and the total score ranges from 17-68 with a higher score indicative of greater fear of movement and re-injury. There are currently no specific score ranges that would indicate the range of the respondent’s fear level i.e., mild, moderate or severe, etc. Nicholas et al. (2008) looked at 5,941 pain patients who had been referred to a pain specialist centre in Australia to establish normative data for chronic pain measures and TSK was included. In the (Nicholas et al. 2008) population studied they found that mean TSK was 41.44 for patients with chronic low back pain and 42.3 for those with pain in two or more sites. Studies using a chronic low back pain population with physiotherapy-led or single profession-led interventions report similar baseline TSK scores (Hay et al. 2005), 40.7; (Woby et al.



2008), 39.5 and (De Moraes Vieira et al. 2013), 42.0. In addition to no clear indicators for score and severity, there is also little in the research about what constitutes a clinically significant change score. Woby et al. (2005) suggested a reduction of at least four points, in their evaluation of the psychometric properties of both the original 17-item TSK and the shortened 11-item version. A reduction of 4-points appeared to correlate with a meaningful reduction in fear avoidance in a chronic low back pain sample. Therefore, using the (Woby et al. 2005) suggestion and the findings of the phase one retrospective service evaluation discussed in chapter 2 (which found a 5.77 point change in TSK) a power calculation was made to estimate sample size. Taking the minimal, clinically-significant difference on the Tampa scale of kinesiophobia (TSK) as an improvement of 4-points and assuming 20% dropout, then by using an 80% power with 2-sided hypothesis and significant level at 5% requires a minimum of 40 patients (see Appendix 9 - Tampa Scale of Kinesiophobia on page 137).

#### 4.7.2 Secondary patient-reported outcome measures

1. The Roland Morris Disability questionnaire (RMDQ) or
2. The Pain Disability Questionnaire (PDQ)
3. The Pain Self Efficacy Questionnaire (PSEQ)
4. The Hospital Anxiety and Depression scale (HAD)

#### 4.7.3 Functional/physical tests

Based on Harding et al. (2004) battery of functional tests for people with chronic pain

5. 20 metre timed walk test
6. 5 minute timed walk test
7. 1 minute timed step-ups

#### 4.7.4 The Roland Morris Disability questionnaire (RMDQ)

The RMDQ is a 24-item self-report questionnaire relating to low back pain. A higher score indicates a greater degree of disability. The RMDQ was originally derived from the 136 item Sickness Impact Profile, a generic health status questionnaire, and was originally intended only for research purposes (Anagnostis et al. 2003). Despite its initial use, the RMDQ is now used routinely in clinical practice as an outcome measure pre- and post-treatment intervention. This measure is widely used in

research for different low back pain populations and displays good levels of reliability and internal validity (Critchley et al. 2007; Woby et al. 2008; Hansen et al. 2010). The above studies report reductions of between 1.8 and 4 points as being indicative of a clinically-meaningful change. Hansen et al. (2010) suggest that studies that include small sample sizes, and only pre- to post-design report a higher change and that this is to be expected post any intervention. Grotle et al. (2004), investigated the responsiveness of the RMDQ compared to other outcome measures and found it to be superior to others in a chronic low back pain population. However, Anagnostis et al. (2003) found that the responsiveness of the RMDQ was most reliable in its mid-range scores and is less sensitive to higher scores equating to a greater perceived degree of disability. Based on the retrospective service evaluation it was envisaged that the sample would score around the mid-scale point (12), this is a similar pre-intervention score to other studies using referrals from a primary care or non-pain specialist centre population, and therefore the RMDQ was considered to have sufficient sensitivity (see Appendix 12 - The Roland-Morris Disability Questionnaire on page 140).

#### 4.7.5 The Pain Disability Questionnaire (PDQ)

The PDQ is a generic disability questionnaire that was devised from a range of other pain-related, dysfunction questionnaires including the RMDQ, short form health questionnaire (SF-36), and the McGill pain questionnaire. It was primarily designed to be used with chronic musculoskeletal conditions, including spinal pain (Gatchel, 2006). The 15-item questionnaire is scored on a 10-point scale (from 0 = no relevance to 10 = excellent relevance). The score ranges from 0 (optimal function) to 150 (total disability) and (Gatchel et al. 2006) reported three distinct categories from the total score; Mild/Moderate (scores of 0-70); Severe (71-100); and extreme (101-150). Their study reported the pre- to post-PDQ score changes 1 year after a multi-disciplinary, functional restoration pain programme for people with chronic pain. They found an association between severe and extreme PDQ scores and depression, absence from work and increased healthcare utilisation, compared to those scoring mild/moderate. Anagnostis et al. (2003) described a thorough validation and reliability process using four different populations including a normative sample, acute pain sample and two chronic pain samples; one working group and one unemployed. The PDQ was

compared to other widely used functional outcome measures including RMDQ and SF-36 and was found to be at least comparable, and in some instances superior, to existing measures. Despite this promising validation and reliability process, the PDQ remains underused in large-scale research trials. It was therefore used in this study as the functional measure for those participants with pain in more than one site. It could have been used as the only functional measure but the decision to include the RMDQ for participants with chronic low back pain was based on its use in previous studies (Hill et al. 2011; Critchley et al. 2007) and (Lamb et al. 2012) using a similar intervention to that reported in this study. It was therefore considered that it would aid comparison and, despite some reservations in its responsiveness, it remains widely used as a low back pain disability measure in research (see Appendix 10 - Pain Disability Questionnaire on page 138).

#### 4.7.6 The Pain Self Efficacy Questionnaire (PSEQ)

The PSEQ is a 10-item scale measuring the respondent's confidence to carry out physical and social activities despite having pain. The score range is between 0-60 with a higher score indicating a greater self-confidence in performing these activities. The development of the Pain Self-Efficacy Questionnaire by (Nicholas, 2007) suggests that the measure can be used as both a screening tool and an outcome measure. Nicholas et al. (2008) report normative data for the PSEQ with a mean score for chronic low back pain as 24.9 and pain in more than two sites at 23.7. The normative data was collated from referrals to a specialist pain centre in Australia from their family doctor. Other studies report a range of different self-efficacy scores from (Nicholas et al. 2013) in a chronic pain sample of 34.1; (Lamb et al. 2012), report a mean PSEQ score of 39.1 in their primary care-recruited chronic low back pain population. Miles et al. (2011) investigated six different forms of self-efficacy measurement tool including the PSEQ and found it had reliable internal consistency but they reported there were problems determining responsiveness. They also highlighted problems with the interpretability of the scores in all six of the self-efficacy measures evaluated and suggested that this could potentially limit use in clinical practice. However (Nicholas, 2007) suggested that post-treatment scores on the pain self-efficacy scale may be predictive of a person's ability to make long lasting behavioural changes and self-manage, or whether they are at risk of relapsing. A

patient who makes behavioural changes but does not score >40 is still at potential risk of relapsing and probably requires follow-up or monitoring, (see Appendix 11 - Pain Self Efficacy Questionnaire on page 140).

#### 4.7.7 The Hospital Anxiety and Depression Scale (HADS)

Depression has been found to be present in many patients who report chronic musculoskeletal pain, although it is not well understood as to whether one is attributable to the other (Yohannes et al. 2010). Linton et al. (2011) reported that depression 52% of patients with chronic pain fulfilled criteria for depression and that the presence of depression is often associated with poor treatment outcomes. The Hospital Anxiety and Depression Scale (HADS) is a fourteen-item scale that measures the level of anxiety and depression in patients with physical health problems (Crawford et al. 2001). Seven items on the scale relate to anxiety and seven to depression. Participants are asked to respond on a scale from 0 to 3 as to how much they agree with each statement. A score of 10 or above has been widely accepted as a score indicating levels of anxiety or depressive symptoms which are clinically relevant and would benefit from referral to appropriate services (Crawford et al. 2001). The HADS was included in this study for several reasons; to assess the level of depression present and also to evaluate the level of depression pre- to post-intervention compared to change scores on the other outcome measures. Although the association between depression and chronic pain is acknowledged, many physiotherapists may feel that managing depression is not within their scope of practice to manage. Woby et al. (2008) demonstrated that with a physiotherapist-led intervention, changes in disability and self-efficacy were associated with a reduction in depression and argues that some levels of depression are therefore affected by physiotherapy treatment. However the study also suggested that there is a level at which severe depression will not be amenable to this type of intervention. The inclusion of the HADS will therefore support the development of future inclusion/exclusion criteria for the study intervention and when referring on to appropriately trained specialists is required. The HADS has shown good internal and external validity in similar chronic pain populations (Hill et al. 2011; Lamb et al. 2012) (see Appendix 13 - The Hospital Anxiety and Depression Scale on page 142).

#### 4.7.8 Physical function tests

The physical tests (5-7) are taken from the work of (Harding et al. 1994) who described a range of different physical tests to try and assess function under controlled conditions. The study found that some of the tests, 20 metre and 5 minute walking test, were reliable while others were unacceptable; the balance and grip strength tests. The validity of the tests was found to be good as most replicated everyday activities e.g. walking, getting out of a chair, etc. The authors highlighted that the reliability of the tests was compromised by the variability in instructions given to each participant by the testers. As a result, in this study the same group physiotherapist, not the principal researcher, recorded the results of the functional tests. The physiotherapist read a set of written instructions so that each patient heard the same information. The physiotherapist was also instructed not to talk to the participant during any of the tests unless the participant reported an adverse reaction or the participant requested to stop the tests (see appendix for full functional test procedure). Amris et al. (2014) used functional tests as their primary outcome measure and self-reported measures as secondary outcomes. Their findings suggested that the functional tests improved but the self-reported measures did not: in their results they found the main difference was between what the patient perceived they could do, (what they reported on the outcome measure), and what the tester actually observed the patient doing during the functional test. Morley et al. (2008) used a 5-minute walk test in addition to self-report measures to add depth to their overall results. They recorded not only the distance covered but also the quality of the walking i.e. use of aids, grimacing, holding onto walls, etc. pre- to post-intervention. Harding et al. (1994) reported that the measures could be used on their own or a selection to add support to patient self-reported outcome measures, but that consideration should be given to the population being studied (see Appendix 8 - Study physical function tests on page 136).

#### 4.8 Ethical issues

##### 4.8.1 Risks, benefits and potential side effects

Potential risk one; was considered as increased pain during or after the exercise session. All participants in this study reported a reduced mobility level pre-intervention and an over activity/underactivity cycle of daily activity. Increased pain

was discussed as an inevitable but normal consequence of increasing activity during session one. Using terms including acceptable and non-acceptable pain to describe this temporary increase in a participant's pain as discussed in (Booth, 2014), reassurance was given as to the physiological reasons behind the increase in pain. This was discussed in terms of an increase in pain being 'normal' and should return to the participant's baseline level within a short period time, although this time was not specifically defined. To minimise this risk, participants were advised before exercising to pace each exercise. This was demonstrated by the physiotherapists leading the group who remained present throughout the exercise component of the session.

Potential risk two; Participants may also have experienced increased discomfort from sitting on different chairs during the discussion component of the group. At the start of each session participants were reminded that they were free to get up and stretch or move around to the back of their chair whenever they needed too but to stay within the chair circle so that they could still participate in the discussions. Regular comfort breaks were timetabled into the group based on recommendations from the Department of Health document; Sedentary Behaviour and Obesity: Review of the Scientific Evidence (2010), which suggests an active break from sitting every 30 minutes.

Potential risk three; increased fatigue or tiredness due to the length of each session. This was minimised by ensuring that the timetable allowed for comfort breaks and that there was access to water during the sessions to help keep the participants hydrated.

Potential burden one; attending the physiotherapy department for 5 weeks and each session lasting 3 hours. This may have required the participant to organise work, caring responsibilities and organisation of themselves to get to the hospital for the start of the session. The group had been running in its current format for over five years and previous attendees of the group had not cited this as a major burden or obstacle to attend. It was also felt that the number of hours is small in comparison to multidisciplinary pain management programmes where the patients are expected to attend full days for up to 2 weeks (Nicholas et al. 2008).

Potential burden two; the time taken to complete the patient-reported outcome measures may be seen as a potentially time consuming part of the group. The number of outcome measures and functional tests were included to capture the multifaceted nature of chronic pain. Previous participants have expressed interest in their pre- to post-group scores and how this related to their symptoms and behaviour changes. Harding et al. (1994) discussed patients undertaking functional and clinical outcome measures and stated that consideration should be given for the population being assisted. This study used a similar range of outcome measures as utilised by studies investigating both a similar intervention and cohort of patients and therefore the time was considered justified (Woby et al. 2008; Hansen et al. 2010; Murphy et al. 2013).

#### 4.8.2 Confidentiality and anonymity

Participant's information for the study was transferred from physiotherapy records onto a data extraction form and was given a unique study code. The form did not have any identifiable participant's details on it. The forms were stored in a locked filing cabinet in the outpatient department of Fairfield General Hospital. This was to ensure anonymity, privacy and confidentiality according to Trust Caldicott regulations that any NHS patient's notes and documentation are required to follow. The data from the form was transferred to an NHS computer. This computer required 2 passwords to access files, and the data was not stored on the hard-drive of the computer. Only the researcher had access to the study data and the filing cabinet. Information gained from the study was not used for any other purpose after the study had finished. The computer data will be deleted 12 months following the study completion and the extraction forms destroyed in the hospital's confidential waste according to trust information governance policy.

#### 4.8.3 Ethical approval

Ethical approval for this study was granted on 31 January 2014 by the National Research Ethics Committee (NRES) North West. REC reference: 14/NW/0042. IRAS project ID: 143694 (see Appendix 18 - NHS REC ethical approval letter on page 148).

Ethical approval was also granted by Manchester Metropolitan University (MMU) Ethics committee on 12 February 2014. MMU ethics application 1217. (See Appendix 22 – MMU ethical approval confirmation on page 152.)

#### 4.9 Data Analysis

Data were analysed using SPSS. Data were analysed in stages. Firstly baseline data including demographic and patient-reported outcome measure was evaluated descriptively as a whole group and then split into referral source groups; primary or secondary care using frequency and mean. Chi-square test was used to explore differences in categorical data. Data was subjected to assumption testing including normality, detection of outliers and homogeneity of variance, to determine whether parametric tests were appropriate for the analysis (Field, 2000). If data was found to violate any of the assumptions tests then the equivalent non-parametric tests were used (Field, 2000) Secondly data collected from the outcome measures at pre, post and follow-up were computed to determine if there were changes and the level of significance using parametric paired t-test. Following paired t-tests Analysis of variance (ANOVA) was computed to look at the level of change between each time point of the study and this was followed with post-hoc tests using a Bonferroni adjustment. Effect sizes were also calculated to provide an indication of the size of change on each of the variables. Effect sizes defined for Cohen's d test as 0.20 small; 0.50 moderate and 0.8 or more as large (Lakens, 2013). Finally the data was split into condition types; low back pain and chronic widespread pain including fibromyalgia and the change scores for each variable were computed pre to post and then independent t-test was computed to assess if there were differences in change scores between the two different groups. Significance was set at  $p < 0.05$ .



## 5 Results

5.1 Patient characteristics for those completing the physiotherapy intervention  
 A total of 78 potentially eligible patients were asked to participate in the study between January and December 2014. A total of 53 (68%) patients consented to take part in the study. Of those who started the study, one hundred percent of participants (n=53) completed the five week intervention, whilst 35 (66%) completed the follow-up session at 12 weeks.

*Table 5.1 - Baseline demographic and background information of patients who completed the 5 weeks intervention n=53*

<b>Characteristic</b>	<b>Completed intervention (n=53)</b>
<b>Age mean (SD)</b>	51.6 (12.08)
<b>Gender</b>	n (%)
<b>Male</b>	8 (15.1)
<b>Female</b>	45 (84.9)
<b>Work status</b>	
<b>Working</b>	11 (20.8)
<b>Not working</b>	22 (41.5)
<b>Retired</b>	20 (37.7)
<b>Ethnicity</b>	
<b>White</b>	44 (83)
<b>Asian</b>	6 (11.3)
<b>Other</b>	3 (5.7)
<b>Condition type</b>	
<b>Low back pain</b>	16 (30.2)
<b>Multi-site pain including Fibromyalgia</b>	37 (69.8)
<b>Co-morbidities</b>	
<b>None</b>	29 (54.7)
<b>1 &gt; co morbidity</b>	24 (45.3)
<b>Referral source</b>	
<b>Primary care</b>	22 (41.5)
<b>Secondary care</b>	31 (58.5)

Table 5.1 shows the demographic characteristics and outcome measures used for participants who started the study (n=53) with baseline scores. The study sample had a mean age of 51.6, was predominantly female 45 (84.9%), white, 44 (83%) and had

multi-site pain, 37 (69.8%). The work status of the participants was slightly higher for those not working, 22 (41.5%), compared to those who were retired, 20 (37.7%) whilst a smaller proportion, 11 (20.8%) were continuing to work. More participants were referred from secondary care (consultant-led services), 31 (58.5%) and had no additional health issues (co-morbidities), 29 (54.7%) compared with primary care referrals.

*Table 5.2 - Baseline scores for Patient reported outcome measures and physical function tests for patients who completed the 5 weeks intervention n=53*

<b>Patient reported outcome measures</b>	<b>Mean (SD)</b>
<b>Fear of movement/re-injury (TSK)</b>	40.9 (7.05)
<b>Disability/low back pain (RMDQ) n=19</b>	11.7 (4.48)
<b>Disability/multi-site (PDQ) n=34</b>	107.6 (19.9)
<b>Anxiety (HADS) n=51</b>	11.9 (4.06)
<b>Depression (HADS) n=51</b>	9.8 (3.60)
<b>Self-efficacy (PSEQ) n=53</b>	25.4 (12.2)
<b>Physical Function test</b>	
<b>20 metre timed walk</b>	21.6 (11.40)
<b>5 minute walk</b>	263.7 (102.36)
<b>Step-ups</b>	19.0 (7.57)

Table 5.2 shows the baseline scores for the outcome measures suggest the sample had high levels of fear of movement 40.9. They also reported moderate levels of psychological distress as measured by the HADS, depression 9.8 and anxiety 11.9. In addition the sample had low levels of self-efficacy 25.4.

## 5.2 Analysis of baseline patient characteristics by referral source

The group offers a service for those referred from both primary care (GP) and secondary care (hospital consultant). As part of the analysis a comparison of demographic and baseline data based on referral source was made to determine if there were any differences, Table 5.3 shows this data. Participants from secondary care were generally younger (mean age 49.7 years), not working 15 (48.4%), with multi-site pain and a fairly equal number had no additional health problems, 15 (48.4%).

### 5.3 Analysis of categorical data

A chi-square test for association was conducted between referral source, co-morbidity, and condition type and work status. All expected cell frequencies were greater than five, apart from condition type and therefore analysis for this variable was not computable. There was no statistically significant association between referral source and co-morbidity,  $\chi^2(1) = 0.62$ ,  $p = 0.43$  or work status,  $\chi^2(2) = 1.02$ ,  $p = 0.60$ . A Mann-Whitney U test was carried out to determine if there were differences in age between those referred from primary and secondary care. Median age was not statistically significant between primary (58.00) and secondary care (50.50),  $U = 249$ ,  $z = -1.725$ ,  $p = 0.08$ .

*Table 5.3 - Baseline characteristics of participants by referral source completed the intervention compared with those who did not complete the follow-up on self-reported outcome measures*

Characteristic	Primary care (n=22 )	Secondary care (n=31)
Age mean, (SD)	54.6 (10.10)	49.7 (13.14)
Gender	n (%)	n (%)
Male	6 (27.3)	2 (6.5)
Female	16 (72.7)	29 (93.5)
Work status		
Working	6 (27.3)	5 (16.1)
Not working	7 (31.8)	15 (48.4)
Retired	9 (40.9)	11 (35.5)
Ethnicity		
White	20 (90.9)	24 (77.4)
Asian	1 (4.5)	5 (16.1)
Other	1 (4.5)	2 (6.5)
Co-morbidities		
None	14 (63.6)	15 (48.4)
1 > co-morbidity	8 (36.4)	16 (51.6)
Condition type		
Low back pain	16 (72.7)	2 (6.5)
Multi-site pain	6 (27.3)	29 (93.5)
Outcome measure name	Mean + SD	
Fear of movement/re-injury(TSK)	39.4 (6.72)	41.6 (7.17)
Disability/low back pain (RMDQ)	11.0 (4.77)	12.3 (3.75)
Disability/multi-site (PDQ)	91.8 (39.81)	109.7 (15.77)

Characteristic	Primary care (n=22 )	Secondary care (n=31)
Anxiety (HADS)	10.7 (4.68)	14.0 (3.29)
Depression (HADS)	7.9 (3.35)	10.6 (3.45)
Self-efficacy (PSEQ)	28.8 (14.32)	23.9 (11.09)
Speed of walking - timed walk over 20 metres	17.8 (8.01)	23.7 (12.51)
5 minute in metres (between 2 markers 20m apart)	325.9 (100.44)	230.6 (88.13)
Total number of Step-ups in 1 minute	22.9 (9.68)	16.9 (5.13)

TSK, Tampa scale of Kinesiophobia; HADS, Hospital Anxiety and Depression Scale; RMDQ, Roland Morris Disability Questionnaire; PDQ, Pain Disability Questionnaire; PSEQ, Pain Self-efficacy questionnaire.

#### 5.4 Analysis of patient-reported outcome measures by referral source

To determine if there were differences in TSK score between referral sources, Independent-samples t-tests were run. Assumptions for the test were only met for TSK, HAD-A, and HAD-D. Analysis was not possible for RMDQ as there was only one participant referred from secondary care with low back pain. Analysis with parametric independent t-test was also not possible for all the physical function tests because there were multiple extreme outliers and data was not normally distributed. Thus non-parametric equivalent was carried out for this analysis using the Friedman's ANOVA test.

Table 5.4 – Independent t-test for TSK, and HADS (anxiety and depression) between referral sources; primary and secondary care.

Variable name	Primary care baseline score (± SD)	Secondary care Baseline score (± SD)	Difference between scores (95% confidence interval)	Independent t-test	Significance p-value <0.05*
Fear of movement/re-injury (TSK)	39.65 (6.13)	41.9 (7.63)	-2.24 (-6.18 to 1.66)	-1.155	< 0.02*
Anxiety (HADS)	10.71 (4.14)	12.70 (3.87)	-1.99 (-4.26 to -0.291)	-1.753	< 0.08
Depression (HADS)	8.57 (3.29)	10.63 (3.60)	-2.062 (-4.053 to -0.071)	-2.081	< 0.04*

TSK, Tampa scale of Kinesiophobia; HADS, Hospital Anxiety and Depression Scale;

#### 5.4.1 Fear of movement (TSK)

There were no outliers in the data, as assessed by inspection of a boxplot. TSK for each level of referral source were normally distributed, as assessed by Shapiro-Wilk's test ( $p > 0.05$ ), and there was homogeneity of variances, as assessed by Levene's test for equality of variances ( $p = 0.198$ ). The mean score was lower for the primary care referrals ( $39.65 \pm 6.13$ ) than secondary care ( $41.9 \pm 7.63$ ), a statistically significant difference of  $-2.24$ , (95% CI,  $-6.18$ - $1.66$ ),  $t(51) = -1.155$ ,  $p = 0.02$ .

#### 5.4.2 Anxiety (HAD-A)

The mean score for primary care referral source was lower in anxiety score ( $10.71 \pm 4.14$ ) than secondary care ( $12.70 \pm 3.87$ ), a non-statistically significant difference between referral sources of  $-1.99$ , (95% CI,  $-4.26$ - $0.291$ ),  $t(49) = -1.753$ ,  $p=0.08$ .

#### 5.4.3 Depression (HAD-D)

The mean score for primary care referral source was lower in depression ( $8.57 \pm 3.29$ ) than secondary care ( $10.63 \pm 3.60$ ), a statistically significant difference between referral sources of  $-2.062$ , (95% CI,  $-4.053$  to  $-0.071$ ),  $t(49) = -2.081$ ,  $p=0.04$ .

The analysis has revealed that the secondary care cohort were significantly more fearful and depressed suggesting a more psychologically distressed cohort which potentially explains why they were under secondary care services. However, there were no other statistically significant differences between referral sources.

#### 5.5 Changes from pre- to post- physiotherapy-led intervention for all outcome measures

Analysis on pre- to post changes that occurred on each of the patient-reported outcome measures and physical function test was undertaken to answer the primary aim of the study; what effects does a physiotherapy-led group intervention have in terms of pre- to post changes in patient-reported outcome measures.

Table 5.5 shows the pre- to post-treatment changes that occurred on each of the outcome measures. Assumptions for a parametric t-test were met and were run on all outcome measures pre- to post-intervention (Table 5.5) and pre- to follow-up (see Appendix 21 - t test for pre to post intervention and pre to follow-up on page 151). A paired-samples t-test was used to determine whether there was a statistically

significant mean difference between the outcome measures from baseline to post-intervention. Data are mean  $\pm$  standard deviation, unless otherwise stated.

Table 5.5 - Pre- to post-intervention for the whole data set n=53

Variable name	Baseline score	Post score	Mean change ( $\pm$ SD)	t-test	Significance p-value	Cohen's d effect size
<b>Fear of movement/re-injury (TSK)</b>	40.9	33.6	-7.33 (5.78)	9.19	< 0.001	1.26
<b>Anxiety (HADS)</b>	11.9	10.6	-1.33 (2.99)	3.18	< 0.003	0.44
<b>Depression (HADS)</b>	9.8	7.4	-2.41 (2.39)	7.22	< 0.001	1.01
<b>Disability/Low back pain (RMDQ)</b>	11.9	9.2	-2.73 (2.88)	-7.66	< 0.001	0.94
<b>Disability/multi-site (PDQ)</b>	107.6	90.4	-17.15 (17.46)	4.14	< 0.001	0.98
<b>Self-efficacy (PSEQ)</b>	25.4	35.5	+10.0 (9.48)	5.73	< 0.001	1.06
<b>Speed of walking - timed walk &gt;20 metres</b>	21.7	17.7	-4.06 (7.49)	3.72	< 0.001	0.54
<b>Distance covered in 5 minutes in metres</b>	261.3	291.7	+30.42 (62.43)	3.38	< 0.001	0.48
<b>Total number of Step-ups in 1 minute</b>	19.0	24.7	+5.68 (5.53)	7.04	< 0.001	1.03

TSK, Tampa scale of Kinesiophobia; HADS, Hospital Anxiety and Depression Scale; RMDQ, Roland Morris Disability Questionnaire; PDQ, Pain Disability Questionnaire; PSEQ, Pain Self-efficacy questionnaire.

#### 5.5.1 Primary outcome measure – fear of movement (TSK)

Participants had a change score from baseline mean (SD) fear of movement (40.92  $\pm$  7.05) to post-intervention (33.62  $\pm$  7.33), a statistically significant decrease of -7.30 (95% CI, 5.71 to 8.89),  $t(52) = 9.192$ ,  $p < 0.001$ , with a large effect size score,  $d = 1.26$ .

Significant reductions were also seen in disability, anxiety and depression (Table 5.5). Whilst there were significant increases (improvements) in self-efficacy, speed and distance of walking in addition to more step-ups performed. Large effect sizes (>0.8) were observed in fear of movement, disability self-efficacy, depression and number of step-ups, and moderate effect size (>0.5) for walking speed and distance and anxiety.

The paired sample t-test analysis suggest that the physiotherapy-led group intervention had a positive impact and was both statistically and clinically significant in terms of both psychological and physical factors pre-to post-intervention and that these changes were sustained at 3-month follow-up. A one-way repeated measures ANOVA was conducted to determine whether there were statistically significant differences in the measures at the three time points used for data collection; baseline, post intervention and 3-month follow-up.

#### 5.6 One way – ANOVA primary outcome measure - fear of movement measured (TSK)

There was one outlier but the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test ( $p > 0.05$ ), respectively. The assumption of sphericity was not violated, as assessed by Mauchly's test of sphericity,  $\chi^2 (2) = 4.878$ ,  $p = 0.87$ . The physiotherapy pain management intervention elicited statistically significant changes in TSK over time,  $F (2, 68) = 39.593$ ,  $p < 0.001$ . with TSK reducing from  $40.94 \pm 7.13$  baseline to  $34.03 \pm 6.89$  post-intervention to  $33.03 \pm 7.27$  at 3-month follow-up. Post hoc analysis with a Bonferroni adjustment revealed that TSK was statistically significantly decreased from baseline to post-intervention  $-6.91$  (95% CI,  $-9.36$  to  $-4.46$ )  $p < 0.001$ , and from baseline to 3-month follow-up  $-7.91$  (95% CI,  $-10.74$  to  $-5.12$ ),  $p < 0.001$ , but not from post-intervention to 3-month follow-up with a trend  $-1.00$  (95% CI,  $-3.01$  to  $1.00$ ),  $p = 0.06$ .

##### 5.6.1 Pain related disability measured for those with low back pain with (RMDQ)

There were no outliers for the RMDQ and the data was normally distributed. The assumption of sphericity was not violated, as assessed by Mauchly's test of sphericity,  $\chi^2 (2) = 0.892$ ,  $p = 0.50$ . The physiotherapy pain management intervention elicited statistically significant changes in RMDQ over time,  $F(2, 26) = 8.823$ ,  $p < 0.001$ . with RMDQ reducing from  $11.93 \pm 4.12$  baseline to  $9.29 \pm 2.52$  post-intervention to  $8.29 \pm 4.79$  at 3-month follow-up. Post hoc analysis with a Bonferroni adjustment revealed that TSK was statistically significantly decreased from baseline to post-intervention  $-2.64$  (95% CI,  $-4.77$  to  $-.516$ ) to  $p < 0.014$ ), and from baseline to 3-month follow-up  $-3.64$  (95% CI,  $-6.46$  to  $-.83$ ),  $p < 0.011$ , but not from post-intervention to 3-month follow-up with a trend  $-1.00$  (95% CI,  $-1.39$  to  $3.39$ ),  $p = 0.81$ .

#### 5.6.2 Pain-related disability measured for those with widespread pain with (PDQ)

There was one outlier for the PDQ and the data was not normally distributed, as assessed by boxplot and Shapiro-Wilk test ( $p < 0.05$ ), respectively. The assumption of sphericity was also violated, as assessed by Mauchly's test of sphericity. Therefore a Friedman test was run to determine if there were differences in disability measured with the PDQ. Pairwise comparisons were performed with a Bonferroni correction for multiple comparisons. PDQ reduction was statistically significantly different at the different time points during the physiotherapy intervention,  $\chi^2(2) = 19.60$ ,  $p < 0.001$ . Post hoc analysis revealed statistically significant differences in PDQ from pre- (Mdn = 113.50) to post-intervention (Mdn = 98.50) ( $p < 0.001$ ) and pre to follow-up (Mdn = 83.50) ( $p = 0.002$ ), but not post-intervention and follow-up ( $p=1.00$ ). The result also represents an overall change from extreme disability (101-150) to moderate disability (71-100) at the end of the study.

#### 5.6.3 Depression measured with HADS

There was one outlier but the data was normally distributed, as assessed by boxplot and Shapiro-Wilk test ( $p > 0.05$ ), respectively. The assumption of sphericity was not violated, as assessed by Mauchly's test of sphericity,  $\chi^2(2) = 1.43$ ,  $p = 0.48$ . The physiotherapy pain management intervention elicited statistically significant changes in depression over time,  $F(2, 64) = 30.02$ ,  $p < 0.001$  with depression reducing from  $9.61 \pm 3.80$  baseline to  $7.30 \pm 3.41$  post-intervention to  $6.33 \pm 3.83$  at 3-month follow-up. Post hoc analysis with a Bonferroni adjustment revealed that depression was statistically significantly decreased from baseline to post-intervention  $-2.30$  (95% CI,  $-3.28$  to  $-1.32$ )  $p < 0.001$ , and from baseline to 3-month follow-up  $-3.27$  (95% CI,  $-4.39$  to  $2.16$ ),  $p = < 0.001$ , but not from post-intervention to 3-month follow-up  $-0.970$  (95% CI,  $-0.21$  to  $2.15$ ),  $p=0.12$ . The change in depression brings the mean score below 10 which has been suggested to be the cut-off point for referral for management to mental health services for depression and is therefore an important change score for a physiotherapy-led intervention.

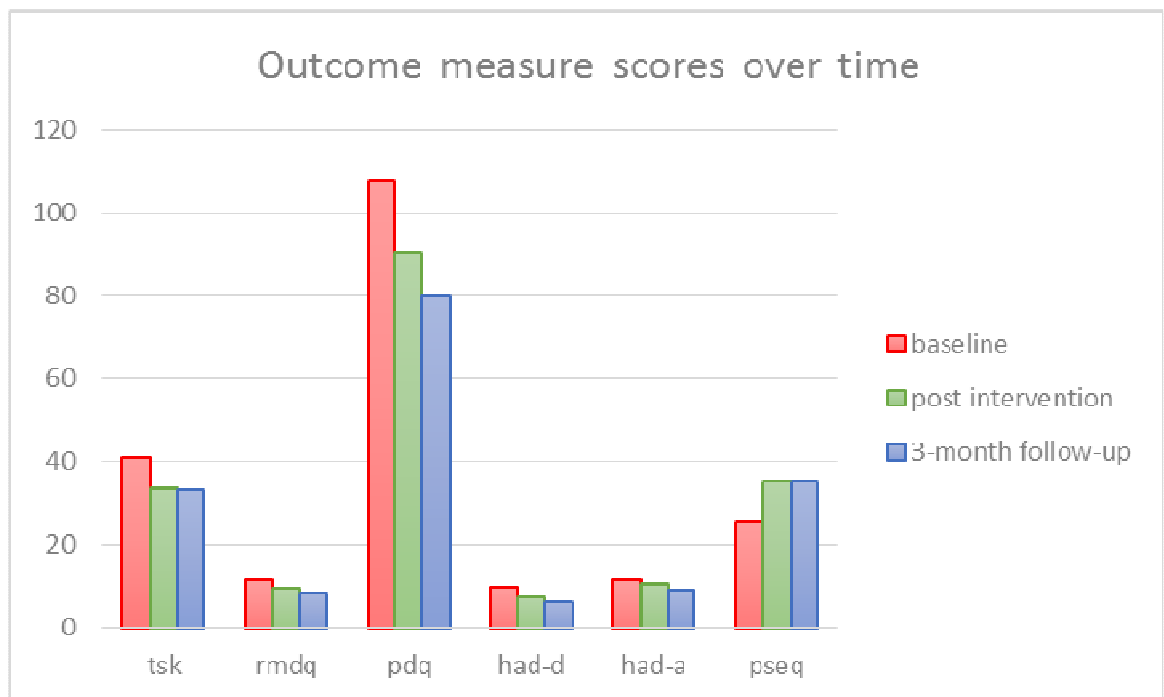
The repeated measures ANOVA has shown that changes pre-to post-intervention and pre-to follow-up were statistically significant but that there was no statistically



significant difference between post intervention to follow-up. This indicates that improvements were maintained at medium term follow-up.

Figure 2 shows patient reported outcome measures (PROMS) from baseline to 3-month follow-up.

Figure 2 - Outcome measure scores over time for PROMs



### 5.7 Analysis of patient-reported measures between condition types

The second part of the data analysis was performed to determine whether there were significant differences in change scores between the different condition types; low back pain and multi-site pain, following the intervention. The current evidence suggests that physiotherapy-led interventions for chronic low back pain are effective however there is no evidence to suggest that physiotherapy-led group intervention for mixed condition types are effective.

Table 5.6 shows the pre- to post-change scores with mean changes for condition type.

Table 5.6 - Differences in self-report and physical function tests between condition types

Variable	Low back pain (n=17) pre-score	Low back pain (n=17) post score	Mean change score	t-test	P value	Multi-site pain (n=36) Pre score	Multi-site pain (n=36) Post score	Mean change score	t-test	P value
<b>TSK</b>	38.84 (7.24)	32.63 (6.53)	-6.21 (3.98)	6.80	.001	42.09 (6.77)	34.18 (7.77)	-7.91 (6.56)	7.04	<.001
<b>HADS-A</b>	10.20 (4.77)	8.95 (3.50)	-1.33 (2.60)	2.36	.030	12.76 (3.75)	11.48	-1.28 (3.22)	2.27	<.030
<b>HADS-D</b>	7.83 (3.55)	5.79 (3.17)	-2.04 (2.21)	4.26	.001	10.85 (3.19)	8.33 (2.87)	-2.52 (2.50)	5.78	<.001
<b>RMDQ</b>	11.95 (4.39)	9.21 (3.58)	-2.74 (2.88)	4.14	.001	n/a	n/a	n/a	n/a	n/a
<b>PDQ</b>	n/a	n/a	n/a	n/a	n/a	107.56 (19.92)	90.41 (27.52)	-17.15 (17.46)	2.94	<.001
<b>PSEQ</b>	32.28 (12.19)	41.58 (10.75)	9.28 (11.17)	- 3.52	.003	21.79 (10.76)	32.29 (11.27)	10.50 (8.61)	- 7.11	<.001
<b>20m walk</b>	18.35 (8.40)	15.13 (8.33)	3.22 (5.78)	2.39	.30	23.35 (12.51)	19.31 (17.32)	4.04 (8.32)	2.94	<.006
<b>5 min Walk</b>	307.06 (113.35)	337.50 (124.12)	30.44 (79.83)	- 1.75	.10	240.62 (89.15)	268.75 (87.39)	28.13 (53.00)	- 3.00	<.001
<b>Step ups</b>	22.90 (9.08)	30.81 (11.65)	8.22 (7.63)	- 4.22	.001	17.06 (5.89)	21.22 (6.08)	4.16 (3.63)	- 6.83	<.001

TSK, Tampa scale of Kinesiophobia; HADS, Hospital Anxiety and Depression Scale; RMDQ, Roland Morris Disability Questionnaire; PDQ, Pain Disability Questionnaire; PSEQ, Pain Self-efficacy questionnaire; 20m, speed of walking in seconds over 20 metres; 5min, distance walked in 5 minutes measured in metres; step ups, total number of step ups in 1 minute.

Data are mean  $\pm$  standard deviation, unless otherwise stated. There were 19 participants with low back pain and 34 chronic widespread pain participants. Analysis was not performed on pain-related disability as there were no comparable groups i.e. different outcome measures used dependent on pain site, (RMDQ or PDQ).

An independent-samples t-test was run to determine if there were differences in outcome to a physiotherapy-led pain management intervention between participants with low back pain and chronic widespread pain. There were no outliers in the TSK and PSEQ data, as assessed by inspection of a boxplot. TSK and PSEQ scores for each condition were normally distributed, as assessed by Shapiro-Wilk's test ( $p > 0.05$ ),

and there was homogeneity of variances, as assessed by Levene's test for equality of variances ( $p = 0.77$  and  $0.18$  respectively). Fear of movement reduced more for participants with CWP ( $-6.21 \pm 3.98$ ) than LBP participants ( $-7.91 \pm 6.55$ ), however this was not statistically significant  $-1.71$  (95% CI,  $-1.62$  to  $5.03$ ),  $t(51) = 1.02$ ,  $p = 0.31$ . Similarly PSEQ improved more for CWP participants ( $10.50 \pm 8.61$ ) than LBP participants ( $9.28 \pm 11.17$ ). Again, this was not statistically different  $-1.22$  (95% CI,  $-6.82$  to  $4.37$ ),  $t(50) = -0.43$ ,  $p = 0.66$ .

Table 5.7 - Between-groups changes by condition type; low back pain versus multi-site pain

Variable name	Low back pain Mean change Baseline to post score	Multi-site pain mean change from baseline to post score	Independent- samples t-test, p value
Fear of movement/re-injury (TSK)	6.21 (3.98)	7.91 (6.56)	$t=1.028$ $p=0.30$
Self-efficacy (PSEQ)	9.28 (11.17)	10.50 (8.61)	$t= -.439$ $p=0.66$

TSK, Tampa scale of Kinesiophobia; PSEQ, Pain Self-efficacy questionnaire.

There were two outliers in HAD Anxiety and depression data, in addition to all of the physical function tests and therefore a Mann-Whitney U test was run to determine if there were differences in HAD and physical function test scores between CWP and LBP. Distributions of the HAD and physical function scores for CWP and LBP were similar, as assessed by visual inspection. Median HAD-A score for CWP (1.00) and LBP (2.00) were not statistically significantly different,  $U = 304$ ,  $z = 0.139$ ,  $p = 0.88$ , using an exact sampling distribution for U (Dineen and Blakesley, 1973).

Median HAD-D score for CWP (2.00) and LBP (3.00) was not statistically significantly different,  $U = 266$ ,  $z = -0.616$ ,  $p = 0.538$ . Similarly, median physical tests for timed 20 metre walk, 5 minute walk and step-up score were not statistically significant; 20 metre, CWP (2.50) and LBP (2.00), ( $U = 243$ ,  $z = -0.113$ ,  $p=0.91$ ); 5 minute walk CWP and LBP (40.00), ( $U = 247.50$ ,  $z = -0.189$ ,  $p=0.85$ ) and finally step up score for CWP (4.00) and LBP (6.50),  $U = 198$ ,  $z = -0.112$ ,  $p=0.26$ .

The results from the independent t-test and Mann-Whitney U tests suggest that there was no statistically significant difference in outcomes between the two condition types; CWP and LBP, receiving the same physiotherapy-led pain management intervention.

## 6 Discussion

### 6.1 Aims and overview of findings

This study aimed to determine what effects a 5-week physiotherapy-led group intervention based on IBMT principles had in reducing fear avoidance, anxiety and depression and improving self-efficacy and physical function in patients with chronic pain. Furthermore, the study examined the medium-term effects of the group therapy with 3-months follow-up.

### 6.2 Summary of Key findings from Phase 2

The physiotherapy-led intervention produced clinically and statistically significant changes at short (pre to post intervention) which were sustained at medium term (3-month post-intervention) in pain related disability, fear of movement and self-efficacy.

There were statistically significant changes were observed for depression, anxiety and physical function however no MCID exists for these measures to determine whether the changes were clinically significant. These changes were observed during the intervention period.

However, no significant change in scores on any measures was observed from post intervention to 3-month. One potential explanation for this may be plateauing or consolidation of effect from the intervention in which the patients are confidence enough to apply it into their daily functioning. Further studies are needed.

As in phase 1, no difference in scores (TSK, PSEQ, HAD-A and -D) were observed between condition types (low back pain and widespread pain) providing further evidence that a physiotherapy-led intervention with a mixed aetiology group can produce positive changes.

#### 6.2.1 Patient characteristics

Those who completed the intervention had a female predominance in all groups analysed; 84.9% overall; 72.7% primary care and 93.5% secondary care. This was expected as females have a higher reporting incidence of pain and multi-site pain, (Blyth et al. 2010, cited in Croft et al. 2010). There is a local need to evaluate why men do not access the service, or to determine whether their requirements are

different, i.e. a preference to individual management or male-only groups, location etc.

This study had no upper age limit during recruitment of the study. Despite this, the mean age of the patients was 51.6 years. There was a no statistically significant difference between patients referred from primary care, mean age 54.6 years, compared to secondary care; 49.7 years despite over a third of the patients (37.7%) being retired. In other studies who investigated patients with chronic pain with no upper age limit (Cecchi et al. 2010; Armis et al. 2014) similar findings were reported. In contrast studies that investigated patients with chronic arthritis pain reported higher mean ages, 67 years (Jessep et al. 2009), and 73.9 years (Nicholas et al. 2013) respectively. This indicates that degenerative arthritis are most likely to affect the older age group compared to patients with widespread pain (Van Hecke et al. 2013). The exact mechanisms for these differences are unclear. However, those of working age appear to be more likely to seek treatment because chronic pain is most likely to interfere with their daily activities. Detailed examination of the data revealed that 41.4% of the patients were not working and this increased with those referred from secondary care (48.4%). They also exhibited higher levels of pain-related disability, fear avoidance, depression and anxiety. Additionally, patients from secondary care had lower physical function, as measured by walking and step-up repetition. It is possible patients who are referred from secondary care have more ill-health as they were most likely to have one or more comorbid diseases with 51.6% compared to primary care 36.4%. An alternative explanation might be the secondary care group with higher psycho-social factors identified on outcome measures are communicating through non-verbal behaviour that they are in pain. This is a common presentation in people suffering with chronic pain and includes protective behaviour such as slower movement, grimacing, sighing, supporting areas of pain and rubbing themselves (Aung et al. 2015).

#### 6.2.2 Fear avoidance

Movement is essential for daily life. The presence of fear, related to movement and re-injury, has been suggested to be one of the mechanisms by which pain-related disability continues. This may interfere in daily activities in patients with chronic pain

(Vlaeyen et al. 1995). However, the direction of the relationship between fear of movement and disability is unclear. Roelofs et al. (2004) suggests that fear of movement can affect mood, self-confidence and increase pain-related disability and vice versa create resulting in a 'vicious cycle'. There is currently no research that defines the level of severity of fear of movement measured by the TSK. The finding of this study with mean TSK baseline score was 40.9; which was similar to other physiotherapy-led studies at baseline was, 40.7 (Hay et al. 2005); 39.5 (Woby et al. 2008), and 39.2 in the medium risk group (Hill et al. 2011) with comparable settings. Furthermore, the baseline score was similar to normative data for a chronic pain cohort compiled by (Nicholas et al. 2008). Their data was taken from a sample of 5,941 Australian patients with chronic pain referred to secondary or tertiary care specialist pain services, low back pain 41.4; and multi-site pain 42.3. Although the figures from (Nicholas et al. 2008) are drawn from a specialist pain service, the TSK score was not significantly different from the studies mentioned above. This would suggest that TSK scores above 40 are reflective of a significant level of fear-related movement enough to effect daily activities. In addition there is no recognised Minimal Clinically Important Difference (MCID) for TSK, though (Woby et al. 2009) suggest a change of 4 points to be clinically significant. The current study reports a mean change of -7.30; ( $40.92 \pm 7.05$ ) to post-intervention ( $33.62 \pm 7.33$ ) which equates to a large effect size score,  $d = 1.26$ . This reduction was also maintained from baseline to 3-month follow-up; a change score of -7.91. This score change was larger than observed in (Woby et al. 2008) 4.6, and (Hill et al. 2011) who reported a mean change of 5.5 in their intervention group, respectively. Hansen et al. (2010) commented that studies with pre and post study designs results should be approached with caution as they do not have control groups for comparison. This caution notwithstanding, however, the prospective phase of this study did include a medium term follow-up and observed the changes were sustained. Interestingly, Roelofs et al. (2011) reported the results of their study to develop norms for TSK using data from 3,082 Dutch, Swedish and Canadian patients with chronic pain. They found an overall mean of 42 but reported patients with low back pain had higher TSK scores (43.2) compared to those with fibromyalgia and multi-site pain (36.6). However the finding of this study did not show this trend as mean TSK score for low

back pain was (38.8), which was lower than for fibromyalgia or multi-site pain (42.1). These differences between the different studies might be due to the perception of fear avoidance in different cultures and social norms accepted in the community. Thus, further study is needed to examine the impact of these factors in patients with chronic pain with long-term study.

### 6.2.3 Depression

Depression is known to be both a risk factor and a consequence of living with chronic pain. Linton et al. (2011) report that it is still unclear as to why its presence is a risk factor for poor outcome following an intervention. This study found that the baseline mean score for depression was (9.8). Crawford et al. (2001) suggest that patients with depression scores above ten would benefit from a referral to psychological services for treatment. If patients are not treated adequately, depression might be a confounding factor for poor compliance to rehabilitation outcomes. It is gratifying in this study to observe that the physiotherapy-led pain programme produced changes in ameliorating depression from baseline score (9.8) to 3-month follow-up (6.3); an overall change of -3.5. Although there are no MCID for the HAD the reduced mean score is within levels reported by (Crawford et al. 2001) as normal (0-7). This reduction in depression was higher than reported in previous studies (Woby et al. 2008; Hill et al. 2011). The potential explanation for the significant improvements may include that all patients were compliant to the full programme and completed the 5-weeks therapy. First, the IBMT approach used in this physiotherapy-led intervention may have reconceptualised the fear of movement for the patients to engage with the exercise aspect of the programme which in turn may have had a short-term 'feel good factor' on their psychological well-being. Secondly, the group exercise programme was designed and tested in the phase 1 study, so was known to be acceptable, appropriate whilst still providing graded exposure to address fear of movement for this patient group. Furthermore, the peer support during or outside the exercise programme may have helped the patients to share their experiences, to gain confidence and persevere with the exercise programme. Third, the educational component of the programme may have specifically addressed some of the fear and misconception of pain, which may have demystified some of the barriers for patients to engage with the exercise programme, this was a reported finding in (Moseley et al.



2004). However, the last assertion may require further testing in larger sample in longitudinal follow-up study.

However, when the group was split with condition type, it was clear that those with multi-site or fibromyalgia had a higher baseline score of depression (10.9) compared to low back pain (7.8). The change scores observed in low back pain of 2.5 and multi-site pain of 2.0 at 5-weeks were sustained at 3-month follow-up. The differences between the two groups were small and not statistically different. These findings give some evidence for physiotherapists that an IBMT approach in a group setting had some effects in reducing depressive symptoms. However it also highlights that patients identified with elevated depressive symptoms should be referred for psychological therapy where appropriate.

#### 6.2.4 Anxiety

The anxiety baseline score in this study was 11.9; over the level that Crawford et.al (2001) suggests referral to mental health services. The score was also higher than the mean score for the high risk group in the STaRT back (Hill et al. 2011). This study's intervention produced change from 11.9 baseline to 9.2, which was a mean change of -2.7 at 3-month follow-up. Again, these changes were statistically significant and potentially clinically significant, but no MCID exists. The high score may be indicative of the cohort's mix from both primary and secondary care. Baseline anxiety scores were higher in secondary care (14.0) compared to primary care (10.6). Additionally, although this study reported statistical and clinically significant changes for both fear avoidance behaviour (TSK) and depression, the changes in anxiety, as measured by the HADS, was smaller. Whether subgroups of patients e.g. from the secondary care may benefit more from this type of specific treatment is still unclear and requires further study. Having said this, there were no group differences between the two groups in baseline demographic characteristics. The alternative explanation might be fear avoidance, although a type of anxiety is specific to movement might be different, whilst the HADS measures generalised health related anxiety may not be specific to pain. Thus, further studies are needed. Interestingly (Crawford et al. 2001) found that in their non-clinical sample, mean anxiety was 6.14 whilst depression was only 3.68, suggesting anxiety is more prevalent in the general population anyway. If anxiety is

higher in a non-clinical sample it is possible that anxiety will be higher in a clinical sample too, the results of this study viewed in this context are therefore not to be expected.

#### 6.2.5 Self-efficacy

Nicholas (2007) suggests the importance of using self-efficacy (PSEQ) scores as both a useful screening tool as well as an outcome measure for interventions. In terms of a screening tool he suggests a very low score defined as <17 would require individual treatment prior to attending a pain programme to address pain belief systems. However, those with a high score >40 might not require a pain management programme approach and the reason for them seeking treatment would be better explored on an individual basis. Based on these suggestions, 26% (14/53 of participants in this study) had baseline scores under 17, and 11% (6/53) scored >40, and would potentially be excluded, leaving only 62% 33/53 of this study cohort. Post-intervention scores revealed that only 4% (2/53) had scores <17 and 40% (21/53) had scores >40. Furthermore, at 3-month follow-up, no participants had a PSEQ under 17 and 49% (17/35) had scores >40. In addition (Nicholas, 2007) discusses that, post-intervention, a participant who makes behavioural changes but does not score >40 is still at potential risk of relapsing and probably requires follow-up or monitoring. The overall mean score in this study changed from baseline (25.42) to post-intervention (35.62) to 3-month follow-up (39.40) indicating a statistically and clinically significant change score was observed. As all the patients in the study have improved in their self-efficacy, the findings may have relevance to the management of pain in patients with chronic diseases.

#### 6.2.6 Pain-related disability measured with the Pain disability questionnaire for multi-site pain and Roland Morris Disability Questionnaire, RMDQ, for low back pain

Physiotherapy-led interventions for chronic low back report large changes in pain-related disability using the RMDQ. Studies using an RCT design (Hay et al. 2005; Critchley et al. 2007; Hill et al. 2011), report large change scores from 5.3 to 6.8 and these were sustained to at least 12-month follow-up. The cohorts used in these studies were mainly primary care and in the specific case of (Hill et al. 2011) patients had psychological risk factors identified prior to intervention. Although (Lamb et al. 2012) had a cohort similar to the medium risk group, in (Hill et al. 2011) the mean

change score was lower at 2.9, although this improvement was sustained to extended follow-up of 36 months (range 20-50 months). This study reports a mean change from the phase 1 preliminary study of -4.5. However, the prospective study produced a change score of 3.4 which, although lower, had a smaller low back pain sample (n=18 compared to n=81). The significance of the change score in this study was despite addressing a mixed condition group; the change in pain-related disability for low back pain was comparable to that observed in (Woby et al. 2008) with a chronic low back pain-only programme. The ANOVA analysis revealed there was no statistical difference between any of the patient-reported outcome measures between the condition types, providing further evidence of the effects of the intervention for a mixed condition group.

Gatchel et al. (2006) reported changes in the level of self-reported disability using the PDQ in a cohort of patients with chronic musculoskeletal pain following an interdisciplinary pain management programme. The PDQ score is divided into three distinct categories; mild/moderate (scores of 0-70); severe (scores of 71-100); and extreme (scores 101-150). Gatchel et al. (2006) report that 85% of their sample were in either the severe or extreme category. This study found that 93% of the sample fell into these categories; (69% extreme; 24% severe). Post-intervention the change score was both statistically significant from baseline to 3-month follow-up and resulted in a change of severity category which suggests a clinical improvement in function, 44% remained extreme and 32% severe. This reduced further at 3-month follow-up; only 10% in extreme category and 65% in severe. Gatchel et al. (2006) report their intensive multi-disciplinary team intervention resulted in only 7% of their cohort remaining in the extreme category and 56% in the mild/moderate category. This study found 25% in the mild/moderate group at 3-month follow-up compared to 7% pre-intervention. Despite these differences in outcome, there was a similar trend in reduction of PDQ scores in both studies. It is positive that the results from the current study are comparable to the findings in (Gatchel et al. 2006). They show that with an equally disabled cohort, significant changes in severity of functional disability are observed and sustained despite the intervention being a physiotherapy-led

programme compared to (Gatchel et al. 2006) using an intensive multi-disciplinary team intervention.

### 6.3 Physical function (measured with step-up repetitions and walking tests; speed and distance)

In this study, both speed and distance of walking, in addition to number of step-ups performed in one minute, have changed following the intervention. There was an 11% change in distance and 22% change in speed of walking, in addition to a 30% change in step-up repetitions. These changes were comparable to (Marcus et al. 2014) who reported similar changes in a cohort of patients with fibromyalgia. They also highlighted the benefit of using physical function tests as their study observed no changes in patient-reported outcome measures. Furthermore, (Moseley et al. 2004) reported a significant improvement in physical function following a pain education session alone and suggest that improvements in physical function are not solely related to the effects of physical training but also changes in cognitive processes, i.e. reduced fear, improved confidence and self-efficacy. The physical tests chosen for this study are considered to be a good representation of everyday activities i.e. walking and climbing stairs, and are potentially meaningful for the patient. Harding et al. (1994) suggests that adding physical function tests provides quality to outcome measurement in chronic pain management services.

### 6.4 Critique of methodology and limitations of study

When considering the apparent effects of this physiotherapy-led intervention there are methodological limitations to the generalisability of the findings. Firstly, the study used a non-experimental study design which (Sim and Wright, 2000) discuss is a threat to both internal and external validity. In the absence of a control or comparison group it is feasible that the same results might have been obtained with individual physiotherapy intervention or natural history rather than the intervention, per se. Both (Woby et al. 2008) and (Sowden et al. 2008) highlighted this as a similar limitation in their studies. However, unsolicited informal verbal feedback received from the participants indicate their appreciation of the programme and that it was helpful in the change they have observed in their physical functioning and ability to engage more in social activities see page 55. A future study might choose a mixed methodological approach to combine patient-reported outcome measures with a

qualitative study to capture any behavioural changes observed after the intervention. There was a 34% dropout from post-intervention to 3-month follow up this was similar to (Critchley et al. 2007; Johnson et al. 2007). In contrast to (Wells-Federman et al. 2002) who reported a 46% attrition rate in their cohort and suggested that this rate was consistent with other studies using a group-based CBT approach. Despite the small sample size, retaining 100% of the cohort in pre-post intervention is positive and may represent satisfaction with the intervention or, potentially, a Hawthorne effect of being part of a research trial and an attempt by participants to please the researchers; this was reported by (Coleman et al. 2014). In addition, those who dropped out of the study post-intervention were more likely to have no additional co-morbidities (77.8%), be referred from secondary care 70.1%, and not working 55.6%. Baseline scores indicated only self-efficacy 22.9 compared to 26.7 and pain-related disability RMDQ, 11.07 compared to 14.1, but these findings were not statistically significant. This suggests that those who dropped out of the study were not different from those who continued from pre- to 3-month follow-up. Unfortunately, this service led intervention was constrained with financial, time and manpower resources for close follow-up of patients after the intervention. Future studies should consider a maintenance programme or telephone contacts in how the patients were engaging with the exercise programme and other lifestyle changes known to be effective in self-management of long-term conditions. Finally, consideration should be given for future studies to include economic analysis of the intervention compared with control group using clinically relevant outcome measures. It is critical that in the face of growing pressures on health services that nay treatments offered provide both the best clinical and cost effective care that are available.

The results from both the preliminary phase 1 on page 55 and the prospective phase suggest that the physiotherapy-led intervention produced positive changes in reducing cognitive and physical factors associated with chronic musculoskeletal pain and there does not appear to be a statistically significant difference in outcomes between different condition types. This is potentially important as previous research trials examining physiotherapists delivering a pain management approach have

focussed on specific condition groups: low back pain (Critchley et al. 2007; Hill et al. 2011; Lamb et al. 2012) and osteoarthritis (Jessep et al. 2009; Coleman et al. 2012). However, caution is required in the interpretation of the findings. 1) The pre-experimental design meant blinding the patients and the treatment team was not possible. 2) The therapists were part of the treatment team, but they were blinded from administering and scoring the outcome measures to avoid bias. 3) The study was conducted in a single centre study compared to previous studies, which are multi-centred studies with large sample size of participants (Lamb et al. 2012; Coleman et al. 2012). 4) There was no control group for comparison of findings. Finally, the study followed patients only for three months. Thus, the longer-term efficacy of intervention at 6 and 12 months are worthy of consideration e.g. return to work.

#### 6.5 Clinical implications

This study was undertaken to review and provide evidence that the current service provision of a mixed aetiology pain management programme delivered by physiotherapists had potential positive clinical effects. It has expanded on the original intervention 'Work Back to Life', described by (Woby et al. 2008) to offer a physiotherapy-led intervention for participants with any chronic musculoskeletal pain, rather than to a limited low back pain cohort which, based on the author's department, only account for 30% of the total referrals. This study also looked at medium-term effects of the intervention by reviewing the outcome measures at 3-months post-intervention. The study found that all improvements in outcome measures were sustained at follow-up review, however the size of change was only significant from pre- to post-intervention and pre-intervention to follow-up but not significant from post-intervention to follow-up. This possibly suggests that participants are either plateauing or consolidating their pain management skills, or no further change will occur, or even that they are starting to relapse. Hansen et al. (2010) suggested a review was important as most significant changes occur immediately post-interventions and therefore their efficacy can be exaggerated. The review process is also supported in the UK Map of Medicines (2013) pathways for pain and in the British Pain Society (2013) pain management programmes guidelines

for adults. A 12-month review of efficacy would be beneficial, but was not possible due to the time limitations of this study. In addition, when exploring the use of cut-off scores for the PSEQ, there is potential of identifying patients who are likely to relapse based on their post-intervention self-efficacy score (Nicholas et al. 2007). This requires consideration as to be able to identify those patients who are likely to relapse would be advantageous for cost and future health care planning.

#### 6.6 Suggestion for future research

Future randomised control trials should investigate the efficacy of the intervention in comparison to individual therapy or an alternative group intervention without CBT principles in a larger sample is recommended. However, Jessep et al. (2009) suggested that, despite using an RCT design, interventions that are interactive are difficult to replicate in strict research protocols. Whilst this is a further issue that effects the generalizability of the results, it also means that such interventions can be highly adaptable in the real-life clinical setting and this could be interpreted as a positive consequence.

One of the clinical aims of this study was to establish a referral pathway for those patients whose level of psychological distress might require additional management. The introduction of the HADS has enabled collection of data on the level of psychological distress in the patient population this intervention serves and to monitor the level pre- to post-intervention. As a result, there are now closer links with primary care partners in mental health services and a referral pathway has been established. There are also developments for primary care mental health services in Bury called 'healthy minds' which offer a taster session within the current physiotherapy programme of mindfulness, an evidence based mediation strategy for people with chronic pain and other conditions. Further studies should also consider the efficacy of physiotherapy-led group intervention based on IBMT principles training opportunities for physiotherapists working in primary care to improve their clinical practice in referring patients to secondary care.

## 6.7 Conclusion

The physiotherapy-led group intervention based on IBMT principles had an effect on reducing fear avoidance, disability, anxiety and depression whilst increasing self-efficacy and physical function in patients with chronic pain.

There is potential that physiotherapists can play a leading role in the development of accessible and cost-effective pain management interventions and services for people with chronic musculoskeletal pain. This study adds to the body of literature suggesting that physiotherapists have the skills to be able to manage patients with a range of psycho-social factors that are currently considered complex and requiring specialist service input. In view of the increasing incidence of chronic pain, combined with an ageing population, the necessity to review current service specification and delivery requires careful consideration. In addition exploring professional boundaries to ensure that health providers can deal with the crisis and people access timely and effective services to enable them to live well, despite pain. This change will require the physiotherapy profession to expand their practice and will have implications for undergraduate education to enable effective workforce planning for the NHS to effectively address the growing problem of chronic pain.



## 7 Overall summary and conclusions

### 7.1 Summary of Phase 1 and 2 studies

This thesis set out to broadly explore the changes, on patient reported outcome measures, which occurred for participants attending a local non-specialist physiotherapy-led chronic pain management group. In phase 1 a review of the current service provision, the Functional Rehabilitation Programme (FRP), at the outpatient physiotherapy department of Pennine acute NHS trust was explored. FRP had been set up in response to increasing numbers of chronic pain referrals, an emerging awareness of the limitations of 'traditional' physiotherapy i.e. 'hands on' mobilisations, electrotherapy, and exercise regimes in addition to the well documented growing healthcare of chronic long term pain (Nicholas, 2015). Initially the programme had been based on the work of (Woby et al. 2008) who observed positive changes with a type of psychologically informed physiotherapy practice termed Interactive Behavioural Modification Therapy (IBMT). One of the main limitations of this approach clinically was the restriction of the approach to patients with chronic low back pain only. An informal 'trial' took place at Fairfield general hospital to ascertain whether the same group intervention using IBMT could produce similar positive changes to those found that (Woby et al. 2008), in a group of patients with mixed chronic pain aetiology. Due to the lack of evidence found for this type of physiotherapy-led intervention in the literature review, a retrospective study -phase 1, was undertaken with the main aims of;

- To evaluate a range of patient reported outcome measures, (PROMS), in terms of clinical and/or statistical of a physiotherapy-led functional restoration programme for patients with persistent musculoskeletal pain in an outpatient setting.
- The secondary objective was to evaluate if there were significant differences in the outcomes between the two condition types (low back pain and widespread pain).
- Finally to determine the sample size for the phase two prospective study

There were several limitations of phase one which have been discussed in full in chapter 2. The most significant limitations included methodological issues, no control group, retrospective data, and incomplete data sets. Despite the limitations of the

phase 1 preliminary evidence was gathered that the intervention appeared to be producing positive changes in the PROMS. However it was acknowledged that changes are most commonly observed from pre to post intervention and are not necessarily attributable to the intervention itself, (Hansen et al. 2010).

Key findings from phase 1 (taken from section 2.11)

- The physiotherapy-led intervention produced clinically and statistically significant short term (pre to post) changes in low back pain related disability (RMDQ) and fear of movement in a cohort of patients with chronic MSK pain.
- Improvements were also observed in pain-related disability for widespread pain (PDQ) and for catastrophizing. Due to the lack of MCID established for these outcome measures it is unclear as to whether the change scores observed were clinically significant however both were statistically significant,  $p < 0.001$ .
- No difference in scores (TSK and Cat-A only) were observed between condition types (low back pain and widespread pain) suggesting that a physiotherapy-led intervention with a mixed aetiology group can produce positive changes. This last observation has potential clinical significance. Chapter 2 highlighted that most physiotherapy research in chronic pain group management has focused on either classes/groups for low back pain or osteoarthritis but not a mixed aetiology chronic pain group.
- Finally, although informal, qualitative responses from participants from the group appear to support changes observed on the PROMS in relation to behaviour and lifestyle changes.

Despite the acknowledged limitations of phase 1, the key findings were used to develop the protocol for the prospective phase 2 section of the thesis. Phase 2 used the preliminary evidence gained from phase 1 and looked to evaluate further the changes that occurred in a broader range of dimensions in the PROMS to capture the multi-faceted nature of chronic pain. A number of physical function tests was also included to measure physical performance. The additional dimensions explored in phase 2 included participants self-efficacy, their confidence to continue with everyday activities despite having pain. Self-efficacy has been described as a core

strategy for effective management of any long term condition (Nicholas, 2015). Additionally the HAD was used to capture information on levels of depression and anxiety within the cohort and observing changes between the different time points. Depression is traditionally seen as an area that physiotherapists do not feel confident about managing and where resources allow refer on to specialist psychological services (Woby et al. 2008). However to enable appropriate referrals and establish the requirements for specialist services more information was required for both clinicians and commissioners on the presence and severity of psychological distress in this patient population.

The key aims of phase 2;

- To explore the changes in fear avoidance, disability, depression and increase in self-efficacy at pre to post 5 weeks intervention following a physiotherapist-led, group-based intervention for patients with chronic musculoskeletal (CMSK) pain.
- To explore the medium-term benefits of the group-based intervention on the same outcomes at 3-month follow-up and to investigate differences between outcomes in terms of condition type and referral sources

One of the key findings from phase 2 suggest that physiotherapy can also have a positive effect on aspects of mood and self-efficacy. However although statistically significant changes were observed for depression and anxiety there are no MCID for the HADS measure to determine whether the changes were clinically significant. Overall the findings from phase 2 are comparable to those found in phase 1. The intervention again produced clinically and statistically significant changes at short (pre to post intervention) but in contrast to phase 1, which had no follow-up, were sustained at medium term (3-month post-intervention) in pain related disability, fear of movement and self-efficacy. Interestingly the changes were observed at pre to post and from pre to follow up. No significant change in scores on any measure was observed from post intervention to 3-month. One explanation may be plateauing or consolidation of effect from the intervention. Finally as in phase 1, no difference in scores (TSK, PSEQ, HAD-A and -D) were observed between condition types (low back pain and widespread pain) providing further evidence that a physiotherapy-led

intervention with a mixed chronic pain aetiology group can produce positive changes in PROMS and physical function.

The climate for healthcare service provision is changing with more competition faced by the NHS from private providers for core services. It is envisaged that the findings from this thesis will be discussed in relation to service development for local pain management services and further research including cost analysis and use of a parallel control group will be undertaken to contribute further to this important area of potential expansion for the physiotherapy profession. Further research into long-term condition management will ensure that physiotherapists and physiotherapy-led services continue to contribute and play a lead role in this important and changing area of health care provision.

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## 9 Appendices

Appendix 1 – Results for the database search carried out on 23/03/2015

No	Search term	AMED and MEDLINE via OVID	CINAHL	SCOPUS	Science direct	MEDLINE	Cochrane
1	Physiotherap* OR Physical therap*	18,881	40,883	144,974	14,989	29,568	33,058
2	"CBT" OR "CBT approach" OR "cog behave ther" OR behav* thera*	1,874	9,591	144,840	2,491	19,656	35,766
3	"chronic pain" OR "persistent pain" OR pain OR "low back pain"	12,632	124,252	73,715	3,084	37,296	7,771
4	"group therapy" OR group OR program* OR class OR "group treatment"	9,170	408,702	2,954,184	155,297	2,457,384	356,721
5	1 & 3 & 4	31	1,959	2,902	74	779	440
6	5 & 2	31	71	80	87	30	190

## Appendix 2 - PEDro scale

### PEDro scale

---

1. eligibility criteria were specified	no <input type="checkbox"/> yes <input type="checkbox"/> where:
2. subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no <input type="checkbox"/> yes <input type="checkbox"/> where:
3. allocation was concealed	no <input type="checkbox"/> yes <input type="checkbox"/> where:
4. the groups were similar at baseline regarding the most important prognostic indicators	no <input type="checkbox"/> yes <input type="checkbox"/> where:
5. there was blinding of all subjects	no <input type="checkbox"/> yes <input type="checkbox"/> where:
6. there was blinding of all therapists who administered the therapy	no <input type="checkbox"/> yes <input type="checkbox"/> where:
7. there was blinding of all assessors who measured at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:
8. measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no <input type="checkbox"/> yes <input type="checkbox"/> where:
9. all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no <input type="checkbox"/> yes <input type="checkbox"/> where:
10. the results of between-group statistical comparisons are reported for at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:
11. the study provides both point measures and measures of variability for at least one key outcome	no <input type="checkbox"/> yes <input type="checkbox"/> where:

---

The PEDro scale is based on the Delphi list developed by Verhagen and colleagues at the Department of Epidemiology, University of Maastricht (Verhagen AP *et al* (1998). *The Delphi list: a criteria list for quality assessment of randomised clinical trials for conducting systematic reviews developed by Delphi consensus. Journal of Clinical Epidemiology*, 51(12):1235-41). The list is based on "expert consensus" not, for the most part, on empirical data. Two additional items not on the Delphi list (PEDro scale items 8 and 10) have been included in the PEDro scale. As more empirical data comes to hand it may become possible to "weight" scale items so that the PEDro score reflects the importance of individual scale items.

The purpose of the PEDro scale is to help the users of the PEDro database rapidly identify which of the known or suspected randomised clinical trials (ie RCTs or CCTs) archived on the PEDro database are likely to be internally valid (criteria 2-9), and could have sufficient statistical information to make their results interpretable (criteria 10-11). An additional criterion (criterion 1) that relates to the external validity (or "generalisability" or "applicability" of the trial) has been retained so that the Delphi list is complete, but this criterion will not be used to calculate the PEDro score reported on the PEDro web site.

The PEDro scale should not be used as a measure of the "validity" of a study's conclusions. In particular, we caution users of the PEDro scale that studies which show significant treatment effects and which score highly on the PEDro scale do not necessarily provide evidence that the treatment is clinically useful. Additional considerations include whether the treatment effect was big enough to be clinically worthwhile, whether the positive effects of the treatment outweigh its negative effects, and the cost-effectiveness of the treatment. The scale should not be used to compare the "quality" of trials performed in different areas of therapy, primarily because it is not possible to satisfy all scale items in some areas of physiotherapy practice.

Last amended June 21st, 1999



**Notes on administration of the PEDro scale:**

- All criteria **Points are only awarded when a criterion is clearly satisfied.** If on a literal reading of the trial report it is possible that a criterion was not satisfied, a point should not be awarded for that criterion.
- Criterion 1 This criterion is satisfied if the report describes the source of subjects and a list of criteria used to determine who was eligible to participate in the study.
- Criterion 2 A study is considered to have used random allocation if the report states that allocation was random. The precise method of randomisation need not be specified. Procedures such as coin-tossing and dice-rolling should be considered random. Quasi-randomisation allocation procedures such as allocation by hospital record number or birth date, or alternation, do not satisfy this criterion.
- Criterion 3 *Concealed allocation* means that the person who determined if a subject was eligible for inclusion in the trial was unaware, when this decision was made, of which group the subject would be allocated to. A point is awarded for this criteria, even if it is not stated that allocation was concealed, when the report states that allocation was by sealed opaque envelopes or that allocation involved contacting the holder of the allocation schedule who was "off-site".
- Criterion 4 At a minimum, in studies of therapeutic interventions, the report must describe at least one measure of the severity of the condition being treated and at least one (different) key outcome measure at baseline. The rater must be satisfied that the groups' outcomes would not be expected to differ, on the basis of baseline differences in prognostic variables alone, by a clinically significant amount. This criterion is satisfied even if only baseline data of study completers are presented.
- Criteria 4, 7-11 *Key outcomes* are those outcomes which provide the primary measure of the effectiveness (or lack of effectiveness) of the therapy. In most studies, more than one variable is used as an outcome measure.
- Criterion 5-7 *Blinding* means the person in question (subject, therapist or assessor) did not know which group the subject had been allocated to. In addition, subjects and therapists are only considered to be "blind" if it could be expected that they would have been unable to distinguish between the treatments applied to different groups. In trials in which key outcomes are self-reported (eg, visual analogue scale, pain diary), the assessor is considered to be blind if the subject was blind.
- Criterion 8 This criterion is only satisfied if the report explicitly states *both* the number of subjects initially allocated to groups *and* the number of subjects from whom key outcome measures were obtained. In trials in which outcomes are measured at several points in time, a key outcome must have been measured in more than 85% of subjects at one of those points in time.
- Criterion 9 An *intention to treat* analysis means that, where subjects did not receive treatment (or the control condition) as allocated, and where measures of outcomes were available, the analysis was performed as if subjects received the treatment (or control condition) they were allocated to. This criterion is satisfied, even if there is no mention of analysis by intention to treat, if the report explicitly states that all subjects received treatment or control conditions as allocated.
- Criterion 10 A *between-group* statistical comparison involves statistical comparison of one group with another. Depending on the design of the study, this may involve comparison of two or more treatments, or comparison of treatment with a control condition. The analysis may be a simple comparison of outcomes measured after the treatment was administered, or a comparison of the change in one group with the change in another (when a factorial analysis of variance has been used to analyse the data, the latter is often reported as a group  $\times$  time interaction). The comparison may be in the form hypothesis testing (which provides a "p" value, describing the probability that the groups differed only by chance) or in the form of an estimate (for example, the mean or median difference, or a difference in proportions, or number needed to treat, or a relative risk or hazard ratio) and its confidence interval.
- Criterion 11 A *point measure* is a measure of the size of the treatment effect. The treatment effect may be described as a difference in group outcomes, or as the outcome in (each of) all groups. *Measures of variability* include standard deviations, standard errors, confidence intervals, interquartile ranges (or other quantile ranges), and ranges. Point measures and/or measures of variability may be provided graphically (for example, SDs may be given as error bars in a Figure) as long as it is clear what is being graphed (for example, as long as it is clear whether error bars represent SDs or SEs). Where outcomes are categorical, this criterion is considered to have been met if the number of subjects in each category is given for each group.



## 12 questions to help you make sense of cohort study

### How to use this appraisal tool

Three broad issues need to be considered when appraising a cohort study:

- Are the results of the study valid? (Section A)
- What are the results? (Section B)
- Will the results help locally? (Section C)

The 12 questions on the following pages are designed to help you think about these issues systematically. The first two questions are screening questions and can be answered quickly. If the answer to both is "yes", it is worth proceeding with the remaining questions.

There is some degree of overlap between the questions, you are asked to record a "yes", "no" or "can't tell" to most of the questions. A number of italicised prompts are given after each question. These are designed to remind you why the question is important. Record your reasons for your answers in the spaces provided.

**These checklists were designed to be used as educational tools as part of a workshop setting**  
There will not be time in the small groups to answer them all in detail!

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## (A) Are the results of the study valid?

### Screening Questions

1. Did the study address a clearly focused issue?

Yes

Can't tell

No

HINT: A question can be 'focused' in terms of

- The population studied
- The risk factors studied
- The outcomes considered
- Is it clear whether the study tried to detect a beneficial or harmful effect?

2. Was the cohort recruited in an acceptable way?

Yes

Can't tell

No

HINT: Look for selection bias which might compromise the generalisability of the findings:

- Was the cohort representative of a defined population?
- Was there something special about the cohort?
- Was everybody included who should have been included?

## Is it worth continuing?



### Detailed questions

3. Was the exposure accurately measured to minimise bias?

Yes

Can't tell

No

HINT: Look for measurement or classification bias:

- Did they use subjective or objective measurements?
- Do the measurements truly reflect what you want them to (have they been validated)?
- Were all the subjects classified into exposure groups using the same procedure

---

4. Was the outcome accurately measured to minimise bias?

Yes

Can't tell

No

HINT: Look for measurement or classification bias:

- Did they use subjective or objective measurements?
- Do the measures truly reflect what you want them to (have they been validated)?
- Has a reliable system been established for detecting all the cases (for measuring disease occurrence)?
- Were the measurement methods similar in the different groups?
- Were the subjects and/or the outcome assessor blinded to exposure (does this matter)?

5. (a) Have the authors identified all important confounding factors?  Yes  Can't tell  No

List the ones you think might be important, that the author missed.

(b) Have they taken account of the confounding factors in the design and/or analysis?  Yes  Can't tell  No

List:

HINT: Look for restriction in design, and techniques e.g. modelling, stratified-, regression-, or sensitivity analysis to correct, control or adjust for confounding factors

---

6. (a) Was the follow up of subjects complete enough?  Yes  Can't tell  No

(b) Was the follow up of subjects long enough?  Yes  Can't tell  No

HINT: Consider

- The good or bad effects should have had long enough to reveal themselves
- The persons that are lost to follow-up may have different outcomes than those available for assessment
- In an open or dynamic cohort, was there anything special about the outcome of the people leaving, or the exposure of the people entering the cohort?

## (B) What are the results?

### 7. What are the results of this study?

HINT: Consider

- What are the bottom line results?
  - Have they reported the rate or the proportion between the exposed/unexposed, the ratio/the rate difference?
  - How strong is the association between exposure and outcome (RR,)?
  - What is the absolute risk reduction (ARR)?
- 

### 8. How precise are the results?

HINT: Look for the range of the confidence intervals, if given.

---

### 9. Do you believe the results?

Yes    Can't tell    No

HINT: Consider

- Big effect is hard to ignore!
- Can it be due to bias, chance or confounding?
- Are the design and methods of this study sufficiently flawed to make the results unreliable?
- Bradford Hills criteria (e.g. time sequence, dose-response gradient, biological plausibility, consistency)

## (C) Will the results help locally?

10. Can the results be applied to the local population?  Yes  Can't tell  No

HINT: Consider whether

- A cohort study was the appropriate method to answer this question
- The subjects covered in this study could be sufficiently different from your population to cause concern
- Your local setting is likely to differ much from that of the study
- You can quantify the local benefits and harms

---

11. Do the results of this study fit with other available evidence?  Yes  Can't tell  No

12. What are the implications of this study for practice?

HINT: Consider

- One observational study rarely provides sufficiently robust evidence to recommend changes to clinical practice or within health policy decision making
- For certain questions observational studies provide the only evidence
- Recommendations from observational studies are always stronger when supported by other evidence

Appendix 4 - Summary of papers in literature review with PEDro scale

Study author/study location	Study design	Pedro score (0-11; 0=worst)	Participant characteristics	Intervention	Outcome measures (OM) Primary outcome measure (POM)	Results
<b>Critchley et al. (2007)</b>	RCT with 18-month follow-up	7	212 patients with chronic low back pain patients. Primary care referrals. Females 65% Mean age 44	Comparison of 3 types of physiotherapy (PT) Individual physiotherapy (IP) Spinal stabilisation exercises (SSE) Physiotherapist-led pain management classes (PPM)	POM -Roland Morris Disability questionnaire (RMDQ) Numerical rating scale (NRS 0-100) EQ-5D (Euroqol) Economic cost and QALY OM recorded at baseline, 6, 12 and 18 months follow-up	RMDQ reduced in all 3 arms, mean >4 and was sustained at 18 months follow-up. No significant difference was detected between treatment arms. PPM found to be most cost effective
<b>Lamb et al. (2012)</b>	RCT With extended follow-up	8	701 UK patients recruited with low back pain for a minimum of 6 weeks. 402 completed the study. Primary care referrals Female 60% Mean age 53	Comparison of Group cognitive behavioural intervention delivered by either a PT, Occupational therapist, psychologist or nurse for 9 hours, 6 x 1.5hr sessions (CBI) or 10-15 minute best care advice and back book (BPA)	POM -RMDQ Modified Von Korff scale (MVK) disability and pain scale EQ-5D, HADS, PSEQ OM recorded at baseline, 3, 6 12 and extended follow-up (between 20-50 months)	RMDQ reduced by 1.6 points in the BPA arm and 2.9 in CBI group at extended follow-up
UK BEAM trial (2004)	RCT With 3 and 12 month follow-up Pedro = 8	8	1334 UK participants with low back age 18-65, primary care referrals, Females 52% Mean age 42.5	Comparison of 3 different treatment approaches; best care advice; back school with CBT; manipulation in NHS and private setting	POM -RMDQ Modified Von Korff scale (MVK) disability and pain scale SF-36, fear avoidance beliefs	All groups improved. Exercise group reduced RMDQ at 3 months only



Study author/study location	Study design	Pedro score (0-11; 0=worst)	Participant characteristics	Intervention	Outcome measures (OM) Primary outcome measure (POM)	Results
Van de Roer et al. (2008)	RCT With 6, 12 and 52 week follow-up	6	210 Dutch participants with non-specific chronic low back pain. Participants had to be insured by one specific insurance company in the Netherlands Female 55% Mean age 41.5%	Comparison of 2 types of physiotherapy intervention. Intensive group training physiotherapists using a behavioural approach participants had 10 individual and 20 group sessions. Compared to Dutch guidelines individual physiotherapy sessions; mean no. of sessions 13	RMDQ NRS TSK	No difference between groups on RMDQ. Both groups by 5 points at 52 weeks. NRS was only significant change in intensive group reduced by 2.3 points compared to individual physiotherapy of 1.3 points.
Cecchi et al. (2010)	RCT with 12 months follow-up	9	210 Italian Participants with chronic non-specific low back pain Females 67% Mean age 59	Comparison of three types of therapy; Individual physiotherapy of 15 hours; Back school group based physiotherapy 15 hours; Spinal manipulation with a physician	RMDQ Pain rating scale (0-6)	Spinal manipulation intervention reduced RMDQ by 6.7 pints compared to individual physio 4.4 and back school 3.7. no difference between groups in pain rating score. 60% of the spinal manipulation group sought further treatment only 10% and 20% of the individual group and back school did

Study author/study location	Study design	Pedro score (0-11; 0=worst)	Participant characteristics	Intervention	Outcome measures (OM) Primary outcome measure (POM)	Results
Hay et al. (2005)	RCT with 3 and 12-month follow-up	10	402 UK participants with sub-acute (>12 weeks duration) non-specific low back pain	Comparison of 2 types of physiotherapy Brief pain management delivered on a 1 to 1 basis maximum of 2 hours and 40 minutes Individual physiotherapy maximum of 6 sessions	RMDQ TSK	Both groups produced large change scores on RMDQ of 8.8 sustained change at 12 month follow-up. TSK increased in both groups by over 6 points (statistically and clinically significant) in both groups at 3 and 12-month follow-up. No discussion as to why this occurred
Coleman et al. (2012)	RCT With 8 week and 6-month follow-up	6	146 Australian primary care participants with osteoarthritis of the knee. Female 75% Mean age 65	Intervention group; a health care professional-led self-management programme for OA of the knee (OAK compared to a waiting list control group	SF-36 WOMAC VAS Physical function test – Timed get up and go (TUG)	Baseline data was different for pain, mental health and physical function on the Sf-36. Worse in the Oak group. OAK observed improvement in all outcome measures except the SF-36 sustained at 6-month. The study reported a drop-out for the waiting list control group at 8 week follow-up and then an increase at 6-month follow up which the authors suggest effected validity of results. Patients also self-enrolled for the study therefore arguably more likely to self-manage

Study author/study location	Study design	Pedro score (0-11; 0=worst)	Participant characteristics	Intervention	Outcome measures (OM) Primary outcome measure (POM)	Results
Jessep et al. (2009)	RCT with 12-month follow-up	7	64 UK participants with chronic knee pain recruited from primary care Female Mean age 67	Compared individual outpatient physiotherapy over a maximum of 10 sessions of 30-minutes with a 7-hour physiotherapy-led programme ESCAPE; (enabling self-management through exercise)	WOMAC NRS HAD	Both groups showed improvement in all outcome measures which were sustained on follow-up no difference between groups. The main finding was that the ESCAPE group cost less and was more cost effective in terms of further health care usage over the 12month follow-up period
Johnson et al. (2007)	RCT 12-month follow-up	8	196 UK participants with persistent low back pain from primary care. Female 59% Mean age 47.9	Compared intervention of a 16-hour physiotherapy-led programme using CBT principles based intervention to a control group of an educational package of information posted to participants.	RMDQ VAS	RMDQ reduced in both groups by 3.2 intervention and 2.2 control. Not statistically significant between groups. Only small non-significant change in pain. No difference between the intervention and control. Cost of the treatment was lower for the group intervention. They demonstrated that patient preference of treatment influenced treatment outcome.

Study author/study location	Study design	Pedro score (0-11; 0=worst)	Participant characteristics	Intervention	Outcome measures (OM) Primary outcome measure (POM)	Results
Hill et al. (2011)	RCT with 4 and 12-month follow-up.	9	851 UK participants with back pain from primary care. Female 59% Mean age 49.5	Compare stratified care pathways for participants with low back pain based on the prognostic Keele STaRT back screening tool. This stratified pathway was compared to a control group of normal physiotherapy care for low back pain	RMDQ TSK HAD PSEQ SF-12 Pain catastrophizing scale	Both control (normal) physiotherapy and stratified care produced positive changes in all outcome measures. The stratified (intervention) care produced larger changes that were sustained at 4 and 12-month follow up. The stratified care was found to be cost effective in terms of further care usage than the control group over 12-months
Woby et al. (2008)	Before and after study design	Not applicable NOT and RCT	137 UK participants with chronic low back pain recruited following physiotherapy assessments from both primary and secondary care	A physiotherapy-led 17.5 hour intervention; 'work back to life' based on a CBT approach. No control group. No follow-up	RMDQ VAS TSK HAD (depression)	Statistically significant change scores observed in RMDQ TSK and depression with smaller changes observed in the other outcome measures

## Appendix 5 - Flag indicators

Table taken directly from URL: [http://www.physio-pedia.com/The\\_Flag\\_System](http://www.physio-pedia.com/The_Flag_System) showing flag indicators used in musculoskeletal assessments. Based on work by (Kendall et al. 1997) and (Nicholas et al. 2011)

	Nature	Examples
<b>Red</b>	Signs of serious pathology	Cauda equina syndrome, fracture, tumour, unremitting night pain, sudden weight loss of 10 pounds over 3 months, bladder & bowel incontinence, previous history of cancer, saddle anaesthesia.
<b>Orange</b>	Psychiatric symptoms	Clinical depression, personality disorder
<b>Yellow</b>	Beliefs, appraisals and judgements	Unhelpful beliefs about pain: indication of injury as uncontrollable or likely to worsen. Expectations of poor treatment outcome, delayed return to work.
	Emotional Responses	Distress not meeting criteria for diagnosis of mental disorder. Worry, fears, anxiety.
	Pain behaviour (including pain and coping strategies)	Avoidance of activities due to expectations of pain and possible reinjury. Over-reliance on passive treatments.
<b>Blue</b>	Perceptions about the relationship between work and health	Belief that work is too onerous and likely to cause further injury. Belief that workplace supervisor and workmates are unsupportive.
<b>Black</b>	System or contextual obstacles	Legislation restricting options for return to work. Conflict with insurance staff over injury claim. Overly solicitous family and health care providers. Heavy work, with little opportunity to modify duties.

Key questions based on (Kendall et al. 1997)

The following are considered useful key questions to ask in an assessment to determine the presence of yellow flag indicators. If the patient responses

- What do you think has caused the problem?
- What do you expect is going to happen?
- How are you coping with things?
- Is it getting you down?
- When do you think you'll get back to work?
- What can be done at work to help?

#### Structured interview

If the responses from the key questions has confirmed that there are flags present then these can be explored in more depth using the acronym: ABCDEFW. Below are examples of areas to explore taken directly from URL: [http://www.physio-pedia.com/The\\_Flag\\_System](http://www.physio-pedia.com/The_Flag_System)

- **Attitudes/Beliefs** – What does the patient think to be the problem and do they have a positive or negative attitude to the pain and potential treatment?
- **Behaviour** – Has the patient changed their behaviour to the pain? Have they reduced activity or compensating for certain movements. Early signs of catastrophising and fear-avoidance?
- **Compensation** – Are they awaiting a claim due to a potential accident? Is this placing unnecessary stress on their life?
- **Diagnosis/Treatment** – Has the language that has been used had an effect on patient thoughts? Have they had previous treatment for the pain before, and was there a conflicting diagnosis? This could cause the patient to over-think the issue, leading to catastrophising and fear-avoidance
- **Emotions** – Does the patient have any underlying emotional issues that could lead to an increased potential for chronic pain? Collect a thorough background on their psychological history
- **Family** – How are the patient's family reacting to their injury? Are they being under-supportive or over-supportive, both of which can affect the patient's concept of their pain
- **Work** – Are they currently off work? Financial issues could potentially arise? What are the patient's thoughts about their working environment?

## Appendix 6 - Programme timetable

	Session 1	Session 2	Session 3	Session 4	Session 5
9.30 – 10.30	Icebreaker – concerns and expectations about the group.  Completion of outcome measures and physical test	Pacing and value based activity theory and discussion	Explain pain (2)	How to manage a flare up of pain	Setback planning/ long term maintenance – change cycle
10.30- 10.40	Comfort break	Comfort break	Comfort break	Comfort break	Break
10.40 – 11.10	Interactive discussion – What effect has chronic pain had on your life? – Chronic pain cycle	Group work – pacing activity	Exercise individual stretching and full circuit	Exercise stretching and full circuit	Health trainer and expert patient tutor session
11.10 – 11.30	Break	Exercise – individual stretching and ½ exercise circuit	Break	Break	Completion of outcome measures and physical tests
11.30 – 11.50	Why is exercise useful -theory	Break	Stress its effects and practical strategies to help manage.	Sleep management	Local exercise on referral scheme (BEATS) talk and discussion
11.50 – 12.20	Practical exercise – stretching group	Explain pain (1)	Practical – abdominal breathing	Comfort break	Individual reviews and 3 month goal setting
12.20- 12.30	Close and questions	Close and questions	Goal setting	Relaxation	Close, questions

## Appendix 7 - Exercise component for study intervention

### 1. Stretching programme for week 1 - 5

#### Week 1

The group works through the stretches together as a group with the physiotherapist demonstrating each stretch.

Patients are asked to try all the stretches and to use these instructions as a guide;

Do each stretch slowly, sustain each stretch for 5 seconds, then slowly release the stretch and repeat each stretch twice.

Patients are asked to complete the exercises on a daily basis at home and provided with an illustrated guide. (See appendix for picture reference for each stretch)

#### Weeks 2 - 5

Patients are encouraged to do the stretches individually or as a group without the physiotherapist leading.

### 2. Exercise circuit for weeks 2 - 5

The circuit has 12 stations that include strengthening, balance and cardiovascular exercises. The exercises are either functional, address positions that patients may be avoiding or have components that patients have identified as a problem area i.e. balance, co-ordination.

#### Week 2

Patients are asked to complete ½ circuit (6 exercises) following the stretches.

#### Week 3 - 5

Patients complete stretching programme and full circuit (12 exercises)

Patients are asked to record the number of repetitions they complete (where applicable) on their exercise sheet.

In addition to their stretching programme patients are asked to complete the circuit exercises at home that do not require specialist equipment i.e. bike, cross trainer etc. They are provided with a home sheet to record this on.

Circuit exercises (H denotes exercises for home)

1. Wobble board
2. Trampet
3. Bouncing gym ball along the floor and turning around
4. Bridging (H) passing small ball underneath hips
5. 4 point kneeling superman (H)
6. Step ups (H)
7. Sit stand from a chair (H)
8. Bike
9. Cross trainer
10. Press ups against wall (H)
11. Lateral raises (H)
12. passing small ball behind back then behind head (H)



## Appendix 8 - Study physical function tests

### Instructions for physiotherapists

Please do not add further instructions to the tests this is to ensure that all participants receive the same information. Please do not talk to the participant during any of the tests unless the participant reports an adverse reaction or the participant requests to stop the tests.

Participants can use whatever walking aid needed for the walking tests and they can hold onto the walls bar if needed during the step-up test.

#### 1. Test 1 speed of walking over 20 metre distance.

Record the speed of walking between the two markers in minutes/seconds and record on the data collection form.

*“Please walk as quickly as you can today between the two markers.”*

Test 2 - Distance covered in 5 minutes between 2 markers set 20 metre apart.

Record the number of whole lengths covered between the two markers and calculate the total distance covered in 5 minutes.

Instruction to the participant that they should walk at their normal walking pace and you will inform them at the end of each minute.

*“Walk in between the two markers for 5 minutes. Walk at your normal walking pace. I will let you know at the end of each minute how long you have left. If you need to stop the test let me know.”*

#### 2. Test 3 - number of step up repetitions in 1 minute

Record the number of whole step ups performed (on and off the step reebok box) in 1 minute.

*“Step on and off the step as many times as you can in 1 minute. I will let you know when you are half way through the test. You can hold onto the wall bars if you need to”*

## Appendix 9 - Tampa Scale of Kinesiophobia

This is a list of phrases which patients have used to express how they view their condition. Please indicate the extent to which you agree or disagree with each statement.

During the past week...	Strongly Disagree	Some-what Disagree	Some-what Agree	Strongly agree
1. I'm 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 aren't taking my medical condition seriously enough	1	2	3	4
6. My accident/condition 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 getting worse	1	2	3	4
11. I wouldn't 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 don't injure myself	1	2	3	4
14. It's really not safe for a person with a condition like mine to be physically active	1	2	3	4
15. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
16. Even though something is causing me a lot of pain, I don't 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

Score

Appendix 10 - Pain Disability Questionnaire

**Name**

**Instructions:** These questions ask your views about how your pain now affects how you function in everyday activities. Please answer every question and mark the ONE number on EACH scale that best describes how you feel.

1. Does your pain interfere with your normal work inside and outside the home?

Work normally Unable to work at all  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

2. Does your pain interfere with personal care (such as washing, dressing, etc.)?

Take care of myself completely Need help with all my personal care  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

3. Does your pain interfere with your travelling?

Travel anywhere I like Only travel to see doctors  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

4. Does your pain affect your ability to sit or stand?

No problems Can not sit/stand at all  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

5. Does your pain affect your ability to lift overhead, grasp objects, or reach for things?

No problems Can not do at all  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

6. Does your pain affect your ability to lift objects off the floor, bend, stoop, or squat?

No problems Can not do at all  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

7. Does your pain affect your ability to walk or run?

No problems Can not walk/run at all  
0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

8. Has your income declined since your pain began?

No decline

Lost all income

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

9. Do you have to take pain medication every day to control your pain?

No medication needed

On pain medication throughout the day

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

10. Does your pain force you to see doctors much more often than before your pain began?

Never see doctors

See doctors weekly

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

11. Does your pain interfere with your ability to see the people who are important to you as much as you would like?

No problem

Never see them

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

12. Does your pain interfere with recreational activities and hobbies that are important to you?

No interference

Total interference

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

13. Do you need the help of your family and friends to complete everyday tasks (including both work outside the home and housework) because of your pain?

Never need help

Need help all the time

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

14. Do you now feel more depressed, tense, or anxious than before your pain began?

No depression/tension

Severe depression/tension

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

15. Are there emotional problems caused by your pain that interfere with your family, social and or work activities?

No problems

Severe problems

0 ----- 1 ----- 2 ----- 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10

## Appendix 11 - Pain Self Efficacy Questionnaire

Please rate how **confident** you are that you can do the following things at present **despite** the pain. To indicate your answer circle **one** of the numbers on the scale under each item, where 0= not at all confident and 6=completely confident.

For example:

0 1 2 3 4 5 6

**Not at all confident**

**completely confident**

Remember this questionnaire is **not** asking whether or not you have been doing these things, but rather **how confident you are that you can do them at present, despite the pain.**

1. I can enjoy things, despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

2. I can do most of the household chores (e.g. tidying –up, washing dishes etc.), despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

3. I can socialise with my friends or family members as often as I used to do, despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

4. I can cope with my pain in most situations.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

5. I can do some form of work, despite the pain. (“Work” includes housework, paid and unpaid work).

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

7. I can cope with my pain without medication.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

8. I can still accomplish most of my goals in life, despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

9. I can live a normal lifestyle, despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

10. I can gradually become more active, despite the pain.

**Not at all confident** 0 1 2 3 4 5 6 **completely confident**

## Appendix 12 - The Roland-Morris Disability Questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you **today**.

As you read the list, think of yourself **today**. When you read a sentence that describes you today, put a tick against it. If the sentence does not describe you, then leave the space blank and go on to the next one. Remember; only tick the sentence if you are sure it describes you today.

1. I stay at home most of the time because of my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of my back.
4. Because of my back I am not doing any of the jobs that 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. I only stand for short periods of time because of my back.
11. Because of my back, I try not to bend or kneel down.
12. I find it difficult to get out of a chair because of my back.
13. My back is painful almost all the time.
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 pain.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of my back.
18. I sleep less well because of my back.
19. Because of my back pain, 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 pain, I am more irritable and bad tempered with people than usual.
23. Because of my back, I go upstairs more slowly than usual.
24. I stay in bed most of the time because of my back.

## Appendix 13 - The Hospital Anxiety and Depression Scale

### HAD SCALE

Name: ..... Date: .....

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.

This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.

Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

*Tick only one box in each section.*

<b>I feel tense or 'wound up:</b> Most of the time ..... A lot of the time ..... Time to time, occasionally. Not at all .....		<b>I feel as if I am slowed down:</b> Nearly all the time ..... Very often ..... Sometimes ..... Not at all .....	
<b>I still enjoy the things I used to enjoy:</b> Definitely as much ..... Not quite so much ..... Only a little ..... Hardly at all .....		<b>I get a sort of frightened feeling like 'butterflies' in the stomach:</b> Not at all ..... Occasionally ..... Quite often ..... Very often .....	
<b>I get a sort of frightened feeling as if something awful is about to happen:</b> Very definitely & quite badly Yes, but not too badly ..... A little, but it doesn't worry me. Not at all .....		<b>I have lost interest in my appearance:</b> Definitely ..... I don't take so much care as I should I may not take quite as much care I take just as much care as ever	
<b>I can laugh and see the funny side of things:</b> As much as I always could Not quite so much now .... Definitely not so much now Not at all .....		<b>I feel restless as if I have to be on the move:</b> Very much indeed ..... Quite a lot ..... Not very much ..... Not at all .....	
<b>Worrying thoughts go through my mind:</b> A great deal of the time .... A lot of the time ..... From time to time but not too often ..... Only occasionally .....		<b>I look forward with enjoyment to things:</b> As much as ever I did ..... Rather less than I used to ..... Definitely less than I used to ... Hardly at all .....	
<b>I feel cheerful:</b> Not at all ..... Not often ..... Sometimes ..... Most of the time .....		<b>I get sudden feelings of panic:</b> Very often indeed ..... Quite often ..... Not very often ..... Not at all .....	
<b>I can sit at ease and feel relaxed:</b> Definitely ..... Usually ..... Not often ..... Not at all .....		<b>I can enjoy a good book or radio or TV programme:</b> Often ..... Sometimes ..... Not often ..... Very seldom .....	

*Do not write below this line*

A - (8-10) .....

D - (8-10) .....

Appendix 14 - NHS permission letter for preliminary study



The Pennine Acute Hospitals NHS Trust

Research and Development  
Trust Headquarters  
North Manchester General Hospital  
Deaunays Road  
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M8 5RB

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Mrs. Lucy Knott – Team Leader Physiotherapist  
Physiotherapy Department  
Fairfield General Hospital  
Rochdale Old Road  
Bury  
Lancashire  
OL12 0NB

22<sup>nd</sup> August 2013

Dear Mrs. Knott

<b>R&amp;D reference number:</b>	13RECNA20
<b>Project title:</b>	Service evaluation following a physiotherapist-led group intervention based on cognitive behavioural principles for patients with chronic musculoskeletal pain.
<b>Site:</b>	FGH

Thank you for providing the Research and Development (R&D) department with the required documentation for the above study. I am pleased to inform you that the study has been noted by the R&D department at The Pennine Acute Hospitals NHS Trust. As this study did not require approval from the National Research Ethics Services (NRES), details of the study will remain on our R&D database for 'notification only' and no further action will be taken.

I would be grateful if you could provide us with a summary of your findings upon completion of your study.

Yours sincerely

Dr. Steve Woby  
Head of Research & Development

*Lucy, I'd be more than happy to have a chat through your findings should you think it might be helpful. My own research background is within this field of research. Best wishes Steve*

cc: Mrs. Angela Barrett – Trust Physiotherapy Manager [angela.barrett@pat.nhs.uk](mailto:angela.barrett@pat.nhs.uk)

Version 3



Patient Identification Number: .....

---

**CONSENT FORM**

---

**Title: A physiotherapist-led group based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain.**

**Researcher: Lucy Knott**

**Please initial all boxes**

1. I confirm that I have read and understand the information sheet dated 30 January 2014 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 Manchester Metropolitan University, 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 understand that my contributions will be anonymous and I will not be personally identified.
5. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date


\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person  
taking consent.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

IRAS Project ID 143694 – L Knott Version 3

The Pennine Acute Hospitals   
NHS Trust

Physiotherapy Department  
Fairfield General Hospital  
Rochdale Old Road  
Bury  
Lancashire  
BL9 7TD

30 January 2014

**Title of the study:  
A physiotherapist-led group based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain.**

Dear Sir/Madam

I am writing to invite you to take part in a study that is being undertaken in the physiotherapy department in partnership with Manchester Metropolitan University. You have been referred to the functional rehabilitation programme to help manage your condition. The purpose of the study is to evaluate whether the current group is effective in the management of your condition in terms of reducing fear and disability and developing coping strategies for pain management. If you choose to participate you will be helping us to evaluate our current services and make changes if required.

Participation in this study means that you will allow us to use data obtained from questionnaires collected before, after and 3 months following the group to be used in the study. The data is not stored alongside any personal information and therefore the data will not identify you personally.

**It is important to note that if you do not wish your data to be used you will still be asked to complete the questionnaires before and after the group as this is part of the group's requirement. You will NOT be asked to participate in the 3-month follow-up session as this is specifically for the study. The data from your questionnaires WILL NOT be used in this study but only for the purpose of producing your discharge report to your referrer, e.g. GP or Consultant.**

Thank you for taking the time to read this information.

Yours sincerely

**Lucy Knott  
Physiotherapist**

IRAS Project ID 143694 – L Knott-Version 3

## The Pennine Acute Hospitals

NHS Trust

Physiotherapy Department  
Fairfield General Hospital  
Rochdale Old Road  
Bury  
Lancashire  
BL9 7TD

Tel: 0161 778 3882

30 January 2014

### Participant Information Sheet

**Title of the study: A physiotherapist-led group based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain.**

I am inviting you to take part in a study to evaluate the effect of the group that you have been referred to for management of your chronic musculoskeletal pain.

#### **What is the purpose of the study?**

As part of on-going service development, we are evaluating the effectiveness of interactive behavioural modification therapy in a group for patients with chronic musculoskeletal pain.

#### **Why have I been asked to take part?**

Your physiotherapist has referred you to participate in the Functional Rehabilitation Programme for the treatment of your chronic pain. The questionnaires that you initially completed, combined with your physiotherapist's assessment, helped us to identify whether you would benefit from the group based exercise programme.

#### **Do I have to take part?**

No, participation in the study is entirely up to you. Your treatment will not be effected by you not participating in this research study.

#### **What will the study involve?**

You will be asked to complete four questionnaires on three occasions: sessions 1 and 5 and 3 months following the completion of the group exercise programme. The questionnaires will take approximately 40 minutes to complete.

**It is important to remember that whether you participate in the study or not you will still need to complete the questionnaires as they formulate part of the routine assessment process for the group.**

However the data collected from the questionnaires will **NOT** be used for this study unless your consent has been obtained. We will collect data from you about your gender, age, condition, referrer and employment status.

**What are the possible disadvantages or risks of taking part?**

There are no risks associated with participating in this study as it is the treatment identified as the most appropriate and potentially beneficial for you by your referring physiotherapist and formulates part of an ongoing service evaluation of the group.

**What are the possible benefits of taking part?**

You will be helping us to evaluate the current service and the potential development of a new follow up service. You may feel that you do not benefit directly from the study at this time.

**What will happen if I do not want my data to be used after I have consented?**

You are free at any time to withdraw your consent for the use of your data to be used in this study without explanation. Your treatment will not be affected now or in the future by your decision.

**Will my data from this study be kept confidential?**

Yes. If you agree to participate in the study, the data collected from the questionnaires is recorded on an electronic database. The data is not kept alongside any information that could identify you. You are given a unique study number so that you remain anonymous during the data analysis and you will not be identified in the thesis that follows from the study. The questionnaires will only be assessed by myself and my research supervisor at Manchester Metropolitan University.

**What will happen to the results of the study?**

The results of the study will be written up as a thesis for a Masters by Research degree and may also be submitted for publication in a medical journal. If you wish to receive a summary of the research findings these can be posted or emailed to you.

**Who is organising the research?**

The study is supported by the Pennine Acute Hospitals NHS Trust in collaboration with the Manchester Metropolitan University.

**Who has reviewed the study?**

This study will be reviewed by the Manchester Metropolitan University Research Ethics Committee and the NHS Research Ethics Committee.

**Contact for further information**

For further information about the study, please contact Lucy Knott, Physiotherapist, Fairfield General Hospital on 0161 778 3882. You can also send your queries via email to [lucy.knott@pat.nhs.uk](mailto:lucy.knott@pat.nhs.uk).

**What do I do if I have a concern about the study?**

If you have a concern about any aspect of the study you can speak to the researcher, Lucy Knott, who will answer your questions on 0161 778 3882 or email

[lucy.knott@pat.nhs.uk](mailto:lucy.knott@pat.nhs.uk)

If you are still unhappy you can telephone the Patient Advisory Service (PALS) on 0161 604 5897 or email [pals@pat.nhs.uk](mailto:pals@pat.nhs.uk)

**What do I do now?**

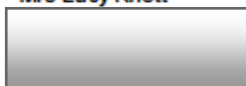
If you wish to participate in the study, please sign and return the consent form to the functional rehabilitation programme physiotherapist or in the envelope provided.

**NRES Committee North West - Preston**  
HRA NRES Centre - Manchester  
Barlow House  
3rd Floor  
4 Minsall Street  
Manchester  
M1 3DZ

Telephone: 0161 625 7818  
Facsimile: 0161 625 7299

31 January 2014

Mrs Lucy Knott



Dear Mrs Knott

**Study title:** A physiotherapist-led, group-based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain.

**REC reference:** 14/NW/0042  
**IRAS project ID:** 143694

Thank you for your letter of 30 January. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 29 January 2014

#### Documents received

The documents received were as follows:

Document	Version	Date
Covering Letter		30 January 2014
Letter of invitation to participant	3	30 January 2014
Participant Consent Form	3	30 January 2014
Participant Information Sheet	5	30 January 2014

#### Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Covering Letter		30 January 2014
Evidence of insurance or indemnity		18 November 2013
Investigator CV	Yohannes	03 January 2014
Investigator CV	Knott	03 January 2014
Letter of invitation to participant	3	30 January 2014

Appendix 19 - Insurance letter

Financial and Legal Services

**Monday, 18 November 2013**

For the attention of  
NHS Research Ethics Committee



Dear Sirs

**Project title: A physiotherapist-led group based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain**

**Postgraduate Student: Lucy Knott**

**Educational Supervisor: Dr Abebaw Yohannes**

**Re - 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 Lucy Knott from 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.

In addition, the University has provision to award indemnity and/or compensation in the event of claims for non-negligent harm. This is on the condition that the project is accepted by the insurers prior to the commencement of the research project and approval has been granted for the project from a suitable ethics committee.

Yours faithfully

A handwritten signature in blue ink, appearing to read "Emma Yeomanson".

**Emma Yeomanson  
Insurance Officer**

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INVESTOR IN PEOPLE



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Research & Knowledge Exchange

DATE 18<sup>th</sup> November 2013  
For the attention of  
NHS Research Ethics Committee



Dear Sir/Madam,

**Project Title: "A physiotherapist-led group based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain"**

**Chief Investigator: Dr Abebaw Yohannes**

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

A handwritten signature in black ink, appearing to read "D. Raper", written over a horizontal line.

Professor David Raper  
Director of Research and Knowledge Exchange

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Appendix 21 - t test for pre to post intervention and pre to follow-up

<b>Variable name</b>	<b>Baseline score (BS)</b>	<b>Post score (PS)</b>	<b>Mean change</b>	<b>p-value (BS-PS)</b>	<b>Follow up (FU)</b>	<b>Mean change BS-FU</b>	<b>p-value BS-FU</b>
Fear of movement/re-injury (TSK)	40.9	33.6	-7.33	.001	33.0	-7.91	.001
Anxiety (HADS)	11.9	10.6	-1.33	.003	9.2	-2.76	.001
Depression (HADS)	9.8	7.4	-2.41	.001	6.3	-3.27	.001
Disability/Low back pain (RMDQ)	11.7	9.4	-2.32	.006	8.3	-3.36	.011
Disability/multi-site (PDQ)	107.6	90.4	-17.15	.001	79.8	-28.10	.001
Self-efficacy (PSEQ)	25.4	35.5	+10.0	.001	35.5	+10.08	.001
Speed of walking -timed walk >20 metre	21.7	17.7	-4.06	.001	17.5	-2.58	.001
Distance covered in 5 minutes in metres	261.3	291.7	+30.42	.001	313.6	+45.16	.001
Total number of Step ups in 1 minute	19.0	24.7	+5.68	.001	24.9	+6.09	.001



Appendix 22 – MMU ethical approval confirmation

**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: Lucy Knott

From: Prof Carol Haigh

Date: 12/02/2014

Subject: Ethics Application 1217

Title: A physiotherapist-led, group-based intervention using Interactive Behavioural Modification Therapy (IBMT) for patients with chronic musculoskeletal pain.

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Thank you for your application for ethical approval.

The Faculty Academic Ethics Committee review process has recommended approval of your ethics application. This approval is granted for 42 months for full-time students or staff and 60 months for part-time students. Extensions to the approval period can be requested.

If your research changes you might need to seek ethical approval for the amendments. Please request an amendment form.

We wish you every success with your project.

Prof Carol Haigh and Prof Jois Stansfield  
Chair and Deputy Chair  
Faculty Academic Ethics Committee