An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care

A thesis submitted to Middlesex University in partial fulfilment of the requirements for the degree of Doctor of Professional Studies

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Abstract

Objectives: To design, implement and evaluate an alternative physiotherapy group exercise programme used for managing chronic low back pain (CLBP) in Primary Care.

Introduction: CLBP is a disabling condition with no established standard management. Conservative treatments such as supervised exercise and manual therapy have demonstrated some benefit. Group exercise programmes used in physiotherapy practice are a cost effective treatment for managing CLBP but currently lack a combination of individualized specific exercises, one to one education and manual therapy ('hands on' techniques). An alternative group programme was designed to address these limitations.

Methods: This thesis consisted of two stages; a survey and a mixed methods design study. The physiotherapy survey was used in stage 1 to investigate what type of exercises are prescribed by physiotherapists and which group programmes are used in clinical practice for managing CLBP. One hundred and fifty-four questionnaires were distributed with a response rate of 63%. Ninety-seven percent of physiotherapists surveyed refer their CLBP patients to group programmes but only 47% of all respondents were able to refer non-English speaking patients. None of the group programmes offered manual therapy. The alternative group physiotherapy programme was developed using this research, review of the literature and consultation with service providers. In stage 2, the alternative group exercise programme was evaluated using a mixed methods preliminary study consisting of a core quantitative and supplementary qualitative phases. The alternative group programme (Group A) was compared to a standard group exercise programme used in clinical practice (Group B) in a single blinded randomised controlled trial. Participants with CLBP were allocated to the two programme groups by block randomisation. Participants in both groups attended six one-hour programme sessions over a 3-month period. Outcomes measuring function, pain, quality of life (EQ-5D) and satisfaction with treatment were used to evaluate the effectiveness of the programmes pre and post programme attendance and at 6 months. Focus groups in the qualitative phase were used to explore patients' experiences regarding their treatment in the two group programmes.

Results Stage 2: Eight-one participants were randomised to the two groups (41 in Group A; 40 in Group B). There was a drop-rate of 33% and only 41% were followed up at 6-months (n=10, Group A; n=12, Group B). There were no statistically significant differences between groups in outcome scores and apart from the EQ-5D at six months, the associated effect sizes were small. The within group analysis revealed significantly lower disability and pain scores post-programme compared to pre-programme in both groups. There were significantly higher EQ-5D scores post-programme compared to pre-programme in Group A but not in Group B. Quality of life deteriorated in Group B at 6-months. The focus group interviews showed that patients prefer individualised exercises and one-to-one education which are components of the alternative programme.

Conclusion: This alternative programme may provide a suitable addition to existing programmes available for managing CLBP. This research may change the way physiotherapists deliver exercise for CLBP patients in a group setting.

Key Words: Chronic low back pain, exercise programme, manual therapy.

Chapter Overview

Chapter 1 provides a short overview of the thesis and Professional Doctorate Programme. The aim of this thesis was to develop, implement and evaluate an alternative group exercise programme used in the management of chronic low back pain (CLBP). There were two integrated stages in this thesis. A mixed methods approach was used to evaluate this programme and the overall plan was to implement into clinical practice. The background and rationale of this thesis highlights the economic and social costs of CLBP and that there is no established standard management. Group exercise programmes are a cost effective treatment for CLBP and greatly vary in type and content. There are a number of limitations with these current programmes which have high drop-out rates and poor long-term outcomes. A need to develop an alternative group exercise programme had been identified to deliver cost effective treatments and quality care in-line with General Practice (GP) consortia commissioning and NHS targets. My professional role is described which highlights my clinical expertise and previous projects to develop group exercise programmes. This experience makes me ideally suited to conduct a work-based project combining theoretical knowledge with clinical evidence to develop and evaluate a suitable alternative programme. How this alternative programme met both NICE and commissioning guidelines is mentioned? The methodological approach is briefly outlined and consists of two integrated stages. **Stage 1** was the physiotherapy survey and **Stage 2** the mixed methods design study to evaluate the alternative group exercise programme. The introduction also describes the impact of change this project will potentially have to individuals and the organisation. Finally, the links between implementation of a novel programme or intervention, change management and leadership relevant to the thesis are introduced.

Chapter 2 covers the literature review. This demonstrates my knowledge of physiotherapy practice and how this may contribute to changing clinical practice. Limitations of my literature search are highlighted such as access to all published research in my chosen area. The development of the research question from previous work-based projects is mentioned as is the scope of the project and how I initiated organisational change whilst developing my leadership skills. This literature review has been divided into three sections.

Section 1 discusses the literature around implementation research regarding evidence-based practice and clinical programmes. The evidence for transferring research findings into clinical practice is mentioned. Interventions should have sufficient evidence before being implemented. For the implementation process to be successful, it requires an active change process within the organisation and starts with individual behavioural change. This links in with Change Management strategies in the healthcare sector which are briefly discussed and Leadership relevant to this thesis. Transactional and transformational models of leadership are discussed as is the importance of distributed leadership for effective organisational change.

Section 2 includes a literature review of physiotherapy surveys which is relevant to **Stage 1** of this thesis. This looked at a small number of surveys which have investigated the physiotherapy management of CLBP. To date no surveys have been conducted in the London area or investigated in detail the type and content of group exercise programmes used in physiotherapy practice. This part of the literature review helped to formulate the research questions for **Stage 1** of the project.

Section 3 provides and discusses the evidence on the physiotherapeutic interventions for managing CLBP including exercise therapy. The benefits of therapeutic exercise for managing CLBP is well known but there is a lack of evidence that one particular exercise type is superior to another. The literature then focuses on the evidence for group physiotherapy programmes in the management of CLBP which is relevant to **Stage 2** of this thesis. The most popular group physiotherapy programmes used in clinical practice are Pilates, Back School, Back to Fitness and Motor Control. There are many other group programmes including yoga which are critiqued. The evidence for manual therapy combined with exercise is also discussed. This is relevant to the current study as the alternative group programme aims to combine exercise with manual therapy in a group setting. Similar to exercise the effect of manual therapy or "hands on" treatment alone or combined with exercise on CLBP has been widely researched. The relatively few studies to date that have investigated the combined effects of manual therapy and exercise are reviewed.

Section 3 also looks at the classification of CLBP. **Stage 2** of study uses the Start Back Tool to classify CLBP patients into sub-groups prior to treatment. A brief review is included regarding the attempts to classify CLBP from a heterogeneous group into small homogenous sub-groups which may respond to specific physiotherapeutic treatments. The premise is that CLBP patients have lower fitness levels and so are de-conditioned. A specific multimodal exercise regimen within the proposed alternative group programme aims to address this de-conditioning. A physical de-conditioning model is described as is the evidence of de-conditioning amongst CLBP patients. The concept of the alternative group physiotherapy programme is highlighted and how it can be specifically tailored to the individual CLBP patient. Finally, the experimental design in **Stage 2** is briefly outlined. This used a mixed methods sequential exploratory design.

Chapter 3 outlines the Methodology. This chapter aims to consider the methodological background and rationale for **Stages 1 and 2** as well as the approaches taken and methods outlined. **Chapter 3** has been divided into two sections. **Section 1** considers my own world view and how it has evolved through an exploration of any underlying ontological and epistemological perspectives. My position as an insider-researcher is discussed in relation to the nature of knowledge sought, the methodological approaches developed and the impact the researcher-practitioner has had on the research itself. The methodological approaches used for **Stages 1 and 2** are discussed as well as how they were developed into the methods used. The rationale for methods of data collection and analysis for **Stage 1** are discussed. The design, development and distribution of the questionnaire in **Stage 1** had been outlined in **Chapter 4**: Project Activity. **Section 1** continues with the outline of approach and experimental design of **Stage 2**. This section finishes with the **Stage 2** research questions and hypothesis. A flow chart of **Stages 1 and 2** which assists to summarize the Stages and link them together is the end of this section. **Section 2** begins with the methods, data collection and analysis used in **Stage 2**. Any issues relating to the validity of the projects and methods of data collection are highlighted throughout. Validity refers to the credibility and accuracy of the basic concepts used in this study. It relates to the instruments used and the data collected as well as the overall findings obtained. Finally, ethical considerations in relation to any stages of the research that had arisen are discussed in **Section 2**.

Chapter 4 outlines the Project Activity undertaken during **Stages 1 and 2** of this thesis and highlights a more personal journey through these stages of the methodology. This chapter is divided into two sections. **Section 1** describes the activities in **Stage 1**: A physiotherapy survey to investigate the use of exercise therapy and group exercise programmes for the management of non-specific chronic low back pain. Information is provided on how the

questionnaire was designed, developed, distributed and results finally disseminated as a published article in an International Journal. **Section 2** concerns the project activity in **Stage 2** which was the mixed methods design study. This describes the ethical process to approve the study and the minor amendments required to go ahead. The training of the programme therapists is also mentioned. This section goes on to describe the process of participant recruitment, data collection and the focus group interviews. This chapter is completed by describing the final stages of analysis, write-up and dissemination.

Chapter 5 is the results section which is also divided into two sections. **Section 1** is the results pertaining to **Stage 1**: The Physiotherapy Survey and **Section 2**, the results of the mixed methods design study. This includes the results of the RCT and the themes of the focus group interviews.

Chapter 6 is the Discussion which is in two sections. **Section 1** covers **Stage 1** of the project which was the physiotherapy survey and **Section 2** covers the mixed methods design study in **Stage 2**. **Section 1** begins with the response rate of the physiotherapy questionnaire and then goes on to discuss specific questions related to the research questions. These topics include group programme referral by physiotherapists and the differences in referral rates between specialist and physiotherapy grade. The types of exercises prescribed for CLBP is also explored and compared with the literature. This part of the discussion then focuses on group physiotherapy programmes such as the most popular types used in clinical practice and the specific content/structure of these programmes. Outcome measures most frequently used in group physiotherapy programmes are highlighted. The limitations of this physiotherapy survey such as non-response bias are discussed. The discussion in **Section 1** concludes with

recommendations and design of the alternative group exercise programme linking **Stage 1** and **Stage 2** of the thesis.

Section 2 discusses the results of the mixed methods design study. Sample size, recruitment and the implication of drop-outs are discussed. The discussion then highlights the specific quantitative measures used in the RCT. This starts with the Start Back Tool developed as a prognostic screening tool for CLBP patients and discusses the findings in the study. The effects of the two group physiotherapy programmes on function/disability, quality of life, pain and patient satisfaction post treatment are compared and discussed. The supplementary qualitative phase: Focus Group Interviews are discussed in detail and the findings are merged with the results found in the quantitative phase. The integration of quantitative and qualitative methods is further discussed in a short section on mixed methods research. **Section 2** then discusses the topics of implementation, change management and leadership integral to this thesis. The limitations of the mixed methods design study are highlighted in detail. The discussion is completed with conclusions, recommendations and an epilogue of the thesis.

Chapter 1

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1.0 Overview of Thesis

The development of an alternative group physiotherapy programme for managing chronic low back pain (CLBP) was the aim of this thesis. Change management and leadership initiatives developed in the current research process may contribute to physiotherapy practice at a local and cross-organisational level. My thesis describes a mixed methods evaluation approach. The overall research process has built up evidence over time regarding group exercise therapy for managing CLBP and about the impact of the alternative group physiotherapy programme on CLBP patients in a primary care setting. The current project can be described as realist evaluation which attempts to determine what is it about the alternative programme that works for whom and in what circumstances. This thesis also includes a discussion regarding the implementation of research findings and new evidence into clinical practice. There are two integrated stages of the research. **Stage 1** aimed to survey physiotherapists regarding the exercises they prescribe for CLBP, referral rates to group exercise programmes, the type and content of group programmes to manage CLBP patients. This helped to develop hypotheses about the mechanisms of group physiotherapy programmes that may affect outcome such as the types of exercises that are used, the nature of education regarding managing back pain provided and the individuals involved in implementing the programme. The alternative group physiotherapy programme was developed for **Stage 2** using the results of the survey (Daulat, 2013), review of the literature and collaboration with service providers within the Trust. Post **Stage 1** adopted an action research approach whereby action was taken to make changes to the alternative programme where the research was taking place in **Stage 2**. The alternative programme was then evaluated in **Stage 2** by comparing it with a standard group programme in a randomised controlled trial (RCT). The alternative

physiotherapy programme was evaluated using a mixed methods sequential exploratory design. This study design consisted of two phases: a core quantitative followed by a supplementary qualitative phase which used a mix of quantitative and qualitative data collection techniques. For example, specific quantitative outcome measures were used to investigate the effect of both interventions on CLBP including a patient satisfaction questionnaire. Focus group interviews were used to explore patient's experiences regarding the treatment programmes. The findings of this research led to a proposed revised version of the alternative group programme. This modified version of the alternative programme was the end product of the thesis. The plan was to fully implement this alternative group physiotherapy programme into clinical practice and continue to evaluate it.

1.1 Background and Rationale

Low back pain is very common in the general population with an estimated lifetime prevalence of up to 80% and one-year prevalence rates of between 50% and 76% (Bronfort et al., 2011; Fidvi and May, 2010). Approximately 20% of the population consult their GP regarding back pain each year (Savigny et al., 2009). It has also been suggested that psycho-social and work related factors have contributed to an increase in the prevalence of this condition (Freburger et al., 2009). The economic and social impact of back pain is substantial due to the high prevalence rates (Maniadakis and Grey, 2000). Low back pain is also one of the main causes of work absenteeism with many lost working days per year (Andersson, 1999). Chronic low back pain (CLBP) is defined as pain and discomfort localised below the costal margin and above the inferior gluteal folds, with or without referred leg pain which has persisted for at least 12 weeks (Airaksinen et al., 2004). Approximately 10-15% experiencing low back

pain will go onto develop CLBP and is responsible for at least 80% of the total costs of low back pain management (Liddle et al., 2004; Liddle et al., 2007). The estimated cost of physiotherapy management for CLBP in the United Kingdom is 24-36 million pounds annually (Norris and Matthews, 2008). CLBP is a disabling condition with many patients developing psychological distress and illness behaviours (Bronfort et al., 2011; Hurley et al., 2009). There has been no established standard management for CLBP. Several conservative therapies such as supervised exercise and manual therapy have demonstrated some benefit (Bronfort et al., 2011).

Group exercise programmes are a cost effective treatment for managing CLBP (Lewis et al., 2005). Many randomised controlled trials (RCTs) investigating group exercise for the management of CLBP have used single mode exercise types such as Pilates, core stability, aerobic or strengthening without being individualised (Kell and Asmundson, 2009; Liddle et al., 2004). Effective exercises for managing CLBP found in the literature are those that are specific, individualised and regularly supervised (Hayden et al., 2005). Patients with CLBP tend to avoid physical activity due to pain and fear avoidance behaviour. They become de-conditioned due to their low activity levels which results in decreased muscle power and cardiac capacity (Dogan et al., 2008). CLBP patients may benefit from a programme that consists of combined exercise types such as strengthening, mobility and aerobic exercise (Wai et al., 2008). Manual therapy combined with exercise therapy has been found to be more effective than manual therapy alone for the treatment of CLBP (Aure et al., 2003; Geisser et al., 2005). Several types of group programme have been described in the literature and vary greatly in content as well as duration (Choi et al., 2010; Heymans

et al., 2011). To date there have been no descriptive surveys investigating physiotherapy management of CLBP using group programmes.

The most widely used group programmes for the management of CLBP are the Back School, Back to Fitness Programme, Motor control/Stabilisation and Pilates. The Back School has been a common management strategy for back pain modelled on the Swedish Programme originating in the 1960s (Klabar-Moffett and McLean, 1986). The Back Class model contains a standard programme of exercises and education which is supervised but not individualised. The Back to Fitness Programme (BTFP) consists of circuit based exercises for back pain patients (Klaber-Moffett and Frost, 2000). Exercises in this programme are generally high intensity and non-specific. This programme consists of a group education component but does not offer individual attention (Carr et al., 2005). Also it does not promote long-term adherence to exercise. Previous research has shown that individuals with CLBP have impaired control and delayed recruitment of the deep trunk muscles that are responsible for maintaining the stability of the spine (Ferreira et al., 2010; Macedo et al., 2012). Motor control exercises are superior to a minimal intervention for treating CLBP but no more effective than other forms of exercise therapy (Macedo et al., 2009). Pilates based on the methods of Joseph Pilates (1880-1967) has become popular form of mind-body exercise for back pain patients (Pereira et al., 2011). It focuses on controlled movement, posture and breathing along with activation of the deep trunk muscles (Lately, 2002). Pilates exercises are not very functional as they are non-weight bearing and mostly performed on mats (Sorosky et al., 2008). They also have a strong flexion bias which may not benefit patients with flexion mediated low back and leg pain (Sorosky et al., 2008). There are several other group exercise programmes

described in the literature but no one group exercise programme seems to be superior to any other and only have moderate effects on CLBP. The literature suggests that group programmes such as the back school model do not have good long-term outcomes (Heymans et al., 2011). Group programme drop-out rates have been quoted as up to 30% (Hurley et al., 2009). The high drop-out rate of group programmes may be largely attributable to long waiting lists and inflexible appointment times (Chown et al., 2008). The current group programme concept is outdated and needs to be more effective.

Low back pain accounts for more than 50% of physiotherapists' workload (Foster et al., 2010). Based on previous GP referral rates, approximately five thousand patients presenting with low back pain are seen in the Ealing physiotherapy service each year (Bernstein, 2011). The London Northwest Healthcare NHS Trust had secured a new investment initiative leading to our service being re-designed in October 2013. This extra funding had resulted in increased staff capacity and patient referrals from GPs which was likely in theory to increase significantly the number of CLBP patients presenting to the out-patient department. Patients presenting with CLBP are referred to our musculoskeletal (MSK) physiotherapy service by their GP. These patients are initially assessed by the physiotherapist on their first visit. The physiotherapist then decides on the appropriate treatment for that patient. CLBP can be managed conservatively in our department with a course of physiotherapy or patients may require further investigation and referral for specialist treatment. Conservative treatment using a course of physiotherapy in our service consists of a combination of exercise, manual techniques and education. CLBP patients are usually treated on a one to one basis but can also be referred to group programmes for further

rehabilitation. The Governments' re-organisation of the NHS has seen Primary Care Trusts (PCTs) replaced by General Practice Consortia (Black, 2010). This process started in April 2013. The GP Consortia are now responsible for commissioning services and are also accountable for NHS performance. It has also been outlined by the operating framework for the NHS that services including physiotherapy need to deliver cost effective treatments whilst maintaining quality and good outcomes (Department of Health (DOH), 2010).

1.2 Professional Role and Relationship with the Project

I have been a physiotherapist for over fifteen years and currently working in an extended physiotherapy role (Extended Scope Practitioner). My role is to assess the physiological and/or psychological functioning of complex musculoskeletal conditions, diseases and disorders. This is entirely a clinical role with no management duties at the present time. I plan, deliver and evaluate interventions and/or treatments for musculoskeletal conditions at a high level. I have the responsibility to triage potential surgical candidates, order diagnostic imaging such as magnetic resonance imaging (MRI), X-ray or laboratory tests (blood tests) as well as injecting medication (steroid injections). In close collaboration with General Practitioners (GPs) and secondary care consultants appropriately, we can refer patients to secondary or tertiary care according to the clinical presentation. My clinical speciality is the management of spinal conditions including CLBP. I was involved in leading a previous work-based project at the NHS Trust between 2009 and 2011 aimed at developing group exercise programmes such as the Back School used to manage back pain (IPL 4060). This work-based project found that only about 20% of our CLBP patients were being referred to these group exercise programmes. The current group

physiotherapy programmes used at the Trust were not producing good outcomes, had long waiting lists and poor attendance rates. This work-based project found the Back School group exercise model was no longer effective and was not available to non-English speaking patients at the Trust. The exercises used in our group programmes were not individualised and there was a lack of individual attention within these groups. The duration of these programmes was 4-6 weeks which may not be sufficient time for neuromuscular changes to occur and therefore address the de-conditioning seen in CLBP patients (Dogan et al., 2008; Jones et al., 1989). A need to develop an alternative group physiotherapy programme was identified which is the objective of this doctorate programme. This consisted of another work-based project to address these limitations seen in the current group format for managing CLBP. I was ideally suited for this work-based project having several years of experience working in this subject area. I was essentially an Insider-Researcher who was able to combine theoretical knowledge and empirical evidence in order to understand how the alternative intervention works and the outcomes produced. Being an insider-researcher may have an advantage over academic researchers (Fox et al., 2007). In this thesis, my objective was to provide solutions to any problems that arose within the workplace by reflecting on and researching physiotherapy practice. Work-based research has the potential to make a contribution and provide new knowledge for improving the management of CLBP.

1.3 Guidelines and Commissioning

The National Institute for Clinical Excellence or NICE 2009 clinical guidelines suggested up to 9 sessions of physiotherapy treatment for non-specific low back pain. NICE recommended patients should also be offered a structured and supervised group exercise programme of up to 10 people. This guideline may be unrealistic for most physiotherapy departments to achieve as treatment costing has previously been based on an average of five physiotherapy sessions (NHS, 2011). The NICE guideline will be revised in 2016. There is at present no evidence base available to support decisions on the appropriate average treatment sessions to deliver optimal outcomes (DOH, 2011a). The alternative group physiotherapy programme aimed to provide up to six sessions of treatment that is not restricted to exercise therapy only and was able to accommodate non-English speaking participants. The alternative group physiotherapy programme planned to combine multimodal individualised exercises and manual therapy. Currently, there are no group physiotherapy programmes in clinical practice which combine individualised exercises with manual therapy. General Practitioners (GPs) who refer CLBP patients to a physiotherapy service are now responsible for spending resources allocated for healthcare in ways that meet the objectives of the health system (Wade et al., 2006). This process of commissioning has already involved competitive tendering to identify the provider who can deliver cost effective services of high quality with good outcomes (Woodin and Wade, 2007). The alternative group physiotherapy programme aims to provide a cost effect service of high quality which delivers responsive, fair and patient-centred care. This alternative model may be attractive to the GP commissioners and highly competitive in the provider market.

1.4 Methodological Approach

The methodological approach is detailed in **Chapter 3**. This thesis has included two integrated stages. **Stage 1:** 'A physiotherapy survey to investigate the use of exercise therapy and group exercise programmes for the management of non-specific chronic low back pain'. This project involved a survey of physiotherapists to explore their use of exercise and group exercise programmes for managing CLBP which had not been done before. Subsequently, an article relating to **Stage 1** was published in the September 2013 issue of a peer review journal: International Musculoskeletal Medicine (Appendix 1). **Stage 2** was titled**:** 'Evaluation of an alternative group physiotherapy programme for the management of chronic low back pain in Primary Care'. This programme had been developed from the review of the literature, consultation with service providers and the results of the survey. The development process of the alternative programme in collaboration with the manager and programme therapists in the physiotherapy department involved integrating the findings from the survey into the programme's final protocol. A randomised controlled trial (RCT) was used to measure the impact of the alternative group physiotherapy programme on CLBP participants. Participants exposed to this intervention were compared with a comparable control group who were matched on the key variables of CLBP. Both interventions in the RCT were evaluated using a mixed methods approach. This approach has been advocated previously to determine the effect of a new intervention and how it may be replicated for future policy development (Pawson, 2006).

1.5 Impact of Change

The overall Doctorate programme had aimed to have an impact on me as a research-practitioner. This will assist me to develop into a respected expert clinician who has a better level of research knowledge, is able to lead change as well as promote new ways of thinking in the management of CLBP. During this thesis, I hoped to show my development as a transformational leader through the project activities of supporting, coaching and developing others to achieve a higher level of practice.

The results of the survey in **Stage 1** may lead to changing how physiotherapists prescribe exercises for CLBP and their referral patterns to group programmes. The alternative group physiotherapy programme may also require clinicians to change their practice in a group setting by providing more comprehensive and individualised treatments. This will require them to be more innovative and creative in their practice but be more stimulating to them. This programme plans to have an impact on the service users. This alternative group physiotherapy programme offers flexible treatments and be available to all as it does not discriminate those individuals for whom English is not their first language. Patients are provided with individualised exercises and advice tailored to them in the programme. Better consistency with exercises, shorter waiting lists and more effective treatments within this alternative programme may improve to adherence to treatment and advice. This may have implications for reducing re-occurrence rates and help patients manage their CLBP in the long-term. It is hoped that my journey through this doctorate programme will be of value to patients, my physiotherapy team and the NHS organisation I work in.

1.6 Aims, Objectives and Products of the Overall Programme and Thesis

1.6.1 Aims

The aim of the overall programme was to improve my research knowledge and capability as well as to develop musculoskeletal physiotherapy practice by producing new knowledge and understanding leading to change.

1.6.2 Objectives

The main objectives of the overall programme and Thesis were:

1) To become an authority/expert in the field of physiotherapy who has demonstrated the application of knowledge and sound research to change or improve clinical practice.
2) To develop as a clinical leader by facilitating evidenced-based practice, innovation and influencing change leading to an improvement in the management of chronic low back pain CLBP at a local level (local change management).
3) To undertake an original research project consisting of two integrated stages resulting in a contribution to the knowledge and understanding of the physiotherapeutic management of CLBP and/or the application of this knowledge to clinical practice.

1.6.3 Products

1) Evidence provided regarding the application of knowledge and research to clinical practice (IPL4040, IPL4060, IPL4016 and IPL5360).
2) Evidence provided for leading a project team in a local change management process to develop an alternative group physiotherapy programme (ILP 4060, IPL4016 and IPL5360).
3) A clinical leader who has shown the ability to communicate a vision or strategy to others and at a service level promoting innovation and promising practice change (ILP 4060, IPL4016 and IPL5360).
4) Two integrated original research stages which have created new knowledge and developed new processes that have had a significant impact on the management of CLBP. A revised or recommended version of an alternative group physiotherapy programme for the management of CLBP was the end product of the programme. This was developed, evaluated and disseminated (IPL 4016 and IPL5360).

1.7 Products of Stage 1

The survey has provided data on the exercises used by therapists for managing CLBP, referral rates to group exercise programmes, the type and content of these programmes. The survey aimed to provide answers to the following questions regarding CLBP and exercise therapy.

1.7.1 Individual Physiotherapists

What are the referral rates to group exercise programmes?

Is there any difference in referral rates between secondary care, community and independent practices?

Is there a relationship between grade or speciality and group programme referral?

How many and what types of exercises are given for CLBP patients?

Are therapists able to refer all patients suitable for group programmes for whom English is not their first language?

1.7.2 Group Exercise

What are the most common group programmes in clinical Practice?

What is the content of these group programmes?

What is the nature of education provided in these programmes?

What outcome measures are used?

1.7.3 Stage 1: Hypotheses to be tested in the survey

Group programmes use single mode exercise regimens.

Exercises given by therapists are different to those in the programme.

Group programmes lack individual attention and a manual therapy component.

Education provided is general and not specific to the patient.

1.8.1 Products of Stage 2

The product of the **Stage 2** was a modified version of an alternative group physiotherapy programme. It was hypothesized that this alternative programme can achieve significant long-term benefits in function and quality of life to CLBP patients as well as being cost effective with lower drop-out rates. It is also hypothesized that the long-term benefits of this alternative programme may be attributable to encouraging participants to continue with their individual exercises and increase their physical activity levels post treatment. Shorter waiting lists by using a rolling programme and more individualised treatment within the group format may also reduce drop-out rates. This original model may change the way CLBP is managed and provide a better alternative to existing group exercise programmes such as the Back School or the Back to Fitness Programme.

1.8.2 Stage 2: Hypothesis

Hypothesis: The alternative group physiotherapy programme is more effective than a standard group programme in the management of non-specific CLBP for improving function and quality of life.

Null Hypothesis: The alternative group physiotherapy programme is not more effective than a standard group programme in the management of non-specific CLBP for improving function and quality of life.

For the purpose of this study in Stage 2: The Null Hypothesis will be tested

1.9 Implementation of Alternative Programme into Clinical Practice

The product of this thesis was the alternative group exercise programme. This programme was developed, implemented, evaluated within the organisation and disseminated. However, a future objective is to implement this programme into clinical practice at a regional or national level. There is the need for commitment amongst policy makers, commissioners and service providers to ensure patients with CLBP receive evidence-based treatments. Bridging the research-practice gap should also be the priority of all researchers, clinicians, commissioners and policy makers. If the alternative group programme is successful, transferring effective programmes into real world settings and sustaining them is a complex long-term process (Evans et al., 2013). Implementation of a new or an alternative clinical programme depends both on organization and system changes as well as on individual clinicians' behaviour (Oldenburg and Glanz, 2008). For implementation to be successful the organisation has to have the capacity and willingness to change. This links in with the change management strategies discussed in the literature (**Chapter 2**). New ideas or innovations require early influence from adopters or champions to facilitate implementation. A champion is an individual who dedicates themselves to supporting and driving through an implementation. My objective to develop as a transformational leader during this thesis will help to influence individual behavioural change and have a direct influence on the implementation of the alternative group programme. The relevant research pertaining to this thesis on leadership and my development as a clinical leader is discussed in the literature.

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2.1 Introduction to the Literature

A literature review allows the doctorate researcher not only to gain but also demonstrate their knowledge in their chosen field and related areas. This is linked in with one of the objectives of the programme to become an authority and expert in the field of physiotherapy. It will be demonstrated how the application of this knowledge and research has contributed to changing or improving clinical practice. Another objective of the programme was to develop as a clinical leader by facilitating evidenced-based practice, innovation and influencing change leading to an improvement in the management of CLBP. This review will look at the literature around implementation research, leadership and change management relating this to my physiotherapy practice. The process of this literature search has also helped to reveal gaps in the evidence that has been addressed by the current research project. This process has helped me develop the research questions for the major work-based project within the framework of the existing knowledge in the physiotherapeutic management of CLBP. The literature search can locate research designs or evaluation methods that have been adopted in relevant CLBP studies and might be applied to the current design (French et al., 2001). For example, the use of focus group interviews as part of a mixed methods design to explore participant's experiences of their physiotherapy treatment. This major work-based project has two distinct interrelated research studies or stages. The first study aimed to investigate the physiotherapy management of CLBP with the use of group exercise programmes. There is no evidence of any studies that have used self-report questionnaires to survey physiotherapists regarding the use, type and content of group exercise programmes for managing CLBP. The results of the survey were used in the design of the alternative group physiotherapy programme. The second larger study or stage used a randomised

controlled study to evaluate the alternative group physiotherapy programme for the management of CLBP and compared this programme with a standard group programme used at the NHS Trust. The aim of this literature review was to evaluate the surveys which have so far explored the physiotherapy management of CLBP. This review will also look at the evidence for physiotherapeutic strategies used to manage CLBP such as exercise therapy, manual therapy and group physiotherapy programmes. This information together with the survey results consolidated the design of the alternative programme. This review has drawn information from journal articles, books, theses and relevant NHS or government publications. For the purposes of this review CLBP had been defined as pain greater than 12-weeks duration.

2.1.1 Terms of Reference

My DProf project aimed to explore the physiotherapy practice of chronic back pain management. The objective was to set out initiatives which may have an impact on clinical practice. This involved relevant change management strategies and the development of my leadership skills.

2.1.2 Limitations of the Literature and Research

A limitation of this research is that only one specific aspect and area of physiotherapy was looked at. This was the physiotherapeutic management of non-specific CLBP using group exercise programmes. Limitations with this literature review include the exclusion of unpublished studies and will only include articles written in English. Studies may not be published due to negative and ambiguous findings. It may be possible to explore this limitation by accessing unpublished research or theses on-line via university repositories or libraries. For example, it was possible to access Sokunbi

et al. (2010) quantitative study (RCT) from the British Library even though the findings had not been published in a peer view journal. However, this may not have an impact on the overall findings or conclusions. Another limitation is that the literature is based on my own analysis and interpretation of the available research. However, I have looked at a number of systematic reviews and meta-analysis on the subject of CLBP in order to view the opinions and analysis of other researchers. My own bias towards the use of exercise therapy for CLBP may also influence this review. This bias can be avoided by reviewing other physiotherapy treatments for CLBP and their effects such as manual therapy. It may not be possible to access all published research in my chosen area such as Doctoral Theses and other obscure journal articles.

2.1.3 Research Question and Scope

My initial journey and development of the research questions started from my lead role in the review of the Back School at my physiotherapy department. This work-based project was described in the RAL 60 claim (IPL4060) which forms part of the overall DProf programme. CLBP at our physiotherapy department is currently managed by a combination of exercise, manual techniques and education. Group exercise programmes such as the Back School are a cost effective treatment for managing CLBP (Lewis et al., 2005). However, only about 20% of our CLBP patients are referred to the group exercise programmes. My work-based project (IPL4060) found a number of flaws with the current Back School programme. The Back School was not available to non-English speaking participants and had shown to have high drop-out rates and poor treatment outcomes. The exercises used in the Back School were not individualised and there was a lack of individual attention within the group.

The duration of the Back School was only 4 weeks. This may not be sufficient time for neuromuscular changes to occur and address the de-conditioning that may be seen in CLBP patients (Dogan et al., 2008; Jones et al., 1989). There was a need to develop an alternative group physiotherapy programme to address these limitations seen in the current group format for managing CLBP. The main research question was: Is this alternative group physiotherapy programme more effective than standard group programmes used at the NHS Trust for managing CLBP? There is an extensive scope to this major project with two interrelated stages demonstrating original research to create new knowledge and develop new processes that may have a significant impact on the management of CLBP. Completion of the major project has helped me to develop as a clinical leader which is one of the objectives of the overall programme. This process has involved leading a clinical team in a multidisciplinary context. Leading a team in a multidisciplinary context requires management of a range of relationships between health professionals, co-workers, managers and service users (Millward and Bryan, 2005). This is a form of distributed leadership, in which my leadership will be seen as leading others to lead themselves. The first stage in this thesis was a survey involving physiotherapists in other trusts and physiotherapy departments. This has involved establishing a professional authority as a leader in the process of coalition-building and inter-organisational networking. Initiating organisational change at a local level and development during the major project has helped to foster my leadership skills. This process has shown my ability as a leader to influence others to change their accepted patterns of thinking and practices of managing CLBP as well as encouraging innovation. If local innovation improves healthcare, a leader needs to support the spread of good practice which may lead to policy change at an organisational level (Hartley and Benington, 2010).

Section 1

2.2 Implementation Research, Change Management and Leadership

2.2.1 Implementation Research

Implementation research is concerned about how interventions work within real world conditions and is the scientific study of methods to promote the effective uptake of research findings (Connell et al., 2014; Lombard et al., 2014). Implementation can be defined as the active and planned efforts to put in place an innovation within a defined setting. Innovation is an idea, practice or object that is perceived as new by an individual or other unit of adoption (Oldenburg and Glanz, 2008). Evidence-based practices are interventions for which consistent scientific evidence shows that they improve patient outcomes. However, improving population health outcomes relies on the implementation of findings from clinical and health services. Transferring research findings into clinical practice is generally an unpredictable and slow process (Evans et al., 2013). Sallis et al. (2000) found that less than 20 percent of academic articles addressed the translation of research into practice. University-based controlled trials have been shown to yield evidence-based treatments in mental health for example. There is little evidence that these treatments are either adopted or successfully implemented in community settings in a timely way (Proctor et al., 2009). Crane and Kuyken (2013) investigated the implementation of a mindfulness based cognitive therapy (MBCT) service. In their survey, they found that only 32% of respondents reported that the implementation of the MCBT service was well supported by clinical staff. It was concluded that implementation relies on achieving significant and planned whole system change involving individuals, teams and

organisations. The processes involved in transferring research to practice settings are complex, interconnected and multifaceted (Crane and Kuyken, 2013). One example in the literature of the implementation of an evidence-based intervention in physiotherapy is GRASP. GRASP is the graded repetitive arm supplementary programme used for patients who have suffered a stroke. This programme aims to increase the intensity of the use of the affected upper limb in stroke patients. A RCT evaluating GRASP was first published in 2009 (Harris et al., 2009) and was included in the Canadian best practice guidelines in 2010. This programme was taken up rapidly in countries worldwide. By 2013, 63% of UK therapists were aware of GRASP. However, only 11% were regular users of this programme. It was concluded that interventions should have a sufficient evidence base before being implemented (Connell et al., 2014). Public health decision makers are often reluctant to consider 'new' interventions when the effectiveness has not been demonstrated in their particular locality, setting or population. These decision makers generally want interventions that can solve problems in the community (Oldenburg and Glanz, 2008). For example, current group exercise programmes used in physiotherapy generally exclude patients for whom English is not their first language which may present a problem with back pain management in an ethnically diverse community. GRASP is an example of bridging the gap between an initial research intervention study which creates knowledge and implementation of this programme into healthcare systems. Although the GRASP concept is widely known it has not necessarily been effective for achieving the targeted behavioural change in the UK.

Scalability involves expanding a programme that has been shown to be efficacious in a small scale controlled setting (RCT). This efficacious programme is then

implemented under real world conditions with the goal of reaching a larger population (Zullig and Bosworth, 2015). Even safe and effective interventions require modification for scale-up. Subsequent evaluation trials would involve samples of 300-600 participants. This would be applicable to the alternative group exercise programme which has been evaluated in a small scale study with the next logical step of implementing in multiple physiotherapy centres for further evaluation. Cost is an important factor in scale-up and whether the programme is cost-effective. Evaluating the programme must encompass a cost-effectiveness and clinical outcomes assessment (Zullig and Bosworth, 2015). This was a limitation with the programme evaluation in this thesis which did not include a cost analysis. However, this could be addressed in future evaluation trials. The standard group exercise programme used in **Stage 2** of this project; the Back to Fitness Programme (BTFP), is one example of a group exercise programme that has been researched, implemented and expanded successfully into physiotherapy practice. The BTFP was originally developed in Oxford for managing CLBP in the 1980's. This programme was evaluated using a RCT and adapted for implementation in a community setting. The BTFP was subject to further evaluation and has since been implemented widely across the UK in physiotherapy departments (Klaber-Moffett and Frost, 2000). My physiotherapy survey in **Stage 1** found that 50% of physiotherapy departments surveyed were using the BTFP (Daulat, 2013). However, there is generally a gap in the research that translates evidence-based interventions from isolated efficacy trials toward effective strategies in the broader population (Lombard et al., 2014). Many interventions found to be effective in health services research studies fail to translate into meaningful patient care outcomes across multiple contexts. For example, Carr et al. (2005) found that patients living in the most deprived areas were more likely to have poorer

outcomes. With regard to the BTFP, Carr et al. (2005) found that patients from the most deprived areas had the worst functional outcomes at treatment follow-up relative to patients from more affluent areas.

The Medical Research Council (MRC) complex interventions framework provides guidance on how an intervention can be implemented in the uncontrolled real world healthcare setting (Medical Research Council, 2008). There are six stages in this guidance.

1. In the context of physiotherapy group programmes; what is the existing provision of group programmes?
2. Understanding the perceived benefits and costs of the alternative programme. A cost analysis has not been performed in the current study as mentioned. This study was a small-scale mixed methods design which aimed to examine the feasibility and effects of a novel intervention. This would be classed as phase two in a five phase process of evaluating interventions. A cost analysis is usually performed in phase five of the evaluation process (Sidani, 2015).
3. What are the facilitators that enable service delivery?
4. What are the barriers that may prevent the service from being delivered?
5. The successful use and accessibility of the programme.
6. The development of an implementation plan in co-operation with stakeholders.

Successful implementation of evidence-based practice or intervention programmes into clinical practice is represented as a function of the interaction between evidence, context and facilitation (Evans et al., 2013). Research evidence was reported to be just one influence among a range of factors that were considered in commissioning and

implementing local policy. Research and implementation often overlap and do not occur in a linear progression. Practice may be opinion-based rather than evidence-based. Implementation of research findings into practice needs a much more active strategy than simply disseminating findings in journals, conferences and in-house lectures (Walker et al., 2013). Evidence implementation generally requires whole system change implicating both the individual and the organisation (Kitson et al., 2008). Other contextual factors such as financial constraints, the lack of value of local research and political influences can affect whether research is used in local policy. Two thirds of organizations efforts to implement change fail. The timing, current organisational climate and the readiness for the organisation to change are factors to consider for implementation. The literature around change management theories are discussed in the next section. There is a degree to which stakeholders perceive the current situation and the need for change. For the implementation process to be successful requires an active change process aimed to achieve individual and organizational level use of the intervention as designed. The intervention may require adaptation to fit within a particular organisation but modified without undermining the integrity of the intervention (Damschroder et al., 2009).

Organisational change starts with individual behavioural change. There is an integration of individual behavioural change within the context of organizational change. Individuals involved with the intervention and/or implementation process have a significant role. Individuals in the organisation will have their own knowledge and beliefs about the intervention. The degree to which new behaviours are positively or negatively valued heightens intention to change which is a precursor to actual change (Damschroder et al., 2009). I regard myself as a leader within the organisation

who has a direct influence on implementation of the alternative group programme. This also links in with my role as an insider-researcher (**discussed in Chapter 3**) who has a significant commitment, involvement and accountability of the alternative programme and its implementation into clinical practice. As I have a similar background with the intended users of the programme (physiotherapists), these individuals will be more likely to adopt the intervention. My development as a clinical leader during this thesis has assisted in the implementation of this alternative programme. The literature of leadership related to my thesis is discussed in **section 2.2.3.** Through **Stage 1** of the thesis, as a leader I have helped to solve problems, adapt the programme using a form of action research, mobilise resources and ensure the alternative programme has become more visible in my organisation. The resources required to implement and sustain a programme include human, organizational and technical as well as physical space (Zullig and Bosworth, 2015). I have shown to be a champion in this process who has dedicated to supporting, marketing and driving an implementation overcoming any indifference or resistance to the intervention.

2.2.2 Change Management

Stage 2 has involved leading a project team in a local change management process to develop an alternative group physiotherapy programme. Change management (CM) has been defined as 'the process of continually reviewing an organisation's direction, structure and capabilities to serve the ever-changing needs of external and internal customers' (Moran and Brightman, 2001). CM is a process by which an organisation gets to its future state. Creating change starts with creating a vision for change such as the way CLBP patients are managed in a group setting. Individuals such as the physiotherapists are empowered to act as change agents to achieve this vision (Lorenzi and Riley, 2000). There are several models of CM in the literature. Lewin's (1947) model is the most extensively used model by organisations in the change process and can also be applied to the healthcare sector (Lorenzi and Riley, 2000).

Lewin's field theory indicates that the present situation in the organisation is being maintained by a set of symbolic forces (Suc et al., 2009). A force field analysis examines the driving and restraining forces in any change situation. The driving forces are those elements of the organisation that support a desired change. The retraining forces keep the organisation in equilibrium. If the two forces are equal the organisation is static (Nixon, 2004). The driving forces must outweigh the restraining forces in any situation if change is to happen (Cameron and Green, 2009). When the change occurs the organisation reverts to a new state of equilibrium which reflects the desired change (Nixon, 2004). Lewin's model further suggested that organisational change has 3 steps: Unfreezing, Moving and Refreezing (Cameron and Green, 2009). Lewin suggested that each step should be completed before moving on to the next one. Unfreezing involves defining the current state and the need for change which

becomes the planning phase (Cameron and Green, 2009). Relevant to **Stage 2**, this has involved providing background research regarding group physiotherapy programmes and the use of workshops or in-service training sessions to communicate the need for change to staff. This is linked to action research whereby individuals need to feel the necessity for change and the most appropriate solution to the situation and its implementation (Suc et al., 2009). For example, why the Back Class programme needed to be changed and what would be a better alternative? It is important then to identify the driving forces such as ambitions, goals and needs which must outweigh the restraining forces for the change project to be successful. The equilibrium would then need to be destabilised or unfrozen before old behaviour can be discarded and a new behaviour adopted. However, change is not easy and this approach may not be able to be applied to all situations (Burnes, 2004). Step 2 moves from a new state through participation and involvement. This translates as the implementation phase (Cameron and Green, 2009). The final step is refreezing. This stabilises the new state of affairs by setting policy, rewarding success and establishes new standards (Cameron and Green, 2009).

Lewin stated that effective change could not take place unless everyone has a full and equal part in the change process. Group dynamics is important in this process to gain support and commitment from all those involved in the project (Suc et al., 2009). Lewin's model may only be relevant to small-scale changes in stable conditions. This model may ignore issues such as organizational politics and conflict (Burnes, 2004). Any significant organizational change such as in **Stage 2** of this thesis involves changing the way physiotherapists work and interact. Resistance to change can occur at the individual and organisational level (Lorenzi and Riley, 2000). Physiotherapists

may be reluctant to discard old behaviours and practices. It may be difficult for the organisation to change its attitude and culture toward managing CLBP which may have existed for some time. Lewin's model has been criticised as being too broad and simplistic (By, 2005). Change is a more complex and dynamic process which should not be treated as a series of linear events (Burnes, 2004).

Bullock and Batton (1985) had developed a four-phase model of planned change which is a highly applicable model for most change situations (Burnes, 2004). Change management initiatives throughout my project have been based on this model. This model looks at the phases of change describing the methods employed to move an organisation from one state to another. These phases describe the stages an organisation must go through to achieve successful change implementation (Bullock and Batton, 1985). These phases are exploration, planning, action and integration (Cameron and Green, 2009). This model in our context has involved a cyclic process in which research, action and evaluation were all interlinked rather than the linear process described in Lewin's CM model. The exploration phase involves verifying the need for change and persuasively communicating to managerial leaders and members of a team that change is necessary (Fernandez and Rainey, 2006). The planning phase actively involves decision making and the action sequence (Cameron and Green, 2009). This has involved decisions on the structure of the alternative programme and how it will be set up. The action phase involves completing the plan with feedback mechanisms in place which allow some re-planning if things go off track. For example, feedback from the administration team regarding the referral process for the alternative programme. The final stage of the change management process is integration (Cameron and Green, 2009). This involves aligning the change with other

areas of the organisation and formalizing the alternative programme as an established practice within the trust for managing CLBP.

This planned approach to organisation change is based on the assumption that organisations operate under constant conditions and can move in a pre-planned manner from one stable state to another. However, organisational change may be more open-ended and continuous process in a fast changing environment. The Bullock and Batten (1985) model may not be applicable to situations that require rapid and transformational change. However, my project could be regarded as being relatively small scale with incremental changes only. This model of change also presumes that all stakeholders in the change project are willing and interested in implementing it. It also assumes that organisational politics and conflict can be easily resolved (Burnes, 2004). However, my project has also used an emergent approach to change management. This approach sees change driven from the bottom-up rather than the top-down and has been a continuous open-ended process of adaptation to changing situations and conditions. Change is perceived as a process of learning such as physiotherapists altering the way they manage CLBP patients in a group setting. This approach is also a method of changing organisational practices and structure (By, 2005). This emergent approach with the emphasis on empowerment, participation and learning at all organisational levels is more likely to produce internalisation (Farrell, 2000).

2.2.3 Leadership

One of the objectives of this thesis was to develop as a clinical leader who has been able to influence change leading to an improvement in the management of CLBP at a local level. Leadership is an essential function to prepare and mobilise the organisation and its individuals for change (Carroll and Edmondson, 2002). Due to the pace and volatility of change in the public sector, leaders have to understand, shape, manage and react to change with higher levels of uncertainty and risk than before. It may be more difficult for a single person to complete these tasks. Shared or distributed leadership across teams and networks may be required for effective clinical care and organisational change. However, there is the need for a formal leader who is accountable and responsible for the change management project (Hartley and Benington, 2010).

The two models of leadership relevant to this project are transactional and transformational. Transactional leadership can be considered as having more managerial qualities. This leadership behaviour clarifies what is expected of the follower's performance explaining how to meet such expectations. A criterion is outlined for the evaluation of this performance. Feedback is then provided on whether the follower is meeting their objectives. Rewards that are contingent on meeting these objectives are allocated. Transactional leadership is effective in hierarchical organisations where the followers are subordinates and where the group is focused on achieving their objectives. Transformative leadership aims to create an environment in which individuals are able to learn for themselves and share their learning experiences within the organisation. This leadership behaviour stimulates interest among colleagues to view their own work from a new perspective. An awareness of

the vision or mission is generated for the team and organisation. The transformational leader then helps to develop colleagues to higher levels of ability and potential (Dionne et al., 2004). This type of leader also helps motivate individuals to look beyond their own interests toward those that will benefit the group or organisation (Farrell, 2000). Transactional and transformational leadership are reviewed as distinct but not mutually exclusive processes (Judge and Piccolo, 2004). Both leadership models make important contributions to leadership and any leader may display some behaviour from each approach (Hartley and Benington, 2010). Bass (1999) argued that the best leaders are both transformational and transactional. However, as transformational leadership involves motivating others, it appears to produce higher performance at the group level. The contingent reward dimension in transactional leadership which clarifies expectations and establishes rewards for meeting these expectations works best in business settings (Judge and Piccolo, 2004). My leadership style has been predominantly transformational. Whereby, I have gained influence to a degree that physiotherapists have identified me as a leader. I have articulated a vision of an alternative programme which has motivated physiotherapists to alter the way they manage CLBP in a group setting. I have encouraged creativity and innovation as well as given individualised consideration. As a mentor to my colleagues, I have attended to their concerns and needs. This bottom-up approach to innovation can help the organisation to be more flexible and adaptive (Yukl, 2009). However, as a transactional leader in this process, I have clarified what is expected of my colleagues when running the group programme and provided feedback on their performance.

It has also been argued that there should be systemic model of leadership. Whereby, a level of leadership beyond the individual or team to the organisational system is

required. This looks at improving the system rather than the individuals (Tate, 2010). A post transformational form of leadership focuses more on shaping the organisational structure and culture in a way that supports behavioural change (Yukl, 2009). However, the organisation needs to be clear about its needs and managers need to challenge the local system (current management of CLBP) and improve the wider system. There also needs to be a clear accountability framework to help manage leadership as a process (Tate, 2010). For example, clarity on specific roles for the design, implementation and on-going monitoring of the alternative group programme. Thus, leadership can be distributed based on the idea that it can exercised at different levels of the organisation. Leading a clinical team can be described as a form of distributed leadership since it requires management of a range of relationships between professionals, managers and service users (Millward and Bryan, 2005). If the alterative group physiotherapy programme improves the management of CLBP, then this may lead to policy change at an organisational level. Leadership at both the corporate and team level would be necessary to support the spread of any new or alternative programme across healthcare organisations (Hartley and Benington, 2010).

Section 2

2.3 Stage 1: Physiotherapy Surveys

This section reviews surveys that have investigated the physiotherapy management of CLBP. There have only been a limited number of survey questionnaires which have investigated the physiotherapeutic management of CLBP including the use of exercise therapy (Liddle et al., 2009). This review has included only surveys that have investigated the physiotherapeutic management of CLBP. Excluded from this review are studies investigating acute low back pain (LBP) only or those that have included other impairments or musculoskeletal conditions such as knee pain. Pensri et al. (2005) had conducted a survey to investigate the physiotherapy management of low back pain in Thailand. This study was excluded from my critical review as there was a discrepancy amongst the Thailand therapist's perception and understanding of a CLBP definition. Twenty-seven percent of the therapists in the study had defined patients with CLBP as having had pain for more than one month.

Foster et al. (1999) conducted probably the first large postal survey over 18 months to investigate the physiotherapeutic management of LBP in Britain and Ireland. A response rate of 58% was achieved from a large sample size of 2654. However, only 53% of those who responded were treating LBP. No distinction was made between acute and CLBP in the survey but 53% of respondents were treating CLBP. The sampling procedure involved selecting four random clusters from a wide geographical area. There was no systematic approach used to select these clusters. These clusters consisted of different population sizes and there was a possibility that the clusters were not representative of the whole population of therapists who treat LBP. The survey found that a wide number of treatment techniques were used to manage LBP.

Manual therapy and electrotherapy were the most popular treatment strategies. Abdominal exercises (18%) and hydrotherapy (5%) were the only data provided on the use of exercise therapy for managing LBP. There was no data provided regarding group exercise programmes except that the researchers stated that there was little evidence for the use of fitness programmes in the management of CLBP.

Gracey et al. (2002) aimed to extend the findings of Foster et al. (1999) by further investigating the clinical practice in the physiotherapeutic management of low back pain in Northern Ireland. This was designed as a prospective census type survey involving two questionnaires. One questionnaire was in relation to the physiotherapists' profile and the other regarding treatment for each patient seen. There was no evidence of any approval for this study as with the Foster et al. (1999) study. It is possible that there was not an ethical framework or stringent application process in place as there is currently when these studies were undertaken. A total of 157 physiotherapists recorded data for 1062 patients treated for LBP over a 12-month period. It was not known how the physiotherapists were sampled and whether all questionnaires distributed were completed. On average physiotherapists would have completed questionnaires on 7 patients. It is not known how these patients were selected for the study. On this basis it would be difficult to replicate this study. LBP was treated with a combination of advice, manual therapy and electrotherapy. Active exercises were more commonly used for CLBP but only 27% of the patients in the study were managed with exercise therapy. As with the Foster et al. (1999) study there was a failure to discriminate between patients with acute and CLBP regarding the prescription of exercise therapy. This study did not provide further evidence on the physiotherapeutic management of LBP particularly exercise therapy.

This was addressed by Byrne et al. (2006) who conducted a small scale cross-sectional survey to investigate the range of exercise therapy approaches used by physiotherapists for managing LBP. This survey was conducted in an acute Hospital setting in the Republic of Ireland. Piloting the questionnaire was used to establish face validity to address the relevance of the instrument (Macdonald et al., 2003). Validity refers to whether a questionnaire is measuring what it purports to (Rattray and Jones, 2007). Face validity is a more superficial subjective impression on whether the questions are clear, relevant and unambiguous. Content validity is more systematic than face validity and refers to judgements by a panel (focus group) on whether the instrument includes the full scope of the domain it is intended to use (Bowling, 2009). Face validity refers to whether the questions are relevant to the topic that is being investigated whereas content validity refers to the extent the questionnaire is measuring all the domains or facets of the topic and is adequate for its intended use (Rattray and Jones, 2007). Only two studies to date had used both a focus group and pilot to develop their questionnaire (Foster et al., 1999; Gracey et al., 2002). It has been recommended that draft questionnaires prior to distribution be subject to expert review using focus groups as well as a minimum of two pre-tests in the field (Macdonald et al., 2003; Presser et al., 2004). This helps to reduce measurement error and assess the likely response rate (Presser et al., 2004). However, test-retest may not work well if the same respondents remembered what they said previously or have different opinions the second time due to a practice effect (Kitchenham and Pfleeger, 2002).

The mean percentage of CLBP patients seen in the Byrne et al. (2006) study was 68%. This was similar to a later retrospective chart survey by Casserley-Feeney et al.

(2008) which found 73% of back pain patients treated in a hospital setting had CLBP. The response rate in the Byrne et al. (2006) study was 73% from 120 distributed questionnaires. Specific spinal stabilisation exercises (51%) was the most popular exercise type used for CLBP followed by the McKenzie approach (17%), general abdominal exercises (10%), general aerobic (9%) and Pilates (7%). Despite the popularly of spinal stabilisation and the McKenzie approach for CLBP, there is conflicting evidence on the effects of these modalities compared with over exercises or treatments (Garcia et al., 2013). Thirty-nine percentage of therapists stated that they conducted group exercise classes but it appears from the results that no group programmes were utilised for managing CLBP. An additional 32% of therapists indicated that would carry out group exercise classes if sufficient resources were available.

Liddle et al. (2009) conducted a later and larger study to investigate the use of exercise therapy for CLBP. They developed a cross-sectional postal questionnaire to investigate physiotherapists' use of advice and exercise for the management of CLBP in Ireland. The questionnaire was mailed to a random sample of 600 members of the Irish CSP. The response rate was 70% which is comparable with other similar surveys. However, only 47% of the respondents treated LBP which may limit the generalisability of the results and comparison with current management of CLBP in other health settings. The number of treatment sessions ranged from 6 to 10 which is higher than the average of 5 sessions reported previously for that region (Gracey et al., 2002). CLBP accounted for 50% of therapists' caseload in the public sector. Exercise therapy was used frequently for managing CLBP but only 56% provided supervised exercises. The survey found that advice and exercises were the most

frequently used treatments for LBP which was also found in the earlier study by Casserley-Feeney et al. (2008). There was no evidence for the routine provision of supervised exercise classes in this study. Strengthening exercise including core stability was the most frequently used regardless of the therapist's level of experience or grade. My study aims to explore this further to determine if there is a difference between physiotherapy grade or speciality regarding the amount and types of exercises given to CLBP patients.

The most recent survey up to **Stage 1** of this thesis was by Fidvi and May (2010). They conducted a survey of self-reported physiotherapy practice in the management of LBP. The study was conducted in a state of India but undertaken from the UK. The questionnaire was sent to 267 physiotherapists who met the inclusion criteria by e-mail. Physiotherapists were asked to provide details on their current treatment methods for LBP. The response rate was 70% which is not different from response rates using postal questionnaires (Remenyi, 2011). Patients on average received between 8-12 physiotherapy sessions with approximately 58% presenting with CLBP. Only 44% of therapists used a combination of manual therapy, exercises and electrotherapy in their treatment but all gave some form of advice. Lumbar stabilisation exercises were found to be the most commonly used type of exercise therapy. The exercises given by physiotherapists in this study were predominantly core strengthening with an absence of aerobic and upper limb strengthening exercises. The first treatment preference was exercise therapy. There were no details given on the number of exercises given or their frequency which was one of the weaknesses of this questionnaire.

2.3.1 Discussion of Physiotherapy Surveys

A small number of surveys have investigated the physiotherapeutic management of CLBP. The majority of these surveys have been conducted in regional areas. **Table 2.1** provides a summary of the surveys in this literature review. To my knowledge there have been no surveys of this type conducted in the London area. London is the most ethnically diverse area in England and Wales with a rising number of minority ethnic groups being identified. The white British population in London is 45% (Office of National Statistics, 2012). Therefore, the population of CLBP patients presenting to London physiotherapy departments is becoming increasingly diverse with English not being the first language for many of these people (Bernstein, 2009). This may have an impact on how group programmes are utilised in this area which is one of the aims of this current survey. The majority of these studies had developed their questionnaires from the review of the literature and had piloted these questionnaires prior to distribution (Byrne et al., 2006; Fidvi and May, 2010). The current questionnaire for this study has been developed from the literature review and in-line with other studies and was subject to peer review/pre-testing before final distribution. Previous surveys had included the management of all patients with LBP whereas this current survey was exclusively related to CLBP.

One of the limitations of these survey studies has been non-response bias. Response rates have been generally between 60-70% (Fidvi and May, 2010; Liddle et al., 2009; Poitras et al., 2005). Therefore, no information is known about the remaining 30-40% in these trials who did not respond (Copeland et al., 2008). Those who take the time to respond to a questionnaire may be different from those who do not. This can compromise the validity of the survey as the results can not necessarily be generalised

Table 2.1: Summary of surveys in the literature review investigating the physiotherapy management of CLBP

Study	Type of Survey	Population	Findings
Fidvi and May (2010)	Survey of self-reported physiotherapy practice in the UK.	267 physiotherapists by e-mail.	70% response rate. Only 44% of therapists used a combination of manual therapy, exercises and electrotherapy in their treatment but all gave some form of advice. Lumbar stabilisation exercises were found to be the most commonly used type of exercise therapy.
Liddle et al. (2009)	A cross-sectional postal questionnaire to investigate physiotherapists' use of advice and exercise for the management of CLBP in Ireland.	600 members of the Irish CSP.	70% response rate. CLBP accounted for 50% of therapists' caseload in the public sector. Advice and exercises were the most frequently used treatments for LBP.
Casserley-Feeney et al. (2008)	A retrospective chart survey of all LBP patients referred for physiotherapy to one Dublin City hospital	249 physiotherapy charts analysed.	Significantly higher use of advice and spinal stabilisation exercises in the public setting.
Byrne et al. (2006)	Small scale cross-sectional survey in an acute Hospital setting in the Republic of Ireland.	120 distributed questionnaires to physiotherapists.	73% response rate. Specific spinal stabilisation exercises (51%) was the most popular exercise type used for CLBP followed by the McKenzie approach (17%), general abdominal exercises (10%), general aerobic (9%) and Pilates (7%).
Gracey et al. (2002)	Prospective census type survey in Northern Ireland.	A total of 157 physiotherapists recorded data for 1062 patients treated for LBP over a 12-month period.	Active exercises were more commonly used for CLBP but only 27% of the patients in the study were managed with exercise therapy.
Foster et al. (1999)	Postal survey over 18 months to investigate the physiotherapeutic management of LBP in Britain and Ireland.	Survey of 2654 physiotherapists.	58% response rate. Manual therapy and electrotherapy were the most popular treatment strategies. Abdominal exercises (18%) and hydrotherapy (5%) were the only data provided on the use of exercise therapy for managing LBP.

beyond those who have responded (Bowling, 2009; Liddle et al., 2009). A number of these studies did not survey predominately physiotherapists in an out-patient setting who would be more likely to treat CLBP. This may have influenced the response rate and completion of the whole questionnaire (Byrne et al., 2006; Liddle et al., 2009). This was addressed in the current study by administering the questionnaire directly to physiotherapy out-patient departments. There is no difference in response rate between postal and e-mailed questionnaires. One study using mailed questionnaires had shown a response rate as high as 77% (Pensri et al., 2005). The survey design in **Stage 1** was a self-administered postal questionnaire.

Previous surveys have supported the use of advice and exercise therapy for CLBP (Gracey et al., 2002; Liddle et al., 2009). Core stability and lumbar stabilisation/motor control were the most commonly used types of exercise therapy. However, the use of active exercise for managing LBP is generally found to be low at 27% (Gracey et al., 2002; Pensri et al., 2005). Few studies showed that therapists provided supervised exercise programmes despite clinical guidelines supporting the use of group exercise classes for managing CLBP (Byrne et al., 2006; Casserley-Feeney et al., 2008). These surveys generally do not provide details of the amount or types of exercises used or show that the treatment provided by the therapists is supported by the current evidence base (Byrne et al., 2006; Foster et al., 1999). A number of research questions for this current study have been developed from the review of previous surveys. These include: What are the amount and type of exercises given to CLBP patients and does this depend on physiotherapy grade or speciality? What are the types of group programmes for CLBP therapists have available at their place work and are there any differences between primary and secondary care? What are the referral rates to group

programmes? Finally, there have been no surveys to date that have investigated in detail group programmes for managing CLBP in clinical practice. What is the structure and content of these group programmes including exercise type, duration, warm-up/warm-down and nature of education provided? The answers to all of these research questions have assisted in the development of the alternative group physiotherapy programme.

Section 3

Stage 2: Physiotherapeutic Interventions for CLBP

Musculoskeletal physiotherapy is one of the most common forms of conservative treatment for CLBP which has consisted of a combination of modalities such as manual therapy, exercise, electrotherapy +/- an education component. These modalities have either been used independently or in combination (Goldby et al., 2006; La Touche et al., 2008). All of these modalities have shown to be moderately and equally effective (Miyamoto et al., 2012). This review will look at current evidence for group exercise programmes and manual therapy combined with exercise for the management of CLBP. Only RCTs will be reviewed and Pilot studies excluded due to their small sample size.

2.4 Exercise Therapy

There is a wealth of literature regarding the therapeutic use of exercise in the treatment of CLBP and has been shown to be an effective treatment for improving function and reducing pain (Lewis et al., 2005, Costa et al., 2009). The definition of exercise varies widely in the literature. It has been defined as "a series of specific movements with the aim of training or developing the body by a routine practice or as physical training to promote good physical health" (Hayden et al., 2005). Exercise therapy been shown to be more beneficial than passive treatments (Wajswelner et al., 2012). There is no evidence that any other treatment is better than those interventions which use exercise therapy as the basis of the treatment (Garcia et al., 2011). Patients with CLBP tend to avoid physical activity due to pain and fear avoidance behaviour. As a result, a vicious circle of decreased muscle power and cardiac capacity occurs

due to their low activity levels leading to a de-conditioning syndrome (Dogan et al., 2008). Exercise can help reverse the de-conditioning or fear of movement associated with CLBP (Ferreira et al., 2007). However, re-conditioning can only occur through the controlled application of progressive and intensive exercise overload (Carpenter and Nelson, 1999). Previous guidelines for the management for CLBP recommend supervised exercise therapy as a first-line treatment for the reduction of pain and disability (Airaksinen et al., 2004). There is evidence that exercise can decrease pain, reduce disability and address the de-conditioning seen in CLBP (Kell and Asmundson, 2009; Costa et al., 2009). However, no recommendations are given for the specific type of exercise to be used and there does not seem to be any consensus on the most effective programme design to maintain any exercise benefits achieved (Lewis et al., 2008; Peterson et al., 2007). Different forms of exercise such as aerobic, strengthening, co-ordination exercises or specific stabilisation exercises have all shown to be effective (Lewis et al., 2005). There is a lack of evidence that one particular exercise is superior and there has been a failure to find differences between various exercise approaches in the management of CLBP (Taylor et al., 2007; Wajswelner et al., 2012). However, Hayden et al. (2005) concluded that exercise programmes that were individually designed, high dose and with regular practitioner follow-up were likely to be most effective for CLBP.

2.5 Group Physiotherapy Programmes

There are many group exercise-based physiotherapy programmes described in the literature that are used for managing CLBP. A group programme can be described as intervention delivered to more than one individual rather than a one to one intervention with clinician and patient. These programmes consist mainly of exercise therapy alone +/- an advice or education component. The most commonly used group programmes described in the literature are Pilates, Motor Control/Stabilisation, Back to Fitness Programme, Back School and Functional Restoration Programmes. There are many other types of group exercise used by physiotherapists that have been evaluated for their effectiveness for managing CLBP. These include general exercises, strengthening exercises +/- gym machines, aerobic only, yoga or hydrotherapy (Mannion et al., 2001). The group exercise therapy format has been considered more cost effective than individual treatments (Lewis et al., 2005). There is no superior therapeutic benefit of group programmes compared to individualised treatments (Chown et al., 2008). Reported barriers to delivering group-based exercise programmes are space, time, insufficient staffing and lack of adequate training equipment. Class drop-out rates have been reported up to 30% in the literature (Hurley el al., 2009). Group treatments are not suitable for all CLBP patients either due to those presenting with multiple or complex problems, language difficulties and inflexible class times (Critchley et al., 2007). The evidence for the most commonly used group programmes for managing CLBP is evaluated in the next sections.

2.5.1 Pilates

Pilates has become an increasingly common group exercise regimen for managing chronic low back pain (Pereira et al., 2011). Since the 1990s, there have been many practitioners using Pilates exercises in the rehabilitation field (Anderson and Spector, 2000). The Pilates method was developed by Joseph Pilates in the 1920s with a focus on controlled movements, posture and breathing. The aim of the Pilates exercise regimen is to improve muscle strength, endurance, flexibility, posture and balance. Exercises are performed on a mat or using specialised equipment such as the reformer, trapeze table or wunda chair (Sorosky et al., 2008, Wells et al., 2012). There are several different versions of the Pilates Method which can be divided into two main approaches: Traditional Pilates and Modern Pilates. However, how Pilates is defined and applied in the treatment of CLBP varies in the literature (Wells et al., 2012).

Traditional Pilates closely follows the original 34 mat based exercises described by Joseph Pilates (Lately, 2002). There are six traditional principles of Pilates: Breathing, centering, control, precision, flow and concentration (Lately, 2002). However, only breathing as a traditional principle has been used in low back pain studies. This may suggest that these principles are not necessarily critical in those with back pain. These original exercises require a high level of strength and endurance which may not be achieved by all CLBP patients (Wells et al., 2012). Modern Pilates and modified versions of this focus on maintaining a neutral spine with activation of transversus abdominis (TrA) and the pelvic floor muscles in combination with controlled breathing (Lately, 2002). This technique is linked closely with the motor control concept. The function of TrA in people with LBP has been investigated extensively

(Richardson et al., 2004). The inhibition and loss of control of this muscle as a result of low back pain or injury does not recover spontaneously. Specific exercises such as Pilates have been advocated to promote recovery (Kermode, 2004). The abdominal hollowing technique (AHT) described by Richardson and Jull (1995) is an exercise taught with the aim of contracting TrA and internal oblique(IO) without activating the more superficial muscles such as external oblique(EO) and rectus abdominis(RA). This technique establishes the 'power house' or core to achieve spinal stability from which multiplanar excursion of the trunk and limbs can proceed (Sorosky et al., 2008). As these movements are successfully completed, they can be progressed by decreasing the assistance or changing the orientation to gravity until a desired functional outcome is achieved (Anderson and Spector, 2000).

Pilates is a popular exercise regimen in all areas of fitness and rehabilitation but to date there seems to be limited scientific evidence on its effectiveness for managing CLBP (La Touche et al., 2008). There has been a lack of well-designed trials investigating the clinical effects of Pilates. There is inconclusive evidence that Pilates is effective for reducing pain and disability in CLBP patients or is superior to other forms of exercise (Wells et al., 2013; Yamato et al., 2015). Patti et al. (2015) in their systematic review investigating the effect of Pilates on CLBP found 29 eligible articles. Thirteen of these were listed as RCT's up to July 2014. They concluded the Pilates method was more effective than no treatment and minimal physical exercise in reducing pain but only in the short-term. Natour et al. (2015) in a recent RCT found Pilates is better than no exercise for reducing pain and improving function. However, this study had a number of methodological flaws including narrow age range (18-50 years), small sample size (60), no blinding, excluding those with a BMI over 30 and

recruiting patients with moderate disability. Wajswelner et al. (2012) in their RCT compared Pilates to general exercises. General exercise was defined as any exercise found not to have been individually prescribed to patients based on their clinical assessment such as walking or stretching exercises. However, Lehtola et al. (2012) concluded that general exercises involved strengthening exercises for all the main muscle groups, co-ordination, stretching and aerobic fitness training. Specific exercise refers to exercises that are individually prescribed by the practitioner based on their clinic assessment. This may include directional specific exercises which aim to ease the participant's pain. Eighty-seven volunteers were randomized to either the Pilates or general exercise group. The participants were volunteers who were not seeking treatment for CLBP and may differ from those have sought treatment from their doctor or therapist. Therefore, the participants in this study may not be representative to the population of CLBP patients presenting to physiotherapy clinics. The two groups were well matched in baseline characteristics. The intervention in both groups consisted of an initial one-hour session +/- two half an hour follow-ups as required and then twelve one hour sessions twice a week for six weeks. This gave a total of 12-14 supervised hours of intervention although a minimum of 20 hours has been recommended for the management of CLBP (Hayden et al., 2005). Participants in each group were also required to perform four exercises regularly at home. However, no details were given on how the exercises for each participant were chosen for the Pilates group. Participants were not blinded leading to potential bias. Both groups showed significant improvements in pain, disability and health related quality of life which was maintained at 24 weeks. However, there was no significant difference between the groups. Thirty-one percent of the participants were lost to follow-up and this group were significantly younger than those remaining in the study. It is not

known how this could have affected the results of the study. This study supported exercise therapy as a management strategy for CLBP but did not indicate that Pilates was superior to general exercise.

Miyamoto et al. (2012) randomized 86 participants to either a six-week programme of modified Pilates or education alone. Participants in the Pilates group attended two one hour sessions weekly for six weeks. However, there was no indication that participants in the Pilates group were required to exercise at home. Both groups were followed-up at six months. The study concluded that modified Pilates exercises only provided small benefits compared to education alone in patients with chronic non-specific low back pain and these effects were not sustained over time.

Curnow et al. (2009) compared three different Pilates exercise regimens. Thirty-nine subjects were initially taught four basic exercises and then randomly allocated to three groups. Group A had no additional exercises, Group B added a relaxation technique to the exercises and Group C added both the relaxation technique plus postural training to the exercises. All participants exercised individually three times a week for six weeks. All groups reported a reduction in pain but these were not sustained after completion of the programme and were not significant. This study had a number of methodological flaws which would limit its relevance to clinical practice. The sample size was small and the participant's characteristics not defined. Participants were volunteers with mild CLBP which may not represent those seen clinically. There is a threat to the external validity of this study as it is uncertain whether the results can be generalised to the population of CLBP patients (French et al., 2001). The three exercise groups were very similar in content which may have been one of the reasons

why there was no significant difference between the groups. There were a low number of exercises which did not conform to the standard Pilates principles. Each exercise was performed for 30-40 repetitions compared to the standard 6-10 repetitions used. This was not only more time-consuming but may have caused muscular fatigue leading to a poorer quality of movement. The Pilates principle encourages quality and precision of movement which may be an important factor for learning new movement patterns (Richardson and Jull, 1995).

Rydeard et al. (2006) randomised thirty-nine patients with CLBP to either a Pilates based exercise group or those who received standard treatment. The average age for the treatment group was 37 years and control group 39 years. This may not be representative of the CLBP population as a peak prevalence of 45-59 years has previously been found for low back pain (Papageorgiou et al., 1995). One of the inclusion criteria was having CLBP for 6 weeks which is not the standard definition for CLBP (Airaksinen et al., 2004). Similar to the Wajswelner et al. (2012) study, the Pilates exercise regimen incorporated the use of reformers which are not generally available in NHS physiotherapy departments. This would make this study difficult to replicate and compare with other studies in clinical practice. The Pilates intervention was only administered for 4 weeks which is not enough time for muscle adaptation to occur (Mcardle et al., 1996). The study showed significant reduction in pain and disability in the Pilates group which was maintained at 12 months. Although all participants completed the Pilates intervention the response rate at 12 months was only 62%. As with the Wajswelner et al. (2012) study, a large percentage of participants were lost to follow-up. It is not known what impact the outcomes of these

participants could have had on the results of the study and how much weight can be given to the current findings.

Gladwell et al. (2006) conducted a single blinded RCT to compare modified Pilates with a control group. Forty-nine participants were allocated to either the control or Pilates group. The Pilates group completed six weekly one-hour group sessions (12 in each group). The authors described a modified version of Pilates which was also performed by participants twice a week at home. The control group were given no intervention but were allowed to continue with their usual activities. However, it was not stated what these activities were or whether participants in the control group should refrain from any specific type of exercise apart from Pilates. Forty-nine participants with CLBP were randomised to the groups but there were no details given regarding the randomisation process. Despite the randomisation the mean age of the Pilates group (37 years) was significantly different from the control group (46 years). Also, on average the control group had suffered from CLBP for two years longer. Therefore, the groups in this small sample size were not well matched for baseline characteristics which may affect the internal validity of the study. Internal validity refers to the extent to which the differences between experimental or control group can be attributed to the intervention and not alternative factors. Hence, it may be difficult to make accurate comparisons between these groups if there are other differences or confounding variables apart from the intervention they received (Godwin et al., 2003). There was a high drop-out rate of 30% (41% in the control group). This may have been due to the control group not receiving any intervention. However, a drop-out rate of 30% is comparable with other studies (Gladwell et al., 2006).

The results showed a significant decrease in the Oswestry Disability Index (ODI) of six points in the control group but not in the Pilates group. This is not a clinically meaningful change as a minimal important change following intervention of 10 points for the ODI has been proposed (Ostelo and de Vet, 2005). The study concluded that Pilates can reduce pain and improve general health compared to no intervention. However, there was no mention as to why the control group had a greater reduction in disability. Both groups recorded low functional disability scores at baseline on the ODI. Low disability scores have been recorded in previous studies which can reduce the scope for improvement following an intervention (Wajswelner et al., 2012). The ODI index is best suited to situations in which patients may have persistent severe disability and therefore higher baseline scores (Roland and Fairbank, 2000). Outcome measures were performed pre and post the six-week programme but there was no long-term follow-up to determine if the benefits from Pilates had been sustained.

2.5.2 Summary of Pilates

The studies reviewed show that Pilates as a management strategy for CLBP reduces pain and improves disability in CLBP but it not known whether these effects are maintained over time. **Table 2.2** shows a summary of RCTs in this literature review investigating the effect of Pilates on CLBP. However, a meta-analysis by Pereira et al. (2011) found no evidence that the Pilates method improves function or pain in patients with low back pain. Pilates has not been shown to be superior to any other form of exercise therapy. Pilates exercises are performed on either mats or machines such as the reformer. The reformer is a single bed frame consisting of a carriage that slides back and forth using springs to add resistance and increase the difficulty of the exercise (Johnson et al., 2007). Pilates exercises are mostly non-weight bearing and it could be argued that this is not very functional (Sorosky et al., 2008). Pilates exercises also have a strong flexion bias. This may not benefit CLBP patients who have lumbar disc disease presenting with flexion mediated low back and sciatica (Sorosky et al., 2008). The studies described in this review have a number of methodological flaws. Sample sizes were small and a large number of participants were lost to follow-up. Some of the studies used machines such as the reformer. This type of equipment is not widely available in NHS physiotherapy departments due to cost and on average participants had 12 hours of exercise therapy. This not only makes these studies difficult to replicate in clinical practice but does not offer a cost-effect method for managing CLBP. These studies may show positive benefits of Pilates to CLBP but there is still no consensus on the frequency, intensity or volume in which the method should be applied so as to achieve therapeutic gains (La Touche et al., 2008).

Table 2.2: Summary of RCTs in the literature review investigating the effect of Pilates on CLBP

Study	Intervention/comparison	Sample size	Outcome
Natour et al. (2015)	Pilates versus no exercise (medication only).	n=60	Pilates better than no exercise with significant improvements to function and quality of lift as well as pain reduction.
Wajswelner et al. (2012)	Pilates versus general home exercises.	n=87	Significant improvements in pain, disability and health related quality of life in both groups which was maintained at 24 weeks. There was no difference found between groups.
Miyamoto et al. (2012)	Modified Pilates versus education alone.	n=86	Modified Pilates exercises only provided small benefits compared to education alone but there was no significant difference in pain or disability scores between the groups at 6-months.
Curnow et al. (2009)	Compared three different Pilates exercise regimens Group A: Pilates but no additional exercises, Group B: Pilates + relaxation technique Group C Pilates + relaxation and postural training.	n=39	All groups reported a reduction in pain but these were not sustained after completion of the programme and were not significant.
Rydeard et al. (2006)	Pilates with reformers versus standard treatment with a health care professional (control).	n=39	Significant reduction in pain and disability in the Pilates group compared to the control group which was maintained at 12 months.
Gladwell et al. (2006)	Modified Pilates versus usual activity (control).	n=49	Significant decrease in the disability in the control group but not in the Pilates group.

2.5.3 Back School

The Back School has been a common management strategy for back pain modelled on the Swedish Programme originating in the 1960s (Klabar-Moffett & McLean, 1986). The original Swedish Back School consisted of four small group sessions lasting 45 minutes over a two-week period (Heymans et al., 2011). Programme duration in the literature varies widely from the original model. It can consist of 4-12 consecutive weeks with 1-2 sessions per week. Sessions can last from 20 to 60 minutes (Choi et al., 2011). The Back School model contains a standard programme of supervised

exercises and education. The education component can consist of information on spinal anatomy, biomechanics, correct posture, ergonomics and self-management strategies (Garcia et al., 2011). A recent review of Back School interventions showed a lack of long-term improvements to function and pain reduction (Heymans et al., 2011). Van Middelkoop et al. (2011) in their review on the effectiveness of physical and rehabilitation interventions for CLBP concluded that there was no statistically short-term difference in treatment effect on pain and disability for back school compared to waiting list or usual treatment. My review of Back School interventions is an update of the Heymans et al. (2011) review and will include RCTs after 2002 not covered in the previous review. It was decided not to repeat the analysis of previous RCTs covered in the Heymans et al. (2011) review. This current review only included RCTs in which one of the treatments consisted of a Back School type intervention with additional interventions allowed. The Back School intervention had to consist of a combination of exercise and education delivered in a group setting. For example, a RCT by Sahin et al. (2011) randomised 146 participants to a Back School programme and a control group which received exercise and physical treatment modalities. However, the Back School Programme only included an education programme delivered by a physician with a separate exercise programme for participants from both groups to attend. Also participants in the study were mostly single sex (housewives). Therefore, this RCT was not included in this review. It was decided not to include RCTs in which the results could not be generalised to the population of CLBP patients. For example, Oguzhan et al. (2011) and Tavafian et al. (2008) in their studies had investigated the effect of Back School on quality of life but only single sex participants were used.

Paolucci et al. (2012) and Morone et al. (2011) performed similar designed single blind randomised trials to investigate the effect of Back School with a 3 and 6-month follow-up. They randomly assigned 50 and 70 participants with CLBP respectively in a 3:2 format to either Back School or a control group. The only difference between studies was that the Paolucci et al. (2012) study stratified patients with elevated scores on the MMPI-II. The MMPI-II is a questionnaire which evaluates emotional disorders. The Back School in both studies was described as multidisciplinary and was mainly focused on education. It consisted of ten one hour sessions in a four-week period. There were 4-5 participants per group which would question the cost effectiveness of these programmes. However, cost effectiveness analyses of Back Schools have not been conducted alongside any of the RCTs reviewed in this literature. Physicians delivered the education in the first session but had no further involvement in the programme. Physiotherapists carried out the other 9 sessions. They provided exercises which were not individualised and further education. Pamphlets were issued with an exercise protocol but it was not stated what these exercises were and how often participants should do them. It was not clear whether the exercise protocol in the pamphlet were the same exercises given in the programme. The control group received medication but no other treatment. The Back School intervention in both studies showed significant improvements in pain, disability and quality of life which were maintained at six months. Paolucci et al. (2012) concluded that it was the education component within the Back School that had positive benefits on the mental status of the participants. However, as the control group received no intervention in both studies it is not known which component of the Back School was effective. It may have been more useful to compare Back School with education only. In contrast, a similar earlier study by Ribeiro et al. (2008) randomised 60 patients to a

Back School programme and a control group which received medication only. There was no significant difference found between groups in pain, function or depression.

Cecchi et al. (2010) conducted a RCT which randomised 210 participants with CLBP to either Back School or individual physiotherapy or spinal manipulation only. The Back School was based on the Swedish model and consisted of fifteen one hour sessions over three weeks. The individual physiotherapy was also fifteen one hour sessions over three weeks consisting of manual therapy and patient specific exercises. The three-week exercise programme given in these two groups is not long enough for neuromuscular adaptation or muscle strengthening to occur and therefore address the de-conditioning seen in CLBP as mentioned previously (Mcardle et al., 1996). It was not made clear whether the Back School group were required to perform home exercises or continue with exercise post programme. The spinal manipulation group consisted of just 4-6 weekly sessions of 20 minutes each but no exercise. At the end of the treatment all three groups reported a significant improvement in disability and pain rating scores. These improvements were sustained over 12 months. The spinal manipulation only group showed a significantly greater reduction in disability scores than the other groups but there was no significant difference between groups in the reduction of pain rating score. However, the groups in this study were not equally matched. Forty-three percent of the spinal manipulation group were not working compared with 56% in the individual group and 64% in the Back School group. Patients were not blinded to the groups which may have caused a placebo effect (Kasai, 2006). The spinal manipulation was given by a physician while the other interventions were given by physiotherapists. Therefore, a possible bias may have occurred with patient's having a different attitude towards the physician which may

have influenced the results. Long-term effects from spinal manipulation were only achieved with further treatment sessions and seemed less effective than Back School or individual physiotherapy for promoting self-management of their symptoms. Back School had shown similar short-term relief and better long-term outcomes than individual physiotherapy and was deemed to be more cost-effective.

2.5.4 Summary of Back School

There are a small number of RCTs since 2002 which have investigated to effect of Back School on CLBP. **Table 2.3** shows a summary of RCTs in this literature review investigating the effect of Back School on CLBP. In contrast to Heymans et al. (2011) review improvements from this intervention seem to be sustained long-term but only one study had a 12-month follow-up. It was not known from these studies which aspect of the Back School was most important for the benefits produced. However, there were flaws in the methodology of these studies seen previously such as small sample sizes and a loss to follow-up. All of the studies reviewed were conducted outside the UK. These programmes consisted on average of 15 clinical hours which would be unrealistic to incorporate into clinical practice in the NHS. The education delivered in Back School programmes is not individualised and may not meet the needs of all those attending the programme. The Back School programme at our Trust had consisted of four consecutive one hour weekly sessions. Functional and disability outcomes were poor and drop-out rates high. There is a lack of good evidence to support the effectiveness for Back School in the management of CLBP. This has led to an alternative group programme design which is the main aim of this project.

Table 2.3: Summary of RCTs in literature review investigating the effect of Back School on CLBP

Study	Intervention/comparison	Sample Size	Outcome
Paolucci et al. (2012)	Back School (BS) versus medication only (control).	n= 50	Significant improvements to pain, disability and quality of life in the BS but not the control group which were maintained at six months.
Morone et al. (2011)	Back School (BS) versus medication only (control).	n= 70	Significant improvements in disability and quality of life in the BS but not in control group. Both groups showed a significant reduction in pain post treatment.
Cecchi et al. (2010)	Back School (BS) versus individual physiotherapy or spinal manipulation only (3 groups).	n=210	All three groups reported significant improvements in disability and pain sustained over 12 months. Spinal manipulation showed better functional improvement than the other groups but received more treatment at follow-up.
Ribeiro et al. (2008)	Back School versus medication only (control).	n= 60	No significant difference found between groups in pain, function or depression.

2.5.5 Back to Fitness Programme

The Back to Fitness Programme (BTFP) was developed in the 1980s. It was designed as physiotherapy led exercise class for back pain patients incorporating cognitive behavioural techniques (Klaber-Moffett and Frost, 2000). The programme includes a combination of low impact aerobics, strengthening and stretching exercises in a circuit based format as well as messages for the day underpinning a cognitive behavioural approach (Carr et al., 2005). A study by Carr et al. (2005) found no significant difference in clinical outcomes in those receiving the BTFP and individual

physiotherapy in patients with LBP. However, this programme had been found to be more clinically effective than GP management and was cost-effective for treating back pain (Hurley et al., 2009; Klaber-Moffett et al., 1999). There have been a limited number of RCTs that have investigated the benefits to CLBP patients of the BTFP and compared it to other treatments. Only RCTs which have investigated the BFTP for CLBP patients only will be discussed in this review.

Frost et al. (1995) randomly allocated 81 participants with CLBP to either Back School (control group) or the BTFP (treatment group). The BTFP consisted of 8 one hour sessions over 4 weeks. There were 15 circuit based exercises with participants spending one minute on each exercise. The treatment and control group were given four individualised exercises to perform at home which they were advised to perform twice daily for six weeks. However, it was not known whether patients were required to continue with their exercises after that period and what their compliance to home exercises was. Both groups also attended the Back School which involved two 90-minute sessions. This was not typically Back School as it provided education only. The results showed a significant difference in ODI scores between groups in favour of the BTFP. The drop-out rate was only 12%. These benefits were maintained after two years in a follow-up study (Frost et al., 1998). The treatment group showed a 7-point reduction in ODI scores compared with only 2.4 points for the control group. A minimal important change mentioned previously following an intervention of 10 points for the ODI has been proposed which was not achieved by either group (Ostelo et al., 2008).

Klaber-Moffett et al. (2004) in their RCT allocated 187 CLBP patients to either the BTFP (89) or usual GP care (98). They hypothesised that the BTFP would promote a gradual return to normal activities and reduce fear avoidance behaviour in those with high baseline fear-avoidance beliefs. The study found that the BTFP benefited most those with higher fear avoidance behaviours. However, this study was not exclusively for CLBP patients as those presenting with symptoms less than 3 months were included.

The BTFP had been evaluated more extensively as part of the UK Beam trial which investigated the effect of adding exercises to spinal manipulation (UK Beam Trial, 2004). Although, this programme alone without spinal manipulation showed reductions in disability at three months, this was not maintained at twelve months. However, this trial did not exclusively include CLBP patients (Only 59% of patients that participated had back pain for more than three months) and therefore will not be discussed further in this section of the review. Ferreira et al. (2007) randomised 240 participants with CLBP to either the BTFP (general exercises), motor control (spinal stabilisation exercises) or spinal manipulative therapy. The effect of these interventions on function, global perceived effect, pain and disability was assessed. A high percentage of patients (68-78%) in the study were not working and were from a disadvantaged socio-economic background. The participants in this study may have more representative of the CLBP population as there is a strong link between social deprivation and low back pain (Unwin et al., 1998). The BTFP consisted of 12 one-hour sessions in a circuit based format. There were 10 exercises performed at one minute each. The programme also included a warm-up and warm-down followed by a brief educational message. Although participants were encouraged to incorporate

exercise into their daily lives, there were no specific home exercises given. In the motor control group, participants were individually trained over 12 sessions to contract their deep abdominal muscles +/- ultrasound feedback. This was then progressed into more functional positions. Participants in the spinal manipulation group had 12 sessions of manual therapy but were not given any exercises or a home exercise programme. Drop-out rates from all interventions was low with 93% followed up at 8-weeks post intervention. The groups receiving motor control exercises or spinal manipulation therapy improved more than the group attending the back to fitness programme in the short-term but there were no differences between groups at 6 or 12 months. This study found that manual therapy and exercise for managing CLBP were equally effective long-term. One flaw with the design was that the spinal manipulation group did not have an exercise component.

2.5.6 Summary of the Back to Fitness Programme

To date there is limited research on the effect of the BTFP as an intervention for CLBP. **Table 2.4** shows a summary of RCTs in this literature review investigating the effect of the Back to Fitness Programme on CLBP. The structure and exercise content of this programme has been described in detail by Klaber-Moffett and Frost (2000). Unlike the Back School which varies greatly, the BTFP is a standardised model which can be applied far easier to clinical practice particularly in the community. It requires minimal space and no gym equipment (Klaber-Moffett et al., 2004). This programme is currently used widely in NHS physiotherapy departments. The BTFP has been shown to be effective as a management strategy for CLBP and may help reduce the fear-avoidance behaviour seen in this patient group. It also has better attendance rates compared to the Back School. Although previous studies which had recruited both

subacute and chronic back pain patients had shown poor class attendance rates (Carr et al., 2005; Klaber-Moffett et al., 2004). The BTFP may not be superior to other interventions as it lacks individual attention. It may also be difficult for patients to carry-over the circuit based exercises into their daily routines in the long-term.

Table 2.4: Summary of RCTs in literature review investigating the effect of Back to Fitness Programme on CLBP

Study	Intervention/Comparison	Sample Size	Outcome
Ferreira et al. (2007)	BTFP (general exercises) versus motor control (spinal stabilisation exercises) or spinal manipulative therapy.	n=240	The groups receiving motor control exercises or spinal manipulation therapy improved more than the group attending the BTFP in the short-term but there were no significant differences between groups at 6 or 12 months.
Klaber-Moffett et al. (2004)	BTFP versus usual GP care. Participants in the study were categorised at baseline as high or low fear-avoiders.	n= 187	Significant improvement to disability in the exercise group for high fear-avoiders compared to GP care.
Frost et al. (1995)	Back School (control group) versus BTFP (treatment group).	n=81	Results showed a significant difference in disability scores between groups in favour of the BTFP.

2.5.7 Motor Control/Stabilisation

Previous research has shown that individuals with CLBP have impaired control and delayed recruitment of the deep trunk muscles that are responsible for maintaining the stability of the spine (Ferreira et al., 2010; Macedo et al., 2012). The premise of the motor control approach is that these muscles need to be re-trained in order to achieve optimal control and co-ordination of the spine. This exercise approach has similarities with the Pilates method which aims to normalise spinal motor control emphasizing the recruitment of the transversus abdominis and obliquus internus abdominis muscles

(Rydeard et al., 2006). These exercises are then progressed to more functional tasks integrating the activation of both deep and superficial trunk muscles. This leads to a reduction of pain and disability (Macedo et al., 2009). However, Saner et al. (2011) suggested that these exercises that aim to improve function through repetitive use should be referred to as motor control impairment exercises rather than motor control exercises. Motor control exercises are used first to retrain the delayed muscle activity of the deep trunk muscles to improve the control and stability of the spine (Saner et al., 2011). It has been suggested that functional exercises alone are not adequate enough to achieve lumbopelvic stability (Maher et al., 2005). Although motor control exercises have been widely researched, there are a small number of RCTs which have investigated the effect of motor control exercises delivered in a group format or used as part of a group programme.

Koumantakis et al. (2005) in their RCT compared the effects of specific trunk muscle stabilisation exercises combined with general exercises with general exercises only in patients with non-specific CLBP. Both programmes consisted of 16 classes each lasting 45-60 minutes. Despite this large dose of exercise therapy, there was a good adherence to the group programmes and home exercises. However, the general exercise programme was very similar in content to the muscle stabilisation programme but did not include local or deep core muscle activation training. Disability improved significantly more in the general exercise group but only in the short term (< 3 months). There was a relatively high drop-out rate in this study resulting in a sample size of only 45 subjects completing the programmes from an initial 67 that fulfilled the inclusion criteria. A small sample size may lead to type II errors and invalid statistical analysis (Hicks, 2009). A type II error occurs when the

experimental hypothesis is rejected in favour of the null hypothesis and the data does support the experimental hypothesis. This study concluded that stabilisation exercises do not provide any additional benefit for patients presenting with CLBP. It was suggested that CLBP patients engaging in activity and safe exercise was a key component to improvement rather than the type of exercise given.

Lewis et al. (2005) in their RCT investigated the effects of combined manual therapy and spinal stabilisation exercises for the management of CLBP using a group or individual format. Eighty patients were either randomised to one to one treatment involving manual therapy and spinal stabilisation exercises or an exercise class format involving aerobic exercises, spinal stabilisation and manual therapy. The class programme of 8 one hour sessions incorporated a mix of aerobic, strengthening and spinal stability exercise stations as well as a manual therapy station. In the methodology, it was not made clear whether patients were also required to exercise at home during the study in either of the two groups. Subjects were assigned to each group using random number tables. There were significant differences in some of the baseline measurements between the groups. Not producing two identically matched groups in a study can represent a failure of the randomisation process (Crombie et al., 1997). Results showed that both treatment interventions showed significant reduction in patients' symptoms as measured by the Quebec disability questionnaire. However, the group exercise programme in this study was circuit based and not individualised. Only 2-5 minutes was allotted for manual therapy with no time for advice or education. The authors reported that the overall cost of group treatment was substantially lower than the individual treatment approach. However, three physiotherapists were required to run this group programme which may question its

cost-effectiveness. One limitation with this study was that there was no control group. The improvements observed in the study may have been due to a natural resolution of exacerbation of LBP rather than the intervention itself.

A well designed study by Goldby et al. (2006) randomised 346 CLBP patients to a 10-week spinal stabilisation group, manual therapy group or a minimal intervention group which acted as the control. The control group received no active treatment. The researchers on ethical grounds reduced the patients randomised to the control group with a 40:40:20 randomization split. In contrast Critchley et al. (2007) considered it unethical to have a non-intervention control group. It could be argued that in the absence of a control group improvements to an intervention might be attributed to other factors or the natural resolution of symptoms. However, the Goldby et al. (2006) study did not have an equal randomisation of participants to intervention and control groups which could be seen as a limitation with this study. In the Goldby et al. (2006) study the spinal stabilisation group consisted of 10 one hour sessions in a group format (12 in each group) in addition to one three-hour Back School (education only). The manual therapy group consisted of 10 sessions and Back School. Both groups were given home exercises but it is not known how these exercises differed from the ones given within the intervention. This study found that spinal stabilisation exercises delivered in a group format were significantly more effective than manual therapy at reducing pain, disability and medication intake. However, there was a difference in the mean number of attendances in the intervention groups. The mean number of attendances for the spinal stabilisation group was 7.6 whereas only 5.3 for the manual therapy group. The improvements seen with the spinal stabilisation exercise programme could have been due to other factors than the exercises themselves. For

example: peer support within the programme, patient empowerment, education or self-management (Goldby et al., 2006). It is not known whether the extra intervention sessions attended in the spinal stabilisation group would have influenced the improvements achieved. Also, only 52% of patients attended all 10 group classes. This may suggest that CLBP patients do not require 10 sessions to see improvements.

A later study by Critchley et al., (2007) compared the effectiveness of three kinds of physiotherapy commonly used to manage CLBP. A total of 212 patients were randomised to either individual physiotherapy, spinal stabilisation classes or a physiotherapy led pain management programme. Participants attended a maximum of 8 spinal stabilisation classes lasting 90 minutes. All three physiotherapy regimens improved disability as well as quality of life and reduced pain but there was no significant difference between the groups. However, the spinal stabilisation group did show greater changes than the individual physiotherapy group in the above outcomes. The spinal stabilisation group received up to 12 hours of intervention whereas the individual physiotherapy group only up to 6 hours. It is possible that the benefits of the spinal stabilisation programme could have been attributed to the greater number of clinical treatment hours provided. The benefits of these interventions were maintained at 18 months although 25% of participants were lost to follow-up. This was higher in the Goldby et al. (2006) study which found 50% of the participants were lost to follow-up between the 12th and 24th month stage. This highlights the difficulties of long-term follow-up in CLBP trials.

2.5.8 Discussion and Summary of Motor Control/Stabilisation Programmes

To date there are few RCTs which have evaluated the effect of motor control exercises delivered in a group format to CLBP. **Table 2.5** shows a summary of RCTs in this literature review investigating the effect of Motor Control/Stabilisation on CLBP. One of the problems with interpreting the available research on motor control training is that it is difficult to separate this type of training from strength training of the core muscles (Micheo et al., 2012). The evidence suggests that this type of exercise therapy is no more effective than other forms of exercise or interventions (Saragiotto et al., 2016). A review by Macedo et al. (2009) found that motor control exercises are superior to a minimal intervention for treating CLBP but no more effective than other forms of exercise therapy. This was in contrast to a later meta-analysis by Bystrom et al. (2013) of RCTs investigating the effectiveness of motor control exercises (MCE). They found that the pooled results favoured MCE compared to general exercises with regard to pain in the short and immediate term and disability in all time periods including long-term defined as 8 months or more but less than 15 months. However, the results of this meta-analysis must be viewed with caution. Seven RCTs comparing MCE with general exercises were used in the analysis. However, two of these studies compared MCE with global trunk strengthening which are specifically targeted exercises rather than general ones. One of the other studies by Miller et al. (2005) compared MCE with McKenzie exercises. The McKenzie method is a specific treatment strategy used by physiotherapists for managing LBP and may not be classed as a general exercise regimen (Petersen et al., 2007).

Table 2.5: Summary of RCTs in literature review investigating the effect of Motor Control on CLBP

Study	Intervention/Comparison	Sample Size	Outcome
Macedo et al. (2012)	Motor control exercises versus graded activity.	n=172	Both groups showed similar effects in reducing pain and increasing function but neither were significant. No significant differences were found between treatment groups.
Unsgaard-Tondel et al. (2010)	Motor control versus sling or general exercises.	n=109	Motor control was superior to general exercises for reducing pain and disability but there was no significant difference between the three exercise groups.
Rasmussen-Barr et al. (2009)	Motor control versus daily walks plus general exercises.	n=369	Significant reduction in disability in favour of motor control but no differences in pain between groups at 12 months.
Critchley et al. (2007)	Individual physiotherapy versus spinal stabilisation classes or a physiotherapy led pain management programme.	n=212	All three physiotherapy regimens improved disability, quality of life and reduced pain but there was no significant difference between the groups.
Goldby et al. (2006)	10-week spinal stabilisation + Back School versus manual therapy (10 sessions) + Back School or a minimal intervention (control).	n= 346	Spinal stabilisation exercises were significantly more effective than manual therapy at reducing pain, disability and medication intake.
Lewis et al. (2005)	One to one treatment involving manual therapy and spinal stabilisation exercises versus an exercise class format involving aerobic exercises, spinal stabilisation and manual therapy.	n=80	Both treatment interventions showed significant reduction in disability but there was no significant difference in outcomes between groups.
Koumantakis et al. (2005)	Compared the effects of specific trunk muscle stabilisation exercises combined with general exercises with general exercises only.	n=67	Disability improved significantly more in the general exercise group but only in the short term (< 3 months).

The results of this study suggested both MCE and McKenzie exercises were beneficial but no significant difference was found between the groups. There were only 30 subjects in the study with CLBP defined as lasting greater than 7 weeks rather than 12 weeks. This study was found to be low quality on the PEDro scale. The physiotherapy evidence database abbreviated to PEDro is a bibliographic database containing randomised trials relating to the field of physiotherapy. Trials are rated with a 10-point checklist called the PEDro scale that considers two aspects of trial quality. These two aspects are: internal validity and whether the trial has sufficient statistical information to make the results interpretable. The PEDro scale is a valid measure of the methodological quality of physiotherapy interventions (de Morton, 2009). Low scores on the PEDro scale relate to low methodological quality. Unsgaard-Tondel et al. (2010) compared MCE, sling and general exercises for managing CLBP. MCE were found to be superior to general exercises for reducing pain and disability but there was no significant difference between the three exercise groups. This study did not achieve the minimum important change in ODI scores in any group. The Ferreira et al. (2007) and Critchley et al. (2007) RCTs included in this meta-analysis have been mentioned elsewhere. Finally, Rasmussen-Barr et al. (2009) compared one to one MCE with daily walks plus general exercises. No information was given regarding the general exercises and there were no follow-up instructions. The walking programme group met initially at week 1 for 45 minutes and then at week 8. In contrast, the MCE group had weekly 45 minute sessions with the therapist and daily home training. The results of the study showed a reduction in pain in favour of the MCE group but only in the short-term. A reduction in perceived disability in favour of the MCE group was sustained at 12 months. This meta-analysis may have showed the benefits of MCE over general exercises. However, in most of the studies

included, MCE were individually supervised whereas those in the 'general' exercise groups were not. The most effective strategy for exercise therapy in the management of CLBP indicated to date are individualised exercise programmes which are regularly supervised and have a specific exercise component (Hayden et al., 2005). A recent study by Macedo et al. (2012) emphasizes this principle. They compared MCE with a graded activity programme in CLBP. Similar treatment effects were found in both exercise groups. This study was not included in the Bystrom et al. (2013) review which included studies up to October 2011. Both interventions in the Macedo et al. (2012) study involved 14 sessions of approximately 20 hours of supervised individualised exercise therapy. In summary, motor control/spinal stabilisation exercises are usually performed on a one to one basis and can be time consuming and not necessarily cost-effective. The studies reviewed in this literature show a relatively high dose of these exercises is required to achieve the benefits seen. Spinal stabilisation exercises are very specific and this limits its use to patients with low back pain only. These exercises may be difficult to maintain and be effective long-term. Lederman (2010) has suggested that the concept of core stability or motor control training is flawed. Weak or dysfunctional abdominal muscles do not necessarily lead to back pain. There is no guarantee that the specific motor control training of the deep abdominal muscles can be transferred to functional or sporting activities. General or more patient specific exercises programmes may be more beneficial for patients especially those who have other chronic health conditions (Critchley et al., 2007).

2.5.9 Functional Restoration Programmes

The functional restoration programme (FRP) was introduced in the USA in the mid-1980s as a treatment strategy to restore function to a reasonable level for activities of daily living including work (Schaafsma et al., 2011). The FRP is an intensive programme of multidisciplinary input designed to negate unhelpful beliefs and fears as well as rehabilitate back to work duties (Jousset et al., 2004). The FRP programme has been found to be no more effective than individual physiotherapy for reducing pain and disability in CLBP (Roche-Leboucher et al., 2011). These programmes may also have a positive effect on sick leave for workers with CLBP (Schaafsma et al., 2011). This type of programme is very time consuming requiring a far greater commitment than other group programmes. It is also expensive and not widely available in the UK. Therefore, this literature review has not included an in-depth analysis of this programme.

2.5.10 Yoga and Other Group Programmes

Yoga

Yoga has become a popular exercise regimen in the Western world with many versions practiced. Some forms of yoga such as Astanga follow closely the ancient traditions whereas others involve more gentle exercises or a programme designed around the participant's needs (Viniyoga). There have been many RCTs investigating the efficacy of yoga on health. These include osteoarthritis, lymphoma, irritable bowel syndrome, mild depression, stress and stress-related conditions such as hypertension and heart disease. These studies have shown positive results for yoga (Sengupta, 2012; Williams et al., 2005). Recent literature suggests that yoga may benefit patients with CLBP but may not be superior to other exercise regimens (Saragiotto et al., 2015). A previous review had shown long-term benefits of yoga for improving pain and disability in CLBP patients (Cramer et al., 2013). However, there was no one standard yoga exercise approach used to manage CLBP. The most popular yoga therapies used in the studies to manage CLBP were Hatha, Iyengar and Viniyoga. In some studies, the type of yoga exercise therapy used was not described. Sherman et al. (2011) investigated the effect of yoga as a group exercise programme on CLBP. This large study randomised 228 CLBP patients to either yoga classes, conventional stretching exercises or a self-care book. They conducted a three arm parallel group stratified controlled trial in which participants were allocated in a 2:2:1 ratio to yoga, stretching and self-care. Participants were recruited via sent invitations to group health members with back pain related visits to primary care providers as well as advertisements. Those participants unable to speak English were excluded from the study. Both the yoga and stretching classes consisted of 12 standardised 75 minute sessions held at the health facility. Participants were encouraged to practice for 20

minutes on non-class days. The stretching class also included aerobic and four strengthening exercises but it was not stated whether all the exercises were repeated outside the classes. Only 65% of participants completed at least eight yoga classes whereas 59% completed at least eight stretching classes. Therefore, it is not known what would have been the full benefits of yoga or stretching exercises to CLBP patients as a high percentage had not completed their allocated treatment sessions. The results showed that yoga was more effective than self-help but no more effective than conventional stretching for reducing disability in CLBP. However, both programmes showed clinically important changes to the Roland Morris (RM) disability scores which were maintained at 6 months. There is little emphasis on relaxation techniques or meditation in these studies which are central components to yogic practice (Daulat, 2015). Tekur et al. (2012) had used an integrated approach of yoga therapy (IAYT) to manage CLBP patients. This intensive week programme had consisted of asanas (exercises) for back pain, pranayama (breathing techniques), relaxation techniques, meditation and yogic counselling for stress management. Although this programme showed positive results there was no long-term follow-up. A more recent RCT (n=320) by Saper et al. (2015) compared a Hatha yoga class with physical therapy for managing CLBP. Both groups showed improvements post treatment at 12 weeks to pain and disability measured by the RM but there was no significant difference between the groups. However, none of the groups achieved a clinically important change to disability after treatment and there was no long-term follow-up.

Other Group Programmes

There have been a large number of RCTs that have evaluated group exercise programmes (separate to the named group programmes described previously) used for the management of CLBP. These programmes vary greatly in exercise type and duration. For the purposes of this literature, I have set inclusion and exclusion criteria based on the previous Lewis et al. (2008) review for the articles included. My inclusion criteria are randomised controlled trials only, CLBP participants only defined > 12-weeks duration, articles written in English and articles including physiotherapist run group exercise programmes. My exclusion criteria include group exercise programmes which have used equipment or facilities generally not available in standard physiotherapy departments such as specialised weight-training machines or aerobic equipment, isokinetic machines, pulleys or reformer (Pilates). Studies that have included any participants presenting with back pain < 12-weeks duration are excluded. Any studies that have investigated hydrotherapy (exercises in water) as part of the management for CLBP are not included. This type of group exercise is not applicable to our study as my Trust does not currently have use of a hydrotherapy pool. Also excluded in this review are multidisciplinary programmes that have used cognitive behavioural therapy or other psychological techniques combined with exercise.

CLBP subjects have been shown to have a reduced aerobic capacity compared to asymptomatic controls (Duque et al., 2011). The benefits of aerobic exercise for back pain patients includes enhanced oxidative capacity of skeletal muscle, improved neuromuscular control and co-ordination (Sculco et al., 2001). Previous evidence suggests that cardiorespiratory exercises are used far less than other exercises for the

management of LBP (Poitras et al., 2005). Shnayderman and Katz-Leurer (2012) compared a group walking programme with a strengthening exercise group. Fifty-two CLBP patients were randomised to either of the two treatment groups. There was a 17% drop-out rate with only 43 participants completing the study. The programmes were delivered twice a week for six weeks totalling just over sixteen hours of therapy time. Participants had to attend in total 14 sessions. The study found that a 6 week walking programme was as effective as a six week strengthening programme for CLBP. This study had a number of methodological flaws. The sample size was small and there was no long-term follow-up. There were no details of the exercises given to the strengthening such as frequency and no indication of a home exercise programme for either group. Significant improvements to all parameters measured were seen in both groups but there was no difference in outcomes between groups. However, the walking group did demonstrate a clinically important difference in ODI scores whereas the strengthening group did not. Interestingly, the six-minute walk test was the main outcome measure of the study. Due to training effect, it would be expected that the walking group would have shown significant improvements in the walk test compared to the strengthening group. This study supports exercise therapy for managing CLBP in the short-term but it is not known whether these benefits would have been sustained.

High intensity general exercise programmes of long duration >15 treatment hours do not necessarily result in better outcomes for CLBP patients. Smeets et al. (2008) investigated the effect of three programmes on CLBP. They cluster randomised 172 participants to either active physical treatment (APT), a graded activity programme and problem solving (GAP), a combined programme of APT and GAP or a waiting

list control group. The APT programme had consisted of a combination of aerobic and strengthening exercises. Participants on average attended 25 sessions lasting 105 minutes each over 10 weeks. All active treatments showed improvements to disability after one year but there was no significant difference between the groups. Only 53% of patients in the APT group reached a clinically relevant reduction of disability at one-year post treatment. These poor outcomes may be attributed to the lack of patient-specific exercises. Although, the APT programme was very intensive it would be difficult for patients to maintain long-term and therefore promote adherence to exercise.

The UK BEAM trial (2004) had suggested that exercise only results in short-term benefits to back pain patients but manipulation may have longer effects. This hypothesis was further tested by Chown et al. (2008). They randomised 239 CLBP patients to a group exercise programme, one to one physiotherapy or osteopathy. Only 154 patients completed the treatment with 98 followed up at six weeks and 65 at twelve months. Therefore, a total of 58% patients who completed the treatment were lost to follow-up at 12 months. The initial drop-out rate of the group exercise programme was 60%. The osteopathy group had the lowest drop-out rates. One of the reasons the authors suggested for this is patients may perceive that a more hands on approach is more effective rather than the exercise-based physiotherapy. All patients in each group were required to attend five treatment sessions lasting 30 minutes over a three-month period. Both the physiotherapy and osteopathy group received manual therapy, exercise and advice. The exercise group consisted of motor control and stretching exercises with education but no manual therapy. All groups showed changes to disability measured by the ODI but failed to achieve clinical significance.

There was no significant difference in outcomes between the groups. The shuttle walk test was also used as an outcome measure but was not sensitive to variations in patient's symptoms. This study did not provide any evidence that one treatment strategy for CLBP was better than another but was limited due to high drop-out rates.

Gatti et al. (2011) conducted a RCT to investigate the efficacy of trunk balance exercises for patients with CLBP. Their hypothesis was that trunk balance becomes impaired due to the motor control dysfunction seen in CLBP and re-training this balance may lead to functional benefits. They randomised 79 CLBP patients to either the experimental or control group. The experimental group performed trunk balance and flexibility exercises and the control group performed strengthening plus flexibility exercises. The exercises were performed in small groups of 4-6 over 10 one hour sessions twice a week. The flexibility exercises were a combination of aerobic, muscle stretches and lumbar directional exercises such as flexion. However, these exercises were not individualised and may not be appropriate for all CLBP patients. For example, some CLBP patients may find lumbar extension painful and performing end of range lumbar extensions may aggravate their pain. The trunk balance exercises were Pilates based and involved core strengthening. There were only four strengthening exercises given compared to six trunk balance exercises. Three of the strengthening exercises were using machines. It would be difficult for subjects to continue with these exercises post treatment if they do not have access to a gym. No home exercises were given for either group. Disability was measured by the RM and quality of life was measured by the 12-item Short Form Health Survey pre-intervention to post-intervention. Both groups showed significant changes to disability and quality of life post-intervention. The improvement in RM score was significantly

greater for the experimental group compared to the control group (p = .011; mean difference, 2.1; 95% CI: 0.7, 3.6). The difference for the experimental group in quality of life score was also significantly greater than for the control group (p = .048; mean difference, 3.2; 95% CI: 0.1, 5.8). However, there was no long-term follow-up. Patients were not blinded to the treatments which may have caused a placebo effect. The strengthening exercises may have been less effective in this study as they did not challenge the core muscles and were not functional. Although part of the exercise programme in this study had included machines it was reviewed because the exercises in the experimental group were multimodal which may be more beneficial for CLBP than single mode exercises.

2.5.11 Summary of Yoga and Other Group Programmes

There are a small number of RCTs meeting my inclusion criteria that have investigated yoga and other group programmes for the management of CLBP. **Table 2.6** shows a summary of RCTs in this literature review investigating the effect of Yoga and other group programmes on CLBP.

Table 2.6: Summary of RCTs in literature review investigating the effect of Yoga and other group programmes on CLBP

Study	Intervention/comparison	Sample Size	Outcome
Saper et al (2015)	Hatha yoga class versus physical therapy.	n=320	Both groups showed improvements post treatment at 12 weeks to pain and disability.
Shnayderman and Katz-Leurer (2012)	Group walking programme versus a strengthening exercise group.	n =52	Significant improvements to all parameters measured were seen in both groups but there was no difference in outcomes between groups.
Sherman et al (2011)	Yoga classes versus a conventional stretching exercises or a self-care book (3 groups).	n=228	Yoga was more effective than self-help but no more effective than conventional stretching for reducing disability. No significant difference found between yoga and stretching exercises.
Gatti et al. (2011)	Trunk balance and flexibility exercises (experimental group) versus a strengthening plus flexibility exercises (control).	n=79	Disability and quality of life significantly improved in both groups but outcomes were significantly greater in the experimental group.
Chown et al. (2008)	Group exercise programme versus one to one physiotherapy or osteopathy (3 groups).	n=239	All groups showed changes to disability measured by the ODI but failed to achieve clinical significance. There was no significant difference in outcomes between the groups.
Smeets et al. (2008)	Active physical treatment (APT) versus a graded activity programme and problem solving (GAP), a combined programme of APT and GAP or a waiting list control group.	n=172	All active treatments showed improvements to disability after one year but there was no significant difference between the groups.

These programmes have varied greatly in exercise type from yoga, aerobic, stretching and high intensity combined exercises. These programmes have only shown moderate benefits to CLBP patients. However, these studies have shown high drop-out rates and participants lost to follow-up. No one group exercise programme seems to be superior to any other. On average these group programmes require over 15 hours of therapy time. Considering that the mean number of visits to physiotherapy for spinal conditions is 7.1 with sessions lasting approximately 30 minutes (Deutscher et al., 2009), this would not seem a cost effective approach for managing CLBP.

2.6 Manual Therapy combined with Exercise

Manual therapy or spinal manipulative therapy can be defined as a broad group of skilled hand movements including but not limited to mobilization and manipulation. Manipulation is a passive technique where a high velocity, low amplitude thrust is applied to the spine at end or near end of the passive range. This procedure is often accompanied by an audible crack (Rubinstein et al., 2011). This 'hands on' treatment is used by therapists to mobilize or manipulate soft tissues and joints for the purpose of reducing pain and increasing joint range of motion (Johnson and Rogers, 2000). Similar to exercise, the effect of manual therapy on CLBP has been widely researched. Manual therapy has been compared with sham treatments and other interventions. Some of which have been described elsewhere in this review. A recent Cochrane Library review on spinal manipulative therapy (SMT) for CLBP found that SMT has a statistically significant short-term effect on pain relief and functional status compared to other interventions. They concluded that the size effects were small and not apparently clinically relevant (Rubinstein et al., 2011). There is moderate evidence that manual therapy combined with exercise is more successful for

managing CLBP than manual therapy or exercise alone (Hidalgo et al., 2014; Geisser et al., 2005). My study aims to investigate the benefits of an intervention which combines exercise and manual therapy in a group format. This review will discuss those RCTs which have investigated the effect of manual therapy combined with exercise for the management of CLBP. Any RCTs that have used participants presenting with back pain of less than 12-weeks duration will not be included in this review. For example, Aure et al. (2003) assigned participants to either an intervention which combined manual therapy with exercise or exercise therapy alone for managing CLBP. However, the participants had presented on average back pain of only 10-weeks duration which does not meet the accepted definition for CLBP.

Niemisto et al. (2003) conducted one of the first RCTs to investigate the effects of combined manual therapy and exercise on CLBP. They randomised 204 CLBP participants to either the experiment group or control group. The experimental group received in total 5 sessions over 4 weeks of combined manual therapy, stabilisation exercises and physician consultation whereas the control group received physician consultation only. Both groups showed significant reductions to pain and disability after 12 months with the experimental group showing greater reductions in outcome measures. However, the difference of ODI scores between the two groups at 12 months was not clinically significant. Participants could not be blinded in the study and were recruiting voluntarily via newspaper advertisement. The age range was narrow at 24-46 years and participants were in employment. ODI scores for both groups at baseline indicated only moderate disability. The investigators suggested that the participants in this study were representative to the population of CLBP patients. However, the CLBP participants in this study would not be representative to those

presenting to NHS physiotherapy outpatient departments. This is due to the narrow age range in the Niemisto et al. (2003) study and CLBP patients generally present with much higher levels of disability in NHS clinics.

Geisser et al. (2005) in their RCT investigated the efficacy of manual therapy with specific adjuvant exercise for treating CLBP. In this RCT, 100 patients were randomised to 1 of 4 treatment groups: Manual therapy with specific adjuvant exercise; Sham manual therapy with specific adjuvant exercise; Manual therapy and non-specific exercise and Sham manual therapy and non-specific exercise. The specific exercise programme consisted of Pilates or motor control based exercises and stretches. Strengthening exercises were also added at 3 weeks but were not described. These exercises were tailored to the patient and aimed to address their musculoskeletal dysfunction. All participants were required to exercise twice daily. The manual therapy and specific exercise group were found to show significant decreases in pain scores compared with the other groups but did not display any significant changes on disability scores. The treatment programmes were only for 6 weeks with both the strengthening and aerobic exercises introduced at 3 weeks. This is not long enough to see the benefits of an exercise programme. This might be one of the reasons for the lack of improvement to disability. There was no long-term follow-up. There was a lack of standardisation of exercise prescription as the non-specific exercise group had an additional aerobic component whereas the specific exercise programme did not. Combining aerobic exercise with the specific exercise group may have altered the results as the non-specific exercise group showed a trend toward reduced disability. There was a drop-out rate of 28% in this study with those who dropped out displaying a significantly higher level of disability and pain. Eighty-five

percent of the participants were white. This study would not be representative of my Trust's population of CLBP patients with at least forty-six percent of the registered population in Ealing being non-white (Bernstein, 2009). In addition, (similar to the Niemisto et al. (2003) study mentioned previously) as high levels of disability are a feature of CLBP this may not make the results of this study applicable to the population of CLBP patients seen at physiotherapy clinics (Andersson, 1999). This study did not support that combined manual therapy and exercise alone are effective for treating CLBP. They suggested that multidisciplinary programmes would be more efficacious for treating CLBP.

Marshall and Murphy (2008) investigated the effect of supervised exercise following a 4-week course of spinal manipulation for managing CLBP. Volunteers recruited by advertisement were assigned to either spinal manipulative treatment or non-manipulative treatment which consisted of electrotherapy and ergonomic advice. Participants were not initially randomised to these two treatments which may cause a threat to internal validity. By not randomising it is difficult to control any confounding variables which might be associated with the observed effects of the treatment (Harris et al., 2006). Following treatment participants were then randomised to either supervised Swiss ball exercises or unsupervised home exercises. The randomised process was not described. Also in the 4-week treatment period, therapists could prescribe any form of exercise to participants but it is not known what these exercises were. This would make it difficult to replicate this study. This study had four groups: Manipulation and home exercises, manipulation and Swiss ball, non-manipulation and home exercises and finally non-manipulation and Swiss ball. Fifty-four participants were effectively divided into four treatment groups creating small

samples size in each group. The study showed that the supervised Swiss ball exercise after the 4-week treatment led to more rapid improvements in self-rated disability and pain compared with unsupervised home exercises. Long-term follow-up at 56 weeks found no difference in self-rated disability between these two groups. There was no difference in outcomes between manipulative or non-manipulative treatment. This study does not support the combined use of manual therapy and exercise for managing CLBP. It does suggest that supervision of exercise may be the important factor rather than the exercise itself.

A recent study similar to Marshall and Murphy (2008) by Balthazard et al. (2012) investigated the effect of manual therapy (MT) as the first intervention plus active exercises on CLBP. The difference with the Marshall and Murphy (2008) study was that the manual therapy treatment had to include manipulation which involves a high velocity low amplitude thrust applied to the spine. They randomised 42 CLBP patients to either a manual therapy as the first line intervention plus exercise group and a sham therapy (ST) plus exercise group. The ST group acted as the control. The title of this study is misleading as MT and active exercise were concurrent treatments. The MT was administered first followed by exercise in the same session. The researchers had aimed to have over 50 participants per group but had to stop the recruitment process due to financial reasons. Participants in both groups received an initial physiotherapy evaluation followed by 8 therapeutic sessions for the MT or ST over a 4 to 8-week period. The active exercise programme consisted of two mobility exercises for the first 2 sessions to be performed twice a day. After the second session participants were given passive stretching exercises and motor control exercises at the 4^{th} session. These were contractions of the transversus abdominis and/or multifidus

muscles progressing from static to dynamic positions. Finally, trunk strengthening exercises were given at the 6th or 7th sessions but the type was not specified. All of these exercises were performed daily during therapy. However, no particular recommendations were given for patients to continue with their exercises once therapy had been completed. The study confirmed the immediate analgesic effect of MT over ST. The MT group plus active exercises showed a significant decrease in pain and disability compared to the control group post treatment which was maintained at 6 months. As the control group consisted of exercise only this study suggests that MT may be clinically relevant for the treatment of CLBP. In contrast Marshall et al. (2008) found no difference between manipulative or non-manipulative treatment in the management of CLBP. Whereas studies by Cecchi et al. (2010) and Ferreira et al. (2007) had found MT alone to be more effective than exercise or physiotherapy for reducing disability in the short-term. However, there was no long-term follow-up in the Balthazard et al. (2012) study. Therefore, the differences between groups may not be significant at 12 months. Ferreira et al. (2007) had shown exercise to be equally effective at 12 months. In the Balthazard et al. (2012) study no data was provided on the duration of symptoms or work status and only 18% of participants were on sick leave. It is possible that the results in the Balthazard et al. (2012) study could have been affected by the regression to the mean. Regression to the mean is a statistical phenomenon that can make natural variation in repeated data or measurements look like real change. This happens when unusually large or small measurements tend to be followed by measurements that are closer to the mean. It may be difficult in this case to determine whether the change in mean scores is a result of the intervention (Barnett et al., 2005).

2.6.1 Summary of Manual Therapy and Exercise

There have been only a few studies which have investigated the combined effects of manual therapy and exercise on CLBP. **Table 2.7** shows a summary of RCTs in this literature review investigating the effect of manual therapy combined with exercise on CLBP.

Table 2.7: Summary of RCTs in literature review investigating the effect of manual therapy combined with exercise on CLBP

Study	Intervention/Comparison	Sample Size	Outcome
Balthazard et al. (2012)	Manual therapy (MT) plus exercise group versus sham therapy (ST) plus exercise group (control).	n=42	The MT group plus active exercises showed a significant decrease in pain and disability compared to the control group post treatment which was maintained at 6 months.
Marshall and Murphy (2008)	Participants randomised to one of four groups. Manipulation and home exercises, Manipulation and Swiss ball, Non-manipulation and home exercises and finally Non-manipulation and Swiss ball.	n=54	There were significant improvements to disability in the Swiss exercise group compered to home exercises. No significance difference in outcomes between manipulative or non-manipulative treatment.
Geisser et al. (2005)	Participants randomised to one of four groups. Manual therapy with specific adjuvant exercise; Sham manual therapy with specific adjuvant exercise; Manual therapy and non-specific exercise and Sham manual therapy and non-specific exercise.	n=100	The manual therapy and specific exercise group were found to show significant decreases in pain scores compared with the other groups but did not display any significant changes on disability scores.
Niemisto et al. (2003)	Combined manual therapy, stabilisation exercises and physician consultation versus physician consultation only (control).	n=204	Both groups showed significant reductions to pain and disability after 12 months with the experimental group showing greater reductions in outcome measures.

I had conducted a pilot feasibility study for a larger trial which investigated the effect of manual therapy combined with exercise for managing CLBP. This pilot showed that function, pain and quality of life improved after treatment (Daulat and Goodlad,

2014). There is an indication that this combined treatment may be beneficial for managing CLBP but the evidence remains inconclusive. There is moderate evidence that manual therapy combined with exercise is more successful for managing CLBP than manual therapy or exercise alone (Hidalgo et al., 2014). Two of the studies reviewed had used voluntary recruitment by advertisement. Participants may have had a positive attitude toward this treatment package and are more likely to benefit from the intervention (Marshall and Murphy, 2008). Studies investigating the effect of manual therapy on CLBP are difficult to replicate. Performing musculoskeletal assessments and manual therapy techniques is a skill which may vary on the clinician performing them. It is therefore difficult to standardise these treatments in these clinical trials. Due to the age ranges in the studies, voluntary recruitment, lack of ethnic diversity and only moderate levels of disability, it is also questionable whether the participants in these studies would be representative of the CLBP population presenting to NHS physiotherapy departments.

2.7 Summary of Physiotherapeutic Interventions for CLBP

There is a wealth of literature using randomised controlled trials (RCT) to compare group rehabilitation programmes with other treatments such as spinal manipulation or home exercises (Cecchi et al., 2010; Chown et al., 2008). The effect of exercise and manual therapy as treatment modalities for CLBP have also been widely researched (O'Sullivan, 2011). Both group exercise and manual therapy have shown equivalent patient-orientated outcomes both in the short and long-term (Hurwitz, 2011). There is also evidence that manual therapy combined with exercise is more effective than single interventions (Balthazard et al., 2012; Geisser et al., 2005). The treatment effects of the studies reviewed are only moderate with outcomes often failing to achieve clinical significance and benefits not sustained in the long-term. The value of *p* may not be a reliable indication of the magnitude of effect of the intervention. A large effect can fail to obtain a conventional level of significance. The most likely cause of a large effect size but lack of significance is due to a small sample size or large variability (Nickerson, 2000). With small participant numbers, there is not much information in the data and typically only larger effects are detected. With continuous outcomes, if there is a lot of variability between patients in the study (i.e. a large standard deviation) this can increase the size of the *p*-values and thus fail to attain a conventional level of significance. Effect sizes have not been consistently reported in back pain studies (Nickerson, 2000). This has been addressed in the current study as the standardised effect size was calculated as a common method of size of effect to determine the magnitude of differences in outcome measure scores between groups. This will allow more effective statistical inference from the outcome data. The *p*-value is the probability that the samples in a study are from the same population with regard to the dependant variable (outcomes). The *p*-value is directly related to the null

hypothesis and determines whether or not we reject the null hypothesis. The *p*-value provides an estimate of how often we would get the obtained result by chance, if in fact the null hypothesis were true. If the *p*-value is small, we can reject the null hypothesis and accept that the sample means are truly different with regard to the outcomes. If the *p*-value is large, we can accept the null hypothesis and conclude that the treatment had no effect on the outcome. If the *p*-value or probability associated with an inferential statistic is equal or less than .05, the result is significant at the .05 level. If the *p* value is >.05 we can't conclude that a significant difference between two means exists and indicates weak evidence against the null hypothesis. Therefore, you fail to reject the null hypothesis. As mentioned, the value of *p* is not a direct indicator of the magnitude of effect (Nickerson, 2000). A *p* value of >.05 may indicate no real effect or significance of an intervention but has not taken into account the magnitude of effect. There will be a failure to reject the null hypothesis when it may be false and conclude the intervention had no effect on the outcomes measured (Nakagawa and Cuthill, 2007, Nickerson, 2000). In general, methodological well conducted studies remain scarce (Rubinstein et al., 2011). Some of these studies would be difficult to replicate due to the incomplete description of their interventions and the non-reporting of average number of treatment sessions given to patients leading to type I errors. A type I error is the false rejection of the null hypothesis (i.e. the hypothesis of no difference between treatment groups). Hence, a Type I error can make a false positive claim that the intervention is effective but in fact is not (Hicks, 2009; Sidani, 2015). This would make it difficult for other researchers to repeat these original studies and add credibility to their conclusions (Hicks, 2009). In this current study (**Stage 2**) the protocols of both group exercise programmes have been described

in detail which would allow not only the study to be replicated but for them to be set up in clinical practice.

2.8.1 Classification of CLBP

The majority of studies have included a heterogeneous group of CLBP patients. Within this group are smaller homogenous groups which may respond to the specific treatments such as manual therapy or exercise. However, the overall effect of the intervention may be diluted due to the absence of response in the other sub-groups (Fersum et al., 2010). CLBP is a complex condition comprising of neurophysiological, pathoanatomical and psychosocial factors. A single intervention is unlikely to target all of these factors (Fersum et al., 2010). A number of classification systems for LBP have been proposed which have included pathoanatomical and psychosocial aspects. Schafer et al. (2009a) have proposed a recent classification system of low back pain. They divided low back related leg pain into four sub-groups according to the predominating pathomechanisms involved. These sub-groups are central sensitization, denervation, peripheral nerve sensitization and musculoskeletal pain. Central sensitization refers to those patients with enhanced peripheral processing and presenting with symptoms such as hyperalgesia and allodynia. This sub-group is linked to chronic pain syndromes influenced by psychosocial factors. This sub-group is unlikely to respond to manual or exercise therapy and may require multi-modal pain management programmes (Schafer et al., 2009b). Denervation is caused by structural nerve damage presenting with sensory or motor deficits on neurological examination. This sub-group of patients are likely to require specialist treatment. Peripheral nerve sensitization (PNS) is caused by nerve root or nerve trunk inflammation which leads to an adverse response during

mechanical provocation. However, patients presenting with this have no significant neurological dysfunction. Musculoskeletal pain (MP) is referred from non-neural structures such as the disc or facet joints (Schafer et al., 2009a). Although in practice patients may present with an overlap between the four groups, a dominant symptom mechanism may be identified in the assessment. Both of the PNS and MP sub-groups may respond to manual therapy and specific exercises (Schafer et al., 2009b). The strict exclusion criteria used in this current study (**Stage 2**) would exclude patients with central sensitization and denervation but include those with a combination of peripheral nerve sensitization and pain referral from musculoskeletal structures. This may produce a sample of patients that represents a homogenous CLBP population that will respond better to the treatment proposed in this study. However, inclusion and exclusion criteria alone may not be sufficient to classify CLBP patients into sub-groups and match the intervention based on that classification (Fersum et al., 2010). Hill et al. (2008) have developed the Start Back screening tool (SBT) designed to sub-group patients with LBP patients in primary care into 3 categories on the basis of the presence of physical and psychosocial risk factors. The SBT is a 9-item questionnaire which categorizes patients into 3 sub-groups – High risk, Medium risk and Low risk. High risk patients have high levels of psychosocial prognostic factors with an unfavourable prognosis (Fritz et al., 2011). These patients are more appropriate for a combined physical and cognitive behavioural management approach (Hill et al., 2008). The SBT was used the current study (**Stage 2**) at the initial assessment in an attempt to classify CLBP patients into three sub-groups. Although, treatment was not matched to these sub-groups based on the specific characteristics within that sub-group, the objective was to determine which sub-group if any would respond better to the group physiotherapy interventions.

2.8.2 The De-Conditioning Syndrome

Many physiotherapists' based exercises are effective for reducing pain in CLBP patients. However, based on the available evidence no single group exercise regimen has been shown to be superior to other exercise regimens. Many of the studies described in this review include exercise therapies which may be of insufficient intensity or duration to classify them as re-conditioning interventions (Liddle et al., 2004). It has been suggested that CLBP patients are de-conditioned due to their low physical activity levels (Dogan et al., 2008; Koes et al., 2001). This de-conditioning leads to a lower level of physical fitness. Physical fitness has a combination of physical parameters such as muscle strength, muscle endurance, flexibility, cardiovascular capacity, motor control and body composition, all of which may be affected by physical de-conditioning (Verbunt et al., 2003). However, others have suggested that there is no convincing proof that the physical de-conditioning theory exists and whether the de-conditioning seen in CLBP exceeds that present in the general population (Smeets and Wittink, 2007; Verbunt et al., 2003). The physical de-conditioning model assumes that the loss of strength, endurance and aerobic capacity is responsible for reduced activity levels leading to functional limitations and disability in CLBP (Smeets et al., 2006). Aerobic capacity or VO_2 Max has been considered as the gold standard for assessing cardiovascular fitness and hence physical de-conditioning. However, there have been contradictory results with cross-sectional studies that have examined loss of aerobic capacity due to persistent back pain (Smeets and Wittink, 2007). Previous studies have not tested participants VO_2 Max until exhaustion but have extrapolated values from submaximal exercise tests to estimate VO_2 Max or calculated predicted values (Verbunt et al., 2010). This extrapolation of VO_2 Max from submaximal efforts can over or underestimate the

VO_2 Max value in healthy subjects by up to 15% (Duque et al., 2011). Duque et al. (2011) found that compared to the asymptomatic population matched for gender and age, patients with CLBP had significantly lower aerobic capacity. This study had measured VO_2 Max using an exercise protocol to exhaustion. However, cross-sectional studies must be treated with caution in terms of drawing conclusions of causality and the generalisability of their findings (Asghari and Nicholas, 2001). It can also be argued that most CLBP patients are unable to achieve maximal effort in functional testing. A lack of motivation and self-efficacy, emotional state, level of pain and fear avoidance can negatively influence effort during these tests resulting in sub-maximal performance (Verbunt et al., 2010). Work status may be an important variable to differentiate between levels of de-conditioning. CLBP patients that fully participate in occupational activities have a fitness level comparable to healthy subjects (Verbunt et al., 2003).

The association between disability and de-conditioning has been shown to be weak or non-existent (Bousema et al., 2007). Although disability has been found to be positively associated with patients' perceived decline in activities after back pain onset. The perception of loss of physical activity levels (PAL) due to pain is itself disabling (Verbunt et al., 2010). According to the fear avoidance model, CLBP patients interpret pain as threatening which leads to a fear of movement and disuse. This then leads to a reduction of PAL and de-conditioning which in turn causes more pain and disability (Vlaeyen and Linton, 2000). Cross-sectional studies have shown similar PAL of patients with CLBP compared to asymptomatic controls which may dispute this theory (Verbunt et al., 2010). However, the results on PAL in CLBP may be inclusive due to different assessment measures used such as self-report and

physiological measurements (Verbunt et al., 2003). There may be a subgroup of CLBP sufferers who are afraid to increase their PAL because of fear avoidance which leads to de-conditioning and functional restrictions (Verbunt et al., 2003). Smeets et al. (2006) argued that CLBP patients have lower PAL leading to a loss of aerobic fitness. Their study found that CLBP patients with associated disability have a lower level of aerobic fitness than healthy controls matched for age, sex and sport activity. However, this was not associated with fear avoidance. In contrast, it has been suggested previously that an increase in functioning after participation in a physical training programme may be due to a decrease in fear avoidance behaviour and psychological distress rather than in an increase in physical fitness (Mannion et al., 2001). However, despite the minimal research evidence that CLBP patients suffer from disuse and physical de-conditioning; physical re-conditioning should be part of their rehabilitation programme (Verbunt et al., 2010).

2.8.3 Alternative Group Programme

The alternative group physiotherapy programme aims to provide supervised individualised multimodal exercises to address the de-conditioning syndrome seen in CLBP. Exercises that are individually tailored to the needs and capabilities of the patient have been shown to be more effective for reducing pain and disability in CLBP (Descarreaux et al., 2002). Also, individually specific exercises and advice regarding suitable lifestyle adaptations have been found to be important factors for patient's in their CLBP treatment (Liddle et al., 2007). However, individualised tailored exercises are generally lacking in group programmes. The integration of exercise therapy, manual therapy and education in a group setting may be more effective. Moseley (2002) had suggested in his study that combined physiotherapy treatment consisting of manual therapy, specific individualised exercise training and education was effective in producing functional and symptomatic improvement in chronic low back pain patients. This package of treatment could be classified as conventional physiotherapy (Cairns et al., 2006) but there is no evidence that this combined treatment has been delivered in a group format.

The concept of a multimodal exercise programme that is directed towards improving spinal mobility, flexibility, trunk and limb muscle strength, endurance and coordination with the aim of re-conditioning to restore normal function is not new. These rehabilitation programmes are usually included as part of multidisciplinary biopsychosocial rehabilitation or functional restoration programmes (Fredrich et al., 2005; Ranville et al., 2002). For example, Luk et al. (2010) had used an extensive 14-week rehabilitation programme consisting of combined strengthening, flexibility and cardiovascular exercise for patients with CLBP. Participants in this study showed

clinically significant reductions in pain and disability at 6 months. Roche-Leboucher et al. (2011) also used an intensive physical rehabilitation programme to manage CLBP. This functional restoration programme (FRP) was performed 6 hours a day, 5 days a week for 5 weeks and was compared to an intensive out-patient physiotherapy programme. The physiotherapy programme consisted of 15 one hour sessions over 5 weeks. At one-year follow-up disability measures and sick-leave days were significantly lower in the FRP group. However, outcome measures which had assessed the physical components of de-conditioning did not differ between the two groups and pain reduction was also similar (Roche-Leboucher et al., 2011). However, these types of rehabilitation programmes described although effective are time-consuming and expensive (Dufour et al., 2010). There is limited potential to apply these interventions to clinical practice in the NHS. Interventions should be tested using an episode of care model that reflects those relevant to clinical practice (Bialocerkowski et al., 2004). For example, it was proposed that the alternative group physiotherapy programme should incorporate a combination of individualised multimodal exercises, manual therapy and advice. Most of which reflects standard practice used in the management of CLBP (Liddle et al., 2009). Torstensen et al. (1998) introduced the concept of a progressively graded group exercise programme for CLBP specific to the patient and tailored to their dysfunction. Their programme allowed up to five patients to be managed at one time using a specially adapted gymnasium. However, it was not explained how the patients would maintain their exercises once they completed the programme particularly if they did not have access to the specialised gym equipment. A similar group programme design to the proposed alternative model in my thesis was used in a RCT by Lewis et al. (2005). They investigated the effects of combined manual therapy and exercise for the management

of CLBP. This study had found a significant reduction in disability post group programme but there was no significant difference between this group programme and individual physiotherapy. However, this programme did not have individually designed and supervised exercises with regular practitioner review. The provision of supervised exercise with regular face to face follow-up is likely to influence exercise adherence and be more effective for managing CLBP (Hayden et al., 2005; Jordan et al., 2010). Lower intensity physical treatment programmes may be sufficient to induce changes that will be sustained long-term, whereas the more intensive programmes seen in functional restoration may be more difficult to maintain. Long-term outcomes may be more closely related to lifestyle changes and the resumption of leisure or sport activities (Roche-Leboucher et al., 2011). My alternative group programme aims to direct patients to self-managing their CLBP by incorporating exercise and increased physical activity levels into their weekly routine which is likely to have a more successful long-term outcome. This is also likely to give patients more confidence in their ability to perform these tasks as well as overcome any barriers to changing their exercise habits and physical activity levels. This refers to a patient's self-efficacy and may be a more important determinant of disability in CLBP than fear avoidance beliefs (Denison et al., 2004). Higher levels of self-efficacy are associated with favourable outcomes for LBP (Lackner and Carosella, 1999).

2.8.4 Experimental Design in Stage 2

The experimental design used in **Stage 2** is discussed in more detail in **Chapter 3**. **Stage 2** of this project used a mixed methods sequential exploratory design. This consisted of two phases: a quantitative followed by a qualitative phase. The quantitative component of **Stage 2** was a randomised single blinded controlled study. This study aimed to assign subjects to either the alternative group physiotherapy programme or a standard group physiotherapy exercise programme which acted as the control. A similar quantitative study design to my current one had been used previously by Koumantakis et al. (2005) to evaluate the effectiveness of two group exercise programmes for patients with CLBP. This study was single blinded in that participants were not aware they had been assigned to the experimental or control group. Pre and post treatment as well as long-term follow-up testing using outcome measures providing data in a numerical form was used in the current study which can further classify the quantitative phase as a pre-test and post-test control group design (Creswell, 2009). The qualitative phase used focus group interviews to explore patients' views and experiences regarding their treatment in the group programmes. The qualitative data analysis was used to validate the quantitative results in order to evaluate the treatment programmes and determine any differences between the two treatment groups.

2.9 Conclusion of Literature

This review has looked at the literature regarding implementation research, change management and leadership relevant to my thesis. This review has also demonstrated my knowledge of the physiotherapeutic management of CLBP, how back pain may be classified and the de-conditioning syndrome as a possible consequence of suffering from CLBP. I have stressed the limitation of this review in that it is based on my own interpretation of the research which I have been able to access. The transfer of research findings into clinical practice can be a slow and haphazard process. A need to change the group physiotherapy programme concept at my Trust was identified but for change to take place all members of the organisation had to play a part. Bullock and Batton (1985) suggested a four-phase model of change most applicable to this project. These interlinked phases were exploration, planning, action and integration. It would be difficult for a single person to complete this process of change and a type of distributed leadership would be required for this to be successful within the organisation. However, a leader at any level of the organization has a direct influence on implementation of an intervention programme. I have developed a predominately transformational style of leadership in this process highlighted in IPL4016, whereby I have championed the implementation of the alternative programme and ensured this intervention has been more visible in the organisation. I was able to articulate my vision of the alternative group physiotherapy programme to my colleagues as well as motivate them to achieve higher levels of performance and change the way they manage patients within a group setting.

Stage 1 was ‘A physiotherapy survey to investigate the use of exercise therapy and group exercise programmes for the management of non-specific chronic low back

pain'. The literature search found a limited number of survey questionnaires that have investigated the physiotherapeutic management of CLBP. Advice and exercise were found to be the most commonly used strategies by physiotherapists to manage CLBP. Spinal stabilisation and core stability were the most frequently used exercise types. Most of these surveys had included the management of all patients with LBP and not exclusively for CLBP. To my knowledge no survey of this type has been conducted solely in the London area. London is becoming increasingly diverse with a rising number of minority ethnic groups being identified. This may have an impact on exercise prescription and the utilisation of group programmes for managing CLBP. There have been no other surveys up to **Stage 1** (March 2013) that have investigated in detail group programmes for managing CLBP in clinical practice.

Stage 2 aimed to evaluate an alternative group physiotherapy programme for the management of chronic low back pain in Primary Care. This alternative programme had been developed from the review of the literature, consultation with service providers and the results of the survey in **Stage 1**. An RCT was used to measure the impact of the alternative group physiotherapy programme on CLBP participants. There is a wealth of literature regarding the physiotherapeutic management of CLBP including exercise therapy with several RCTs conducted to compare group rehabilitation programmes with other treatments such as manual therapy. Group exercise programmes are a cost effective method for managing CLBP. There are several group exercise programmes described in the literature with the most common being Pilates, Back School, Lumbar stabilisation (Motor Control) and the Back to Fitness programme. None of the group programmes in the literature have been found superior to another. Both group exercise and manual therapy have shown equivalent

patient-orientated outcomes. There is also evidence that manual therapy combined with exercise is more effective than single interventions. The treatment effects of the studies reviewed are only moderate with outcomes often failing to achieve clinical significance and benefits not sustained in the long-term. One of the limitations with these studies is that it may be difficult to replicate their group programmes described in clinical practice.

CLBP may contain a number of homogenous sub-groups which respond to specific physiotherapeutic interventions although the majority of studies have included heterogeneous samples. A number of classification systems have been proposed for LBP. It was decided in **Stage 2** to the use the Start Back screening tool which categorizes CLBP patients into three sub-groups based on the presence of physical and psychosocial risk factors. This may help determine which sub-group of patient respond better to the group physiotherapy interventions. There is evidence that CLBP patients are de-conditioned due to their low physical activity levels. This de-conditioning leads to a lower level of physical fitness. The alternative group physiotherapy programme aims to address this de-conditioning syndrome by providing an individualised multimodal exercise programme and also offers manual therapy. Although the concept of re-conditioning to restore normal function is not new, previous interventions described have been too intensive, not cost-effective and have limited potential to be applied in clinical practice. The alternative group physiotherapy programme is less intensive and promotes participants to manage their CLBP in the long-term. **Stage 2** used a mixed methods sequential exploratory design with a quantitative followed by a supplementary qualitative phase. The quantitative component of **Stage 2** was a randomised single blinded controlled study. This study

aimed to assign subjects to either the alternative group physiotherapy programme or a standard group physiotherapy exercise programme which acted as the control. The qualitative phase used focus group interviews to explore patients' views and experiences regarding their treatment in the group programmes.

Chapter 3: Methodology

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3.0 Introduction to the Methodology

This chapter aims to consider the methodological background and rationale for **Stages 1 and 2** as well as the approaches taken and methods outlined. **Chapter 3** has been divided into two sections.

Section 1

3.1 World View, Ontological and Epistemological Perspectives

There are a basic set of beliefs or philosophical assumptions that guide the researcher's perspectives and actions regarding research. These are also referred to paradigms, epistemologies and ontologies (Creswell, 2009). It is important to consider these assumptions as these can have a significant impact on what and how to research. Ontology philosophizes about the nature of reality and generates theories about what can be known. Epistemology is concerned with the origin, nature and limits of human knowledge as well as the knowledge gathering process itself (Grix, 2004). Ontological and epistemological positions are shaped by our being, beliefs and our perspectives. Ontology and epistemology are inextricably linked. In that what is the researchers' philosophy of research and the type of methodology employed which is their ontological position can be linked to what new knowledge can be discovered being their epistemological position. The methodological approach is how we go about acquiring this knowledge. Research methods will enable us as researchers to create the link between theory and reality. The choice of method may be influenced by the researcher's world view or set of beliefs and experiences as well as the theory to be tested or the knowledge that is sought.

My own world view as a novice researcher had been dominated by the medical model and thus associated with a positivist philosophy. Physiotherapists in general have been closely allied to this world view. This is a view that there is a real objective world which exists independent of human belief, perception, culture and language used to describe it (Fox et al., 2007). This world is observable and scientific research has been used in the past to investigate the effectiveness of physiotherapy for the management of CLBP (Klaber-Moffett and Mclean, 2006). This positivist position has been adopted due to my previous experience, training and skills. I had previously searched for facts and causes through methods such as specific measurement instruments and questionnaires. These methods typically produce quantitative data allowing statistics to prove or disprove any relationships between variables. The quantitative research method approach is based on the assumption that reality is an entity that can be captured objectively. Experimentation and observation does not establish scientific laws but helps to give rise to theoretical explanations which can be tested further. Empirical evidence has a vital role in scientific research as it is capable of limiting the scope or falsifying theories but can never establish the absolute truth. However, the data obtained from experimentation can support more than one theory and provide a number of explanations (Pawson, 2013). We cannot be absolutely certain about any theory that is based on evidence, since new evidence may always appear to undermine it (Thompson, 2012). There is also a question of the validity of a scientific study. Is there any truth in the conclusion that the observed effects have been due to the intervention such as the alternative group exercise programme? Any scientific methods used may have validity due to the statistical control of the variables and rigorous measurement. A purely evidence-based approach to researching clinical practice aims to compile evidence through observable and measurable parameters.

This evidence has provided in the past a means of evaluating clinical practice and a basis for practice change. This empirical approach used previously to investigate the relationship between physiotherapy and CLBP focuses on the here and now. An ontology that assumes reality to be static and immanent which translates to the concept that participants can be accessed, assessed and measured at one moment in time (Raadschelders, 2011). This reality may not consider patients' experiences or meanings of their chronic back pain over time. In quantitative research the opportunity to understand how a physiotherapy intervention changes individual perspectives or behaviour is rarely considered. Experimental study of CLBP reduces the illness experience and treatment effect to quantifiable measures. Questionnaires are often used to measure a patient's health status which is reduced to a numerical score. Suffering and social consequences of chronic pain are either neglected or reduced to homogeneous variables (Jones et al., 2006). CLBP is a complex multidimensional condition where disability is more closely associated with cognitive and behavioural aspects of pain rather than the biomedical ones (Gatchel et al., 2007). This reductionist approach of dealing with complex disorders in a simplistic way may account for the lack of consistent evidence for the long-term effect of group rehabilitation interventions on CLBP (Van Middlekoop et al., 2011).

A positivistic approach had been my ontological position. This approach does not acknowledge multiple realities or realise that individuals may experience an intervention differently (Raadschelders, 2011). My research journey in this Doctorate programme has helped me realise that knowledge from quantitative methodology is only a particular kind or objective fact which can be measured. A neutral or value-free position in my research cannot be taken, so to be completely objective is impossible

(Fox et al., 2007). Evidence in research is always imperfect and fallible. Hypotheses are not proved but an indication to reject the hypothesis is given (Creswell, 2009). However, even the best scientific method cannot yield infallible results. The absolute truth of knowledge using the scientific method can never be found but can be used as the basis for further work as well as giving a new and original view of the subject matter (Thompson, 2012). Post-positivists advocate a realist perspective of science. This is a fundamental different conceptualization from positivism in that the unobservable is deemed to have existence and the capability of explaining the functioning of observable phenomena. Evidence from research is not confined to what can be perceived but can be inferred from interview or questionnaires (Clark, 1998). In contrast to positivism and post-positivism, the interpretivist approach considers humans to be continuously interpreting the world around them. The researcher aims to enter the social world of the research subjects and to understand the world from their perspective. This is considered as an inductive approach to studying phenomena and understanding multiple realities (Townsend et al., 2010). The qualitative research paradigm operates under the philosophical assumption that the truth and reality are not absolute. Reality is constructed by individuals through their life experiences resulting in unique and contextually framed experiences (Jones et al., 2006). For example, experiences such as pain are perceived and interpreted differently by ethnic and socioeconomic groups (Allison, 2002; Collister, 2003). Qualitative research attempts to draw inferences from observed phenomena but there may be difficulties collecting and interpreting data in this way. This can potentially compromise the integrity of the research process (Drake and Heath, 2011).

I have discovered that there is no simple, unique or ideally adequate concept framework for describing the world. I have challenged the concept that quantitative and qualitative research methods have distinct epistemological assumptions. Quantitative methods require qualitative observations at some points whereas qualitative analysis requires some quantifying to support their findings (Keating and Porta, 2010). The methodology and methods used may not be necessarily derived from prior epistemological or ontological positions but should be guided by the research questions (Grix, 2004). The methodological choices made may also depend on research funds, capacity and time as well as individual skills. It can be argued that a review of the philosophy is a vital aspect of the research process as it will open the mind to alternate research designs or methodologies. Indeed, my interpretation of the research findings may highlight my underlying philosophy but all knowledge produced from research is knowledge from some point of view. However, my development through the Doctorate Programme may have led me to take a more pragmatic approach to my research project. Pragmatism accepts philosophically that there are singular and multiple realities open to empirical inquiry to help solve problems in the real world (Feilzer, 2009). This approach accepts that all individuals have their own unique interpretations of the world. This pragmatic view applies methods to suit the problem and is not committed to any one system of philosophy (Creswell, 2009). Pragmatism can be regarded as a practical activity aimed at producing useful knowledge rather than understanding the true nature of the world (Mingers, 2004). This paradigm does not dictate what kind of research methods a researcher would have to use (Mengshoel, 2012). I have therefore decided to use quantitative and qualitative methods of inquiry or a mixed methods approach in my

project to produce knowledge that best represents reality regarding CLBP management.

3.2 The Insider-Researcher

The practitioner or insider-researcher has more experience and knowledge of practice in their particular area in question than the traditional researcher. This has the potential to produce new knowledge regarding CLBP management that is more relevant and of greater value to clinical practice. Solutions to problems within the workplace should not come from academic researchers but rather from practitioners reflecting on and researching the practice within the workplace (Fox et al., 2007). In the past, allied health professionals have lacked influence in the research field and may have been as regarded as subordinate professionals (Nairn, 2012). However, the culture of research within physiotherapy has changed in recent times directed toward evaluating practice with the objective of improving clinical effectiveness and credibility (Wrightson and Cross, 2004). The practitioner may also understand the implications of a new idea such as the alternative physiotherapy programme, has knowledge of the workplace setting and a means by which knowledge can be generated, particularly how a research protocol may be conducted in a busy physiotherapy department. There may be points of time during the research process that action is required to make changes where the research is situated. The insider-researcher has a greater advantage of using this action research approach. The aim of action research is to improve practice as part of a process of change. My study was not an action research project in the real sense as this type of research is context-bound and participative involving a continuous cycle of evaluation, collaboration and sharing of newly generated knowledge (Richards and Hallberg, 2015). This may be applicable to future implementation and evaluation of the alternative group programme but beyond the scope of this current thesis. The insider researcher's consideration of epistemology contributes to the research questions leading to the

knowledge and methodology through which these questions can be answered. If research uses the appropriate methodology to answer the research questions and the findings have implications for policy or practice change. Then any research findings are more likely to have an impact and be accepted by peer review journals for dissemination (Stockton and Morran, 2010; Trowler, 2011).

I have to consider the impact I have had on the research itself. Together with a self-awareness of my influence as a researcher I may have had on the work setting, participants and colleagues. In the focus group interviews, I was the moderator who introduced the topic and items for discussion. My role was to assist and facilitate participants to discuss the topics, encourage interaction and guide the conversations. I therefore played a major role in obtaining relevant and accurate information from the focus groups. It is possible that my relationship with the participants might have an impact on their behaviour whether negative or positive such that they may have behaved in a way they would not normally. This type of researcher-participant relationship could potentially affect the internal validity of the study (Drake and Heath, 2011).

Colleagues involved in the research project as part of their normal work have been required to spend extra time providing data for the projects such as completing additional questionnaires. I as the researcher have provided additional training sessions and presentations (See **Chapter 4**: Project Activity) to inform what was expected of colleagues and the objectives of the research. Informing colleagues about the research helps to create a supportive environment for the insider-researcher in the organisation (Costley

et al., 2010). I have to consider my relationship with colleagues as both researcher and practitioner. I cannot assume that colleagues will or should necessarily co-operate with the research or perform the tasks of the project as you would want them or expect them to do. For example, colleagues may have decided not to actively recruit participants into the study who met the inclusion criteria or document the reasons why the patient decided not to participate in the study.

It has been important to consider how the research process has changed me as a person by reshaping my thinking and beliefs as a researcher as well as how this may have had an impact on the research process. By understanding and undertaking reflexivity within the research process, an insider-researcher can maintain quality, enhance clinical practice and bridge the research-practice divide (Etherington, 2004). Reflection on the research being undertaken, reflection on self and reflection on self within the research process has been an essential aspect in the stages of this thesis. For example, I have reflected on whether the research findings are valuable and valued by my colleagues. I have also reflected whether the knowledge gained will be meaningful and useable to the individual physiotherapists or at an organisational level.

Reflexivity is the capacity to reflect upon my own actions and values during the research, data production and write-up. My aim has been to become a better researcher and not become rooted in dogmatic habits or attitudes. Being reflective is a process of questioning ourselves and the way we have done things. For example, what factors underlie the decision to use a particular experimental design, method or outcome instrument. Thus, throughout this programme, I have examined critically the

way in which I have conducted this research which is termed epistemological reflexivity (Macfarlane, 2009). My own view of the world can frame my interaction with what research I am doing and this can depend on my ontological view. For example, if my approach is objective, knowledge is seen as governed by the laws of nature. In contrast, if my approach is subjective, knowledge is seen as something interpreted by individuals. Research is also likely to be affected by personal experiences and the context of the research involved whether quantitative or qualitative methods are employed (Labaree, 2002).

I can also consider what I have learnt from the research process and what would I do differently next time. There had been the dilemma of doing a postal or Internet survey. The trend has been to conduct Internet surveys rather than postal ones. I had decided on a postal survey as this in my view was more personalised with similar response rates. However, postal surveys present with a greater challenge compared to Internet surveys in the analysis of the data. Researchers have the potential to introduce bias by affecting data collection and analysis. The researcher's philosophy, background or values may affect the interpretation of the research findings and communication of conclusions. Reflexivity or self-reflection is a means of understanding the impact of the researcher's views and can be seen as adding credibility to the research findings (Carolan, 2003). Reflexivity can serve against biased interpretations of data whether good or bad. The researcher can present unbiased results and be as objective as possible. This includes discussing the limitations and strengths of the study as well as the transferability of findings to other settings. I have adopted a more honest and open approach to writing up my research including my experiences of the research processes and data produced. Being

reflexive may assist to provide a critical account of the researcher's subjectivity on study design, data analysis and presentation of findings. This will add a richness and greater truth to the text rather than a self-justificatory narrative (Macfarlane, 2009). However, one issue with providing an open reflexive account of my research is to risk unnecessarily undermining its quality by highlighting the subjectivities and weaknesses. Those with a positivist philosophy may see subjectivity as a threat to validity. Word restrictions in peer review journal articles may limit the degree to which researchers can provide such detailed reflexive accounts of their research (Newton et al., 2011).

3.3 Research Approaches and Methods

The appropriate research approach used in the stages of this project will depend on the research question. The research method used must allow this research question to be answered. The literature had shown a great deal was known regarding physiotherapy, exercise and CLBP. However, there was a gap in the knowledge regarding the use and content of group programmes for managing CLBP in clinical practice. My position in this research project had also been influenced by my experience, beliefs, interests and knowledge of spinal conditions. My consideration of the ontological assumptions has helped me identify the nature of my study. My epistemological stance in this study was to discover the true nature of knowledge regarding group physiotherapy programmes for managing CLBP and the appropriate way of producing such knowledge. I was also aware of the limits of inquiry and the validity of my research. I had discovered that the research question should always precede the desire to apply a particular methodology.

3.4.1 Stage 1: Approach and Method of data collection

Stage 1 used a survey to investigate the use of exercise therapy and group programmes for managing CLBP providing quantitative data for analysis. Survey research uses individuals as units of observation and analysis. It invokes characteristics at a higher level of analysis such as physiotherapy grade as the explanatory variables for the patterns of group programme referral. My ontological position may assume that only individuals exist and act but there may be conceptual categories of research beyond the individual which are important (Keating and Porta, 2010). The method to use a self-completion questionnaire in **Stage 1** to collect information may not be derived from my ontological or epistemological position but the choice was made due to pragmatic reasons. A cross-sectional self-report postal questionnaire was used to survey a population of physiotherapists involved in the management of CLBP. This was the chosen method of data collection in my study as it has the advantage of collecting data from a large sample of participants in a specific setting to explore how group exercise programmes are utilised. Cross-sectional studies collect data from the population of interest at one point in time. However, only a small sample from the population of physiotherapists was used. This can only yield estimates of association and inferences about the use of group exercise programmes for managing CLBP. There is the expectation that survey respondents comprehend the questions posed to them in the same way as the researcher. Do the respondents have the same attitudes to the issues and the same views regarding exercise therapy for CLBP? Those who have agreed to take part though have accepted the framework of the questions and have worked within that framework (Feilzer, 2009). It was decided to divide the questionnaire into two sections. The first section included clinical details about the responding physiotherapist and asked to provide information regarding their

referral of patients to group programmes for the management of CLBP as well as the exercises they prescribe. The second section asked those physiotherapists involved in running group programmes to provide specific details regarding the content of these programmes. This meant that the most respondents would have been only required to complete section 1. This was an attempt to reduce the number of questions participants were required to complete and thus improve the response rate. The questionnaire in my study was predominated by closed-ended questions with the use of a nominal, ranked or descriptive answer format. This format increases question specificity and facilitates quantitative analysis allowing direct comparisons between respondents to be made (Hicks, 2009; Macdonald et al., 2003). Although closed dichotomous questions are limited by the degree to which definitive conclusions can be made (Coole et al., 2010). Closed questions may also lead to increased errors if they suggest an answer that a respondent may not have otherwise provided and may not be sufficiently comprehensive (Bowling, 2009). This was addressed in the design of my questionnaire by including an unspecified option i.e. the other (specify) category for some of the questions and a free space at the end of the questionnaire which allowed the respondent to write down any other comments. A 'Don't know' category was also added to some of the questions. This ensured that if respondents were not sure of the right answer they would choose the 'Don't know' option rather than guess. This may improve accuracy but not completeness (Macdonald et al., 2003). It could be argued that the richness of data is lost due to the restriction of the response category in closed questions but they are easier to complete and analyse. However, it may not be possible to structure or order all the closed questions in a manner that ensures that they have the same meaning for all participants leading to differing interpretations (Gbrich, 1999; Liddle et al., 2009). Alternatively,

questionnaires also use open questions which allow for the exploration of a patient's experiences and can produce detailed narrative responses (Gbrich, 1999). It was decided not to use open questions in this questionnaire as they can be burdensome and difficult to analyse especially if the answers are detailed or complicated (Hicks, 2009; Macdonald et al., 2003). Open questions can lack specificity as it may not specify how the question should be answered (Macdonald et al., 2003). In practice only a relative small number of respondents offer more than one or two word replies and completing the questionnaire may take more time and concentration (Remenyi, 2011). This then could affect the questionnaire response rate.

The questionnaire collects data related to the respondents' reported or perceived behaviour which may be different from reality (Copeland et al., 2008). What can be known about physiotherapists' use of exercise therapy or referral to group exercise programmes may also be influenced by a social desirability bias on responses (Liddle et al., 2009). Social desirability concerns can be seen as a special case of threat of disclosure which involves a specific type of interpersonal consequence of revealing information in a questionnaire (Tourangeau and Yan, 2007). Threat of disclosure can give concerns about possible consequences of giving a truthful answer should the information become known to a third party. However, this was not applicable to my questionnaires as assurances of confidentiality and anonymity were given.

3.4.2 Questionnaire Design, Development and Distribution

The design and development of the questionnaire using pre-testing methods and a focus group is outlined in **Chapter 4**: Project Activity. This questionnaire can be found in Appendix 2. **Chapter 4** also informs how the questionnaire was distributed.

3.4.3 Stage 1: Data Analysis

All questionnaires were sent back to the researcher for analysis. Descriptive analysis of the questionnaire was mostly used utilizing figures and tables to visually represent data collected. The quantitative data produced in the questionnaire using closed questions was nominal and was not normally distributed. Nominal measures are often classified as discrete and are analysed using a binominal class of statistical tests such as chi-square and logistic regression (Newsom, 2006). Non-parametric tests only were used for the analysis where appropriate using the Statistical Package Stata version 12.1. The Chi-square (χ^2) test was used when the different groups of participants gave a single score on a rating scale with a level of significance set at $\boldsymbol{p < .05}$. Ratings are an example of an ordinal scale of measurement with the data not being suitable for parametric testing (Hole, 2011; Harris and Taylor, 2004). For example, to determine whether there was an association between physiotherapy banding and the percentage of actual referrals to group programmes. Research validity is a concept deriving from statistical investigation and refers to research answering the questions asked.

3.5 Stage 2: Outline of Approach and Experimental Design

This next section will outline the rationale for the approach and experimental design used in **Stage 2**.

3.5.1 The Critical Realist Perspective

Stage 1 used a questionnaire to survey physiotherapists regarding the content and use of group programmes to manage CLBP patients. The results of the survey had helped to develop hypotheses about the mechanisms of group physiotherapy programmes that may affect outcome such as the duration of the programme, type of exercises used and the nature of education regarding managing back pain provided. The alternative group physiotherapy programme was developed using this research (Daulat, 2013), and the project's recommendations described in section 1 of the discussion (**Chapter 6**), review of the literature and consultation with service providers. The objective of **Stage 2** was to evaluate the benefits of the alternative group exercise programme for CLBP patients in Primary care. The randomised controlled trial (RCT) which is appropriately designed, conducted and reported represents the gold standard in evaluating healthcare interventions (Schulz et al., 2010). This experimental method creates an artificial closed system that attempts to identify whether a causal mechanism embodied in an intervention has been efficacious (Porter and O'Halloran, 2012). RCT results can provide accurate and unbiased information about the generative powers of a specific mechanism but cannot tell us of the outcomes resulting from these powers in an open system. The RCT from an empirical perspective infers a causal relationship between two events requires an understanding of the mechanism that connects the two events and the context within which they occur (Pawson, 2013). The primary purpose of scientific inquiry is to obtain

knowledge about underlying causal mechanisms (McEvoy and Richards, 2003). An outcome can only be measured when both context and mechanism have been understood. It could be argued that complex healthcare interventions take place in open systems with a number of other factors possibly affecting the effectiveness of the intervention rather than the intervention itself. These factors may include organizational structure, resources, the interpretations and actions of the participants involved including the researcher (Porter and O'Halloran, 2012). To overcome this dilemma as a researcher, I had further developed a critical realist perspective during this thesis and programme of study. This is a philosophical approach that combines a realist ontological perspective with a relativist epistemology. Critical realism is an alternative to the established paradigms of positivism and interpretivism. This philosophical approach distinguishes between three different ontological domains of reality. The empirical domain refers to those aspects of reality that can be experienced either directly or indirectly. The aspect of reality that occurs but may not necessarily be experienced is referred to as the actual domain. Reality does not conform to our experience of events. Event 2 does not always follow event 1 as in a closed system. Reality is complex, temporal and changing. The real domain refers to deep structures or causal mechanisms that generate phenomena. Critical realists suggest that generative mechanisms that may not be directly observable are real and can be identified through their effects using empirical investigation and theory construction (McEvoy and Richards, 2006). Essentially, generative mechanisms are used to explain why things happen in scientific research (Pawson, 2006). The natural world functions as a multidimensional open system unlike the closed system of the RCT. Generative mechanisms that explain how things work beneath an observable

appearance may become latent until they are activated in specific circumstances (McEvoy and Richards, 2003). The objective of critical realists in research is not to identify generalizable (positivism) laws or to identify the lived in experience or beliefs of individuals (interpretivism) but to develop deeper levels of explanation and understanding. For example, my objective in this research project was to understand what mechanisms within the alternative programme lead to the outcomes produced and the experiences described by participants.

Critical realists argue that the choice of methods should be dictated by the nature of the research problem. The most effective approach may use a combination of quantitative and qualitative methods (Olsen, 2002). Quantitative methods may be used to develop reliable descriptions and provide accurate comparisons. This method can also test out theories about causal mechanisms operating under particular sets of conditions (Mingers, 2004). Qualitative methods in contrast can help to allow themes to emerge during the course of an inquiry that could have not been anticipated in advance and can be more open ended. Relationships may be realised that were unlikely to be captured by predetermined response categories on a questionnaire or standardised quantitative measures. The alternative group exercise programme was an active intervention and achieved its effect via active input from managers, clinicians and patients. The evaluation of this physiotherapy intervention in **Stage 2** helped to understand the effects being produced and used a mixed methods approach. In this study, the programmes were evaluated by triangulating the research data for the purpose of confirmation in order to enhance the reliability and validity of the findings. Hence, a combination of outcome and process evaluation was used. Thus, outcome evaluation was concerned with the overall effectiveness of the programme using

quantitative data. Process evaluation was concerned with understanding the impact and meaning of the programme to patients using qualitative data. This combination of methods attempted to counteract any biases associated with purely single method studies (McEvoy and Richards, 2006).

However, we can't assume that our methods and approach to research makes our results either context-bound or generalizable. There is a need to investigate the factors that affect whether the knowledge gained can be transferred to other settings (Morgan, 2007). Will the results from this particular programme evaluation have implications for the use of similar programmes in other contexts? A single study evaluation may provide inadequate basis for drawing conclusions about the alternative intervention and providing theory-driven evaluation. Realist evaluation is an approach which allows the researcher to understand what aspects of an intervention make it effective or ineffective, in what context and why it has succeeded or failed (Tilley, 2000). Realistic evaluation is a cyclical process that allows the researcher to build up evidence about an impact of a programme on participants in particular contexts (Fox et al., 2007). However, this is a time consuming process and beyond the scope of this thesis as several well conducted studies may need to be combined to explain why this particular intervention works or not but for whom and under what circumstances.

3.5.2 The Mixed Methods Design Approach

Mixed methods research is a type of research in which the researcher combines elements of quantitative and qualitative research approaches such as data collection, analysis and inference techniques for the purpose of a broader and deeper understanding of the research topic. It could be debated that quantitative or qualitative methods used in isolation may not be sufficient to develop a complete analysis of the intervention. It is suggested that quantitative and qualitative findings may corroborate each other and support a more robust conclusion than either source of data could support alone. Others have suggested that these methods should not be combined as the qualitative and quantitative paradigms are so radically different (McEvoy and Richards, 2006). It is argued that this approach assumes there is a tangible social reality which takes a positivist and critical realist perspective but contradicts the interpretivist perspective. The interpretivist perspective stresses the importance of alternative subjective positions and different ways of making sense of the world. Critical realism involves a term called retroduction. Retroduction postulates about the underlying structures and mechanisms that account for the phenomena involved. However, retroduction may not be compatible with either the positivist or interpretivist perspective. Positivists maintain that researchers should make observations about empirical events as they search for statistical regularities from which to make generalisations. They cannot make claims about social structures and mechanisms that are not observed. The interpretivists have the ontological view that is restricted to the understanding of subjective meaning and thus the material aspects of reality are intangible. There may be no firm basis from the interpretivist perspective to support retroductive inferences about social structures or mechanisms. Are quantitative and qualitative methods mutually translatable and observing the same

reality? Assumptions may have to be made regarding conflicting evidence produced from these two methods (Harrits, 2011). For example, the evaluation may not demonstrate significantly different outcome scores between the group programmes but respondents may describe in the focus group interviews better experiences in one of the programmes. Hence, such triangulation of the two research methods can achieve a better level of understanding about the effects of the intervention with a greater level of detail from the data obtained. Both quantitative and qualitative methods can be used to reveal different facets of the same reality and also examine that reality from different perspectives (McEvoy and Richards, 2006).

A quantitative dominant mixed methods research design used in this project is the type of mixed research which relies on a quantitative, post-positivist view of the research process as well as concurrently recognizing that the addition of qualitative data may benefit the project. During the data analysis stage this qualitative data may play an important role by describing, interpreting and validating quantitative results. This may allow the researcher to be more confident about their results and stimulates the development of creative ways of collecting data (Johnson et al., 2007). However, it may be difficult to link highly contextualised interpretative findings with quantitative findings that establish empirical generalisations. For example, the respondents may report that the alternative programme has helped them to self-manage their back pain more effectively but quantitatively there is no difference between the groups in functional improvement or pain reduction. The empirical generalisation will be that neither programme is more effective than the other but in reality the respondents may have found the format or content of one programme more beneficial to them. There will also be a need to view what processes shaped

respondent's views in the qualitative phase and assess to what extent their views may be distorted by their ideology or ideals. From previous clinical experience and the Back School development project (ILP 4060), patients have indicated that they would like more sessions of treatment and greater individual attention. This may not be realistic due to NHS funding, capacity and staffing levels. **Stage 2** as mentioned previously used a mixed methods sequential explanatory design. This usually consists of two phases: a quantitative followed by a qualitative phase (Morse and Niehaus, 2009). However, as the same research question was being addressed by both approaches, the objective was to triangulate the two sets of data produced to either complement or verify the study's findings.

3.5.3 The Quantitative Component

The quantitative component of **Stage 2** was characterised by experimentation involving data collection to test hypotheses. My previous epistemological assumption before taking a critical realist perspective was that valid knowledge about the effect of my intervention on CLBP can only be discovered through an experimental design. **Stage 2** was a randomised single blinded controlled study. The random allocation between experimental and control groups was required. This study assigned subjects to either the alternative group physiotherapy programme or a standard group physiotherapy exercise programme which acted as the control. The participants were then exposed to either the alternative or standard group exercise programme and the differences observed. There have only been a limited number of studies that have compared one group programme with another for managing CLBP (Gatti et al., 2011; Koumantakis et al., 2005; Brooks et al., 2012). However, the patients were not generally blinded to the interventions as in the Gatti et al. (2011) study. A similar

quantitative study design to the current one had been used previously by Koumantakis et al. (2005) to evaluate the effectiveness of two group exercise programmes for patients with CLBP. This study was single blinded in that participants were not aware they had been assigned to the experimental or control group. Patients were informed that they would be volunteering for an exercise trial to investigate the effects of two different exercise programmes on CLBP. This single blinding would help to control expectation bias (Brooks et al., 2012). Double blinding was not used in this current study as it is very difficult blinding both patients and clinicians in exercise therapy trials (Cairns et al., 2006). It was not possible for the therapists running the programmes in this current study to be blinded. This is usually expected in studies which compare the effectiveness of an intervention such as exercise therapy (Garcia et al., 2011). However, this is acceptable if both interventions were equally credible and acceptable to the patients (Van Tulder et al., 2000). This study was further strengthened as the referring therapists had no influence over the randomization process and treatment allocation. Outcomes were patient completed measures only which reduces assessor bias on the outcome assessments (Schulz and Grimes, 2002). Pre and post treatment as well as long-term follow-up testing using outcome measures providing data in a numerical form was used in the current study which can further classify the quantitative phase as a pre-test and post-test control group design (Creswell, 2009).

3.5.4 The Qualitative Component

The RCT makes the positivist assumption that the active role of the participant in the experiment is a passive responder to stimuli which was the physiotherapy treatment. It does not give us the opportunity to understand how the intervention may have changed the individuals' behaviour or lifestyle (Jones et al., 2006). This empirico-analytical approach has been used previously by physiotherapists for evidence based practice because it generates repeatable and reliable results (Donaghy and Morss, 2000). The qualitative component of **Stage 2** then explored what the intervention meant to the participants. This was taking an interpretivist perspective restricted to the understanding of subjective meaning whereby it is assumed that all individuals have their own unique interpretations of that world or in this case the group programme interventions (McEvoy and Richards, 2006; Morgan, 2007). Focus groups were used to explore patients' views and satisfaction regarding their treatment. Patients were given the opportunity to rate and discuss the benefit of the programme to them. Patients discussed what the barriers of continuing with physical activity were and what might be their main reasons for continued participation in exercise or physical activity. This supplemental qualitative stage could identify a set of barriers that would predictably block the effectiveness of the back pain interventions. This could lead to identifying strategies for reducing these barriers and emphasizing facilitators which could lead to specific variations in future programmes. Any future versions of a group programme could be more effective by offering alternatives that would be more suitable by meeting specific requirements of specific client groups (Morgan, 2014). The aim was not to reach a consensus on the discussed issues but encourage a range of responses to provide a greater understanding of the attitudes, opinions or perceptions of the participants regarding the group programmes. The focus group

interview was used in preference to an individual interview as it encourages interaction between other participants rather than with the moderator. Interaction is a key feature of the focus group interview as group processes assist participants to explore and clarify their point of view which may not be possible in an individual interview. Group interaction allows the researcher to experience different communication forms which participants use in their everyday interaction. This may include joking, arguing or recalling past experiences. It may be much more difficult to reveal the true knowledge or attitudes of individuals by asking them to respond to direct questions from questionnaires. The focus group method allowed me as the researcher to follow-up comments in the session and cross-check with participants in a more interactive manner which a questionnaire or individual interview can't offer. However, the disadvantage of focus group interviews is that some of the participants may not actively take part in the group discussions. Other participants with dominant personalities may have strong or opposing opinions and influence the group discussion. Some participants may feel that they cannot disagree with these dominant personalities or present an alternative view to the group. The depth or intensity of discussion may not be sufficient to have a good understanding of the participants' experiences that may be obtained in an individual interview (Halcomb et al., 2007).

There have been a small number of studies which have used qualitative designs such as semi-structured questionnaires or focus group interviews to investigate the views of patients with back pain and their experiences on the treatment that they received (Slade et al., 2009a; Sokunbi et al., 2010). These methods of data collection may also give the researcher the opportunity to understand how a physiotherapy intervention has changed individuals' perspectives or behaviours. Focus group interviews have not

been used widely to explore the issues surrounding the management of CLBP (Liddle et al., 2007). Sokunbi et al. (2010) used focus group interviews to explore subjective exercises of participants who had taken part in a spinal stabilisation programme as part of an RCT. They found that participants had indicated a positive behavioural change in managing their back pain and had achieved a greater self-confidence through participating in the exercise programme. Few participants had continued with their exercises post programme. Reasons given for non-adherence were unsuitable home environment, lack of supervision and equipment and the inability to adapt to daily routines. One of the limitations of using focus groups in this study was that only small sample sizes were interviewed which may reduce the generalisability of the findings to the population of CLBP patients. This is due to the time constraints as they are very time-consuming and small numbers may be willing or able to participate. This may also lead to a likely positivity bias and lack of ethnic diversity (Rajendran et al., 2012). Another limitation is the subjectivity of the researcher's interpretation of the transcribed data (Liddle et al., 2007). A questionnaire using open questions was used by Underwood et al. (2006) to further explore patients' experiences and views following their treatment for low back pain in the UK BEAM trial. This method had produced a large number of detailed narrative responses from participants which was very time consuming to analyse. This type of questionnaire did give the respondent more flexibility and the opportunity to provide extra information regarding their treatment.

The analysis of the qualitative phase in **Stage 2** helped to explain or elaborate on the quantitative results obtained in the initial instance. Thus, the quantitative data and the subsequent analysis provided a general understanding of the effects of the group

programmes. The qualitative data and its analysis attempted to explain the statistical results by exploring participants' views in more depth. Arguably, such a process can be time consuming and dependent on the feasibility of resources to collect and analyse both types of data (Ivankova et al., 2006). Priority in **Stage 2** was given to the quantitative approach because quantitative data collection came first in the sequence and presented the major aspect of the mixed-methods data followed by the smaller qualitative component. The decision to follow the quantitative-qualitative data collection and analysis sequence in this design was based on the project's purpose to evaluate an alternative group exercise programme. The smaller qualitative component aimed to seek a contextual practice-based explanation of the statistical results.

3.6 Research Questions and Hypothesis for Stage 2

The primary research question asked whether the alternative group physiotherapy programme was more effective for improving function and quality of life than a standard programme used at the NHS Trust. Are patients that have attended the alternative group programme more satisfied with their treatment and with their improvement than those that attended the standard group programme? The secondary research questions were established during the design process of the alternative programme. Hence, these secondary research questions relate to the different content and format of the group programmes. The alternative group exercise programme has individualised exercises specific to the patient and carried over from one to one physiotherapy sessions. Whereas, the standard group programme consists of general circuit based exercises not individualised to the patient. Are specific individualised exercises in a group setting more beneficial than non-specific exercises? The standard group programme has a group education component on back pain management. The alternative programme does not have any group education but provides education individually. Is group education preferred to individual education for managing CLBP? The alternative group programme provides more individual attention for the patient than the standard programme including the option of manual therapy. Is providing more individual attention in a group programme more beneficial to the patient? The alternative group exercise programme aims to encourage patients to continue with regular exercise and self-manage their back pain. The final research question asked, what are the barriers to adhering to regular exercise and an adequate level of physical activity?

<u>Primary Hypothesis:</u> The alternative group physiotherapy programme is more effective than a standard group programme in the management of non-specific CLBP for improving function and quality of life.

<u>Null Hypothesis:</u> The alternative group physiotherapy programme is not more effective than a standard group programme in the management of non-specific CLBP for improving function and quality of life.

For the purpose of this study, the Null Hypothesis was tested.

3.7 Summary of Section 1

This research aimed to extend the knowledge and understanding of the evidence base for managing CLBP in a group setting. How I viewed knowledge regarding CLBP management changed throughout this thesis as I developed greater epistemological maturity. My own world view which favoured a positivistic approach changed to searching for the most accurate and complete way of answering the research questions. This view had influenced my research design which has determined the methods for accessing new knowledge about managing CLBP. This research journey had led me to adopting a critical realist perspective. This perspective maintains that something is real it has an effect or makes a difference. Although, the RCT represented the gold standard for evaluating healthcare interventions, the real is not simply at the level of the empirical. Fundamentally it is about different causal mechanisms at work. For example, what are the mechanisms in the alternative group programme that have improved back pain management? Is it related to the patient specific exercises, individual attention or the promotion of self-care? My objective has been to examine the different ways that these mechanisms interact with each other. I have learnt that there is a diversity of truths out there which can be explored through different forms of inquiry. However, I have acknowledged the limitations with the methods used and the results found cannot be expected to be completely representative of the true reality of back pain management in a group setting.

I also considered what influence as an insider-researcher has had on the research, methods used and those involved in the research process. Reflexivity was an important part of this consideration. I aimed to be both reflective about my own practice as well as understanding my own position and the position of others in the

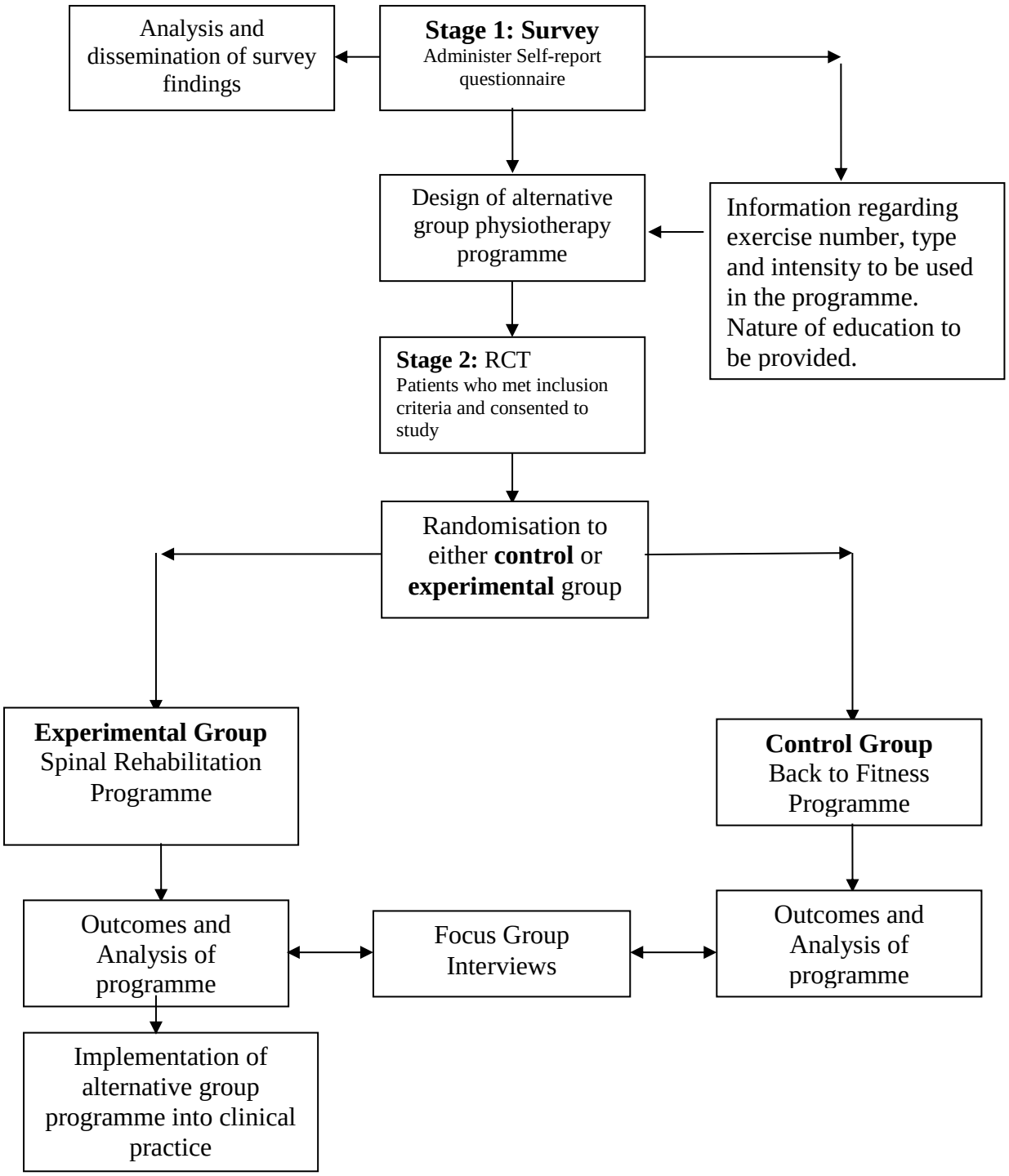
research. My many years of experience as a practitioner working with spinal conditions and exercise therapy had lead me to assumptions and ideas about what methods I was going to use and what I expected to find out. I had already a theoretical stance before beginning these projects. For example, my assumption that all chronic low back pain (CLBP) patients are de-conditioned due to inactivity and require multimodal exercise therapy to address this. I realised that such closeness to the research may had the potential to compromise my ability to critically engage with the practices or information revealed during the study. The collaboration with colleagues was essential for my research study as they recruited patients to the group programmes and some were involved in delivering the interventions. This resulted in a role change from practitioner to researcher whereby a new authority amongst colleagues was established adopting an unfamiliar role to me. I also had interactions with some of the participants in my study as an insider-researcher in the focus groups. I had to consider that my that the relationships with the participants in these group might have had an impact on their behaviour and I would need to reflect on this in my results.

In **Stage 1**, a cross-sectional self-report postal questionnaire was used to survey a population of physiotherapists involved in the management of CLBP. This was the chosen method of data collection in my study as it had the advantage of collecting data from a large sample of participants in a specific setting to explore what exercises physiotherapists prescribe for CLBP and how group exercise programmes are utilised. The questionnaire in **Stage 1** using closed questions produced quantitative data which was nominal and not normally distributed. The questionnaire was analysed descriptively utilizing figures and tables to visually represent data collected. The Chi-

square (χ^2) test was used when the different groups of participants gave a single score on a rating scale with a level of significance set at $p < .05$. The results of the survey, review of literature and consultation with stakeholders were used in the design of the alternative group physiotherapy programme. **Stage 2** aimed to compare this alternative programme with a standard group programme used in Primary care.

A critical realist perspective had been taken in this research whereby the choice of methods was dictated by the nature of the research problem. The most effective approach decided on a combination of quantitative and qualitative methods. The quantitative method aimed to test out theories about causal mechanisms operating in the group programmes under particular sets of conditions. Qualitative methods using focus group interviews in contrast helped to allow themes to emerge during the course of this inquiry which could have not been anticipated in advance and were more open ended. This method attempted to establish or realise aspects of the group programmes that were unlikely to be captured by predetermined response categories on a questionnaire or the standardised quantitative measures used. Thus, the evaluation of the group programmes in **Stage 2** had utilised a mixed methods approach. This was a mixed methods sequential explanatory design consisting of two phases. These phases included a RCT using quantitative measures as methods of data collection. Focus groups were used in the second sequence which has enhanced the depth of data provided. Each of these methods of inquiry had been valued for their contribution to knowledge development and physiotherapy practice. This approach has helped determine the effect of the alternative intervention and how it may be replicated for future policy development.

Figure 3.1: *Flow Chart of Stages 1 and 2*



Section 2

Section 2 will describe the processes and procedures used in **Stage 2**, the methods and how the data obtained in this study was collected and analysed. This section will end with the ethical considerations pertaining to **Stage 2** and the overall programme.

3.8 Processes and Procedures in Stage 2

3.8.1 Setting, Population and Sample

This study took place at an adult musculoskeletal out-patient department within Ealing as part of the London North West Healthcare NHS Trust. Both groups in the study were similar except that the control group did not receive the independent variable which is the alternative group physiotherapy programme. This was named the spinal rehabilitation programme (SRP). Participants were chosen by convenience purposive sampling from CLBP patients referred to the department via their general practitioner. Specific inclusion and exclusion criteria are outlined in section **3.8.3**. If participants with CLBP met the inclusion criteria, they were allocated to each treatment group by block randomisation. This ensured that all participants in the study were representative of the population of CLBP patients in Ealing. The exclusion criteria aimed to maintain the studies external validity (Creswell, 2009). External validity refers to whether the results of a study can be generalized to the population of CLBP patients (French et al., 2001).

3.8.2 Power and Sample Size

In order to ensure that a study will have the adequate power to detect the desired difference between groups an adequate numbers of subjects needs to be enrolled (Freedman, 1999). If the sample size is small then the study may be susceptible to type II errors (Hicks, 2009). A type II error occurs when the experimental hypothesis is rejected in favour of the null hypothesis (no relationship) and the data does support the experimental hypothesis. It is concluded that there is no relationship between variables but in fact there is (Richards and Hallberg, 2015). Hence, there is no intervention effect, when in fact one does exist (i.e. the trial yields a false-negative finding). Studies that overestimate the effect size in a sample size calculation or fail to achieve the target recruitment are susceptible to type II errors. Power calculations before the start of the study can be used to minimize these errors and determine the minimum number of subjects required for the study (Freedman, 1999). The minimum information needed to calculate the sample size for this study would be the power, level of significance, group variation and the size of the treatment effect sought (Kirby et al., 2002). The power of a study is the ability to detect a true difference in outcome between the two groups i.e. experimental and control group. The probability of failing to reject the null hypothesis or false negative error (β-error) is the probability of not finding a difference when one actually exists. This can be set at 90% to reduce to 10% the possibility of a false-negative result or type II error (Kirby et al., 2002). The probability of falsely rejecting a true null hypothesis is the α-error. This is also called the false-positive error and is the probability of finding a difference where none exists. The α-error is linked to the *p*-value or probability value and is conventionally set at 5% (Gogtay, 2010). Standard values for the α and β error are found in Appendix 3. The effect of treatment in a trial can be expressed as an absolute

difference. For example, the difference in outcome measures between the two groups. The primary outcome measure in this study was the Functional Rating Index (FRI). The mean difference that was expected in this study between the two groups post programme was 10% or more. This would be of clinical importance (Feise and Menke, 2001). The standard deviation is the measure of dispersion or variability in the quantitative data. The standard deviation can be estimated from previous studies undertaking similar work with similar samples (Hicks, 2009). I conducted a previous study investigating the effect of two different exercise regimens plus manual therapy on CLBP. The FRI was the main outcome measure and a range of scores from 20% to 65% with a standard deviation of 13 was found in the pilot group (Daulat and Goodlad, 2014). There are a number of formulae available for calculating the required sample size. The formula or method used for calculating the sample size in this study was quoted by Kadam and Bhalerao (2010) and can be found in Appendix 3. The sample size calculation using a 5% level of significance and 90% power to show an absolute difference of 10% between the two groups with a standard deviation of 13 would require 36 subjects in each group or 27 subjects per group with 80% power. However, it was expected that some participants would drop-out of the study. Drop-out rates were estimated initially to be up to 20%. Therefore, to account for any drop-outs in the study, it was decided to randomise a minimum of 40 subjects to each group. This would give a minimum total participant recruitment of 80 subjects based on the minimum power of 80%.

3.8.3 Inclusion and Exclusion Criteria

Inclusion criteria

1. Male and female subjects between ages of 20-75 years. This is slightly outside the standard adult age range (20-65) used in previous CLBP studies investigating the effect of exercise and /or manual therapy (Bronfort et al., 2011; Lewis et al., 2008). It was decided that if patients with CLBP were medically fit and were able to participate then age should not be a limitation. In addition, low back pain has been found to have a peak prevalence of 45-59 years which would be within the age range used in this study and be representative of the chronic low back pain population (Papageorgiou et al., 1995).
2. Mechanical CLBP lasting more than three months (Airaksinen et al., 2004). Mechanical pain was defined as LBP increased with activity such as lifting, lumbar movements, prolonged standing/sitting, walking or driving (Walker and Williamson, 2009). Any subjects with non-mechanical back pain would not be appropriate for physiotherapy and may require further investigation or specialist review.
3. Motivated and willing to attend both the physiotherapy group programmes.

Exclusion criteria

1. Cardiac, respiratory, kidney, blood pressure or blood circulatory problems which may prevent participation in any strenuous exercise programme (Geisser et al., 2005).

2. Recent spinal surgery within one year which may affect the ability to participate in group exercise programmes. These patients are usually excluded from CLBP studies (Harts et al., 2008; Kell and Asmundson, 2009).
3. Acute fracture or recent trauma require specialist management and would not be suitable for group rehabilitation programmes (Luk et al., 2010).
4. Inflammatory or infectious diseases of the spine.
5. Metabolic or bone disease such as osteoporosis.

   Both 4 and 5 conditions are a contraindication to physiotherapy and would require further investigation and onward referral (Ferreira et al., 2007).
6. Neurological signs or symptoms such as sensation loss in a specific dermatome, myotomal muscle weakness or abnormal reflexes. These neurological deficits may require further investigation or monitoring and would not be appropriate for an extensive exercise programme or manual therapy (Bronfort et al., 2011; Cecchi et al., 2010).
7. Advanced rheumatoid arthritis or uncontrolled diabetes. These conditions are contraindicated to manual therapy and exercise programmes (Maitland, 1999). These conditions would also require specialist review.
8. Subjects who were pregnant or attempting to become pregnant (Mannion et al., 2001).

9. Chronic pain syndrome patients with severe physical or psychological impairment (Dufour et al., 2010). This includes the group of patients presenting with widespread sensory hypersensitivity mediated by central pain mechanisms. These patients are unlikely to respond to exercise and/or manual therapy and may need to be referred for multimodal pain management programmes or pain clinic (Schafer et al., 2009a). There is also evidence that

exercise may increase generalised pain sensitivity in this sub-group of chronic pain patients (Daenen et al., 2015).

10. Participated in a regular exercise programme or had previous physiotherapy or any other treatment within the last six months.
11. Any spinal condition requiring further investigation or on-ward referral and not likely to respond to conservative treatment.

3.8.4 Study Procedure

Participants with CLBP referred from their GP were assessed by their physiotherapist. Both group programmes took place at the same out-patient physiotherapy department. All those participants that met the programme inclusion criteria and consented to the study were randomized to either of the two group interventions (Appendix 4: Consent form-RCT). Referring therapists were required to complete a checklist form (Appendix 5) for all participants and agreed with them up to three objectives or goals for attending the group programmes. These may have also included education goals such as how to lift correctly or manage any back pain flare-ups. The referring physiotherapist administered the Start Back Screening Tool (SBT) to all participants prior to randomization (Appendix 6: Validated Questionnaires). The SBT has been designed to sub-group patients with LBP patients in primary care into 3 categories on the basis of the presence of physical and psychosocial risk factors (Hill et al., 2008). The SBT was used in this study in an attempt to classify CLBP patients into sub-groups with the objective to determine which sub-group if any would respond better to the group physiotherapy interventions. The SBT is a 9-item questionnaire which categorizes patients into 3 sub-groups – High risk, Medium risk and Low risk. SBT overall scores ranging from 0 to 9 are determined by summing all positive responses.

SBT psychosocial subscale scores ranging from 0 to 5 are determined by summing items related to bothersomeness, fear, catastrophizing, anxiety and depression. Based on the overall and psychosocial subscale scoring, patients can be categorized as high risk (psychosocial subscale scores $\geq$4) in which high levels of psychosocial prognostic factors are present with or without physical factors, or medium risk (overall score >3; psychosocial subscale scores <4) in which physical and psychosocial factors are present but not a high level of psychosocial factors. Finally, low risk (overall score 0-3) in which few prognostic factors are present (Newell et al., 2014).

3.8.5 Randomisation Process

Block randomisation was used in this study. In smaller trials of less than a thousand participants, simple randomisation may not give a good balance in the number of subjects allocated to each group. Subsequently, the groups may not be equally matched in age or sex. A good balance is maintained by block randomisation (Beller et al., 2002). A block which has an equal number of As and Bs (A = intervention and B = control for example) would be used. The order of treatments within the block is randomly permuted. For example, a block of four has six possible arrangements of two As and two Bs. The six possible four block combinations are AABB, ABAB, ABBA, BAAB, BABA and BBAA. A block of six has twelve possible arrangements of three As and three Bs. The twelve possible six block combinations are AAABBB, AABABB, AABBAB, ABABAB, ABBAAB, ABABBA, BBBAAA, BBAAAB, BBAABA, BBABAA, BAABBA and BABAAB. A random number sequence is then used to choose a particular block which sets the allocation order for the first four subjects. The process is then repeated for the next four subjects and so on (Beller et al., 2002). Blocks of 6, 9 or 15 could also be used (Ferreira et al., 2007). Prior to the study a sequence of randomly permuted blocks of sizes 4 and 6 were generated. This was done in the following way. Each of the two block combinations size 4 and size 6 to be used were written on a card and placed in two unmarked envelopes. All 6 block combinations for size 4 were written on a card and placed in separate sealed envelopes each labelled 4. The same was done for the 12 block combination for size 6. One of the two envelopes containing block size was chosen randomly by the researcher to select a block size. If the block size selected was 4, then an envelope from the size 4 collection was randomly selected by the researcher. This would set the allocation order for the first four subjects. This process was repeated to generate

enough random blocks of size 4 or 6 to cover up to 120 participants (if required). All these blocks had an equal number of As and Bs (A = Experimental Group and B = Control Group). After the assessment, participants were assigned to their respective intervention by the physiotherapist who referred to these permuted blocks via a shared drive which determined the order of group allocation (Appendix 7: Randomisation Chart). This allocation procedure is known as permuted block randomisation and was remote from the researcher. This process ensures an equal chance of either experimental or control assignment with evenly balanced group numbers (Bowling, 2009). The method used to assign treatments (or other interventions) to participants should be clearly stated in any trial i.e. whether mechanical means, a computer generated random list or random number table has been used (Saghaei, 2004). It was decided not to use any random allocation computer software for this study as the mechanical method described was robust and adequate for a single centre, small scale study. The use of random allocation software programmes would need to be considered for any future larger trials conducted at the NHS Trust.

3.9 Interventions

3.9.1 Spinal Rehabilitation Programme (SRP)

The content of the SRP had been developed following **Stage 1** (Daulat, 2013), review of the literature and collaboration with service providers. Service users had not been involved in the development of this programme. The referring therapists guide to the RCT and programme therapist protocol for the SRP are found in Appendix 17 and Appendix 8 respectively. The SRP consisted of group multimodal exercise therapy and one to one sessions consisting of manual therapy and education. In the first session, participants were required to complete their outcome measures. All participants in the group completed a warm-up lasting 5 minutes for general stretches and a warm-down at the end of the programme for 5 minutes also. Following the warm-up participants started their individual exercises by selecting the appropriate exercise station and then moving on the next station when completed. There was no time limit at the exercise stations and all patients were supervised by the assistant physiotherapist. There were seven stations: **One to one (education and/or manual therapy)**, **core stability on mats, upper limb strengthening, lower limb strengthening, functional exercises, stretches/spinal mobility and cardiovascular.** During the group exercise session, participants were called to attend the one to one station. Patients had up to six one-hour treatment sessions but not consecutive. The SRP was run by a physiotherapist and assistant physiotherapist. Both group programme sessions had a maximum of 10 patients attending. Participants also had the opportunity to choose when they attended and had up to three months to complete the programme. Each patient was given a specific individualised exercise programme which they were required to do at home during the course of their treatment. Patients

were also encouraged to continue with their prescribed exercises after their treatment. There is no evidence of this alternative programme in the literature.

i) Exercises within the SRP

Individualised exercises were prescribed by the referring therapist prior to the programme. Each participant referred to the SRP was given 8-10 exercises as recommended from the findings in **Stage 1** (Daulat, 2013). Referring physiotherapists were required to select at least one exercise for the following five categories: **Core stability, lumbar mobility/stretches, functional, upper limb strengthening and lower limb strengthening.** These exercises were supervised and progressed by the programme physiotherapist as appropriate.

Participants were advised to maintain during the programme and thereafter their prescribed exercises. Participants in this study were not instructed as initially planned to maintain their physical activity levels in accordance with the NICE 2013 guidelines.

ii) One to one therapist sessions within the SRP

Advice sessions and/or manual therapy specific to the participants were provided for every patient each session. Education regarding back pain management was delivered on an individual basis based on the programme goal/objectives agreed on the initial assessment. Individual patient education can be defined as an experience in a one-to one situation which consists of one or more methods such as the provision of information or advice that may influence patients' health behaviour and coping strategies for their pain (Engers et al., 2011). All participants were provided with the

Arthritis Research UK, Back Pain Booklet. This is a published information booklet and is a comprehensive up to date guide for back pain and how it can be managed. The education material in this booklet is very similar to that provided in previous Back School research (Moseley et al., 2004). Written information for back pain can be considered as long as it is evidence-based and up to date (Engers et al., 2011). The referring physiotherapist indicated on the checklist form (Appendix 5) whether manual therapy was indicated and what has been done previously. Manual therapy if appropriate could be applied during the one to one session by the programme therapist.

3.9.2 Standard Group Programme or Back to Fitness Programme (BTFP)

The standard group programme was based on the model designed by Klaber-Moffat and Frost (2000). The programme therapists' guide for the BTFP and exercise sheet for the standard group programme can be found in the Appendix 9. It consisted of six one-hour general exercise sessions using a circuit based exercise format and was run by a physiotherapist and physiotherapy assistant. There were weekly group exercise education sessions at the end of the exercise period. A crib sheet guide for the education component to assist the programme therapists is also provided in Appendix 9. All participants were also provided with the Arthritis Research UK, Back Pain Booklet. Patients were advised to maintain during this programme and thereafter their prescribed home exercises as in the SRP group. The circuit training exercise sheets were given to each patient.

3.10 Methods of Data Collection in Stage 2

The methods are defined as the techniques or procedures used to collect and analyse data (Grix, 2004). This next section will outline the quantitative and qualitative methods of data collection in **Stage 2**. As well as providing a rationale for using these particular data collection methods.

3.10.1 Quantitative Methods of Data Collection

The Functional Rating Index (FRI), the 11-point Numerical Pain Rating Scale (NPRS) and the EQ-5D-5L were three of the primary outcome measure instruments used in my study to investigate the effect of the standard and alternative group physiotherapy programme for the management of CLBP. The Participant Satisfaction Reporting Scale (PSRS) is a 5-item report instrument which was used as a secondary outcome in my study to evaluate patient's satisfaction of their treatment and improvement. All outcome measures used in this study can be found in Appendix 6 (validated questionnaires). Outcome measures are tools for measuring the outcomes in back pain research studies that have compared one particular health care intervention with another (Liddle et al., 2004). A number of condition specific outcome measures have been used to investigate the effect of an intervention for CLBP (Heymans et al., 2011). These condition specific instruments have the advantage of targeting specific components of function or disability which are relevant to CLBP and may be more responsive than generic measures (Resnik and Dobrykowski, 2005). There has been a move away from physiological outcomes such as spinal flexibility and muscle strength because they correlate poorly with clinical status and do not put emphasis on the individual's activity limitation (Copeland et al., 2008; Heymans et al., 2011). The lack of long-term difference in outcomes including disability between CLBP interventions may be due to a ceiling effect of some of these outcome measures used. The most common disability measures used in CLBP studies are the Oswestry Disability Index (ODI) and Roland Morris (RM) questionnaire. A floor effect may miss clinical deterioration whereas a ceiling effect may miss clinical improvement (Fairbank and Pynsent, 2000). The ODI is best suited to situations in which patients may have persistent severe disability and therefore higher baseline scores (Roland and

Fairbank, 2000). However, the majority of studies have shown moderate disability ODI scores at baseline. The RM questionnaire in contrast is better suited to patients with minor disability and lower baseline scores (Fairbank and Pynsent, 2000).

There has been a shift in rehabilitation evaluation to use patient-specific measures such as the Measure Yourself Medical Outcome Profile (MYMOP) and the Patient Specific Functional Scale (Horn et al., 2012). Both the MYMOP (4% of those surveyed) and Patient Specific Functional Scale (9% of those surveyed) were found to be used by some therapists in the survey (**Stage 1**) to evaluate their group programmes. These patient-specific outcome measures may unlike fixed-item measures, allow patients to select and rate activities that are important or relevant to them. However, a disadvantage of using these measures as they require structured guidance to complete which may be time consuming particularly in a group setting. In my experience, back pain patients find it difficult to identify their most important problem apart from pain. In addition, the treatment effects of the programme that are not related to the chosen problem will not be measured. The Patient Specific Functional Scale has been used as a baseline measure only. Its validity as an outcome measure to detect change over time or make comparisons between groups as not been established (Horn et al., 2012).

Most of CLBP studies have not included a measure of functional status (Harts et al., 2008). Self-report measures which assess everyday functioning and symptoms may be important to establish the impact of an intervention on daily life (Beurskens et al., 1995). The Functional Rating Index (FRI) is a validated outcome measure which has been chosen for this study as it can be used for both minor and severe effects on

functional ability but will still be able to detect change (Feise and Menke, 2010). In addition, I had used the FRI as an outcome measure in a phase II pilot study investigating the effect of exercise plus manual therapy in the management of CLBP. The study found that the FRI was responsive to change and would be suitable to use in a larger RCT (Daulat and Goodlad, 2014). It was decided not to use any physical testing of CLBP patients such as muscle strength or flexibility in this current study as there is strong evidence to suggest that changes in physical performance capacity correlate poorly to changes of pain or disability (Copeland et al., 2008; Heymans et al., 2011). The FRI has ten items with a 5-point Likert scale (i.e. 0 none to 4 severe) for each item. Scores for each item (maximum of 4) are totalled to give an index score. There are ten items. This index score, out of 40 is multiplied by 100 to give a percentage. Higher percentage scores indicate higher perceived dysfunction and pain. If only 9 items are completed, then an index score out of 36 can be multiplied by 100 in order to give a percentage score. This may be applicable as one item relates to work. Some patients do not work and therefore would not be able to answer this question. However, the FRI would be invalid if less than 9 items were completed. The FRI scale also estimates disability. 0-20% is classified as minimal disability, 21-40% moderate disability, 41-60% severe disability and greater than 61% very severe disability (Feise and Menke, 2001).

The EQ-5D-5L gives a comprehensive measure of the patient's quality of life. Health rated quality of life is substantially influenced by chronic pain and generally CLBP patients have a lower health-related quality of life than the general population (Campbell et al., 2006). This measure been chosen as an outcome measure as it can reflect the overall impact of the patient's health status following an intervention

(Liddle et al., 2004). The original EQ-5D had previously been shown to exhibit ceiling effects with no level for mild problems (Luo et al., 2009). However, the new EQ-5D-5L includes five levels of severity in five dimensions and claims to reduce the ceiling effects seen in the original version (Rabin et al., 2011). In contrast to the SF-36 which is a widely used generic health profile in back pain research (Luo et al., 2009); it is quick and easy to use. The EQ-5D-5L takes minutes to complete and indicates the subject's own assessment of their health state and may be used to analyse changes in this health state over time. The EQ-5D-5L has five dimensions: Mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five possible response categories 1-5. For example: 1 = no problems and level 5 = inability or extreme problems. The responses to these items combine to give a descriptive health state classification with 5 digits e.g. 12345. The EQ-5D-5L gives a total of a possible 3125 health states. A set of valuations for each health state is available from the UK crosswalk value sets table on the Euroqol website (http://www.euroqol.org/) which has been calculated for the population of the UK. A minimum score is -0.594 and a maximum score is 1. The EQ-VAS was also used as an outcome. The EQ-VAS is part of the EQ-5D-5L and is a self-rating scale which records the respondent's own assessment of their health status that day. The EQ-VAS scores are measured from 0-100 where 100 = the best health you can imagine and 0 = the worst health you can imagine.

The NPRS is a pain outcome measure which was used in this study. It is an 11-point pain rating scale ranging from 0 (no pain) to 10 (worse pain imaginable). A brief measure of pain severity is recommended as part of a core set of outcomes in back pain studies (Bombardier, 2000). The survey in **Stage 1** found that only 11% of the

respondents used a pain measure such as the NPRS or visual analogue scale (VAS) as an outcome for their group exercise programmes for managing chronic low back pain (**Chapter 5**: Results). Williamson and Hoggart (2005) found the VAS had a high failure rate in clinical practice and was more difficult to use than the NPRS. In the current study, the NPRS was used to assess the participant's current pain intensity as well as the best and worst level of pain during the last 24 hours. These three levels were averaged to give the participant's pain score pre-programme, post programme and at 6-months post programme in the two groups. The NPRS is easier to understand and quicker to score than the visual analogue scale (Childs et al., 2005). It is therefore easy to administer, record and more useful for research purposes. The NPRS has an 11, 21 or 101-point scale where the end points are the extremes of no pain and pain as bad as it could be. This scale has the advantage over other pain measures as it can be graphically or verbally delivered (Williamson and Hoggart, 2005). This was suitable for the current study as the scale if applicable could be administered by telephone contact at 6-months post group programme. The NPRS consists of an interval scale which provides data for parametric analysis. It is also sensitive the change. Critchley et al. (2007) had used the 101 point NPRS scale in their back pain study to measure pain. However, the 11 and 21 point scales of the NPRS are more than adequate for the assessment of pain. The 101-point scale has more levels of discrimination than most patients use i.e. most patients use multiples of 5 or 10 when using the 101-point scale. In fact, it has been found that 75% of patients had used the scale as if it had 11-points (Williamson and Hoggart, 2005). It was therefore decided to use the 11-point NPRS as a measure of pain in this study as it is a suitable measure to quantify a participant's pain following treatment.

The PSRS is classed as an attitude measurement scale. Attitude measurement scales are frequently used in health care research to measure in a quantifiable manner an individual's opinion about the treatment they received (Hicks, 2009). Attitude measurement scales are used to assess the extent to which individuals agree or disagree with various opinion statements (Bowling, 2009). The self-evaluation of a patient's attitude toward their treatment (i.e. from completely satisfied to completely dissatisfied with the treatment they received) is represented as a numerical score (Hirsh et al., 2005). However, this may only be an indirect measurement of attitudes towards treatment and can only be used as basis for inferences regarding participants' perceptions. Attitude scales may not express fully the attitudes and beliefs of the patient. It may not mean the same thing for all patients who express that they are completely satisfied with their treatment (Silverman, 2000). The PSRS may not produce detailed narrative responses regarding patients' perceptions which can be obtained in interview or open question design. This may not allow further exploration of the patients' experiences and feelings regarding their treatment for CLBP. There are a number of instruments in the literature for measuring patient satisfaction but few have been used in physiotherapy (Rowell and Polipnick, 2008). It was decided to use the PSRS in this study as it is quick and easy to score. Most self-report questionnaires only include questions regarding satisfaction with care and not satisfaction with outcome (Beattie et al., 2002). The PSRS to my knowledge is the only attitude scale measure which allows patients to rate their satisfaction with their treatment as well as to rate their satisfaction with improvement. The PSRS has five items with a 6-point Likert scale (i.e. 0 completely dissatisfied to 5 completely satisfied) for each item. Scores for each item (maximum of 5) are totalled to give an index score. There are five items which gives an index score out of 25. A high score indicates a higher

perceived level of satisfaction with treatment or with improvement (Hirsh et al., 2005). One important question to ask regarding the outcome measures described: Is the minimal important difference in the scale score measured by a particular instrument an assessment of change? It was possible in this study to compare the changes with the other outcomes which were assumed to move in the same direction. It would be expected that changes in function would be correlated with improvements to quality of life (Bowling, 2009). Outcome measures used previously in CLBP studies may be subject to the "regression to the mean effect" which might also explain only moderate long-term effects of these interventions. This occurs when participants have an extreme measurement on a variable such as disability or pain which may be short-lived and unusual. With subsequent measurements this value will tend to return to normal. In an attempt to the limit this effect in my study multiple data collection periods (pre and post programme as well as 6-months post programme) were used and a comparison of these outcome measures was made with a control group.

The patient-reported outcome measures used in this study were chosen as they were relevant to CLBP, concise, practical to use in a short space of time as well as being all valid, reliable and responsive to change. The outcome measure instruments used in the RCT with the full range of scores are summarised in **Table 3.1.** The use of outcome measures in this study must adequately reflect the effect of the exercise programmes may have on all aspects of the patient's life. Hence, reflecting the biopsychosocial nature of CLBP. The initiative on methods, measurements and pain assessment in clinical trials (IMMPACT) suggested the use of both condition-specific and health-related quality of life measures should be considered in the design of

chronic pain clinical trials (Turk et al., 2003). The FRI evaluates diverse aspects of a participant's life including personal care, walking and recreation.

Table 3.1: Outcome measure instruments used in the RCT

Outcome Measure	Evaluating	Full Range of Scores
Functional Rating Index (FRI)	Function/ disability	**0-100%** 0-20% (minimal disability), 21-40% (moderate disability), 41-60% (severe disability) >61% (very severe disability)
EQ-5D-5L	Quality of Life	**-0.594** (minimum score)- **1** (maximum score)
EQ-VAS	Health Status	**0** (worst health)-**100** (best health)
Numerical Pain Rating Scale (NPRS)	Pain	**0** (no pain)-**10** (worse pain imaginable).
Participant Satisfaction Reporting Scale (PSRS)	Participant satisfaction with their treatment and improvement	**0** (completely dissatisfied)- **25** (completely satisfied)

This condition-specific measure (FRI) is more likely to reveal clinically important improvement or deterioration in function that may be the consequence of treatment. The EQ-5D-5L and EQ-VAS provides a general representation of the participant's health and well-being and can provide a different perspective on health outcomes. A self-reported pain measurement tool was used in this study but a reduction in pain does not necessarily lead to an improvement in function and satisfaction with treatment (Turk et al., 2003). Pain intensity and other measures of impairment such as back extensor muscle strength alone may not be suitable as a means of assessing treatment outcome. Impairments may not necessarily change as a result of the intervention but function may improve significantly (Liddle et al., 2004). There has been a move away from pain reduction as the primary goal in the management of CLBP. In clinical practice, we encourage CLBP patients to focus more on functional

goals related to daily activities rather than a goal of pain reduction. Although, both the FRI and EQ-5D-5L have individual items on the intensity and frequency of pain, it was decided to have a separate measuring instrument for pain which was the NPRS. Bombardier (2000) recommended that trials were considered to have relevant outcome measures if they included three or more of the five categories of measures. There five categories are Back specific function, Generic health status, Pain, Work Disability and Satisfaction with care/treatment. My study (**Stage 2**) included four of the five categories recommended. The FRI measures Back Specific function; NPRS measures pain; EQ-5D-5L and EQ-VAS measures Generic health status, and the PSRS measures satisfaction with treatment as well as with improvement. Work disability generally refers to days off work, work status and return to work (Liddle et al., 2004). More recently, return to work as an outcome measure has not been recommended unless the specific study question is focused on this domain (Chapman et al., 2011). In addition, work disability may not be relevant in this study as a proportion of participants in the Ealing Area may not be working. Ealing has the lowest employment rate in West London and the second highest number on jobseeker's allowance (Ealing Council, 2009). In a previous CLBP study, Ferreira et al. (2007) compared the effects of general exercise, motor control (spinal stabilisation exercises) and spinal manipulative therapy on function, global perceived effect, pain and disability in CLBP patients. 68-78% of participants in their study reported that they were not working and were from a disadvantaged socio-economic background. The participants in that study may be representative of the CLBP population as there is a strong link between social deprivation and low back pain (Unwin et al., 1998). Therefore, an outcome measure of work disability may not be relevant for all patients

presenting with CLBP and it was decided not to use this particular measure in this study.

The outcome measurement instruments used this study are all essentially questionnaires used for measuring a variable of interest such as function or quality of life. There is no single definitive outcome measure used in CLBP trials. All outcome measures will have their strengths and limitations. These quantitative measures are linked to the physical world and can only determine one truth or single objective reality. A patient's pain or disability levels are reduced to a numerical score by these measures in an attempt to reduce the illness experience and treatment effect to a quantifiable measure (Jones et al., 2006). This oversimplification of CLBP does not measure individual differences or the psychosocial consequences of chronic pain. It has also been widely recognised that patient satisfaction with their treatment may not relate to outcomes recorded in the outcome measure questionnaires (Underwood et al., 2006). Previous research using quantitative designs have only found exercise therapy to be moderately effective for CLBP with many different programme designs having similar effects (Hayden et al., 2005). Quantitative measures used in these studies have not been able to explore the impact of the treatment programme to the patient or what are the barriers to exercise participation. The integration of quantitative methods of data collection with the qualitative focus group interviews was used in this study to address the limitations of using quantitative outcome measures alone.

3.10.2 Qualitative Methods of Data Collection and Analysis

As described in **Section 3.5**, it was decided to use focus groups to explore patients' experience of their treatment within the group programmes. This had given a proportion of RCT participants an opportunity to express their views regarding their treatment. The objective was to integrate these views with the quantitative findings to evaluate the group programmes more effectively. Integrating patients' views may help improve healthcare delivery (Wensing and Elwyn, 2003). In this qualitative phase of **Stage 2**, data was collected and analysed second in sequence to the quantitative component. Participants' perceptions of the group programmes were explored by the use of focus group interviews once the recruitment process had finished and all participants had completed or near-completed their group programme sessions. All participants were invited to take part by letter and were required to sign consent form prior to the focus group interview. It had been predicted based on similar studies that less than 20% of the participants would be willing or able to attend the focus group interviews. Recruitment of participants to focus groups is usually on a voluntary basis which is essentially a self-selection process. This could potentially create bias in the study as those volunteering could either have some form of loyalty to the study or be greatly dissatisfied with their experiences of the group interventions (Halcomb et al., 2007). There were two focus groups consisting of 8 participants. This sample size is comparable to similar studies using focus groups (Learmonth et al., 2012; Sokunbi et al., 2010). It has also been quoted in the literature that 20% of participants fail to attend the focus group session having previously confirmed that they would attend (Halcomb et al., 2007). For these reasons all participants that took part in the study were invited to ensure that the focus groups could be successfully conducted. It has been considered that the optimal focus group size is between 4 and 10 individuals.

Participants in these focus groups had the opportunity to discuss their experiences with the aim of exploring the impact of the programme on them as individuals. Prompts were used to facilitate further discussion. A checklist of topics was developed based on the version used by Liamputtong (2011). This checklist included topics such as experiences of the group sessions, participant expectations, benefits of the group programmes and barriers to participating in regular exercise post programme. This ensured the same areas were covered in both focus groups (Appendix 10: Focus group question guide based on the format suggested by Liamputtong, 2011). Each focus group took place over a two-hour period and was moderated by the researcher. I had previous experience in **Stage 1**, as the focus group facilitator for pre-testing the questionnaire prior to distribution. An assistant moderator or note-taker was also present during the focus group interviews. This colleague was an experienced researcher at a Masters level (MSc). The note-taker's role was as a non-participant observer to maintain field notes of any interactions that occurred within the group. This also included any non-verbal communication or participant interaction that would not be picked up in audio-recording (Dictaphone). Their role was to minute and record the group meeting by Dictaphone. The researcher and assistant moderator met after the session to debrief and assess the quality of the field notes to ensure they were representative of the interview that had just taken place. Data obtained from the focus groups in-line with previous research was transcribed, the content analysed, coded and categorised into main topics relevant to the focus questions and then divided into themes and sub-themes as appropriate (Creswell, 2009; Slade et al., 2009). The transcribed data was re-checked and verified with the original interview recordings. Reference was also made to Gibbs on-line series to assist with the qualitative data analysis. An independent researcher at MSc

level not involved in the study reviewed the transcripts for reliability of the identified themes and sub-themes. I met up with the independent researcher to reach agreement on the topic and theme categories before analysis proceeded. This method previously used by Sokunbi et al. (2010), ensured that participants' opinions are accurately portrayed and documented. These themes were then subject to further analysis and interpretation.

3.11 Proposed Data Analysis for Stage 2-RCT

It was predicted that some of the participants in the RCT may fail to receive or complete either of the two interventions. For example, they may choose later on not to undergo the alternative intervention after agreeing to participate in the study or drop-out having been randomised to the experimental or control group. However, it is still preferable to include this participant in the experimental group analysis. This is termed intention to treat analysis and avoids the possibility of bias or distortion of results that may occur because this participant had certain characteristics such as severe disability due to their back pain (Sugarman and Sulmasy, 2010). Patient characteristics such as age, sex and duration of symptoms were recorded for both groups as well as work status. Scores from the FRI, EQ-5D-5L, EQ-VAS, NPRS and the PSRS completed by each subject pre and post treatment and at 6-months follow-up were collected. Scores from these outcome measures was calculated and recorded for all subjects in the two groups. This data was entered into a statistical package for statistical analysis (Statistical Package Stata version 13.1). If the data is normally distributed then parametric statistical tests are used for the analysis (Burns, 2000; Harris and Taylor, 2004). To determine whether there was any significant difference in the groups between outcome scores, repeated measures analyses of variance

(ANOVA) was used. This determines the effects of the treatment within groups over time (Park et al., 2009). The level of significance was set at $p <$ **.05**. If the *p*-value or probability associated with an inferential statistic is equal or less than **.05**, the result is significant at the **.05** level. If the *p* value is >**.05** we can't conclude that a significant difference between two means exists and indicates weak evidence against the null hypothesis. If the data is skewed and does not fit the normal distribution then non-parametric tests are used for statistical analysis where appropriate (Burns, 2000). A within group comparison was also included in the analysis. Paired t-tests were used to assess for differences between pre-programme and post programme and pre-programme and 6-month follow-up scores for the outcomes separately within both the SRP and the BTFP. Effect size together with a confidence interval (CI) of 95% was calculated. This determines the magnitude of differences in outcome measure scores between groups (Harris and Taylor, 2004). This allowed more effective statistical inference from the outcome data whereas a ***p*** value of >**.05** will indicate no real effect or significance of the group interventions (Nakagawa and Cuthill, 2007).

3.12 Ethical Considerations

Researchers must be aware of their legal and ethical duties when conducting clinical trials. Most professional bodies such as the Chartered Society of Physiotherapists (CSP) have developed a code of ethics for carrying out research (Bowling, 2009). Ethical approval was gained via application through Riverside Research Ethics committee and permission to use the NHS sites for this study was granted by my Trust's Research Governance Department. I was also required to complete an A1 category ethics form and submit this with the ethics approval letter to Middlesex University. The ethical principle of autonomy recognises the rights of participants. These include the rights to be informed of the study, to freely decide whether to participate in the study and to withdraw at any time without penalty (Orb et al., 2001; Townsend et al., 2010). This was addressed as all participants who met the inclusion criteria were given a participant information leaflet to inform them of the study (Appendix 11). All participants were then given a minimum of seven days to decide whether they wished to take part. This gave them the opportunity to read the information leaflet, discuss with family/friends, reflect and/or ask questions regarding the study. Participants were made aware that there was no coercion to take part in the study and that they are also free to withdraw at any time without affecting their treatment. Those patients who did not consent to participate in the study were offered treatment within the service including referral to either of the group interventions. The patient's GP was also informed of their participation in the study via letter but only if the patient had agreed to their GP being informed

The ethical principle of nonmalefience states that research ought not to inflict harm on the participant and the risks of harm should be minimised (Emanuel et al., 2000).

This study at all times provided patient welfare and safety as well as ensured that none of the patients come to any harm as a result of their treatment. This was achieved by on-going regular review and reassessment of participants during the study by the programme therapists. A risk assessment was performed on site prior to the study (Appendix 12: Risk Assessment form). This risk assessment ensured that all therapists involved in the group programmes had appropriate safety knowledge and training so as not to put themselves' or patients at risk during the study. If any participants experienced any adverse reactions or change to their clinical status; they were provided with appropriate treatment and where necessary removed from the study. Participants were also treated equally preventing any issue of discrimination (Tschudin, 2003). Forty-six percent of the registered population in Ealing is non-white compared to 9% across England with English not being the first language for many of these people (Bernstein, 2009). Subjects who meet the inclusion criteria but English was not their first language were provided with interpreters as appropriate during their attendance to the group exercise programmes.

Researchers have the legal and ethical duty to ensure confidentiality of personal information and secure storage of participant data under the Data Protection Act of 1998 which is a legally binding document. The former Primary Care Trust (PCT) policy for record management in accordance with Records Management: NHS code of conduct (2006) guidelines was followed to ensure patient confidentiality and secure storage of personal information. The confidential policy used by the trust has four requirements which were implemented at all times.

Trust Confidential Policy

1) Patients information will be protected and looked after as detailed previously.

2) All patients will be informed and ensured that they are aware of how their information is used. This was achieved via the participation information sheet.

3) Patients will be given choice. They will be allowed to decide whether their information can be disclosed or used for the research.

4) The Trust will continue to look for better ways to protect, inform and provide choice regarding personal data.

The participant's privacy was respected at all times during the study and all data collected was analysed appropriately. Participants initial assessment notes were recorded electronically on the Trust's RIO system. This was the patient data system used by the Trust at the time of the research, participant recruitment and completion of the group programmes. The RIO data system was replaced by System 1 in October 2015, although the transition period from one system to the other started from August 2015. All participants had a computer identification number (RIO) from which their GP referral and details could be accessed. Access to this required a password and could only be accessed by NHS staff. To date (up to March 2016) it has not been necessary to access any patient data from System 1 which would have been transferred from RIO. Patient data is accessed in the same way as the RIO system using the patient's NHS number instead. Any participant paper documentation including consent forms, checklist with goals and completed questionnaires was stored in separate study file for each intervention. This file was always stored after use at the department in a secured filing cabinet. No patient identifiable data was on the outcome measure sheets used in the study. The researcher's employer has a record

management policy which was ratified in March 2008. This policy has adopted the notes retention periods set out in the Records Management: NHS code of conduct (2006). All physiotherapy notes are kept for a maximum of 12 months at the local Primary Care Trust site. These notes would then be sent for archiving and stored on CD. Archived records are usually kept for eight years following conclusion of treatment and then destroyed.

All participants were invited by letter to attend focus group interviews to explore their experiences of the group programmes used in the study. This invitation also included a separate information sheet to inform them of focus groups and what they involve. All those who wanted to attend phoned the department to book their place. Prior to attending these focus group interviews, all participants were required to sign another consent form in the presence of the researcher (Appendix 13, Focus Group consent form). This gave consent for the researcher to make recordings of this interview session using audio-tape or Dictaphone. In accordance with the Trust's audio/visual recordings policy, all audio-tape or Dictaphone recordings are stored for a minimum of 12 months. This policy states for audio records even though the dominant purpose of an audio-visual record may be for training purposes, where patients are identifiable in them and issues relating to the care and treatment of the patients are discussed on them, or they are used to assist in the assessment, evaluation or determination of care and treatment, they must be treated as health records and retained in accordance with the periods outlined. Where the above caveat is not relevant, they may be destroyed after a year. Therefore, if these recordings were to contain any participant identifiable information or were classed as a health record, they are stored for a further 8 years in line with the Trust policy. If they do not contain such information they will be

destroyed at 12 months. Participants also gave consent for any of their direct quotations to be published. Direct quotations from respondents can highlight their experiences of the group programmes and adds to the focus group analysis. Any transcribed data from the focus group interviews was stored securely at the department in a locked filing cabinet. There was no identifiable patient information on the transcribed data. In line with the Trust policy for patient paper notes, the transcribed data will be stored at the physiotherapy department for up to 12 months and then sent for microfilming and then eventually destroyed after 8 years.

Finally, a number of ethical issues have been considered in the overall doctorate programme. These have included the gain of consent from participants to take part in the RCT and focus groups. Discrimination has been avoided by giving the opportunity for non-English speaking participants to take part. I have ensured mutual respect of clinicians by being transparent about my research and what has been expected of them. Ethically, there has been a need to involve patients by giving them the opportunity in the focus groups to express their opinions on the treatment which they received. This may lead to their input on future decisions made regarding treatment for CLBP (Swisher, 2002; Weinstein et al., 2007). My own views and ideology as a researcher needs to be considered in preparing an impartial approach to the research as well a recording and reporting the research data. Ethically, I must ensure the sharing of information regarding health research to all stakeholders and the public. The ethics committee had specified that my study must be registered on a publicly accessible database six weeks before the first participants are recruited. This is to ensure transparency in my research. This involved registering my study to obtain an International standard randomised controlled trial number (ISRCTN). The ISRCTN is

a simple numeric system for the unique identification of clinical trials worldwide. The allocated ISRCTN is automatically added to the UK CRN Portfolio database. This registration ensures that my study can be simply and unambiguously tracked throughout its lifecycle from initial protocol to results publication. Last of all, I have an ethical responsibility to accurately represent my research findings and legally must adhere to the laws of copyright regarding any of my work which is published in peer review journals.

3.13 Summary for Section 2

The RCT in **Stage 2** took place at an adult musculoskeletal out-patient department within the Northwest London Hospitals NHS Trust. Participants with CLBP referred from their GP were assessed by their physiotherapist. Eighty-one participants who met the inclusion criteria were randomised by block randomisation to the experimental and control group. This number was based on the sample size calculation and accounting for drop-outs. Please refer to chapters **4, 5** and **6** regarding participant recruitment. Specific exclusion criteria were used to maintain the study's external validity. The referring physiotherapist administered the Start Back Screening Tool (SBT) to all participants prior to randomization. The SBT was used in this study in an attempt to classify CLBP patients into sub-groups with the objective to determine which sub-group if any would respond better to the group physiotherapy interventions.

The alternative group physiotherapy or experimental group (Group A) was named the Spinal Rehabilitation Programme (SRP). The SRP consisted of group multimodal exercise therapy and one to one sessions consisting of manual therapy as appropriate and individualised education. The standard programme or control group (Group B) was named the Back to Fitness Programme (BTFP). The BTFP programme consists of circuit based exercises and group education sessions. Both group programmes consisted of six one hour sessions over a three-month period and was run by a physiotherapist plus an assistant. All participants were also provided with the Arthritis Research UK, Back Pain Booklet. All participants were advised to maintain during this programme and thereafter their prescribed home exercises and not to participate in any other exercise regimen or treatment.

The primary quantitative methods of data collection were the FRI, EQ-5D-5L and NPRS. These are validated outcome measures used to measure changes to function, quality of life and pain respectively. These outcome measures were administered pre and post group programmes and at 6-months post programme. A secondary outcome measure was administered post programme. This was the PSRS. The PSRS is an attitude scale measure which allows patients to rate their satisfaction with their treatment as well to rate their satisfaction with improvement. Once all participants had been recruited to the study and completed their treatment in their respective group programmes, they were invited to attend the focus group interviews by letter. The focus group interviews were the qualitative method of data collection used and was analysed second in sequence to the quantitative component. This had given some participants the opportunity to express their views in their own terms regarding their treatment. The objective was to integrate these views with the quantitative findings in order to evaluate the group programmes. All data generated from this study was analysed appropriately using statistical testing or by theme coding and content analysis.

There were a number of ethical issues which had arisen from this project. Ethical approval for **Stage 2** was gained via application through Riverside Research Ethics committee and permission to use the NHS sites for this study was granted by my Trust's Research Governance Department. In addition, I was required to complete the ethics application process for Middlesex University. This study could not take place until approval by all parties had been given. Ethical considerations included the rights of participants to take part in the study without coercion and written consent given to take part. Equal treatment of participants was ensured preventing discrimination as

well as ensuring the safety and welfare of participants at all times during the study. The study respected patient confidentiality and the secure storage and handling of patient records which adhered to the local trust guidelines. Finally, in the overall programme, it was my ethical responsibility to prepare an impartial approach to my research as well as accurately record and report all the research findings.

Chapter 4: Project Activity

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4.1 Introduction

This chapter follows on from **Chapter 3** and describes the activities that took place in both **Stages 1 and 2**. Section 1 describes the activities in **Stage 1**: A physiotherapy survey to investigate the use of exercise therapy and group exercise programmes for the management of non-specific chronic low back pain. Information is provided on how the questionnaire was designed, developed, distributed and results finally disseminated. Section 2 describes all activities pertaining to **Stage 2** of the thesis.

Section 1: Stage 1 Activity

4.2.1 Questionnaire Design and Development

A cross-sectional self-report postal questionnaire was used to survey physiotherapists in the greater London Area. This questionnaire was developed following a literature review of previous studies which have investigated how physiotherapists manage CLBP (Fidvi and May, 2010; Byrne et al., 2006). Thus, using a similar structure and topic, this had enhanced the content validity of the questionnaire (Casserly-Feeney et al., 2008). This was an on-going process to achieve a final draft version (Appendix 2) of the questionnaire prior to pre-testing and peer review. This had involved consultation with academic supervisors and those with previous survey experience at a Masters level of academic qualification and above. The draft questionnaire was also pre-tested with two physiotherapy colleagues to obtain further feedback. This process had highlighted some changes to produce the final draft version of the questionnaire.

A definition of CLBP was added to the information sheet on the questionnaire in line with previous questionnaires. It was decided that clinicians may not know the types of group programme available to them and this would be highlighted in section 2 of the

questionnaire anyway. A question regarding the percentage of the current therapist's caseload presenting with CLBP was added instead (**Question 4**). Previous questionnaires had investigated the types of outcome measures used post treatment for CLBP (Liddle et al., 2009). In clinical practice outcome measures are commonly used in group exercise programmes. This had been highlighted in Module IPL 4060 RAL claim as part of the overall programme. It was therefore decided to add an extra question regarding the type of outcome measures used for the group programmes (**Question 25**).

4.2.2 Peer Review of Questionnaire

This questionnaire was further pre-tested before distribution using a focus group consisting of physiotherapists, Musculoskeletal GP Physicians and survey experts within the local NHS Trust. A focus group is a good method for identifying problems with questionnaire items and can enhance both the validity and reliability of the questionnaire (Macdonald et al., 2003; Presser et al., 2004; Remenyi, 2011).

There were 11 peer group members in the focus group composing of:

3 GP specialist MSK physicians

1 Physiotherapy Manager

7 Extended Scope Practitioners.

All individuals in the group had at least a Masters level of education.

2 with post graduate experience of surveys.

The questionnaire was revised in response to the feedback received. This process further establishes the questionnaires content validity (Kitchenham and Pfleeger, 2002).

There were a number of changes made to the questionnaire following pre-testing and peer review:

A clearer definition of CLBP was recommended. A definition of CLBP was added to the cover information sheet and to **question 4**.

4.2.3 Revisions and Changes to Survey Questions

Section 1

The paragraph on page 3 of the questionnaire was deemed to be confusing and unclear.

'The following questions refer to your referral to group programmes and exercises you prescribe patients. For the purposes of this questionnaire, this relates to patients with chronic non-specific mechanical low back pain. Excluded are those with any spinal condition requiring further investigation or on-ward referral and not likely to respond to conservative treatment. Also excluded are any of your patients who are not capable of participating in a graded exercise programme or tolerate manual therapy; due to either severe physical or psychological impairment. This would also include the group of patients presenting with widespread sensory hypersensitivity mediated by central pain mechanisms who are best suited for multimodal pain management or chronic pain programmes.'

This was made more concise to:

The following questions refer to your referral to group exercise programmes and exercises you prescribe patients. For the purposes of this questionnaire, this relates to patients with chronic non-specific mechanical low back pain. This does not include

the group of patients presenting with widespread sensory hypersensitivity mediated by central pain mechanisms who are best suited for multimodal pain management or chronic pain programmes. Any of your patients who are not appropriate for or capable of participating in a graded exercise programme due to either severe physical or psychological impairment should also be excluded.

Question 2:

It was suggested that the Band 8 agenda for change banding be subcategorised into a, b or c. Therefore, this question included categories of band 8 agenda for change (a, b and c). There is an 8d and 9 banding but this is at a high management level and such individuals are unlikely to have a clinical caseload.

Question 3: Do you have a speciality in your current post? Please tick the most appropriate answer.

It was highlighted that some therapists are part of a triage or clinical assessment and treatment service (CATS). This is a speciality in that this requires additional training and is usually conducted by experienced therapists. Those involved in triage may only see a patient once and have limited to time to prescribe exercises before referring on to group programmes. It was suggested that this be reflected in the questionnaire so as to be accounted for in the results analysis. Therefore, the specialty of Triage was added as an option for **Question 3.**

Question 4:

It was decided that clinicians may not know the types of group programme available and this would be highlighted in **section 2** of the questionnaire anyway. A question regarding the percentage of the current CLBP caseload was added instead.

Questionnaire 6: What percentage of your back pain patients do you actually refer to group programmes? Please tick the percentage.

It was suggested that a section be added for therapists to state, why they don't refer to group programmes. A space was added to state why therapists might not refer to group exercise programmes.

Question 7: On average how many sessions do you have with your patients before you refer them to a group programme? Please tick the number below.

It was mentioned that this may not be applicable to those therapists who are involved in Triage. They may see a patient only once and then refer to the group programme directly. It was decided to have a not applicable section in this question.

Question 8:

If yes to 8a how many exercises are prescribed?

It was unclear whether this meant individual patients or on average. This was changed to how many exercises on average were prescribed.

Question 9: The next question refers to the types of exercises that you give to patients as a part of their back pain management? Please tick the box that matches how often you use the type of exercise listed.

It was unclear amongst some in the group what functional exercises are? A definition of functional exercises was added.

Question 10: Are your exercises different or the same to those given out in the group programmes at your place of work? Please tick

This was poorly worded and not understood. This was changed to: Are your exercises the same as those given out in the group programmes at your place of work? Please tick.

Question 12:

It was decided that this question (Do you have or have had any involvement in the group programmes run at your place of work?) would not add any relevant information to the survey or assist in the design of the alternative group programme. This was changed to: Are you able to refer all patients suitable for group programmes whom English is not their first language? This would help to establish whether these patients could be referred to group programmes. Therapists were also provided with a space to state why they could not refer these patients to group programmes. This question was reviewed by the peer group.

Section 2 of Questionnaire

Question 17: How many exercises are given in the group programme? Please tick.

It was mentioned that in Pilates there is not a set number of exercises given but different exercises were added weekly during the 6-week programme. It was therefore suggested to change the question to: How many exercises on average are given in the group programme? Please tick.

Question 25:

An extra question added regarding the type of outcome measures used for the group programmes (**Question 25**).

The changes to the questionnaire following the pre-test were minimal. Only one question was removed and replaced with an alternative (**Question 12**). Generally, the feedback was positive. Questions were clear and related to the title and the research questions of the project. It was decided that a further pre-test was not required. The final version was then re-checked by one of the peer group before distribution.

4.2.4 Questionnaire Content

The questionnaire was divided into two sections. It aimed to explore the processes of group exercise at individual physiotherapy departments and how physiotherapists manage CLBP by the utilisation of these programmes. The first section included clinical details about the responding physiotherapist and asked to provide information regarding their referral of patients to group programmes for the management of CLBP as well as the exercises they prescribe. Section 1 of the questionnaire aimed to investigate five main questions below.

1) What are the referral rates to group programmes?
2) Is there any difference in referral rates between secondary care, community and independent practices?
3) Is there a relationship between grade or speciality and group programme referral?
4) How many and what types of exercises are given for CLBP patients by physiotherapists?
5) Are therapists able to refer all patients suitable for group programmes for whom English is not their first language?

The second section of the questionnaire asked those therapists involved in the running or management of group programmes to provide specific details regarding the content of these programmes. **Section 2** aimed to investigate four main questions below.

1) What are the most common group programmes in clinical Practice?
2) What is the content of these group programmes?
3) What is the nature of education provided in these programmes?
4) What outcome measures are used?

The main hypotheses for **Stage 1** were:

Group programmes use single mode exercise regimens.

Exercises given by therapists are different to those in the group programme.

Group programmes lack individual attention and a manual therapy component.

Education provided is general and not specific to the patient.

This questionnaire was predominated by closed-ended questions with the use of a nominal, ranked or descriptive answer format. However, free response spaces were provided where applicable (Appendix 2, physiotherapy survey).

4.3 Ethics and R&D Approval

Ethical approval was not required for the **Stage 1** as this did not involve patients. Permission to administer the questionnaire to the physiotherapy departments was granted by their Research and Development departments (R&D). Some physiotherapy departments were covered by the same R&D site. In total permission had to be granted from six R&D departments including one for the Independent or Private physiotherapy practices. Copies of the approval letters can be found in Appendix 14. The whole approval process took approximately four months.

4.4 Questionnaire Distribution

Convenience sampling was used for this self-report questionnaire but the aim was to survey different regions within the greater London area. A NHS Trust may incorporate several physiotherapy departments. In recent times a number of NHS Trusts have merged forming a much larger organisation. Therefore, such organisations may have a number of physiotherapy departments in a wide geographical area. For example, the researcher's own organisation has five physiotherapy departments which all cater for different populations of patients in the Greater London area. All potential physiotherapy departments were contacted prior to the study to determine whether they wish to participate. Not all departments contacted were willing to take part in the survey. Of a total of 17 departments contacted, two had not responded despite reminders and it was assumed that they did not wish to take part. The questionnaire was sent out to 13 NHS musculoskeletal out-patient departments within 7 NHS trusts or ICOs in the greater London area who had all agreed to take part. This included eight departments in secondary care and five in the community. Two independent practices also took part in the survey. General MSK out-patient physiotherapists who manage CLBP patients completed the questionnaire. The number of questionnaires sent out varied between departments. Some departments could only accommodate a small number of questionnaires due to the size of the department. Before distribution departments were contacted to confirm how many questionnaires they could or were willing to accept. This was a strategy for improving questionnaire response rate. This ranged from 1 to 23. In total 154 questionnaires were distributed. Questionnaires sent to each physiotherapy department were given a unique identification code to monitor response rate. The questionnaire package contained a hand signed covering statement, the questionnaire

with cover sheet explaining the study and postage paid pre-printed return envelopes with each questionnaire. Three weeks after the initial distribution of the questionnaires an e-mail reminder was sent out to all departments. At 8-weeks post distribution a final reminder by e-mail was sent to low responders. Data collection in **Stage 1** took place over a four-month period from March 2013 to June 2013 in line with previous self-report questionnaire surveys (Fidvi and May, 2010). The analysis of the questionnaire is described in **Chapter 3**.

4.5 Results and Discussion Stage 1

The results and discussion of findings for **Stage 1** is found in **Chapters 5** and **6** respectively.

4.6 Stage 1: Dissemination

I decided to submit an academic paper relating to **Stage 1** to the Journal of International Musculoskeletal Medicine. The maximum word limit for this article was 5000 words. My paper was accepted and was published in the September 2013 issue of the journal. A further abstract of this paper with an added future research section regarding **Stage 2** was submitted to the Society of Musculoskeletal Medicine (SOMM) conference. This abstract was accepted and displayed at the conference on 15th March 2014 (Appendix 15). I also wrote an article for the Frontline Magazine in the research section. This was regarding my publication and future research for **Stage 2**. The article was in the April 2014 edition of the magazine. Frontline is available to all members of the CSP and this was an effective way of promoting my research. I attended the Summer Conference at Middlesex University in June 2014 and produced a poster as well as giving a short poster presentation. In April 2015, I gave a

presentation regarding my research to another physiotherapy department within the Trust. This gave me an opportunity to promote the alternative group exercise programme and disseminate my research findings up to that period. I also presented my research to the summer conference at Middlesex University in June 2015 (see later).

Section 2: Stage 2-Project Activity

4.7.1 Ethics and R&D Approval

Stage 2 used a mixed methods sequential explanatory design. This consisted of two phases: a core quantitative followed by a supplementary qualitative phase. The quantitative component was a randomised single blinded controlled study. This study aimed to assign subjects to either the alternative group physiotherapy programme or a standard group physiotherapy exercise programme which acted as the control. The qualitative component used focus group interviews to explore patients' views regarding their treatment in the two group programmes. **Stage 2** required ethics approval from both the Research Ethics Committee (REC) and my own Trust's Research and Development Department.

The REC meeting took place on 2nd December 2013 at the Riverside NRES Committee: London. The committee gave a favourable opinion for the study to proceed with only one condition. This was to amend a paragraph in the participant information sheet seen below.

What are the possible disadvantages and risks of taking part?

It is possible that if the treatment is given to a pregnant woman it will harm the unborn child. Pregnant women must not therefore take part in this study and neither should women who plan to become pregnant during the study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the researcher and her GP.

This paragraph was amended to:

Pregnant women in their first trimester are advised not to undertake any new physiotherapy exercises as part of their standard care and therefore they will be excluded from taking part in the study. Pregnant women must not therefore take part in this study and neither should women who plan to become pregnant during the study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the researcher and her GP.

Following the ethics approval **(**Appendix 16**),** I submitted my application to the local Research and Development office. Approval to proceed with my study was granted on 31/1/2014 (Appendix 14). The next stage was to meet with my manager and team on several occasions to set up the study as well planning to implement the alternative group programme. During these meetings the findings in **Stage 1** were presented and integrated into the alternative programme protocol. This included the exercises provided including a cardiovascular station (walking on the treadmill or step-ups), the type of education given and the outcome measures to be used for evaluating the programme. A final version of the programme protocol (Appendix 8) was agreed by the team before implementation. Due to other service commitments beyond my control, the study did not commence until June 2015. It was also a condition of the ethics committee that all clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publicly accessible database within 6 weeks of recruitment of the first participant. I registered my trial to obtain the International standard randomised controlled trial number (ISRCTN). Once issued with this unique

number, this can be used to search for my study via the ISRCTN registry website. My study registration number is ISRCTN96496625.

Prior to participant recruitment in the study, I conducted a number of training sessions with all referring therapists in the Ealing MSK Community service and also the individual therapists responsible for running the two group programmes. A RCT referrers guide was developed to assist therapists in the study recruitment process (Appendix 17).

4.7.2 Stage 2: Mixed Methods study

Participant recruitment for the RCT (quantitative component of **Stage 2**) started in June 2014 and finished in May 2015 (Recruitment period of 12 months). This required close supervision and liaison with the therapists running the programmes. It was the researcher's responsibility to ensure outcome data was being collected and inputted on to the spread sheets. The researcher also followed up all participants at 6 months by post to complete their outcomes. Once recruitment was completed all participants were invited by letter to the focus group interviews with follow-up telephone consultation to confirm their attendance. Once participants had confirmed their attendance, they were each sent an appointment letter and map. The focus group interviews were held in June 2015. There were two sessions lasting 2 hours. Each session was conducted by the researcher with a note taker in attendance. The note taker was a MSK physiotherapist. Their role was to record all conservations and any non-verbal aspects of the interviews. I led the session which was recorded using a Dictaphone. I used the focus group question guide (refer to the **Chapter 3**) but also gave the group the opportunity to discuss any other experiences regarding the group

programmes they attended. The recordings and notes were later transcribed for analysis.

4.8.1 Participant Recruitment in the RCT

Recruiting participants to the study had been more difficult than expected. There were a number of reasons for the lower than expected recruitment levels. Some clinicians did not wish to take part in the study and therefore did not recruit patients. Other physiotherapists had indicated that the process of recruiting was too time consuming. The physiotherapy service was re-designed in October 2013 due to the new GP consortia commissioning structure. One of the objectives to fulfil the tendering contract in 2014-15 was to reduce waiting lists for patients requiring physiotherapy. This increased the work load of therapists which may have influenced participant recruitment. This waiting list initiative had been achieved but the number of CLBP patients presenting to the department that would be eligible for the study had reduced. Due to service reasons such as Trust organisational changes and adopting a new computerised booking system from late summer 2015, it was not possible to extend the recruiting period beyond 12 months. However, to recruit significantly more participants (if possible) may have taken many months in a single centre study which would not be feasible within this programme of study. Participant follow-up was planned to be twelve-months post programme. Only 41% of participants had returned their completed outcomes at six-months follow-up and this would likely have decreased further. It was therefore decided not to follow-up at one year.

4.8.2 Focus Group Recruitment and Attendance

In contrast to the quantitative phase, the focus group attendance was very good. Nineteen participants responded to the invitation letter and confirmed their attendance. One withdrew prior to the group meeting and a further two did not attend on the day. There were sixteen participants in the focus groups, 8 in each group. Both focus groups were conducted on the same day, a morning and afternoon session. Due to availability it was not possible to have a separate focus group for each programme. It was more beneficial to have mixed groups as participants were all able to discuss their experiences, particularly having individual input and group education. Participants were identified by their identification number on the computerised notes system (RIO). I was therefore able to identify which group programme they had attended. However, it was also possible during the analysis of the conversations to determine which group the participant had attended. The results/discussion of the quantitative and qualitative components of the study can be found in **Chapters 5** and **6**.

4.9 Post Recruitment

After the recruitment period had finished and the focus groups completed, I presented my research work at the Middlesex University Research Student Summer 2015 Conference. This duration of the presentation was fifteen minutes with 5 minutes of questions (Appendix 18: Certificate of Attendance). In June 2015, I self-published a book via CreateSpace titled "A history of exercise therapy: From ancient to modern times". This was an adjunct to my research which looked at the history of exercise therapy such as Pilates and yoga particularly for managing back pain. This book was reviewed by the CSP and appeared in the 2015 September issue of the Frontline magazine. The six-month participant follow-up period was completed by the end of January 2016 and hence completion of **Stage 2**. The ethics committee were informed regarding the completion of the study. The next stage of the programme was to complete my analysis for **Stage 2**, write-up and prepare for the thesis viva.

Chapter 5: Results

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Chapter 5: Results

Section 1-Stage 1

Section 1 of the Questionnaire

Section 1 of the questionnaire included clinical details about the responding physiotherapist and asked to provide information regarding their referral of patients to group programmes for the management of CLBP as well as the exercises they prescribe.

5.1 Respondents

There was a 63% response rate (n= 97/154). Fifty-six percent (n= 54/97) were employed in primary care, 28% in secondary care (n=27/97) and 16% in Independent practice (n=16/97). Twenty-three percent of respondents were Band 8 (n=22/96), 33% at Band 7 (n=32/96), 31% at Band 6 (n=30/96), 5% at Band 5 (n=5/96) and 7% classified as other (n=7/96). Other includes those in Independent practice and three GP physicians in Primary Care who specialise in MSK conditions. One respondent completed section 2 of the questionnaire only.

Sixty percent of the respondents (n=58/96) recorded no speciality. A number of respondents listed more than one speciality but there was a total of seven different specialities in the survey. Thirty-eight percent of the total number of specialities listed (n=19/50) specialised in Spinal Conditions. **Table 5.1** lists percentages of the different specialities.

Table 5.1: **The percentage of different physiotherapy specialties found in the survey**

Physiotherapy Speciality(n=50)	Percentage of Respondents Specialising
Spinal Conditions	38%
Lower Limb	12%
Upper Limb	16%
Rheumatology	4%
Triage	8%
Pain Management	18%
Women's Health	4%

Those that specialised in Upper limb and Lower Limb were 16% (n=8/50) and 12% (n=6/50) respectively. Four percent (n=2/50) specialised in Rheumatology, 18% (n=9/50) in Pain Management and 8% (n=4/50) in Triage. Four percent (n=2/50) specialised in Women's Health.

5.2 Caseload

Respondents were asked to state approximately what their CLBP patient caseload was. Seven percent (n=7/96) stated that their CLBP patient caseload was between 0-20%, 35% (n= 34/96) between 21-40%, 24% (n= 23/96) between 41-60%, 25% (n= 24/96) between 61-80% and 6% (n= 6/96) greater than 80%.

Where appropriate, the Chi-square (χ^2) test was used to compare between variables where there were three or more categories. Statistical testing was able to examine whether different specialties were associated with the caseload of CLBP patients. Attention was restricted to those specialities that were most commonly observed in the dataset. Specialities that were rarer were not formally analysed. The results are summarised in **Table 5.2**. The figures reported are the percentage of CLBP patients for those with and without particular specialities.

Table 5.2: **Summary of Chi-square (χ^2) test for the association between speciality and CLBP caseload**

Speciality	Caseload	Without Speciality N (%)	With Speciality N (%)	χ^2 P-value
Upper Limbs	0% - 20%	4 (5%)	3 (38%)	**0.01**
	21% - 40%	33 (38%)	1 (13%)	
	41% - 60%	21 (24%)	2 (25%)	
	61% - 80%	22 (26%)	2 (25%)	
	81+%	6 (7%)	0 (0%)	
Spinal Conditions	0% - 20%	6 (8%)	1 (5%)	**0.001**
	21% - 40%	31 (41%)	3 (16%)	
	41% - 60%	19 (25%)	4 (21%)	
	61% - 80%	18 (24%)	6 (32%)	
	81+%	1 (1%)	5 (26%)	
Pain Management	0% - 20%	7 (8%)	0 (0%)	0.86
	21% - 40%	32 (36%)	2 (40%)	
	41% - 60%	21 (24%)	2 (40%)	
	61% - 80%	23 (26%)	1 (20%)	
	81+%	6 (7%)	0 (0%)	

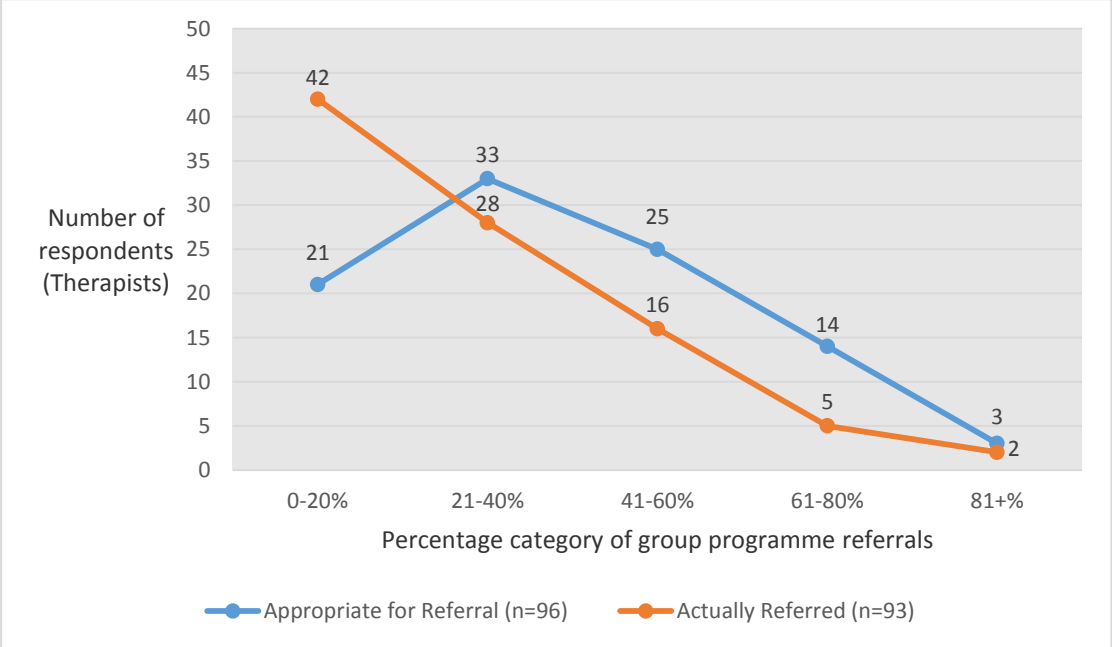
Statistical test details: Test used, test (χ^2) statistic and degrees of freedom
Upper Limbs: Chi-square, χ^2=12.52, 4
Spinal conditions: Chi-square, χ^2=18.16, 4
Pain Management: Chi-square, χ^2=1.34, 4

Those respondents specialising in upper limb and spinal conditions were associated with higher caseloads of CLBP patients. Fifty-eight percent of those with a speciality in spinal conditions had a caseload of 61+%, compared to only a quarter of patients without such a speciality.

5.3 Group Programme Referrals

Respondents were asked approximately what percentage of their CLBP patients would be appropriate for group programme referral and approximately what percentage of these patients they actually referred. The results show generally there was a greater percentage of patients that would be appropriate for group referral than those who were actually referred. **Figure 5.1** demonstrates this difference. Twenty-one respondents or 22% (21/96) stated that between 0-20% of their CLBP would be appropriate for group referral and 75 respondents or 78% (75/96) stated that >21% would be appropriate, whereas forty-two respondents or 45% (42/93) were actually referring just 0-20% of their patients and 51 respondents or 55% (51/93) stated that >21% were being actually referred.

Figure 5.1: Percentage categories of CLBP patients appropriate for Group Programme referral compared with those actually referred



Seventy-seven percent of all respondents reported that >21% (n= 74/96) of their CLBP patients would be appropriate for group programme referral but only 53% (n=51/96) referred >21% of their CLBP patients to the group programmes. Three percent (n=3/96) for all respondents did not refer to group programmes. Fifty-five percent of Band 8 respondents reported that >21% of their patients would be appropriate for group programme referral compared to 81% Band 7, 87% Band 6 and 100% Band 5. Those respondents specialising in spinal conditions generally referred less of their CLBP caseload to group programmes compared to all respondents with 42% (n=19) referring >21% of their patients. In contrast those specialising in Pain Management tended to refer more of their patients to Group programmes with 63% (n=8) >21% referrals.

Further statistical analyses examined if the speciality of the respondents was associated with the actual referral rates. The results suggested that none of the three specialities examined were significantly associated with the percentage of actual patients referred. A summary of the analysis results is given in **Table 5.3**.

Table 5.3: **Summary of Chi-square (χ^2) test for the association between speciality and actual referral rates**

Speciality	Referral	Without Speciality N (%)	With Speciality N (%)	χ^2 P-value
Upper Limbs	0% - 20%	38 (45%)	4 (40%)	0.90
	21% - 40%	26 (31%)	2 (25%)	
	41% - 60%	14 (16%)	2 (25%)	
	61% - 80%	5 (6%)	0 (0%)	
	81+%	2 (2%)	0 (0%)	
Spinal Conditions	0% - 20%	31 (41%)	11 (61%)	0.61
	21% - 40%	24 (32%)	4 (22%)	
	41% - 60%	14 (19%)	2 (11%)	
	61% - 80%	4 (5%)	1 (6%)	
	81+%	2 (3%)	0 (0%)	
Pain Management	0% - 20%	40 (45%)	2 (40%)	0.65
	21% - 40%	27 (31%)	1 (20%)	
	41% - 60%	15 (17%)	1 (20%)	
	61% - 80%	4 (5%)	1 (20%)	
	81+%	2 (2%)	0 (0%)	

Statistical test details: Test used, test (χ^2) statistic and degrees of freedom
Upper Limbs: Chi-square, χ^2=1.09, 4
Spinal conditions: Chi-square, χ^2=2.68, 4
Pain Management: Chi-square, χ^2=2.45, 4

Those respondents with a lower banding (Band 5 and 6) tended to refer more patients to group programmes than the other bands. Eighty percent (n=4/5) of Band 5 respondents and sixty-seven percent (n=20/30) of Band 6 respondents referred >21% of their patients to group programmes compared to 53% (n=17/32) Band 7 and 32% (n=7/22) Band 8.

Further analysis showed that there was no significant difference found between bands in terms of percentage of appropriate or actual referrals. Referrals were highest in band 5/6 respondents with 36% of those referring 41% or more of their patients. This is highlighted in **Table 5.4**.

Table 5.4: **Summary of Chi-square (χ^2) test for percentage referral to Group Programmes by different Banding**

Variable	Category	Band 5/6	Band 7 N (%)	Band 8 N (%)	Other N (%)	χ^2 P-value
Appropriate Referral	0% - 20%	4 (11%)	6 (19%)	10 (45%)	2 (29%)	0.09
	21% - 40%	11 (31%)	15 (47%)	3 (14%)	3 (43%)	
	41% - 60%	11 (31%)	7 (22%)	7 (32%)	0 (0%)	
	61% - 80%	7 (20%)	3 (9%)	2 (9%)	2 (29%)	
	81+%	2 (6%)	1 (3%)	0 (0%)	0 (0%)	
Actual Referral	0% - 20%	9 (27%)	15 (47%)	14 (67%)	4 (57%)	0.45
	21% - 40%	12 (36%)	10 (31%)	3 (14%)	3 (43%)	
	41% - 60%	8 (24%)	5 (16%)	3 (14%)	0 (0%)	
	61% - 80%	3 (9%)	1 (3%)	1 (5%)	0 (0%)	
	81+%	1 (3%)	1 (3%)	0 (0%)	0 (0%)	

Statistical test details: Test used, test (χ^2) statistic and degrees of freedom
Appropriate referral: Chi-square, χ^2=12.64, 18.84
Actual referral: Chi-square, χ^2=12.01, 12

Respondents in secondary care tended to refer more patients to group programmes than in those Primary Care and Independent Practice. Fifty-two percent (n=29/56) of respondents in Primary Care referred just 0-20% of their patients to group programmes compared with 44% (n= 7/16) in Independent Practice and 25% (n=6/24) in Secondary Care. Whereas seventy-five percent (n=18/24) of respondents in Secondary Care referred >21% of their patients to group programmes compared to 46% (n=26/56) in Primary Care and 44% (n= 7/16) in Independent Practice.

Further statistical analysis using the Chi-square (χ^2) test suggested that there was no significant difference between locations in terms of percentage of appropriate referrals. Those in Secondary care had the highest rate of referral, with 37% referring 41+% of their patients compared to only 23% in Primary Care and 7% in Independent

practice. However, statistically there was no significant difference in terms of percentage of actual referrals. This statistical analysis is highlighted in **Table 5.5**.

Table 5.5: **Summary of Chi-square (χ^2) test for percentage referral to Group Programmes by location**

Variable	Category	Primary N (%)	Secondary N (%)	Independent N (%)	χ^2 P-value
Appropriate Referral	0% - 20%	15 (28%)	3 (11%)	4 (25%)	0.37
	21% - 40%	19 (36%)	8 (30%)	5 (31%)	
	41% - 60%	10 (19%)	11 (41%)	4 (25%)	
	61% - 80%	8 (15%)	3 (11%)	3 (19%)	
	81+%	1 (2%)	2 (7%)	0 (0%)	
Actual Referral	0% - 20%	28 (54%)	7 (26%)	7 (50%)	0.35
	21% - 40%	12 (23%)	10 (37%)	6 (43%)	
	41% - 60%	8 (15%)	7 (26%)	1 (7%)	
	61% - 80%	3 (6%)	2 (7%)	0 (0%)	
	81+%	1 (2%)	1 (4%)	0 (0%)	

Statistical test details: Test used, test (χ^2) statistic and degrees of freedom
Appropriate referral: Chi-square, χ^2=8.64, 8
Actual referral: Chi-square, χ^2=8.90, 8

5.4 Sessions and Exercise Therapy

Thirty-eight percent (n=37/96) of respondents had 1-2 sessions with patients before group referral and 48% (n=46/96) had 3-4 sessions before referring their patients. Only 12.5% (n=12/96) of respondents routinely followed up their patients after they had completed the group programme. Ninety percent (n=86/96) of respondents prescribed up to six exercises to their CLBP patients but only 44% (n=42/96) reported that these exercises were the same or similar to those given in the group programmes.

Respondents were asked what exercises they prescribed their CLBP patients as part of back pain management. All respondents prescribed exercises (n=96). The frequency of exercises prescribed is presented as the total percentage of therapists prescribing exercises often and very often. Stretching or flexibility exercises were most frequently used (78%) with core stability ranked second (73%, 27% very often) and lumbar stabilisation exercises ranked third (73%, 26% very often). The type of exercises prescribed less frequently were upper limb strengthening (6%) followed by balance (24%) and directional specific exercises or McKenzie (36%).

The most frequent exercises used by Band 8 therapists (n=22), were aerobic ranked first (76%) followed by stretches (68%) and functional (63%). For Band 7 therapists (n=32), stretches (87%) ranked first followed by core stability (75%, 41% very often) and lumbar stabilisation exercises (75%, 31% very often). For Band 6 and Band 5 therapists (n=35), the most frequent exercises used were core stability (80%, 43% very often) followed by stretches (80%, 31% very often) and lumbar stabilisation (79%). For respondents in Independent Practice (n=16), Core stability (94%) was ranked first followed by stretches (81%) and lumbar stabilisation (79%).

5.5 Section 2-Group Physiotherapy Programmes

Section 2 of the questionnaire asked respondents involved in group programmes about the type and content of the group programmes they were involved in at their place of work. One physiotherapy department did not provide any data regarding their group programmes and some respondents had listed two group programmes on their questionnaire. The most frequently used group physiotherapy programme for managing non-specific CLBP was the Back to Fitness Programme. This made up 37% of the total number of group programmes in the survey (n=14/38), followed by Pilates, 18% (n=7/38), combined group programmes 18% (n=7/38), core stability/lumbar stabilisation, 16% (n=6/38), spinal hydrotherapy, 5% (n=2/38), Back Class/School, 2% (n=1/38) and Yoga, 2% (n=1/38). Fifty-percent of the physiotherapy departments surveyed were using the BTFP. The combined group programmes included a mix of Pilates, core stability, circuit training and functional exercises. These group programmes were generally combinations or variations of the standard programmes found in the literature. For example, the Spinal Fitness Class had used a new classification of LBP to tailor the exercises to their patients reporting good results. This programme also included upper limb strengthening exercises such as biceps curl and wall press-ups as well as functional such as lunges and step-ups.

5.6 General Content of Group Programmes

The group programmes in this survey all consisted of general exercises (n=33/33). Seventy-three percent used circuit based exercises (n=24/33) followed by functional exercises at 64% (n=21/33) and postural correction, 61% (20/33). Seventy-three percent of the group programmes included an education component (n=24/33). Relaxation techniques at 33% (n=11/33) were used less often. None of these group programmes offered manual therapy to patients. Only 33% (n=11/33) of group programmes had individualised exercises for their patients. Individualised exercises were given in one programme when patients were unable to do the set exercises.

5.7 Education

Seventy percent (n=23/33) of the programmes in this survey provided education regarding CLBP management in a group setting with only 18% (n=6/33) given on an individual basis. Written Information regarding back care was given in 30% (n=10/33) of the programmes. Some physiotherapy departments had developed their own education booklet containing a home exercise programme with advice on pacing activities, managing flare-ups and pain relief education (n=5). Only 5 group programmes had used published education booklets such as the ARC: Back Pain information booklet (n=5). Generally, the Pilates Group Programmes provided no written information regarding back care.

5.8 Specific Content of Group Programmes

Sixty-seven percent (n=22/33) had a warm-up/warm-down lasting between 5-10 minutes. Thirty percent (n=10/33) had 9-10 exercises in their programmes and 55% (18/33) had >10 exercises. The most frequent types of exercise used in group programmes were stretches (28/33), strengthening (28/33) and aerobic (28/33) all at 85%. This was followed by core stability at 82% (27/33), circuit training 70% (23/33), functional exercises 58% (19/33), Pilates and postural correction both 33% (11/33).

Respondents were asked to state which type of strengthening exercise they used in their group programmes. The most frequently used strengthening exercises were lower limb at 85% (28/33), abdominal strengthening 79% (26/33) and back strengthening 73% (24/33). This was followed by functional strengthening at 64% (21/33), upper limb 55% (18/33) and plyometric 6% (2/33). Other strengthening exercises at 21% (7/33) included balance, Pilates with gym ball and theraband.

Respondents were also asked to state which type of aerobic exercise they used in their group programmes. Walking at 67% (22/33) was the most frequently used aerobic exercise followed by stepper/step-ups 58% (19/33) and cycling 55% (18/33). This was followed by running at 30% (10/33), cross-trainer 18% (6/33), dance 15% (5/33) and rowing 6% (2/33). Other aerobic exercise at 15% (5/33) included marching on the spot, step exercises, health rider and cardiovascular exercise included in the warm-up.

5.9 Programme Intensity and Duration

Forty-two percent (n= 14/33) of group programmes consisted of low intensity exercises only and 48% (n=16/33) were a mixture of high and low intensity. There were no high intensity exercise programmes. Twenty-five percent of the group programmes were 4 weeks or less duration (n=9/36), 5% (n=2/36) were 5-weeks duration, 47% were 6-weeks duration (n=17/36), 19% (n=7/36) between 7 to 8-weeks duration and 3% (n=1/36) greater than 8-weeks duration. All programmes were held once a week on consecutive weeks. One Independent Practice was able to provide Pilates classes with no time limit as clients were paying.

5.10 Referral for non-English Speaking Patients

Forty-seven percent (n=45/96) of all respondents were able to refer non-English speaking patients to the group programmes run at their department. Many respondents used the free space provided to quote problems with interpreters and the fact that it was not appropriate to have interpreters in their classes. There was a group programme for Turkish speaking patients provided in the Spinal Fitness Class. Below are of quotes by respondents regarding interpreters and their group programmes.

'Unable to offer interpreters for the class'.

'Not appropriate as includes education component and class too busy to accommodate individual interpreters'.

'No interpreters and due to language barrier not appropriate for goal setting in class'.

'Difficulty of explanation of complex exercises in group environment'.

'No option of language specific class and too disruptive to have interpreter during education session'.

'Problems with interpretation as use a telephone based service'.

'Difficulties managing class as warm-up requires some instruction'

5.11 Outcome Measures used in Group Physiotherapy Programmes

Respondents reporting using a variety of outcome measures for their group programmes (n=53). All group programmes used patient-reported outcome measures and no functional measures. Condition specific measures such as the Roland Morris Disability Questionnaire (RM) and the Oswestry Disability Index (ODI) were used most frequently at 23% (n=12/53) and 17% (n=9/53) respectively. The EQ-5D-5L which is a health-related quality of life measure accounted for 11% (n=6/53). Measure Yourself Medical Outcome Profile (MYMOP) and the Patient Specific Functional Scale (PSFS) which are patient specific measures accounted for 4% (n=2/53) and 9% (n=5/53) respectively. Outcomes measuring pain used were the Visual Analogue Scale (VAS) and the Numerical Pain Rating Scale (NPRS) and accounted for 11% (n=6/53). Other outcomes included the Pain Catastrophizing Scale (PCS) which accounted for 8% (n=4/53). Therapist set goals or objective improvements accounted for 11% (n=6/53) and percentage reported improvement 6% (n=3/53).

Section 2: Stage 2-Core Quantitative Phase

5.12 Statistical Methods Used

Descriptive statistics were used to analyse the baseline characteristics in each of the two groups: experimental (SRP) and control (BTFP). For normally distributed baseline characteristics, the number available, mean, standard deviation (SD) and minimum and maximum were presented. In the case where the baseline characteristic was not normally distributed then the following statistics were presented: number available, median, 25% percentile, 75% percentile, minimum and maximum. For categorical baseline characteristics, i.e. sex, Start Back Tool and employment status, the count and percentage was presented. Statistical tests were used to assess whether there were any differences between the two groups at baseline. For normally distributed continuous baseline characteristics an independent groups t-test was performed. A Wilcoxon Mann-Whitney U test was used to test for differences between groups in the non-normally distributed variables and finally a Chi-square test was used to test for differences in categorical variables between groups.

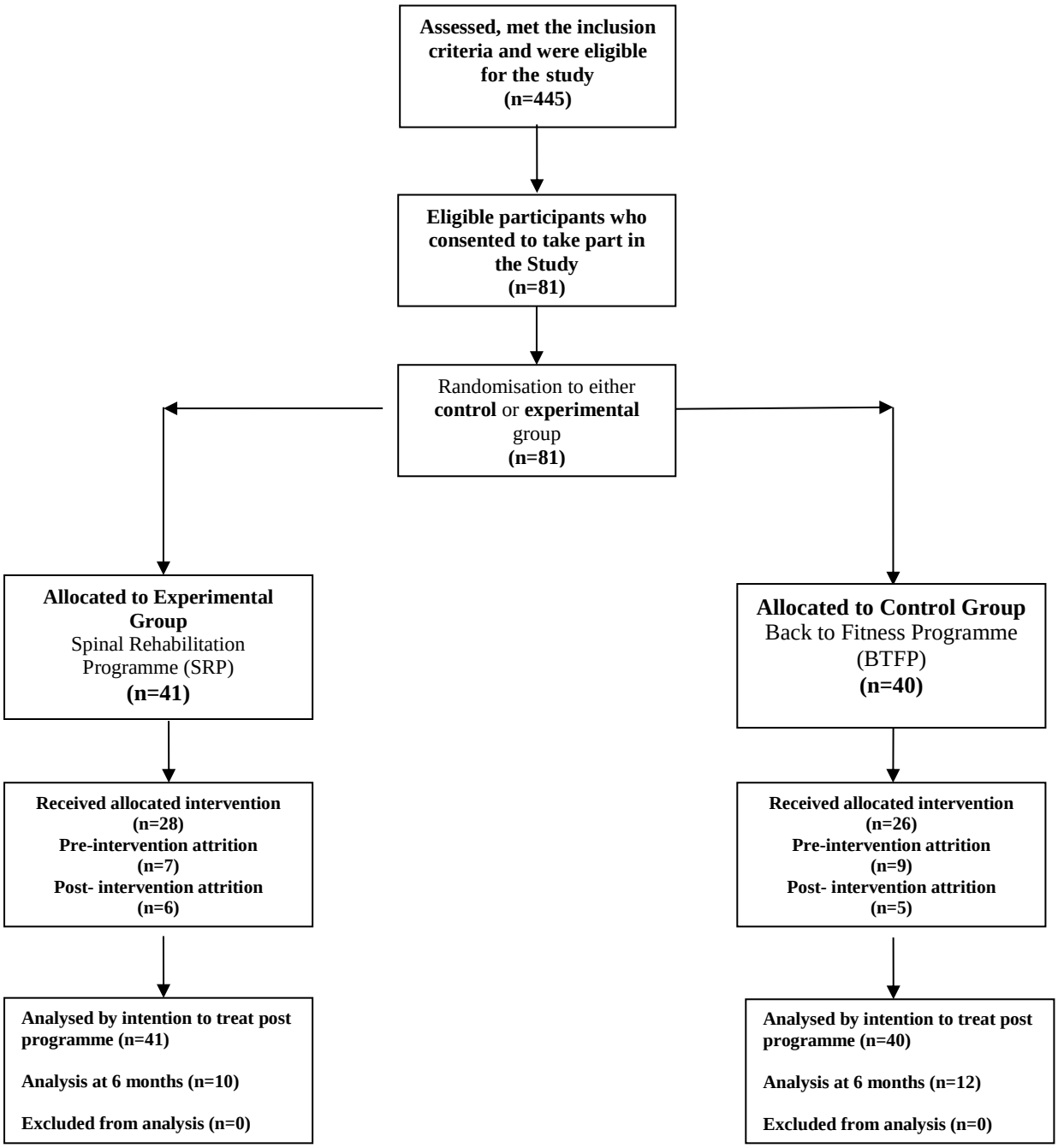
Analysis of covariance (ANCOVA) models were used to assess for differences in outcomes between groups adjusting for the baseline outcome. Separate models were fitted for the post outcome and at six-months follow-up outcome. An independent groups t-test was used to test for differences between groups in the outcome PSRS. Paired t-tests were used to assess for differences between pre-programme and post programme and pre-programme and 6-month follow-up scores for the outcomes separately within the SRP and within the BTFP.

For each outcome, the standardised effect size was calculated as a common method of size of effect. This was calculated as the baseline-adjusted mean difference between groups, divided by the standard deviation of the baseline scores (using the mean standard deviation between the two groups). A standardised effect size can mean different things. Cohen's *d*, the most common one used, was designed for use where scores of the two populations or groups are continuous and normally distributed (Rice and Harris, 2005). This is essentially a measure of the size of effect in terms of the number of standard deviations. So in other words, mean difference between groups (experimental minus control), divided by the standard deviation of the measurements. The way this was done in this statistical analysis was to base the SD on the values at the baseline time period and to use the mean difference as the values obtained from the data analysis.

5.13 Participant Recruitment

Participant recruitment took place from June 2014 to May 2015. It was not possible to extend this period due to the low levels of recruitment as a result of changes to the service and other factors (see discussion in **Chapter 6**). A retrospective review of the physiotherapy spinal clinics found that within the study recruitment period, 445 CLBP patients from the caseload met the inclusion criteria and were eligible for the study. Eighty-one participants consented to the study and were randomised to the two groups. Participant flow through the RCT is shown in **Figure 5.2**. Thirty-three percent (n=27) dropped out of the study resulting in 54 participants completing the two group programmes. Only 41% (n=22) of the participants completed outcomes at six months. The reasons of dropping out of the study were varied and most choose not to give a reason particularly at pre-study inclusion. One participant withdrew at pre-study due to his wife giving birth. Other reasons for pre-intervention attrition were inconvenient appointment times and preferred to do their exercises at home. In the experimental group post-intervention attrition (n=6): was due to illness (n=2), referred back to the physiotherapist for another MSK condition (n=1), problems with parking (n=1) and no reason given (n=2). In the standard group post-intervention attrition (n=5): was due to illness (n=1), not what they expected (n=1), requiring MRI imaging due to a deterioration of their symptoms (n=1), referred back to the physiotherapist for another MSK condition (n=1) and no reason given (n=1). There were no adverse effects to participants reported due to the treatment they received in this study.

Figure 5.2: *Participant flow through the RCT in Stage 2*



5.14 Demographic and Baseline Characteristics

The results are broken down into sections focusing on baseline characteristics, drop-outs and analysis of the outcomes. Forty-one participants were randomised to the experimental group (SRP). Thirty-seven percent were male (n=15) and 63% female (n=26). The average age was 46 years and mean duration of symptoms was 59 months. Forty-six percent of this group were in full-time work (n=19), 2% part-time (n=1), 7% were retired (n=3) and 44% (n=18) were recorded as not working. Forty participants were randomised to the control group or standard group programme (BTFP). Forty percent were male (n=16) and 60% (n=24) female. The average age in this group was 43 years and mean duration of symptoms was 54 months. Seventy-percent in the control group were working full-time (n=28), 10% part-time (n=4) and 20% (n=8) were not working.

Table 5.6 shows the baseline characteristics of the two treatment groups**.**

Table 5.6: Baseline characteristics of the two treatment groups

Baseline characteristic	Programme		All Patients (N=81)	P-value
	SRP (N=41)	BTFP (N=40)		
i. Age, mean ± SD	46.4 ± 12.1	43.3 ± 12.7	44.9 ± 12.4	0.25
n	41	40	81	
ii. Sex, n (%)				0.75
Male	15 (36.6%)	16 (40%)	31 (38.3%)	
Female	26 (63.4%)	24 (60%)	50 (61.7%)	
iii. Duration of symptoms, median (P25, P75)	36 (11, 72)	21.5 (10, 72)	24 (10, 72)	0.30
n	41	40	81	
iv. Start Back Tool, n (%)				0.16
Low	16 (39.0%)	19 (47.5%)	35 (43.2%)	
Medium	9 (22.0%)	13 (32.5%)	22 (27.2%)	
High	16 (39.0%)	8 (20.0%)	24 (29.6%)	
v. Employment, n (%)				0.003
Working	20 (48.8%)	32 (80.0%)	52 (64.2%)	
Non-working	21 (51.2%)	8 (20.0%)	29 (35.8%)	
vi. FRI*, mean ± SD	54.0 ± 23.2	48.2 ± 13.7	51.2 ± 19.4	0.23
n	34	31	65	
vii. EQ-5D*, median (P25, P75)	0.48 (0.30, 0.68)	0.59 (0.53, 0.69)	0.57 (0.35, 0.69)	0.048
n	33	31	64	
viii. NPRS*, mean ± SD	5.09 ± 2.75	4.91 ± 1.34	5.00 ± 2.18	0.74
n	33	30	63	
ix. EQ-VAS*, median (P25, P75)	50.0 (30.0, 80.0)	62.5 (50.0, 70.0)	60.0 (40.0, 80.0)	0.20
n	33	30	63	

P25 is defined as the 25th percentile and P75 is defined as the 75th percentile; SD = standard deviation, SRP = spinal rehabilitation programme, BTFP = Back to Fitness programme

*Measured pre-treatment

Statistical test details: Test used, test statistic and degrees of freedom

- **i. Independent samples t-test, t=1.16, 79**
- **ii. Pearson Chi-square, χ^2=0.10, 1**
- **iii. Wilcoxon- Mann Whitney U, z=1.04, n/a**
- **iv. Wilcoxon- Mann Whitney U, z=1.39, n/a**
- **v. Pearson Chi-Square, χ^2=8.59, 1**
- **vi. Independent samples t-test, t=1.20, 63**
- **vii. Wilcoxon-Mann Whitney U, z=-1.98, n/a**
- **viii. Independent samples t-test, t=0.33, 61**
- **ix. Wilcoxon-Mann Whitney U, z=-1.29, n/a**

Baseline characteristics appears to be well-balanced between the two programme groups apart from employment status. There appears to be a higher number of working subjects (full time or part time) in the BTFP group compared to the SRP group, 80% versus 49%.

Table 5.7a shows the study attrition by group and overall.

Table 5.7a: Study attrition by group and overall

	Physiotherapy Programme		All Patients (N=81)	P-value
	SRP (N=41)	BTFP (N=40)		
i. Drop out status, n (%)				0.75
Dropped out	13 (31.7%)	14 (35.0%)	27 (33.3%)	
Remained in study	28 (68.3%)	26 (65.0%)	54 (66.7%)	
ii. Number of sessions, n (%*)				0.43
0	0 (0.0%)	1 (3.9%)	1 (1.9%)	
2	6 (21.4%)	6 (23.1%)	12 (22.2%)	
4	4 (14.3%)	5 (19.2%)	9 (16.7%)	
5	18 (64.3%)	14 (53.9%)	32 (59.3%)	
6				

*Denominator used to calculate percentage is based on subjects who remained in the study. The denominator is the number at the bottom part of a fraction. So for example, if you are calculating the fraction 2/10, then 10 is the denominator. More generally if the fraction is x/y, then y is the denominator. i.e. for the SRP, the denominator is the number of subjects remaining in the study, 28 (y) and 6 (x) is the number of subjects completing 2 sessions. 6(x)/28 (y) = 21.4% as shown in **Table 5.7a**

Statistical test details: Test used, test statistic and degrees of freedom

i. **Pearson Chi-square, χ^2=0.10, 1**
ii. **Wilcoxon-Mann Whitney U, z=0.79, n/a**

Approximately one third of subjects dropped out of this study and this was evenly split across the two programmes. Of the subjects who remained in the study, the number of sessions which were attended was reasonably even across the two groups.

5.15 Drop-outs

Patients were categorised as completing the study (not dropping out), or dropping out. Statistical tests were used to assess whether there were any differences between those dropping and not dropping out. The variables assessed were the demographics of the patients, and the baseline values of the outcome variables. For normally distributed continuous variables an independent groups t-test was performed. A Wilcoxon Mann-Whitney U test was used to test for differences between groups in the non-normally distributed variables and finally a Chi-square test was used to test for differences in categorical variables between groups.

Table 5.7b summarises the characteristics and results of patients who did and did not drop out.

Table 5.7b: Characteristics and results of patients who did and did not drop out

Baseline characteristic	Dropout		P-value
	No (N=54)	Yes (N=27)	
i. Age, mean ± SD	46.2 ± 12.7	40.3 ± 10.7	0.02
n	54	27	
ii. Sex, n (%)			0.87
Male	33 (61.1%)	17 (63.0%)	
Female	21 (38.9%)	10 (37.0%)	
iii. Duration of symptoms, median (P25, P75)	29 (10, 84)	24 (10, 48)	0.76
n	54	27	
iv. Start Back Tool, n (%)			0.11
Low	19 (35.2%)	16 (59.3%)	
Medium	16 (29.6%)	6 (22.2%)	
High	19 (35.2%)	5 (18.5%)	
v. Employment, n (%)			0.07
Working	31 (57.4%)	21 (77.8%)	
Non-working	23 (42.6%)	6 (22.2%)	
vi. FRI*, mean ± SD	50.8 ± 19.1	53.2 ± 21.6	0.72
n	54	11	
vii. EQ-5D*, median (P25, P75)	0.57 (0.39, 0.69)	0.59 (0.30, 0.76)	0.88
n	54	101	
viii. NPRS*, mean ± SD	4.99 ± 2.12	5.09 ± 2.61	0.90
n	54	9	
ix. EQ-VAS*, median (P25, P75)	60.0 (40.0, 80.0)	50.0 (45.0, 60.0)	0.24
n	54	9	

P25 is defined as the 25th percentile and P75 is defined as the 75th percentile; SD = standard deviation
*Measured pre-treatment

Statistical test details: Test used, test statistic and degrees of freedom

- **i. Independent samples t-test, t=2.43, 79**
- **ii. Pearson Chi-square, χ^2=0.03, 1**
- **iii. Wilcoxon- Mann Whitney U, z=0.31, n/a**
- **iv. Pearson Chi-square, χ^2=4.47, 2**
- **v. Pearson Chi-square, χ^2=3.25, 1**
- **vi. Independent samples t-test, t=-0.36, 63**
- **vii. Wilcoxon- Mann Whitney U, z=0.15, n/a**
- **viii. Independent samples t-test, t=-0.13, 61**
- **ix. Wilcoxon- Mann Whitney U, z=1.19, n/a**

The results suggested that only age was strongly significantly associated with dropping out of the study. Patients who dropped-out tended to be younger, with a mean age of 40, compared to a mean of 46 for those completing the study.
There was also slight evidence that the drop-out group had a higher proportion of working subjects, but this result was not quite statistically significant. The other characteristics examined were not significantly associated with dropping out of the study.

5.16 Analysis of Outcomes between Groups

This section shows the adjusted means derived from the analysis of covariance models for each outcome (post programme and 6-month follow-up) adjusting for the pre programme measurement.

Each table in this section shows the mean and standard deviation outcome values, as well as the 95% confidence intervals (CIs) in each group. The adjusted means are the mean values at the latter time point adjusted for baseline values. Also reported are the mean difference in outcome between groups, along with the 95% CIs, standardised effect sizes, and also *p*-values indicating the significance of the results.

In the analysis the differences at follow-up for the FRI, EQ-5D, NPRS and EQ-VAS were adjusted for the pre-programme values. In these analyses, the effects of both the pre-programme value and the treatment upon the post-programme values are essentially being examined jointly. Aside from the group difference, this aimed to provide information on the relationship between the pre-programme score and the follow-up score for that particular outcome. For example, the null hypothesis would

be that there was no relationship between pre-programme FRI and follow-up FRI. Any highly significant *p*-value found in the analysis (e.g. p<**0.0001**) suggested this not to be true. So in other words there was a significant association between pre-programme and follow-up. It would be typically expected to observe those with higher pre-programme values to have higher follow-up values on average.

Tables 5.8a and 5.8b show post programme and 6 month outcomes for the FRI.

Table 5.8a: Outcome: FRI post-programme (n=54)

	Programme		Adjusted mean difference (95% CI) (SRP-BTFP)	Effect size	P-value
	SRP (N=28)	BTFP (N=26)			
Mean ± SD	40.3 ± 24.2	42.7 ± 14.0			
Adjusted mean (95% CI)	39.5(34.2, 44.8)	43.6(38.0, 49.1)	-4.0(-11.7, 3.6)	-0.21	0.29

Statistical test details: Test used, test statistic and degrees of freedom
ANOVA test, 1.12, 1
After adjustment for FRI score pre-programme (p<0.0001), there appears to be no significant difference in the FRI post treatment score between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 54.52, df 1 and 51.

Table 5.8b: Outcome: FRI 6-month follow-up (n=22)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=10)	BTFP (N=12)			
Mean ± SD	38.8 ± 28.5	42.6 ± 22.3			
Adjusted mean (95% CI)	41.4 (27.4, 55.4)	40.4(27.6, 53.2)	1.0(-18.1, 20.1)	0.05	0.92

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 0.01, 1
After adjustment for FRI score pre-programme (p=0.005), there appears to be no significant difference in the FRI score at 6-month follow-up between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 10.02, df 1 and 19.

Tables 5.9a and 5.9b show post programme and 6 month outcomes for the EQ-5D.

Table 5.9a: Outcome: EQ-5D post-programme (n=54)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=28)	BTFP (N=26)			
Mean ± SD	0.55 ± 0.30	0.65 ± 0.15			
Adjusted mean (95% CI)	0.59(0.53, 0.66)	0.60(0.53, 0.67)	-0.01(-0.11, 0.09)	-0.04	0.88

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 0.02, 1

After adjustment for EQ-5D score pre- programme ($p<0.0001$), there appears to be no significant difference in the EQ-5D score post-treatment between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 49.15, df 1 and 51.

Table 5.9b Outcome: EQ-5D 6-month follow-up (n=22)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=10)	BTFP (N=12)			
Mean ± SD	0.56 ± 0.38	0.54 ± 0.26			
Adjusted mean (95% CI)	0.63(0.47, 0.78)	0.49(0.35, 0.63)	0.13(-0.07, 0.34)	0.50	0.19

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 1.81, 1

After adjustment for EQ-5D score pre-treatment ($p=0.0002$), there appears to be no significant difference in the EQ-5D score at 6 months between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 21.73, df 1 and 19. There was an effect size of 0.50 at 6 months which would be considered as moderate (Searle et al., 2015).

Tables 5.10a and 5.10b show post programme and 6 month outcomes for the NPRS.

Table 5.10a: Outcome: NPRS post-programme (n=54)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=28)	BTFP (N=26)			
Mean ± SD	3.88 ± 2.55	4.32 ± 1.71			
Adjusted mean (95% CI)	3.90 (3.19, 4.62)	4.29 (3.55, 5.03)	-0.39 (-1.42, 0.64)	-0.18	0.45

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 0.58, 1

After adjustment for NPRS score pre-programme (p=0.0001), there appears to be no significant difference in the NPRS score at post-programme between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 19.02, df 1 and 51.

Table 5.10b: Outcome: NPRS 6-month follow-up (n=22)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=10)	BTFP (N=12)			
Mean ± SD	3.63 ± 2.92	4.23 ± 2.35			
Adjusted mean (95% CI)	3.82 (2.37, 5.27)	4.08 (2.75, 5.40)	-0.25 (-2.22, 1.72)	-0.12	0.79

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 0.07, 1

After adjustment for NPRS score pre-programme (p=0.005), there appears to be no significant difference in the NPRS score at 6-month follow-up between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 9.91, df 1 and 19.

Tables 5.11a and 5.11b show post programme and 6 month outcomes for the EQ-VAS.

Table 5.11a: Outcome: EQ-VAS post-programme (n=54)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=28)	BTFP (N=26)			
Mean ± SD	63.1 ± 23.8	67.3 ± 19.0			
Adjusted mean (95% CI)	64.0 (56.3, 71.7)	66.3 (58.3, 74.3)	-2.3 (-13.5, 8.9)	0.10	0.68

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 0.17, 1

After adjustment for EQ-VAS score pre-programme (p=0.007), there appears to be no significant difference in the EQ-VAS score post-programme between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 7.98, df 1 and 51.

Table 5.11b: Outcome: EQ-VAS 6-month follow-up (n=22)

	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	Effect size	P-value
	SRP (N=10)	BTFP (N=12)			
Mean ± SD	65.5 ± 26.8	65.6 ± 22.9			
Adjusted mean (95% CI)	66.0 (50.6, 81.4)	65.2 (51.1, 79.2)	0.9 (-20.0, 21.7)	0.04	0.93

Statistical test details: Test used, test (F) statistic and degrees of freedom
ANOVA test, 0.01, 1

After adjustment for EQ-VAS score pre-programme (p=0.07), there appears to be no significant difference in the EQ-VAS score at 6-month follow-up between the SRP and BTFP groups. The *p*-value mentioned above was obtained as part of the ANCOVA analyses, test (F) statistic 3.72, df 1 and 19.

Table 5.12 shows post programme outcomes for the PSRS.

Table 5.12: Outcome: PSRS (n=54)

	Programme		P-value
	SRP (N=28)	BTFP (N=26)	
Median (P25, P75)	20.0 (17.4, 21.5)	19.0 (15.0, 21.0)	0.19

P25 is defined as the 25th percentile and P75 is defined as the 75th percentile
Statistical test details: Test used, test (z) statistic and degrees of freedom
Wilcoxon-Mann Whitney U test, 1.30, n/a

The Wilcoxon Mann-Whitney U test shows that there appears to be no significant difference in the PSRS score between the SRP and BTFP groups.

5.17 Analysis of Outcomes within Groups

This section shows the differences between pre-programme and post programme and pre-programme and 6-month follow-up scores for the outcomes separately within the SRP and within the BTFP assessed by paired t-tests. Raw mean and 95% CI are presented for pre-programme and post-programme/6-month follow-up and also for the difference between post-programme/6-month follow-up and pre-programme scores.

Table 5.13: **Pre versus Post-Programme/Follow-up for SRP patients (n=28)**

Outcome	Pre Raw mean (95% CI)	Post/Follow-up Raw mean (95% CI)	Raw mean difference (95% CI) (Post/Follow-up minus Pre)	P-value
i. FRI pre versus post-programme (n=28)	51.9 (42.9, 61.0)	40.3 (30.9, 49.7)	-11.6 (-17.5, -5.7)	0.0004
ii. FRI pre versus 6-month follow-up (n=10)	49.6 (35.2, 63.9)	38.8 (18.4, 59.2)	-10.8 (-22.9, 1.3)	0.07
iii. EQ-5D pre versus post-programme (n=28)	0.47 (0.35, 0.58)	0.55 (0.44, 0.67)	0.08 (0.02, 0.16)	0.02
iv. EQ-5D 6-month follow-up (n=10)	0.46 (0.20, 0.71)	0.56 (0.29, 0.84)	0.10 (0.01, 0.20)	0.04
v. NPRS post-programme (n=28)	4.94 (3.88, 6.00)	3.88 (2.89, 4.86)	-1.06 (-2.08, -0.05)	0.04
vi. NPRS 6-month follow-up (n=10)	4.92 (2.66, 7.17)	3.63 (1.54, 5.72)	-1.28 (-3.20, 0.64)	0.17
vii. EQ-VAS post-programme (n=28)	56.4 (46.0, 66.8)	63.1 (53.9, 72.3)	6.7 (-4.5, 17.8)	0.22
viii. EQ-VAS 6-month follow-up (n=10)	56.0 (33.3, 78.7)	65.5 (46.3, 84.7)	10.3 (-13.9, 32.9)	0.38

Statistical test details: Test used was Paired t-test, test (t) statistic and degrees of freedom
i. -4.02, 27; ii. -2.01, 9; iii. 2.49, 27; iv. 2.28, 9; v. -2.16, 27; vi. -1.51, 9; vii. 1.23, 27; viii. 0.92, 9

Patients in the SRP have a significantly lower FRI score (p=0.0004) and NPRS score (p=0.04) post-programme compared to pre-programme and a significantly higher EQ-5D score post-programme (p=0.02) and at the 6-month follow-up (p=0.04) compared to pre-programme.

Table 5.14: Pre versus Post-Programme/Follow-up for BTFP patients (n=26)

Outcome	Pre Raw mean (95% CI)	Post/Follow-up Raw mean (95% CI)	Raw mean difference (95% CI) (Post/Follow-up minus Pre)	P-value
i. FRI pre versus post-programme (n=26)	49.7 (44.2, 55.1)	42.7 (37.0, 48.3)	-7.0 (-12.6, -1.3)	0.02
ii. FRI pre versus 6-month follow-up (n=12)	54.8 (47.4, 62.2)	42.6 (28.4, 56.8)	-12.1 (-26.8, 2.5)	0.10
iii. EQ-5D pre versus post-programme (n=26)	0.59 (0.53, 0.66)	0.65 (0.59, 0.71)	0.06 (-0.02, 0.13)	0.14
iv. EQ-5D 6-month follow-up (n=12)	0.60 (0.47, 0.72)	0.54 (0.38, 0.71)	-0.05 (-0.23, 0.12)	0.52
v. NPRS post-programme (n=26)	5.04 (4.54, 5.54)	4.32 (3.63, 5.01)	-0.72 (-1.29, -0.15)	0.02
vi. NPRS 6-month follow-up (n=12)	5.43 (4.71, 6.15)	4.23 (2.74, 5.73)	-1.20 (-2.35, -0.04)	0.04
vii. EQ-VAS post-programme (n=26)	61.7 (55.3, 68.2)	67.3 (59.6, 75.0)	5.6 (-2.2, 13.4)	0.15
viii. EQ-VAS 6-month follow-up (n=12)	58.3 (47.1, 69.6)	65.6 (51.0, 80.1)	7.3 (-6.5, 21.0)	0.27

Statistical test details: Test used was Paired t-test, test (t) statistic and degrees of freedom
i. -2.53, 25; ii. -1.83, 11; iii. 1.51, 25; iv. 0.67, 11; v. -2.59, 25; vi. -2.28, 11; vii. 1.47, 25; viii. 1.16, 11

Patients in the BTFP have a significantly lower FRI score post-programme (p=0.02) and NPRS score post-programme (p=0.02) and NPRS score at the 6-month follow-up (p=0.04) compared to pre-programme. There were no significant improvements to quality of life which deteriorated at 6-months.

Figure 5.3: Raw mean percentage FRI scores with 95% confidence intervals (CI) pre and post-programme for within the SRP (n=28) and BTFP (n=26)

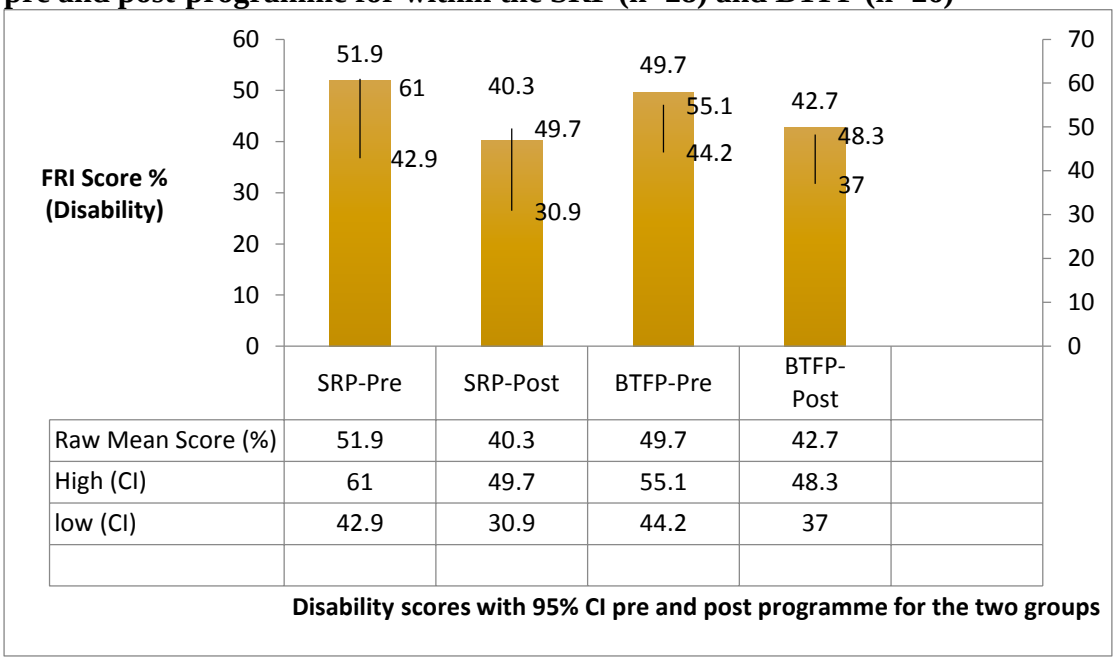


Figure 5.3 shows the raw mean percentage FRI scores with 95% CI pre and post-programme for within the SRP and BTFP. The SRP demonstrated a mean difference from pre to post treatment of -11.6% (95% CI, -17.5 to -5.7) in the FRI compared with -7.0% (95% CI, -12.6 to -1.3) in the BTFP. Both programmes had significantly lower FRI scores post programme (Paired t-test, t = -4.02, df = 27, *p*= 0.0004, SRP and Paired t-test, t = -2.53, df = 25, *p*= 0.02, BTFP).

Figure 5.4: Raw mean EQ-5D scores with 95% confidence intervals (CI) pre and post-programme for the within SRP (n=28) and BTFP (n=26)

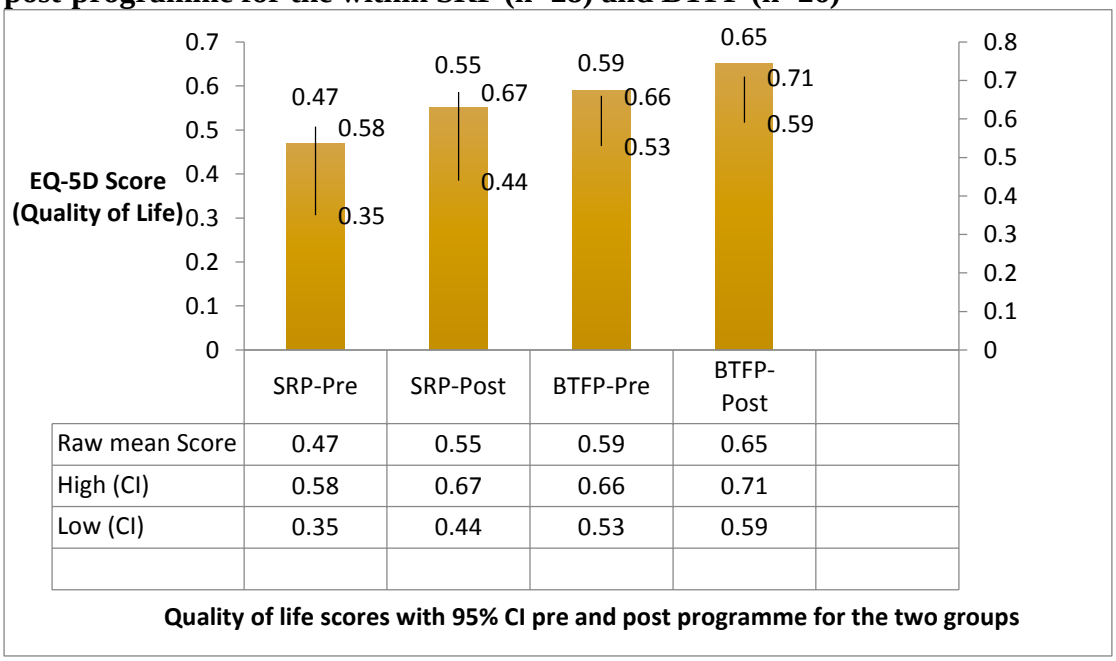


Figure 5.4 shows the raw mean percentage EQ-5D scores with 95% CI pre and post-programme for within the SRP and BTFP. The SRP demonstrated a mean difference from pre to post treatment of 0.08 (95% CI, 0.02 to 0.16) in the EQ-5D compared with 0.06 (95% CI, -0.02 to 0.13) in the BTFP. The SRP had significantly higher EQ-5D scores post programme but quality of life did not improve significantly in the BTFP (Paired t-test, t = 2.49, df = 27, *p*= 0.02, SRP and Paired t-test, t = 1.51, df = 25, *p*= 0.14, BTFP).

Figure 5.5: Raw mean NPRS scores with 95% confidence intervals (CI) pre and post-programme for the within SRP (n=28) and BTFP (n=26)

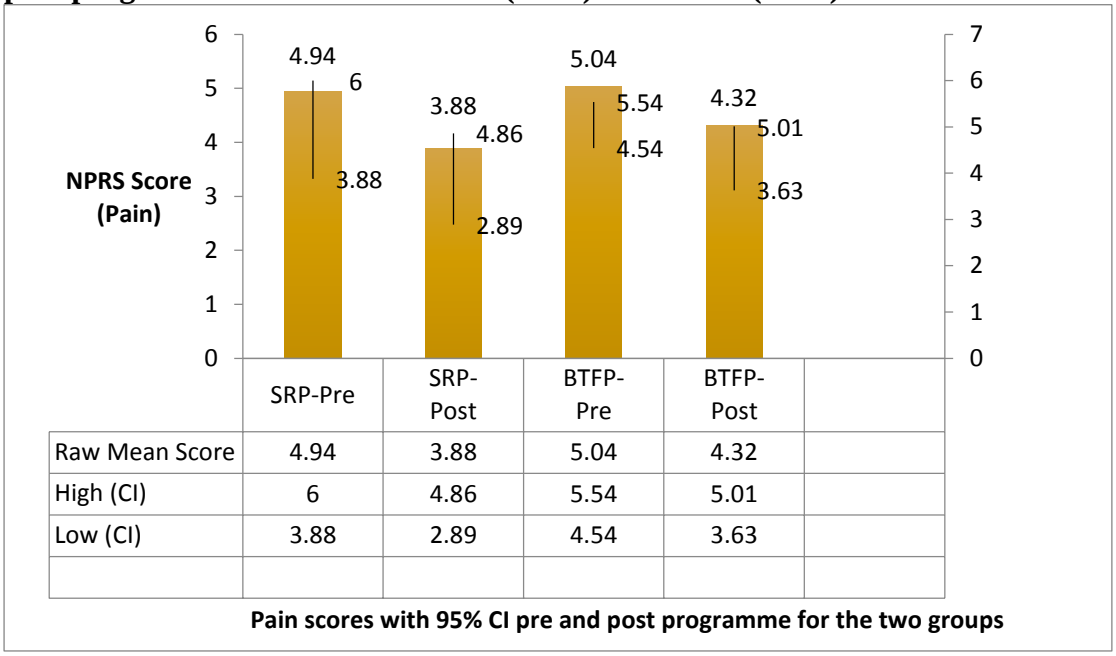


Figure 5.5 shows the raw mean percentage NPRS scores with 95% CI pre and post-programme for within the SRP and BTFP. The SRP demonstrated a mean difference from pre to post treatment of -1.06 (95% CI, -2.08 to -0.05) in the NPRS compared with -0.72 (95% CI, -1.29 to -0.15) in the BTFP. Both programmes had significantly lower NPRS scores post programme (Paired t-test, t = -2.16, df = 27, p= 0.04, SRP and Paired t-test, t = -2.59, df = 25, p= 0.02, BTFP).

5.18 Minimally Clinical Important Difference

The patients who achieved a minimally clinical important difference (MCID) were assessed for the FRI post-programme compared to pre-programme and also for the EQ-5D post-programme compared to pre-programme. The MCID for the FRI was specified as a 10% decrease in FRI score post-programme compared to pre-programme. The MCID for the EQ-5D was specified to a 0.082 increase in score post-programme compared to pre-programme. Chi-square tests were used to assess whether there was a significant difference in the proportion of patients who achieved the MCID between the SRP and BTFP.

Table 5.15: Minimally Clinical important difference (MCID) for the FRI post-programme versus pre-programme

	Programme		P-value
	SRP	BTFP	
i. FRI ≥10% decrease post-programme	11 (39.3%) N=28	9 (34.6%) N=26	0.72
ii. FRI ≥10% decrease 6-month follow-up	4 (40.0%) N=10	8 (66.7%) N=12	0.21

Statistical test details: Test used was Pearson Chi-square, test (χ^2) statistic and degrees of freedom. i. 0.13, 1; ii. 0.56, 1

There is no significant difference between the proportion of patients who achieved the MCID in the FRI post-programme or at the 6-month follow-up in the SRP compared to the BTFP.

Table 5.16: Minimally Clinical important difference (MCID) for the EQ-5D post-programme versus pre-programme

	Programme		P-value
	SRP	BTFP	
i. EQ-5D ≥0.082 increase post-programme	13 (46.4%) N=28	10 (38.5%) N=26	0.55
ii. EQ-5D ≥0.082 increase 6/12 follow-up	5 (50.0%) N=10	3 (25.0%) N=12	0.22

Statistical test details: Test used was Pearson Chi-square, test (χ^2) statistic and degrees of freedom. i. 0.35, 1; ii. 1.47, 1

There is no significant difference between the proportion of patients who achieved the MCID in the EQ-5D post-programme or at 6-month follow-up in the SRP compared to the BTFP.

5.19 Start Back Tool (SBT)Analysis

The SBT was used in this study in an attempt to classify CLBP patients into sub-groups with the objective to determine which sub-group if any would respond better to the group physiotherapy interventions.

Table 5.17: Percentage of patients in the SRP(n=41) and BTFP(n=40) categorised by the SBT to the three risk groups

Programme	Low Risk	Medium Risk	High Risk
SRP	39%	22%	39%
BTFP	47.5%	32.5%	20%

Table 5.17 shows the percentage of participants categorised into the three risk groups determined by the SBT- Low, Medium and High. There were more participants categorised in the low risk group who were allocated to the BFTP (47.5% compared to 39% in the SRP). In contrast, there were more participants categorised in the high risk group who were allocated to the SRP (39% compared to 20% in the BTFP).

5.19.1 Statistical Analysis of the Start Back Tool

Within each SBT category, ANCOVA models were used to assess for differences in outcomes between the SRP and BTFP adjusting for the baseline outcome. Separate models were fitted for the post outcome and the 6-month follow-up outcome. Adjusted means and 95% CIs were presented for each programme and also for the difference between the two programmes. Due to non-normal distribution, a Wilcoxon Mann-Whitney U test was used to test for differences between groups in the outcome PSRS. The median, 25th percentile and 75% percentile were presented instead.

Table 5.18: Analysis of outcomes for SRP versus BTFP for patients categorised as low risk

Outcome	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	P-value
	SRP Adjusted* mean (95% CI)	BTFP Adjusted* mean (95% CI)		
i. FRI-post-programme	34.3 (27.6, 40.9) N=11	44.1 (36.3, 51.9) N=8	-9.8 (-20.1, 0.4)	0.06
ii. FRI- 6-month follow-up	37.4 (25.1, 49.7) N=5	36.8 (20.8, 52.9) N=3	0.5 (-20.0, 21.1)	0.95
iii. EQ-5D post-programme	0.69 (0.62, 0.77) N=11	0.69 (0.60, 0.78) N=8	0.00 (-0.11, 0.12)	0.95
iv.EQ-5D 6-month follow-up	0.74 (0.60, 0.89) N=5	0.46 (0.27, 0.65) N=3	0.28 (0.03, 0.53)	0.03
v. NPRS post-programme	2.69 (1.66, 3.72) N=11	4.11 (2.90, 5.32) N=8	-1.43 (-3.02, 0.17)	0.08
vi. NPRS 6-month follow-up	2.47 (0.44, 4.49) N=5	3.94 (1.33, 6.56) N=3	-1.48 (-4.80, 1.84)	0.30
vii. EQ-VAS post-programme	69.4 (57.4, 81.3) N=11	63.0 (49.0, 77.0) N=8	6.4 (-12.0, 24.8)	0.47
viii. EQ-VAS 6-month follow-up	62.8 (30.9, 94.8) N=5	61.9 (20.5, 103.3) N=3	0.9 (-51.6, 53.4)	0.97
PSRS	20 (18, 24) N=11	17 (13.5, 19.5) N=8		0.07

*Adjusted for outcome pre-programme. For PSRS outcome, median, 25th percentile and 75th percentile are presented instead of adjusted mean and 95% CI and z statistic (z=1.81) from Wilcoxon-Mann Whitney U test rather than F test from ANOVA.

Statistical test details: Test used was F test from ANOVA, test (t) statistic and degrees of freedom i. 4.14, 1; ii. 0.00, 1; iii. 0.00, 1; iv. 8.53, 1; v. 3.61, 1; vi. 1.31, 1; vii. 0.54, 1; viii. 0.00, 1

Patients categorised as low risk in the SRP have a significantly higher EQ-5D score at 6-month follow up compared to patients in the BTFP.

Table 5.19: Analysis of outcomes for SRP versus BTFP for patients categorised as medium risk

Outcome	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	P-value
	SRP Adjusted* mean (95% CI)	BTFP Adjusted* mean (95% CI)		
i. FRI-post-programme	40.6 (28.1, 53.0) N=5	35.1 (27.0, 43.2) N=11	5.5 (-10.0, 20.9)	0.46
ii. Fri 6-month follow-up	38.9 (-4.8, 82.7) N=2	41.7 (15.6, 67.9) N=5	-2.8 (-56.4, 50.7)	0.89
iii. EQ-5D post-programme	0.51 (0.29, 0.73) N=5	0.61 (0.46, 0.76) N=11	-0.10 (-0.37, 0.16)	0.42
iv.EQ-5D 6-month follow-up	0.69 (0.34, 1.04) N=2	0.42 (0.21, 0.63) N=5	0.27 (-0.15, 0.70)	0.15
v. NPRS post-programme	4.51 (2.44, 6.57) N=5	3.63 (2.37, 4.89) N=11	0.87 (-1.80, 3.55)	0.49
vi. NPRS 6-month follow-up	5.54 (1.23, 9.85) N=2	3.65 (1.43, 5.87) N=5	1.89 (-3.76, 7.53)	0.41
vii. EQ-VAS post-programme	57.6 (37.1, 78.0) N=5	78.4 (65.3, 91.5) N=11	-20.8 (-46.5, 4.9)	0.10
viii. EQ-VAS 6-month follow-up	73.4 (44.1, 102.7) N=2	75.6 (59.2, 92.1) N=5	-2.2 (-39.3, 34.8)	0.88
PSRS	20 (17, 20) N=5	20 (18, 23) N=11		0.43

*Adjusted for outcome pre-programme. For PSRS outcome, median, 25th percentile and 75th percentile are presented instead of adjusted mean and 95% CI and z statistic (z=-0.80) from Wilcoxon-Mann Whitney U test rather than F test from ANOVA.

Statistical test details: Test used was F test from ANOVA, test (t) statistic and degrees of freedom i. 0.59, 1; ii. 0.02, 1; iii. 0.68, 1; iv. 3.16, 1; v. 0.50, 1; vi. 0.86, 1; vii. 3.07, 1; viii. 0.03, 1

There are no significant differences in the outcomes between the SRP and BTFP for patients categorised as medium risk.

Table 5.20: Analysis of outcomes for SRP versus BTFP for patients categorised as high risk

Outcome	Programme		Adjusted mean difference (95% CI) (SRP – BTFP)	P-value
	SRP Adjusted* mean (95% CI)	BTFP Adjusted* mean (95% CI)		
i. FRI-post-programme	44.8 (33.9. 55.6) N=12	54.7 (40.4, 69.0) N=7	-10.0 (-28.1, 8.2)	0.26
ii. Fri 6-month follow-up	29.1 (-23.0, 81.3) N=3	56.9 (13.1, 100.8) N=4	-27.8 (-102.6, 47.0)	0.36
iii. EQ-5D post-programme	0.52 (0.41, 0.64) N=12	0.50 (0.34, 0.67) N=7	0.02 (-0.20, 0.24)	0.85
iv. EQ-5D 6-month follow-up	0.65 (0.03, 1.26) N=3	0.41 (-0.10, 0.92) N=4	0.23 (-0.68, 1.15)	0.52
v. NPRS post-programme	4.95 (3.61, 6.29) N=12	5.20 (3.44, 6.95) N=7	-0.24 (-2.46, 1.98)	0.82
vi. NPRS 6-month follow-up	5.68 (0.00, 11.36) N=3	4.16 (-0.74, 9.05) N=4	1.52 (-6.08, 9.13)	0.61
vii. EQ-VAS post-programme	55.2 (40.9, 69.6) N=12	62.4 (42.4, 82.5) N=7	-7.2 (-34.5, 20.1)	0.59
viii. EQ-VAS 6-month follow-up	58.2 (-44.5, 160.8) N=3	60.6 (-20.6, 141.8) N=4	-2.4 (-168.6, 163.7)	0.97
PSRS	20 (16, 22.5) N=12	19 (8, 20) N=7		0.23

*Adjusted for outcome pre-programme. For PSRS outcome, median, 25th percentile and 75th percentile are presented instead of adjusted mean and 95% CI and z statistic (z= 1.20) from Wilcoxon-Mann Whitney U test rather than F test from ANOVA.

Statistical test details: Test used was F test from ANOVA, test (t) statistic and degrees of freedom i. 1.35, 1; ii. 1.07, 1; iii. 0.04, 1; iv. 0.51, 1; v. 0.05, 1; vi. 0.31, 1; vii. 0.31, 1; viii. 0.00, 1

There are no significant differences in the outcomes between the SRP and BTFP for patients categorised as high risk.

5.20 Results Stage 2-Supplementary Qualitative Phase

Two focus groups were conducted in June 2015. Nineteen participants accepted the invitation with 16 attending (drop-out rate of 16%). Each group consisted of 8 participants. In focus group 1, there were 2 males and 6 females. The average age in group 1 was 54 years (SD 4.94). 5 participants had attended the alternative group programme (SRP-Group A) and 3 had attended the standard group programme (BTFP-Group B). Participants were identified by their unique identification number (RIO). In focus group 2, there were also 2 males and 6 females. The average age of this group was 57 years (SD 4.94). In this group also, 5 participants had attended the alternative group programme (SRP-Group A) and 3 had attended the standard group programme (BTFP-Group B). Therefore, participants in both focus groups were very similar. The recordings of both focus groups together with the written notes were transcribed, categorised into topics relating to the focus questions and divided into the themes and sub-themes. This analysis was verified and agreed by an independent researcher at Masters Level.

The focus group topics and questions are listed below:

Introductory Question: Can you please tell us about your experience of attending the group programme?

Transition Question: Can you tell us about what in the programme has helped with your chronic back pain?

Focus Questions:

1. What were your expectations of the group programme?

2. Do you think education regarding back pain should be provided in a group or individually?

3. What are the barriers to participating in this programme and regular exercise afterwards?

Summarising Question: Think back on your experiences and this discussion today and tell us what else we can do to improve the management of chronic low back pain.

Concluding Question: Is there anything else that anyone feels that we should have discussed today?

Topics, themes and sub-themes

There were six topics categorised with their associated themes and sub-themes. These are described in more detail in **Chapter 6**.

Topic 1: Experience of Group Programmes

Both focus groups concluded that their experience of the group programmes was a positive one.

Themes:

1. Very good programmes which were enjoyable, beneficial and brilliant.
2. There is a support group and social element to it. Obtaining information from other people and also makes you realize that you are not the only person in isolation with back pain.
3. Specific individualized exercises very helpful.

   Sub-theme: Individualized input useful to correct if doing exercises wrong.

   Sub-theme: Need to be self-motivated to benefit from programme and individual exercises.
4. First impression was not positive in the SRP. Session seemed disorganised and chaotic with people not knowing what they were doing. This improved with subsequent sessions.
5. Back to fitness programme**:** The exercises had more structure and a good warm-up.

   Sub-theme: There was a bit of competition set up within the group to do better than last time in the circuits.

   Sub-theme: Circuit training good because you had a different exercise on each circuit and the variation was useful.

6. Programmes are not consecutive and more flexible particularly if you can't make it one week.

Topic 2: How have the programmes helped with your back pain

Both programmes helped reduce back pain but the improvements to pain in the SRP were greater.

Themes:

1. Generally, both programmes have helped manage back pain.
2. Back pain virtually resolved after attending the SRP.
3. Progress has been slow and expected quicker results.
4. Education in the BTFP helped reduce health anxieties and provided advice on managing CLBP.

Topic 3: Expectations

Generally, there were no expectations of these group programmes as participants had suffered from CLBP for a long time.

Themes:

1. To improve my mobility, reduce my level of pain and how to manage it.
2. No expectations but opened minded.

   Sub-theme: Needed something to help manage back pain.

   Sub-theme: Did not realize that it would be that kind of exercise such as exercises that strengthen my back.

Topic 4: Education

This topic relates to the education given to participants in the two groups.

Themes

1. Group education useful on how to manage back pain.

   Sub-theme: Education on manual handling, correct lifting technique, the structure of the back (spine model), ergonomics and how to manage flare-ups was useful.

   Sub-theme: Emphasise that once the treatment is over, you must carry-on the exercises and self-manage which will take time.
2. One-to-one advice/education was very good/brilliant as able to ask questions and speaking with someone caters for your own individual needs (tailor made).
3. Education is very important and the more the better. Consensus that both group and individual education would be preferred.

Topic 5: Barriers

This topic relates to any barriers encountered attending the programmes and continuing with exercise thereafter.

Themes

1. No barriers accept an illness or virus that may stop exercises.
2. Linguistic barrier, in circuits some patient's English was not that good and had trouble understanding how to do the exercises properly.
3. Other MSK problems such as joint arthritis may affect exercise participation and be a barrier.

4. Inflexible class times in the middle of the afternoon. Difficult to get time off work.
5. Expensive to go to outside classes (Pilates), gyms etc.
6. Lack of follow-up and guidance to carry-on self-managing or continuing with exercise.
7. Parking difficult.

Topic 6: <u>Suggestions to Improve Programmes</u>

Participants were given the opportunity to discuss what improvements could be made to the programmes.

Themes:

1. Exercise progressions as progress after the course is lacking.
2. Follow-up sessions or another six sessions.
3. Drop-in centre for advice.
4. Resources to check on such as suitable websites on back pain management.

Chapter 6: Discussion

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Section 1- Stage 1

6.1 Response Rate

This was a small scale survey to further explore the use of exercise therapy for managing CLBP and referral rates to group programmes. The type and content of these group exercise programmes in clinical practice was also explored. This type of survey has not been done before. A response rate of 63% achieved in this study was comparable to other physiotherapy or health surveys but less than previous surveys investigating the physiotherapy management of LBP (Iles and Davidson, 2006). The data collected regarding CLBP patients was comparable to other studies. Three questionnaires were received over 3 months after the data collection period from March 2013 to June 2013. This would have increased the response rate to 65%. However, all of these questionnaires were received after the article publication date on the 9th October 2013. It is not known whether the respondents would have had access to this article and thus may have led to the possibility of bias on their responses. Therefore, these questionnaires were not included in the analysis. A number of strategies were used in **Stage 1** to improve response rate. This included contacting physiotherapy departments directly to determine how many questionnaires they were willing to accept. Reminders were also sent out at 3 and 8-weeks post distribution. Reminder systems have been shown to have the most significant effect on response rates and can improve response by an average of 24% (Nakash et al., 2006). Contacting participants before sending questionnaires has shown an increased response as well as follow-up contact. All respondents in **Stage 1** were provided with a second copy of the questionnaire by e-mail. Ten percent of the respondents returned their questionnaires by e-mail. It has also been shown that providing non-respondents or low respondents with a second copy of the questionnaire can improve response

rates (Edwards et al., 2002). Questionnaires designed to be of more interest to participants were more likely to be returned. Saliency of a questionnaire to the recipient has been shown to be a strong predictor of response (Nakash et al., 2006). The use of exercise therapy and group exercise programmes for the management of CLBP could be regarded as a salient topic amongst out-patient physiotherapists.

6.2 Group Programme Referral

The results show that the majority of therapists except for 3% refer their CLBP to group programmes. The majority of respondents were working in Primary Care even though their place of work was within a hospital setting. This reflects the development of the ICO which combines both primary and secondary care. Those therapists working in secondary care tended to refer far more often than those in Primary Care and Independent Practice. This may be explained by the fact the group programmes are more likely to take place on site in secondary care making it easier to refer and for patients to attend. In Primary Care, a number of therapists work in smaller departments, satellite or GP clinics which don't always have the facility for group programmes and are often held at a different location. It may be more difficult for patients to attend these sites and discourage referral. Although group programmes were available in Independent Practice, therapists tended to refer less probably because patients are expecting more 'hands on' treatment. Band 5 and Band 6 therapists tended to refer more of their CLBP caseload to group programmes than the higher bandings. Both Band 7 and Band 8 therapists may see more complex CLBP patients whereby a group exercise programme is not necessarily an appropriate management strategy.

Those therapists who specialized in spinal conditions tended to have a higher CLBP caseload but referred less to group programmes than the other therapists. Although there was no significant statistical association between speciality and the percentage of actual patients referred. Specialist spinal therapists see a number of these patients in Interface or Orthopaedic clinics who may not be appropriate for physiotherapy and require further investigation or surgical review. In contrast, those respondents

specializing in Pain Management tended to refer more of their patients to group programmes. Their CLBP caseload may not be appropriate for invasive treatment but more suitable for exercise therapy. The percentage difference between those appropriate for group programme referral and those actually referred was virtually the same for the bands but slightly higher for the Band 7 therapists (Band 8: 23%, Band 7: 28%, Band 6: 20% and Band 5: 20% = % difference for >21% patient referral). This may indicate that Band 7 therapists could refer more of their CLBP patients to group exercise programmes. Only 47% of all respondents were able to refer non-English speaking patients to the group programmes run at their department which may account partly to the difference between those appropriate for group referral and those actually referred.

6.3 Sessions and Exercise Therapy

Forty-nine percent of respondents gave patients 3-4 sessions before referring their patients to the group programmes which may have reduced the need to follow-up patients post programme as only 14% of respondents routinely followed up their patients after they had completed the group programme. However, the alternative group programme proposes that patient should only require 1-2 therapy sessions before referral which may help to reduce the therapist's case load and physiotherapy waiting lists. The majority of therapists provided up to six exercises for their patients and only in 44% were these similar to those in the group programmes. There was a discrepancy between the number of exercises prescribed by individual therapists (up to 6) and those offered in the group programme (9-10). It has been recommended that adults should improve their muscle strength by exercising all the major muscle groups on at least 2 days a week in accordance with the physical activity guidelines set by the Chief Medical Officer and NICE guidelines (DOH, 2011b; NICE, 2013). It has been suggested that CLBP patients are de-conditioned due to their low physical activity levels (Dogan et al., 2008; Koes et al., 2001). This de-conditioning leads to a lower level of physical fitness. Physical fitness has a combination of physical parameters such as muscle strength, muscle endurance, flexibility, cardiovascular capacity, motor control and body composition. All of which may be affected by physical de-conditioning (Verbunt et al., 2003). CLBP patients should be given multimodal exercises including strengthening to address their de-conditioning. Six exercises may be insufficient for a comprehensive conditioning programme and more than 10 may reduce compliance. The American college of sports medicine have recommended that aerobic, strength, flexibility and functional exercise components be included in an exercise programme with 8-10 exercises performed on two or more non-consecutive

days. This programme should be modified according to the individual's physical function and health status (Garber et al., 2011; Haskell et al., 2007). In my physiotherapy department, patients have often had one set of exercises given by their therapist and a set of different exercises given in the group programme. The alternative group programme plans to allow patients to continue with the same individualised exercises given initially by the referring therapist which may increase adherence to exercise post programme.

This is the first survey to provide the details of the types of exercises prescribed for CLBP patients and compare with different physiotherapy grades. The most frequent exercises prescribed by respondents are stretches, core stability and lumbar stabilisation. Previous physiotherapy surveys have found that core stability and lumbar stabilisation exercises were the most frequently used regardless of the therapist's grade (Byrne et al., 2006; Liddle et al., 2009). Lumbar stabilisation or motor control exercises specific to the deep abdominal muscles are frequently prescribed but these exercises are difficult for patients to transfer from functional or sporting activities in the long-term (Critchley et al., 2007). Band 8 therapists tended to prescribe aerobic and functional exercises more frequently than the other bands. This is in contrast to the Fidvi and May (2010) survey where aerobic exercises were not prescribed to their CLBP patients. Promoting aerobic exercise or physical activity at a moderate-intensity is in line with the guidelines set by the Chief Medical Officer for adults between 19 and 65 years (DOH, 2011b). General and functional exercises may be more beneficial for CLBP in the long-term. Upper limb strengthening exercises were not often prescribed by respondents. Behm et al. (2010) defined the anatomical core as the axial skeleton consisting of both the pelvic and shoulder girdles and all the

soft tissues including muscle with a proximal attachment to the axial skeleton. This would include upper and lower extremities. Hence, training the upper limbs also stimulates the spinal stabilisers (Behm et al., 2010). Kell and Asmundson (2009) found that a resistance training programme for CLBP that stressed the large muscle groups of the whole body including the upper quadrant showed significant improvements in pain and disability. It was found that McKenzie exercises are not widely used (third least prescribed exercise type) by the therapists in this survey which is in contrast to the Byrne et al. (2006) study which found the McKenzie approach the second most popular management strategy for CLBP. Exercise therapy by the McKenzie method has been a popular treatment strategy for LBP amongst physiotherapists (Petersen et al., 2007). However, to date there are no good quality RCTs published to support the effectiveness of this method. McKenzie exercises may be less effective for CLBP and no longer frequently used due to the lack of evidence for its effectiveness. A recent RCT comparing Back School with McKenzie exercises in patients with CLBP found the McKenzie approach no more effective long-term for reducing pain and disability (Garcia et al., 2013).

6.4 Group Physiotherapy Programmes

This survey found that that most popular group exercise programmes such as Pilates, the Back to Fitness Programme (BTFP), Lumbar stability/motor control and yoga quoted in the literature are being used in clinical practice as part of back pain management. The most widely used Group Physiotherapy programme was the BTFP. The BTFP is a standardised model of group exercise which can be applied easily into clinical practice (Klaber-Moffett et al., 2004). It was interesting that the traditional Back School widely quoted in the literature was used by only one physiotherapy department in this survey. However, some of the combined group programmes had included exercise and education components which could be classed as Back School. A hydrotherapy class for CLBP was also used by one department. Hydrotherapy or exercises in the water have been used for managing musculoskeletal conditions for some time. However, there is no evidence to date that hydrotherapy is an effective treatment for CLBP (Maher, 2004). All these group programmes tended to use multi-modal exercises with a combination of strengthening, stretches and aerobic but under-utilised upper limb strengthening. Walking was the most frequently used aerobic exercise in the group programmes. This type of exercise is low impact and can be continued post programme as well as going towards achieving the weekly physical activity guidelines. Functional exercises were also used in these programmes which may be more relevant to patients and promote adherence. However, a circuit based format was often used which does not allow patients to perform their exercises at their own pace and exercises are generally not individualised to the patient. This would make it difficult for patients to carry-on with exercise therapy long-term especially if they do not have access to gyms or external exercise classes. Education was provided in these group programmes but usually in a group format. The information provided

in the group education sessions may not be relevant to all patients. To date, there has been no clinically important effect found of group education programmes for CLBP (Moseley et al., 2004). Only a small number of the group programmes provided published written information (30%) regarding CLBP self-management. In some instances, only exercise sheets were given out. Information booklets have been developed in the past to help health care providers educate their patients. For back pain for example, the back book has been developed by a multidisciplinary team from the evidence-base to accompany back-pain guidelines (Coudeyre et al., 2007). Educational booklets such as the back book are based on the biopsychosocial model of back pain have been shown to increase patients' knowledge and modify their beliefs (Henrotin et al., 2006). Manual therapy was not offered at all in these programmes. The alternative group programme planned to offer patients individual education sessions and manual therapy as appropriate but also provide written information regarding back pain management and/or advice. None of the group programmes used high intensity exercises only. This reflects that CLBP patients are de-conditioned and generally exercising at a lower intensity. Exercise programmes containing low intensity exercise may be sufficient to induce changes that will be sustained long-term. Group programme duration was between 4-8 weeks with 6 weeks being most common which is quoted in the literature. However, all group programmes were run on consecutive weeks. This type of format does not allow patients to join the group at any time and will generally have to wait until the current group programme has finished. From previous experience, many patients do not attend all their group sessions as the programme duration may clash with other commitments. The alternative group programme is not run on consecutive weeks and thus give patients more flexibility to attend all the six sessions allotted to them.

6.5 Outcome Measures

The RM and ODI were the most frequently used outcome measures in the group programmes (40%). These condition-specific outcome measures which are generally used in back pain studies may be more relevant to patients than objective outcome measures such as spinal flexibility or muscle strength and are more related to a specific condition (Longo et al., 2010). The VAS and NPRS were used as pain outcomes (11%) generally because of their ease of administration and responsiveness. Physiotherapy objective markers were used as outcome measures for the group programmes (11%). However, these objective measures should not be considered as the only primary outcomes in the treatment of CLBP (Haywood, 2006). There has been a shift in rehabilitation evaluation to use patient-specific measures such as the MYMOP and PSFS (Horn et al., 2012). These patient-specific outcome measures may unlike fixed-item measures, allow patients to select and rate activities that are important or relevant to them. A disadvantage with using these measures is that they require structured guidance to complete which may be time consuming particularly in a group setting. In my experience, patients find it difficult to identify their most important problem. In addition, the treatment effects of the programme that are not related to the chosen problem will not be measured. The PSFS has been used as a baseline measure only. Its validity as an outcome measure to detect change over time or make comparisons between groups as not been established (Horn et al., 2012). The Pain Catastrophizing Scale (PCS) is a self-report measure used in people with chronic pain. Participants reflect on past painful experiences and indicate the degree to which they experienced a number of thoughts or feelings when experiencing pain. Catastrophizing in CLBP patients is related to helplessness and pessimism concerning one's ability to deal with the pain experience (Van Damme et al., 2002). Patient's

attitudes and beliefs about pain have increasing been found to be risk factors to chronic pain. Cognitive treatments focusing on these attitudes and beliefs are used in the behavioural treatment of CLBP (Picavet et al., 2002). It was interesting that the PCS was used as an outcome measure as behavioural treatments for reducing pain catastrophizing are outside the scope of most group physiotherapy exercise programmes. It has been suggested that psychosocial measures such as the PCS are best used as screening tools prior to surgery and not as CLBP treatment outcomes because of their lack of responsiveness (Chapman et al., 2011). No attitude measurement scales were used to determine the patients' opinion about the treatment they received in the group programme.

6.6 Limitations: Stage 1

A major disadvantage with postal questionnaires and in this study was non-response. This reduces the effective sample size and may introduce bias (Edwards et al., 2002). This may also threaten the validity of the research as non-responders may differ significantly from responders. Non-response bias may also limit the generalisability of these current findings to all out-patient physiotherapists treating CLBP (Byrne et al., 2006). It was not possible in this study to contact individual non-respondents directly to determine why they did not respond. However, one department that took part in this current study had indicated that the current changes taking place in the NHS may be responsible for their low return rates. The Health and Social Care act which came into force on April 1st 2013 brings major reforms to the NHS. Many NHS Trusts and departments including my Trust are going through re-organisation. This busy time for some physiotherapy departments may have affected response rates particularly as this was during the data collection period. Initially, one trust had indicated that they could only accept a smaller number of questionnaires due to their current re-organisation. Commissioners of NHS services will be expected after April 1st to make greater use of tendering with competition becoming the norm for placing NHS contracts (Ham, 2013). This may raise social desirability concerns particularly when revealing details regarding patient management such as the content of their group physiotherapy programmes. This factor could affect response rate in that different trusts may be perceive that they are competing against each other. In general, at an organizational level such as the NHS there have been a number of reasons examined for non-response. These included being too busy, not considered relevant and not having an address to return the questionnaire but up to a quarter do not provide any clear reasons for not responding (Baruch and Holtom, 2008).

Unless a questionnaire is coercively administered to the target population, a 100% response rate is rarely achieved (Rogelberg and Stanton, 2007). The mean response rate to mail surveys for organizational respondents has been found to be only 35.7% (Baruch and Holtom, 2008). Response rates to mail surveys vary widely from 16% to 91% among health professionals (Lusk et al., 2007). Low response rates for surveys of physiotherapists are not unusual but may be comparable to other health surveys (Iles and Davidson, 2006). For example, the response rate of staff NHS postal surveys in 2010 and 2011 were both 54% (Gov.uk, 2012), whereas the response rate of previous physiotherapy based surveys have been similar to this value (Iles and Davidson, 2006; van Trijffel et al., 2009). Baruch and Holtom (2008) have concluded that a target response rate at an individual level should be around 50%. A response rate below 60% has been regarded as sub-optimal (Bowling, 2009). However, in the literature there is a lack of consistency on what should be the minimally acceptable response rate level.

This study recorded self-reported behaviour such as types of exercise prescribed for CLBP and referral rates to group exercise programmes. However, this study may not have captured real clinical practice which is difficult to measure. Inferences were made on the data provided in the survey but issues such as the barriers to group programme referral was not established. One of the reasons quoted for patients not joining a group programme was logistics and patient preference. The questionnaire in this survey did provide a free response space to give respondents the opportunity to add any other comments. This free response space was utilized by some but not be the majority of respondents. Finally, some physiotherapy departments ran more than one type of group exercise programme such as Back to Fitness and Pilates. It was beyond

the scope of this survey to establish their criteria for referring patients to a particular group programme. In **Stage 2** of this thesis, the Start Back screening tool (SBT) was used to help categorize patients in three sub-groups based on the presence of physical and psychosocial risk factors. The SBT may help therapists decide which group programme to refer based on the patient's physical ability and individual attention required.

6.7 Conclusion in Stage 1

The survey found that physiotherapy group exercise programmes are utilized by the majority of therapists as a management strategy for CLBP. There is a discrepancy between those who would be appropriate for group referral and those actually referred. Ethnic groups for whom English is not their first language are generally unsuitable for group programme referral due to the difficulty with interpreters. This may be an issue as the population of CLBP patients presenting to London physiotherapy departments is becoming increasingly diverse with English not being the first language for many of these people (Bernstein, 2009). Those therapists working in secondary care tended to refer more to group programmes. Therapists at a lower banding tended to refer more than the higher bands. However, there was evidence that Band 7 therapists could refer more of their patients to group exercise programmes. Interestingly, therapists specializing in spinal conditions referred less to group programmes but those in pain management had higher referral rates. The majority of therapists prescribed up to six exercises to their patients with stretches, core stability and lumbar stabilization the most frequently prescribed exercises. However, Band 8 therapists differed in their exercise prescription from the other bands prescribing more frequently aerobic and functional exercises. The exercises prescribed by therapists were not always the same as those in the group programmes which may have an effect on adherence to exercise long-term.

Summary of the survey results: There was a 63% response rate and 97% therapists in the survey referred to Group Programmes. Higher referral rates were in Secondary care and the lowest in Independent practice. Lower Grades (Bands 5 and 6) tended to refer more of their patients to group programmes. Those therapists specialising in pain

management tended to refer more of their patients to group programmes. Only 47% were able to refer non-English speaking patients to the group programmes. The most popular group programme in clinical practice was the Back to Fitness Programme (used by 50% of physiotherapy departments surveyed). Ninety-one percent of therapists provided only up to six exercises for their patients and only in 44% were these similar to those in the group programmes. The most frequent exercises prescribed by therapists are stretches, core stability and lumbar stabilisation. Upper limb strengthening exercises were not often prescribed by therapists. Advanced therapists (Band 8) tended to prescribe aerobic and functional exercises more frequently than less experienced therapists. Programmes used a combination of stretches, strengthening, aerobic and functional exercises but mostly in a circuit based format (not individualised). None of the programmes had a manual therapy component and only 18% provided education on an individual basis. Disability measures such as the RM and ODI were used most frequently to evaluate treatment within the group programme (40%).

Three of the four null hypotheses regarding group programmes were rejected. Generally, exercises given by therapists were different to those in the programme, these programmes lacked individual attention and a manual therapy component, and education provided was general and not specific to the patient. However, the null hypothesis that group programmes do not use single mode exercise regimens was accepted. These programmes do use a combination of stretches, strengthening, aerobic and functional exercises but mostly in a circuit based format. There is a place for an alternative group programme model alongside current group programmes to address the limitations of those used in clinical practice.

6.8 Recommendations from the survey and the link between Stage 1 to Stage 2 in the development of the alternative group exercise programme

It is recommended that therapists should prescribe between 8-10 multimodal individualized exercises for CLBP patients in order to improve their physical fitness. This should include core stability, lower limb and upper limb strengthening where appropriate, stretches/spinal mobility, functional and aerobic exercises as recommended by the American College of Sports Medicine. This exercise programme should be modified according to the individual's physical function and health status (Garber et al., 2011). It is proposed that there should be a shift away from lumbar stabilisation exercises to more functional types of exercise and those that reflect the NICE 2013 physical activity guidelines. Group exercise programmes should be used as a treatment strategy for CLBP patients. It is proposed that there is a place for an alternative group physiotherapy programme to address the limitations of the current programmes. This would consist of an individualised multimodal exercise programme carried over from the referring therapist. Referring therapists need only to give appropriate patients 1-2 sessions before referring them to the alternative group programme. This would assist with their caseload and reduce physiotherapy waiting times. The exercise component of the group programme should allow patients to perform their exercises at their own pace and not be circuit based. These exercises can be supervised and progressed as necessary. Patients should be encouraged to perform their 8-10 individualized exercises outside the programme sessions as well as increasing their physical activity to meet the NICE 2013 guidelines. All patients would be required to complete a warm-up lasting between 5-10 minutes. This programme should include an aerobic component such as walking or step-ups.

Patients would have a minimum of six group sessions but not consecutive weeks. A rolling programme would allow patients to join the group at any week and reduce waiting times to attend. The group programme would also consist of a one to one station with the therapist. This would consist of individual education sessions and manual therapy if appropriate. Patients should also be provided with a published information booklet which is a comprehensive up to date guide on back pain and how it can be managed. Patients for whom English is not their first language, interpreters can be arranged and this would not disrupt the group. The group programme should be evaluated by patient-reported outcome measures specific to disability or function and an attitude measurement scale.

*Integration from **Stage 1** to **Stage 2** and the development of the alternative group programme*

The alternative group physiotherapy programme (SRP) aimed to integrate multimodal individualised tailored exercises, one-to-one education and manual therapy. These components combined are generally lacking in NHS group exercise programmes for managing CLBP. Luk et al. (2010) had used multimodal exercises in a 14-week programme effectively for CLBP patients to reduce pain and disability. There is limited potential to apply this intensive intervention to clinical practice in the NHS. The objective of the survey in **Stage 1** was to inform on the referral rates to group programmes, the type of exercises prescribed and the structure of group programmes currently available in clinical practice. The results of the survey (**Chapter 5**) provided information regarding how the alternative programme should be structured, the types of exercises to be prescribed and the nature of education to be provided. The development process of the SRP in collaboration with the physiotherapy manager and

programme therapists involved integrating these findings from the survey into the protocol of the alternative programme. The findings of the survey were discussed in meetings between the manager, researcher and programme therapists (**Chapter 4**-Project Activity). Where appropriate these findings were integrated to produce a final programme protocol to be used in **Stage 2** of the study. The final protocol (Appendix 8) was agreed and training provided by the researcher for the programme therapists. The SRP was implemented into clinical practice and then evaluated.

The results of the survey in **Stage 1** of this thesis had contributed to the development of the SRP in the following ways. The survey found that group programmes use multimodal exercises but in a circuit-based format. Upper limb exercises were not often prescribed to patients. These exercises in the group programme were generally different from those prescribed from the referring therapist. The SRP was designed to include multimodal exercises but individualised and carried over from the referring therapist. More experienced therapists at Band 8 level had prescribed functional and aerobic exercises more frequently than the less experienced therapists. CLBP patients have been found to have a significantly lower aerobic capacity than the asymptomatic population (Duque et al., 2011). Shnayderman and Katz-Leurer (2012) found that moderate-intensity walking improves function in CLBP patients. Walking was the most frequently used aerobic exercise by group programmes in the survey. Upper limb, functional and cardiovascular exercises were included in the SRP based on the survey findings. Thus, the exercises within the SRP were modified according to the individual's physical function and health status as recommended by the American college of sports medicine (Garber et al., 2011).

None of the programmes in the survey had a manual therapy component and only 18% provided education on an individual basis. A one-to-one station with the therapist was added to the SRP. This would provide individual education sessions for patients and manual therapy as appropriate. A small number of the group programmes in the survey provided published written information regarding CLBP and self-management. Educational booklets such as the back book have been shown to increase patient's knowledge and modify their beliefs. Therefore, a published information booklet was provided in the SRP for patients to give a comprehensive up--to-date guide for back pain and how it can be managed. Disability patient-report measures such as the RM and ODI were used most frequently by respondents in the survey to evaluate treatment within the group programme. This finding confirmed that a disability patient-reported measure should be used to evaluate the alternative group programme.

Finally, the survey found that group programmes were all run on consecutive weeks and only 47% of those surveyed were able to refer non-English speaking patients. The SRP was designed as a rolling programme. This would allow patients to join the group at any week and provide greater flexibility with the aim of reducing drop-out rates. Patients for whom English is not their first language would also be able to attend with the provision of interpreters as appropriate.

Section 2: Stage 2 Discussion

6.9.1 Sample Size, Recruitment and Drop-outs

For the purposes of the discussion the alternative group exercise programme (experimental group) will be referred to as the SRP and the standard group programme (control group) will be referred to as the BTFP. This current RCT ended as a small scale single centre study and can be regarded as a first-line or preliminary study to evaluate the alternative group exercise programme. Participants were recruited from one physiotherapy department. The sample size of 81 was same as the RCT used by Frost et al. (1995) to evaluate the BTFP. There were 445 potentially eligible CLBP patients for the study who met the inclusion criteria but not all were informed of the study. Only approximately 18% of these eligible participants consented to take part. Grapou et al. (2006) have previously found that there is a high rate of refusal to enrol in a study. I had conducted previously a phase II pilot randomised controlled trial at the same Trust. This had compared a home total body strengthening programme plus manual therapy with a standard physiotherapy exercise regimen plus manual therapy for the management of non-specific chronic low back pain (CLBP). This pilot study determined that a larger randomised controlled trial was feasible in my Trust with successful implementation of the exercise programmes, predicted good participant retention rates and responsiveness of the outcome measures used (Daulat and Goodlad, 2014). Previous research has found that 50% of RCTs fail to achieve their recruitment targets (Sully et al., 2013). There were a number of reasons why eligible participants declined to participate. These include inconvenient programme times, work commitments, childcare, feeling better and parking issues. Some potential participants were concerned regarding confidentiality of their data, although the participant information leaflet provided assurance of confidentiality

(Appendix 11). An increased number of patients with CLBP preferred individual one--to-one treatment and further investigation rather than attending a group programme. There were a number of cases where no reason was given for not participating. The overall drop-out rate from 81 participants in the study was higher than expected at 33%. Pre-study attrition was 20% (n=16) leaving 65 participants to begin their treatment. The drop-out rate of those participants receiving treatment in both groups was 17% (n=11/65). Group programme drop-out rates have been reported up to 30% in the literature (Hurley et al., 2009). Age was significantly associated with dropping out of the study with participants dropping out being younger than those not dropping out (independent samples t-test, t = 2.43, df = 79, ***p* = 0.02**). It is interesting that those in full or part-time work had an overall drop-out rate of 40% (n=21/52) whereas those who were not working only had a drop-out rate of 21% (n=6/29). It is very possible that work commitments contributed to drop-out rates as the programmes were run during the day. Although in most cases no reason was given for withdrawing from the study. The most common reasons for drop-out were feeling better, inconvenient appointment times, preferred to do exercises at home and not what they expected. Goldby et al. (2006) who compared a spinal stability programme with one-to-one physiotherapy and education alone had a drop-out rate of 29%. Chown et al. (2008) compared group exercise with individual physiotherapy and osteopathy. Only 40% of those randomised to the group exercise programme completed the treatment and just 16% responded to the final follow-up at 12 months. A recent study by Hurley et al. (2015) comparing a walking programme with the BTFP and usual physiotherapy had a drop-rate of 19% at 3 months. Fifty-five percent of participants in the Hurley et al. (2015) study were not adhering to their treatment protocol at 12 months. This may

indicate the challenges of conducting RCTs in physiotherapy clinical practice due to high drop-up rates and high percentages of patients lost to follow-up.

Implication of Drop-outs in this study

The objective of the SRP developed in this thesis was to improve the attendance rates to group exercise programmes in clinical practice. In theory, this would be achieved by providing a more flexible rolling programme and shorter waiting lists to the attend the programme. The drop-out rates observed in the Back School previously used at the Trust were high (IPL 4060) but a rolling programme was not used. There was a high drop-out rate from the group programmes in this study at 33% but lower than that previously seen in the Back School at 40%. The high drop-out rate from this study and loss to follow-up has implications for evaluating the SRP and its future implementation into clinical practice. Small participant numbers can lead to substantial uncertainty about the magnitude of the benefit of both interventions in this study. Failing to recruit sufficient participants or problems with participant retention can produce inclusive results. Participants lost to follow-up provide no outcome data which may result in an underpowered trial leading to non-significant results (Treweek et al., 2010). The higher the power of a study, the lower the chance of drawing incorrect conclusions i.e. there was no effect of the intervention on the outcomes, when in fact there was (Hicks, 2009). Drop-outs can prevent observing the benefits of the intervention to them. We can't say for sure if the SRP has been effective or not for CLBP patients. There may be a biased estimation of the treatment effects and problems concerning the generalisability of the results obtained (Kemmler et al., 2005). Generalisability can be defined as the extent to which research findings are applied to settings other than the study sample in which they were tested (Fewtrell et

al., 2008). Generalisation becomes more difficult, as the results are only applicable to those who completed the treatment (Armijo-Olivo et al., 2009). Non-significant findings may increase the risk that an effective intervention such as the SRP will be abandoned before its true value is appreciated. This has implications for implementing the SRP into clinical practice as there is a lack of evidence for its effectiveness but the potential benefits of this programme to CLBP patients can't be ruled out. Public health decision makers are often reluctant to consider new interventions when effectiveness has not been demonstrated in their particular locality, setting or population (Oldenburg and Glanz, 2008). The SRP was developed internally and may have a relative advantage over existing programmes as well as meeting local needs with the inclusion of non-English speaking patients. This may support the organisation's commitment to implementation and further evaluation on a small scale. Further implementation of a modified version of the SRP (see section **6.14**) would aim to make it more widely available to CLBP patients by adopting it at multiple sites within the NHS Trust. Subsequent evaluation trials would require scaling-up and involve samples of 300-600 participants. This evaluation must encompass both cost-effectiveness and clinical outcome assessments (Zullig and Bosworth, 2015).

6.9.2 Start Back Tool

The Start Back Tool (SBT) was developed as a prognostic screening tool. This stratifies patients on the presence of modifiable physical and psychological prognostic indicators of persistent low back pain. Patients are stratified as low, medium or high risk of persisting symptoms and treatment can be targeted according to the patient's risk group. Those patients categorised in the high risk group display higher levels of anxiety, low mood and fear (Murphy et al., 2013). These patients may benefit more from psychological therapies such as cognitive behavioural therapy to manage their CLBP. Patients in the high risk group would be expected to have poorer outcomes with physiotherapy (Murphy et al., 2013). There were no significant differences in the outcomes post treatment between the SRP and BTFP for patients categorised as low, medium or high risk. The number of patients in the SBT analysis was small particularly in the medium risk category. This makes it unlikely that there is enough power to find a significant difference between pre-programme and post-programme outcome scores. Fritz et al. (2011) found that those categorised in the high risk group exhibited favourable changes in outcome compared with the low risk group. In contrast, Newell et al. (2014) found that individuals with LBP having chiropractic treatment did well irrespective of the subgroup they were placed in by the SBT. Those classified in the medium risk group at baseline did better at short to medium follow-up than the other risk groups in the Newell et al. (2014) study. This finding may not be surprising as those in the medium risk group have predominantly physical barriers to recovery and may benefit more from manual therapy delivered by the chiropractors. Although psychological risk factors may be infrequent in chiropractic patients (Kongsted, et al., 2016).

6.9.3 Function and Disability

The Functional Rating Index (FRI) was the primary outcome instrument in this study. The FRI is designed to quantitatively measure the subjective perception of function and pain of spinal conditions (LBP) in the clinical setting. The FRI emphasizes function while concurrently measures the patient's opinion, attitude and self-rating of disability. This measure provides an important description of a patient's function and the negative effects LBP has on daily activities (Ceran and Ozcan, 2006). The FRI is quick and easy to use for therapist and patients alike. It quantifies the patient's current mental comprehension of spinal pain and dysfunction as well as being a reliable and valid measure (Hosseinifar et al., 2013). The majority of back pain trials have used the Oswestry Disability Index (ODI) and Roland Morris (RM) questionnaires to measure disability. The FRI is able to estimate disability and there is a strong correlation between the RM and the FRI. This correlation implies that functional status is associated with disability (Ceran and Ozcan, 2006). The FRI was modelled from the ODI and therefore has been found to have a strong correlation with this measure. No outcome instrument is known to be significantly more advantageous than the ODI for low back pain (Feise and Menke, 2001). Both measures are equally effective in distinguishing between patients who have improved and those who have not (Childs and Piva, 2005). Due to the strong correction between the FRI, ODI and RM questionnaires, I believe that disability scores obtained in CLBP from these measures in clinical trials can be compared. A previous audit of the Back School at my Trust (IPL4060) and my previous pilot study (Daulat and Goodlad, 2014) had used the FRI as an outcome measure. In both instances the FRI was reliable and sensitive to change. In my opinion this strengthens the suitability of using the FRI as the primary outcome measure in this current study.

The BTFP used as the standard programme in **Stage 2** RCT has been evaluated previously. However, patients in these studies presented with moderate disability (Frost et al., 1995; Klaber Moffett and Frost, 2000; Hurley et al., 2015). The patients in the current study were categorized with severe disability (>41%). There may be a link between social deprivation and perception of disability in CLBP. Bath and Grona (2015) found in their sample of back pain patients that only 27% rated themselves with severe disability using the Oswestry Disability questionnaire. However, 82% were regarded as affluent with a household income greater than thirty thousand pounds. The perceived rating of disability was lower at baseline in the BTFP group but the differences were not significant. It is interesting that 80% of participants in the BTFP group were in full or part time work compared to 49% in the SRP group. This in part may support the link between lower income or social deprivation (not in full-time work and therefore lower annual income) and the perception of disability in CLBP. It has been suggested that the BTFP may only be suitable for mild to moderately disabled patients and those with more severe disability may benefit from intensive multidisciplinary pain programmes (Klaber Moffett and Frost, 2000). More participants in the SRP were categorised by the Start Back questionnaire as being in the high risk group than the BTFP (39% to 20%). This may account for the higher baseline disability scores in the SRP although there was no significant difference between the groups at baseline as mentioned. There was no significant difference in disability post treatment between the groups measured by the FRI in this study. Effect size was also small. The within group analysis revealed significantly lower FRI scores post-programme compared to pre-programme in both groups (paired t-test, t = -4.02, df = 27, ***p*= 0.0004**, SRP and paired t-test, t = -2.53, df = 25, ***p*= 0.02**, BTFP). A 10% absolute change in the FRI is estimated to represent a minimally clinically important

difference (MCID). This study found that 39.3% of participants in the SRP (n=11/28) compared to 34.6% (n=9/26) in the BTFP achieved the MCID for the FRI. There was no significant difference found between groups in the proportion of patients who achieved the MCID for the FRI. Hurley et al. (2015) compared a walking programme with the BTFP and usual physiotherapy. There was no significant difference found between groups but similar to the current study there were significant changes within groups in disability measured by the ODI. In contrast, the Frost et al. (1995) study comparing the BTFP with Back School found a significant difference in disability scores measured by the ODI between groups in favour of the BTFP. Change scores in the Hurley et al. (2015) study for the ODI were 6.9%, CI -3.6 to -10.2 achieved in the walking programme; 5.9%, CI -2.7 to -9.2 in the BTFP and 5.1%, CI -1.9 to -8.2 with usual physiotherapy. In comparison, change scores in the current study for disability measured by the FRI were 11.6%, CI -17.7 to -5.7 achieved in the SRP and 7.0%, CI -12.6 to -1.3 in the BTFP (within group analysis). The statistical analysis in this study found relatively wide confidence intervals in comparison to the Hurley et al. (2015) study for example. The confidence interval generates a lower and upper limit for the mean. The narrower the interval, the more precise is the estimate of the mean whereas larger intervals provide a less precise estimate. A small sample size and greater group variability measured by the standard deviation tend to generate wider confidence intervals (Poole, 2001). The reasons for the improvements to function seen in the SRP may be due to the individualised exercises and one-to-one input. This may have increased participants' adherence to exercise and improved their ability to self-manage their CLBP during the programme and long-term. Chronic low back remains a complex condition with many individual, psychosocial and work related factors playing a role in its development. There is evidence of complex aetiology. Dunn et al.

(2006) cited by Pransky et al. (2010) have identified different clusters of LBP each representing a different course of pain. These are persistent but mild, recovering, severe and chronic and fluctuating. Early prognostic screening and the sub-grouping of CLBP may assist to deliver the appropriate therapy more effectively. Attempts have been made to sub-group CLBP patients and identify those who are more likely to respond to specific treatments. An important component of managing CLBP is exercise therapy. In subjects aged 20 to 64 years, the prevalence of chronic pain was 10 to 12% lower for those exercising 1 to 3 times per week for at least thirty minutes, relative to those not exercising (Hurley et al., 2015). Exercise is more effective than no intervention but the effect size compared to other treatments remains small. Magalhães et al. (2015) compared a physiotherapy exercise programme consisting of stretches and core strengthening with a graded activity programme. They found no significant differences between the groups post treatment at six weeks. Mean change scores to disability measured by the RM questionnaire achieved clinical importance in both groups. A limitation with this study is that there was no long-term follow-up and participants had a moderate level of disability which may not be generalizable to the population of CLBP patients seen in NHS physiotherapy clinics. The authors concluded that in accordance with the current literature, no form of exercise is better than another for patients with CLBP. However, individually designed exercises with supervision (a component of the SRP) have shown larger treatment effects (Macedo et al., 2014). Exercise not only facilitates functional improvement despite on-going pain but also reduces fear avoidance behaviour. These benefits are generally maintained in the long-term (Manek and MacGregor, 2005).

6.9.4 Quality of Life

The EQ-5D-5L (EQ-5D) was used to measure quality of life. There was no significant difference between groups post programme in mean EQ-5D scores. However, the within group analysis revealed significantly higher EQ-5D scores post-programme compared to pre-programme in the SRP but not the BTFP (paired t-test, t = 2.49, df = 27, ***p*= 0.02**, SRP and paired t-test, t = 1.51, df = 25, ***p*= 0.14**, BTFP). The SRP demonstrated a mean difference of 0.08 (95% CI, 0.02 to 0.16) in the EQ-5D compared with 0.06 (95% CI, -0.02 to 0.13) in the BTFP. Interestingly, quality of life deteriorated in the BTFP group at 6 months but continued to improve in the SRP group. This was the only outcome measure which showed a moderate effect size (0.50) at six months. The EQ-5D has an EQ-VAS which is a measure of the patient's perceived health status, whereby the individual rates their own health that day on a scale of 0-100. The within group analysis found no significant improvement to the EQ-VAS score in either group post treatment. The MCID is also the smallest but important or meaningful difference in health related quality of life (Luo et al., 2010). For the UK EQ-5D index the mean MCID has been calculated as 0.082 (0.032 SD). A higher percentage of participants achieved an MCID for the EQ-5D in the SRP group (46.4%, n=13/28) compared with the BTFP group (38.5%, n=10/26). There was no significant difference between groups in the proportion of patients who achieved the MCID for the EQ-5D. The EQ-5D has been shown to have reduced ceiling effect and improved discriminatory power compared to the older version: EQ-5D-3L (Janssen et al., 2013). Tordrup and Mossman (2014) concluded in their review that the EQ-5D does not adequately reflect patient health status across a range of conditions. Fifteen percent of patients in this review were found to achieve perfect health at baseline (1) compared to just 2.5% in the current study. They suggested a significant proportion of

subjective patient experience is not accounted for by this index. Their review showed limited responsiveness of the EQ-5D to clinical improvement or deterioration. However, in this current study the EQ-5D showed good responsiveness to clinical change. Few studies previously had demonstrated significant mean changes between outcome groups (Tordrup et al., 2014). Kimman et al. (2009) investigated the responsiveness of the EQ-5D in breast cancer patients in their first year after treatment. Moderate to large improvements in health status was reported after one year. The index score at baseline was 0.71 and 0.83 at one year (a 0.13 difference). Obrudovic et al. (2013) investigated the validity and responsiveness of the EQ-5D in chronic pain. They pooled data from three RCTs with two active treatment groups. Patients in these studies suffered from OA knee and low back pain. The analysis included 1977 patients and showed a mean change of the EQ-5D of 0.15 (0.43 to 0.58). The EQ-5D baseline values found by Obrudovic et al. (2013) are similar to the baseline values found in the SRP (0.48). In the UK it has been found that more people live with MSK conditions including CLBP than any other condition which has a significant impact on quality of life (Daulat, 2015).

6.9.5 Pain

There was no significant difference between groups in mean pain scores post programme measured by the NPRS. The within group analysis revealed significantly lower NPRS scores post-programme compared to pre-programme in both groups (paired t-test, t = -2.16, df = 27, ***p*=0.04**, SRP and paired t-test, t = -2.59, df = 25, ***p*= 0.02**, BTFP). The SRP demonstrated a mean difference of -1.06 (95% CI, -2.08 to -0.05) in the NPRS compared with -0.72 (95% CI, -1.29 to -0.15) in the BTFP post treatment. The MCID of the NPRS is 2 points which was achieved by only 19% (n=10) of all patients who completed their treatment in the study. Ceran and Ozcan (2006) found that changes in disability were affected by changes in pain (using the VAS) and quality of life. In contrast, others have found no relationship between clinical pain intensity and disability in CLBP (Geisser et al., 2005). Unsgaard et al. (2010) compared low-load motor control exercises with high load sling exercises and general exercises in participants with CLBP. No exercise type was found to be superior to another. All exercise groups showed improvements to disability (ODI) and pain measured by the NPRS. However, the mean change scores in this study did not achieve a MCID for the NPRS. Pain is one of the primary reasons patients seek treatment but is a subjective and multidimensional phenomenon. The NPRS and the VAS are commonly used measures in clinical trials. The NPRS was used in this study because it was easy to administer and simple to score. However, the NPRS is a unidimensional measure which assesses only the perceived intensity of pain (Kahl and Cleland, 2010). The McGill Pain Questionnaire (MPQ) measures pain as a multidimensional variable. The MPQ provides a measure of the subjective pain experience across sensory, affective, and evaluative dimensions of pain. It is a highly reliable and valid measure of pain (Dworkin et al., 2009; Melzack, 1987). The revised

short-form MPQ (SF-MPQ) published by Melzack in 1987 attempted to provide a quick and more efficient measure of pain for clinical assessment and research purposes (Dworkin et al., 2009). The SF-MPQ has been used extensively in the literature since its publication and is reported to be a valid and reliable measure of pain quality and intensity. The SF-MPQ was used as an outcome measure in my pilot study comparing Pilates and total body strengthening exercises (Daulat and Goodlad, 2014). Although, clinically significant mean pain scores were found using this outcome measure, participants from both treatment groups had difficulty interpreting some words on the SF-MPQ requiring guidance completing. The SF-MPQ would not have been appropriate for use in group programmes due to its greater complexity. Providing patients with effective pain relief is an objective in CLBP management. However, achieving complete pain relief in CLBP patients may not be realistic. The participants in the current study on average had suffered from LBP for many years. The focus group interviews (see later) had identified that patients had accepted that their LBP was an on-going thing and perhaps complete pain relief was not possible for them.

6.9.6 Patient Satisfaction

Patient satisfaction was recorded using the Participant Satisfaction Reporting Scale (PSRS). Although, there were slightly higher mean satisfaction scores in the SRP (SRP: 20/25; BTFP: 19/25), there were no significant differences between groups in patient satisfaction with the treatment they received. Very few participants added comments in the space provided by the PSRS questionnaire but those who did praised the group programmes. The small sample in the focus group interviews also gave favourable comments regarding both group programmes. It has been well recognized that patient satisfaction with treatment might not correlate well with the other validated outcome measures for disability or quality of life (Underwood et al., 2006). Client satisfaction is a multidimensional construct and may not be adequately reflected by the PSRS. The factors most frequently reported to contributing to satisfaction include the duration of consultation and access to the therapist as well as treatment outcomes. Participants are also more satisfied when a good explanation of the condition is provided. This enables them to develop self-management strategies. Participants may be dissatisfied when adequate knowledge of their condition is lacking (Hills and Kitchen, 2007). It has been found previously that clients who are dissatisfied change health provider (Knight et al., 2010). There was a drop-out rate of 17% (those who had received treatment) in this current study but it is not known whether these participants were dissatisfied with the treatment they received and hence sought alternative treatment. Satisfaction is usually linked with participation and it is assumed that those completing the programmes would have been reasonably satisfied. There may be a link between satisfaction and expectation. McCarthy et al. (2005) found that clients with LBP were more satisfied when their expectations of treatment were met. Hills and Kitchen (2007) found those with lower expectations of

treatment reported higher satisfaction with therapy, although this was reported as a weak relationship. However, they found that chronic pain patients expected symptomatic improvement but were dubious of the outcome or had unrealistically high expectations. The usefulness of measuring satisfaction using the PSRS in this study is questionable as participants may have had unrealistic expectations of the group programmes which they perceived not to have been met.

6.10 Supplementary Qualitative Phase: Focus Groups

Research into the experiences of patients who have participated in group exercise programmes may be important to understanding their motivation, engagement and participation (Slade et al., 2009a). It was not possible to hold more than two focus groups but the size of each group in this study would be considered as being the optimal (between 5 and 10 participants). Focus groups are used to evaluate services or programmes but also seek opinions, values and beliefs. This has been an appropriate method of data collection to inform the larger quantitative study and theoretical claims. Focus groups have small sample sizes and the ability to generalise beyond the study sample may be limited. However, in this small scale study the focus group sample size comprised 20% (n=16) of those who had been recruited to the quantitative study (n=81) and 30% of those who had completed their treatment in the two groups. Both focus groups were well balanced with an equal number of male and female participants as well as an equal representation from the two group exercise programmes. The average age of those attending the focus group interviews was 56 years compared with 45 years completing treatment in the RCT. This is in contrast to Sokunbi et al. (2010) whose mean age of focus group participants was not markedly different from that of the RCT participants. It is not known why there was an age difference between participants in the RCT and focus groups. The focus groups in this study found the individuals involved were valuable sources of information and they were able to express their own feelings and behaviours. The recruitment of participants to the focus groups was achieved by invitation. There is a degree of self-selection occurring as the participant must volunteer to take part. This creates a potential for bias within the study as those who volunteer to participate may have some loyalty to the study or a great dissatisfaction of the treatment they received

(Halcomb et al., 2007). The subjectivity of the researcher's interpretation of the transcribed data may be a limitation of focus group interviews (Liddle et al., 2007).

6.10.1 Focus Group Topics and Themes

The next section discusses the general topics and themes from the transcript analysis of both focus groups. I have included direct participant quotes from the recordings in italics with the group programme they attended in brackets.

6.10.2 *Topic 1*: Experience of Group Programmes

Topic 1 related to the participants' general experiences of the group programmes they attended. Both focus groups concluded that their experience of both group programmes was a positive one.

"I really enjoyed it. Found it very helpful-sessions very positive". (BTFP)

The programmes provided group support and a social element. Patients were able to chat with other CLBP patients and obtain further information. This was beneficial as they realized they were not the only people suffering from back pain.

"It was good to be with other people that have back problems as I felt alone for years as everybody is bored stiff of back problems". (SRP)

"Good to know someone has the same problem as you. You are not the only one". (SRP)

Participants in the SRP found the individual exercises very helpful particularly correction if they were doing the exercises wrong. Hayden et al. (2005) concluded that the most effective exercise strategy for the treatment of back pain seems to be individualised programmes which are regularly supervised and have a specific exercise component. Cecchi et al. (2014) used a prospective cohort study to investigate the effect of an individually designed exercise programme for managing CLBP. The individualised programme was designed on the basis of the physiotherapy

assessment and consisted of adapted personalized exercises. They concluded that the individually designed exercise programme was associated with a clinically significant functional improvement both on discharge and at a year follow-up. Liddle et al. (2007) found in their study using focus groups to explore CLBP patient's experience of their clinical management found that individually specific exercises and advice regarding suitable lifestyle adaptations were important to them. Kolt and McEvoy (2003) found that supervised individualised exercise and self-management techniques have demonstrated a positive effect on exercise adherence. There was a consensus that one had to be motivated to benefit from the programme and individual exercises.

"Our particular group all had individual exercises. A good physio and rehab assistant they come round, it is individually catered and they are quite particular. As long as you are interested, they will tell you how to do things which is really good, and the idea is to go back and do them on a regular basis". (SRP)

"I found some of it beneficial to me but I am self-motivated". (SRP)

In contrast to individual exercises, the circuit training had more structure to it and a good warm-up. This provided exercise variation and competition to do better on the next session. The circuits were found to be more of a gym work-out to strengthen the muscles rather than stretching exercises. The circuit exercises in the BTFP have been developed over a long time and do target all the major muscles of the body. This circuit-based exercise programme provides strengthening, stretching and cardiovascular exercises.

"Circuit training good because you had a different exercise on each circuit. Variation useful but others (patients) seem to start at a certain point and get the hard/difficult ones out of the way. After the first session you knew what was to be expected".

"Expected stretching exercises, but not exercises that build up the muscles for the back".

However, these circuit exercises may not be suitable for all and can be difficult doing at home particularly as a gym ball is required.

"My problem with the circuit training as I tend to overdo it. I get very competitive with myself and I had to do better than the previous week".

"*Circuit exercises weren't adequate, individuality better".*

Some did not have access to a gym ball which also had storage issues at home. This may affect long-term adherence to exercise and may be a limitation with circuit-based exercises for managing CLBP.

"Only able to some of the circuit exercises at home".

The first impression of the SRP was not a positive one. The programme seemed to be initially disorganised and chaotic but did improve with subsequent sessions.

*"First impression of the **SRP** was negative in that it appeared at first disorganised. Patients were told to do the exercises at home but it seemed some had not and were not actively taking part and doing their own thing".*

"I found the first session not very good to be honest, but subsequent sessions have been very good". (SRP)

This negative first impression may have contributed to the drop-rates but the drop-rates in both groups receiving treatment were similar although slightly higher in the SRP group (18% post-treatment attrition in the SRP and 16% in the BTFP). It is possible the patients were expecting a more structured programme in the SRP and patients doing their own exercises may be perceived as disorganised. This improved with further attendances as patients understood the principles of the programme. Moving forward a better induction of new patients to this programme on their first visit would be recommended (see recommendations).

Participants reported that as the programmes (including the BTFP for the purposes of the study) are not consecutive this makes it more flexible particularly if you can't make it one week.

"I have been on this programme a while and you can book whenever you want. You can ring up and they are quite flexible about making arrangements".

The BTFP was designed to be run over 6-8 consecutive weeks and is therefore not flexible particularly if patients are ill or unable to attend one week. Previous studies evaluating the BTFP have shown that only between 59% and 76% of the available sessions were attended (Ferreira et al., 2007; Hurley et al., 2015). The current study found that 5.2/6 sessions of the BTFP (86%) compared to 5.4/6 (90%) of the SRP were attended which was probably due to the flexible booking system employed.

6.10.3 *Topic 2*: How have the Programmes helped with your Back Pain?

Topic 2 related to how the programmes had helped with participants' back pain. Participants reported that both programmes helped reduce back pain but the improvements described in the SRP were greater. This may correlate with the findings in the quantitative phase of the study (within group analysis) which found a significant difference to quality of life post-programme in the SRP but not in the BTFP. However, it is possible that the reported outcome improvements including function in the SRP may not have occurred entirely as a result of the programme but might be due to other factors. Underwood et al. (2006) found a substantial difference in the reported experience of participants in the treatment groups but this was not reflected in the effect size observed in their quantitative analysis. Effect size in physiotherapy interventions are generally small-to-moderate but don't take into account the positive experiences of participants. Some of these positive experiences are highlighted below.

"I came to you and you gave me some exercises (specific) and the pain has gone". (SRP)

"it is amazing that since I finished the course. Have helped with the symptoms- and I have had only one spell of back pain (in 6/12). Generally speaking, I am far more mobile now with these exercises and sometimes forget that I have a problem". (SRP)

"I still have back pain. The pain is not as severe but I still got it". (BTFP)

These results in this study are also supported by Sokunbi et al. (2010) who found that participants were generally satisfied with the benefits of a spinal stabilisation exercise programme on pain and level of function.

Participants expected quicker results from the exercise programme but realised that this was unrealistic considering the length of time they had been suffering from CLBP.

"We were all expecting to be cured straight away but it does not work that way".

"Did help with back pain but quicker results expected".

Those who attended the BTFP felt that the education they received had helped reduced health anxieties and provide information on self-management of their CLBP.

"Being told this is the natural course and not to worry about it- makes people more relaxed and a lot easier".

"education mentioned about the back, how to manage back pain and flare-ups".

"Explanation on flare-ups was helpful and made feel more relaxed".

This may support the benefits of group education in the management of CLBP (see later).

6.10.4 ***Topic 3*: Expectations**

Topic 3 relates to participant expectations before attending the group programmes. Generally, there were no specific expectations as participants had suffered from CLBP for a long time and were open minded. Participants did expect that by attending the programme this would improve their spinal mobility, reduce pain and that they would be able to manage it better. Others realised they needed something to help manage their CLBP.

"I am not sure what expectations I had but I knew I needed something remedial".

The exercises in the BTFP were better than expected.

"Did not realise that it would be that kind of exercise. Expected stretching exercises, but not exercises that build up the muscles for the back".

And for some the programme met their expectations.

"Yes, programme met my expectations".

6.10.5 ***Topic 4*: Education**

This topic related to the education given to participants in the two groups with the aim to determine whether group education or one-to-one education would be preferred. Group education was found to be useful for managing back pain. Particularly useful was education on manual handling, correct lifting technique, the structure of the back (spine model), ergonomics and how to manage flare-ups.

"Found the group education useful on how to manage back pain and structure of the back (spine model) also useful. How to pick up things from the floor and how to move around i.e. advice on correct lifting technique".

"well structured, information on theory and ergonomic advice".

"education mentioned about the back, how to manage back pain and flare-ups".

There is moderate to strong evidence that education can improve pain and function in CLBP patients (Liddle et al., 2007). Slade et al. (2009b) found the provision of education and information to be important. CLBP patients have a strong motivation to understand and explain their situation and to be given education material and resources but these should be free from jargon. Durmus et al. (2014) found that the addition of Back School education including functional anatomy and lifting techniques to a multimodal exercise programme had better outcomes than providing exercise alone. They proposed that the Back School education had assisted patients developing coping strategies and managing their fear avoidance behaviour. However, as mentioned in the literature (**Chapter 2**) there is no convincing evidence of the effectiveness of Back Schools for managing disability and fear avoidance in CLBP (Heymans et al., 2011). The type of information provided in the BTFP and Back Schools are based on a medical or structural pathology model which many not target psychological change (Moseley et al., 2004). Some researchers have proposed that education about pain neurophysiology should be included in the wider pain

management approach. Pain neurophysiology education (PNE) uses the explanation of pain neurophysiology with a focus on the role of the central nervous system to change maladaptive pain cognitions, illness perceptions and coping strategies (Pires et al., 2015). There is insufficient evidence that PNE is superior to other types of education and may only have small effects on functional disability (Clarke et al., 2011; Moseley et al., 2004). It has been suggested that many education-based interventions for CLBP place an emphasis on knowledge about a wide variety of topics rather than focusing in areas important to patients for managing their condition (Sokunbi et al., 2010). It did seem that the education provided to patients in the standard programme was applicable to them.

A sub-theme of the education provided was the emphasis on self-management in the long-term and continuing with the exercises which will take time. Cooper et al. (2009) found that exercises were reportedly the most common self-management strategy in use for CLBP.

"emphasise that once the session is over, you must carry-on the exercises".

"Got to tell them to carry-on with the exercises and that will help and explain that it will take time and that it is not a short fix course".

"Managing back pain is an on-going process".

Participants found that the one-to-one sessions in the SRP for advice/education were very good and catered for individual requirements.

"One-to-one was very good as I was able to ask questions, speaking with someone was absolutely great".

"Physios were wonderful and I was getting individual attention".

"I think it should be individual to cater for your what your fears and expectations are".

"One to one was brilliant. That one to one advice just for that tailor made thing".

"Physio (one-to-one) really catered to my views regarding the MRI scan and medication".

One of the hypotheses of the study was individual education is more beneficial than education delivered to a group as this method caters for the individual needs of the patient. I suggested that some components of the group education would not be of interest to all patients. However, participants in the focus groups suggested that both group and individual education should be provided.

"Works good as a group as well as individually because everyone has a different thing".

"Both group and individually as everybody's backs are different. It is good to have input to wherever you can get it".

"I think both". (i.e. both individual and group education should be provided).

Including a group education component to the alternative group exercise programme may further improve patients' ability to self-manage their CLBP in the long-term. There is strong evidence that exercise therapy and patient advice/education are most effective for CLBP when prescribed together (Liddle et al., 2007).

6.10.6 *Topic 5:* Barriers

This topic related to participating in the group programmes and regular exercise afterwards. Critchley et al. (2007) suggested group treatments are not suitable for all CLBP patients either due to those presenting with multiple or complex problems, language difficulties and inflexible class times. These three themes were found in the current focus group interviews. Having other MSK problems such as joint arthritis was regarded as a potential barrier as this may affect exercise participation. This may be addressed by targeting. By producing more stringent exclusion criteria such as excluding those patient presenting with multiple joint pain or other co-morbidities would make changes to the target population that the intervention is designed for i.e. CLBP rather than modifying the intervention itself. A linguistic barrier was also discussed as it was mentioned that some patients' English was not that good and had trouble understanding how to do the exercises properly. There was the facility to book interpreters for patients in both exercise groups. However, this may not have been widely utilised as only two patients in the study had interpreters booked for them. The group programmes were held in the afternoon which was mentioned as inflexible for some, particularly getting time off work. In my experience, a suitable time for all to attend these group programmes is never going to be achieved in clinical practice. The fact that the alternative group programme is not run on consecutive weeks may make it more flexible for others. Many patients found parking an issue which was identified as a barrier to participation. One participant quoted in the comments box provided in the PSRS *"I stopped coming because of traffic and parking problem".* The group programmes were conducted at a hospital site which traditionally has parking issues. Conducting the programmes at an alternative community setting may address this issue but may be less accessible to those who don't have access to a car.

There were three themes regarding barriers to continuing with exercises after the programme. One was illness which would prevent exercise participation but this would only be a temporary barrier. A lack of follow-up and guidance to carry-on self-managing or continuing with exercise was a perceived barrier. The final barrier to exercise was expense and being able to afford outside classes etc. The programmes encourage home exercise but this may be difficult for some. One participant commented on the PSRS that home exercise is difficult because of two very small children around. Slade et al. (2014) suggested exercise adherence was affected by a lack of time and the ability to fit into daily life. Sokunbi et al. (2010) found in their focus group interviews that few participants had continued with their exercises post programme. Reasons given for non-adherence were unsuitable home environment, lack of supervision and the inability to adapt to daily routines.

6.10.7 *Topic 6*: Suggestions to Improve Group Programmes

This topic related to what else we can do to improve the management of chronic low back pain. Participants felt that exercise progressions and follow-up sessions were lacking. Cooper et al. (2009) conducted semi-structured interviews on patients with CLBP to explore their perception of physiotherapy management. Participants in this study also reported the need for follow-up to support self-management of their CLBP i.e. future access to physiotherapy. They suggested that follow-up would provide motivation and reassurance. This could take the form of return visits, telephone calls or e-mails suggested by participants in the current study. Liddle et al. (2007) found that exercises were the predominant self-management strategy used by CLBP patients. Individually tailored made advice from the physiotherapist may enhance self-management. Cooper et al. (2009) found that management strategies in use by the participants with CLBP were mostly self-taught. Physiotherapists provided their sample with one skill (exercises) and any other strategies seemed to be lacking.

"The pain is not as severe but I still got it. For me, the whole point of it being chronic, is that it is going to be there- based on how you understand and manage the pain. Issue is how you understand pain. How you change your triggers and transmissions in the body. Is it really the pain or something else going on? Accepting the pain is going to be there and how you learn to manage".

The above quote from a participant in the focus groups implies how the patient has developed their own strategies for learning how to understand, accept and manage their pain. These strategies may have been self-taught rather than skills provided in the group programmes.

The absence of follow-up may affect long-term adherence to exercise. Sokunbi et al. (2010) found that only a minority of participants demonstrated sustained effort to continue with their exercises once the programme had finished.

"6 sessions available plus perhaps more, particularly as patients not doing their exercises at home". (SRP)

"An incentive or follow-up is required for chronic low back pain". (BTFP)

"once the course has finished, that is it. That's it finished and no kind of follow-on. Anything around the area where they can try and help, another place where they could try and do their exercises somewhere or speak to somebody". (BFTP)

Due to NHS resources it is not generally possible to provide patients with a further six sessions. Exercise referral schemes have been used in the past, whereby patients are referred by their physiotherapists to a gym to continue with a supervised exercise programme. However, the same problem arises once this programme has finished as the evidence is lacking that patients maintain their exercises or activity levels in the long-term (Daulat, 2015). It was suggested that a drop-in centre be provided for advice and resources provided such as suitable websites on back pain management. The Arthritis research UK Back pain booklet was provided to each participant but it may be a good idea for physiotherapists to provide details of where additional information regarding CLBP can be found on the Internet. However, these Internet sites must be endorsed by the CSP or other professional healthcare bodies. In other NHS Trusts patients can go to additional hydrotherapy classes for a small fee held at the physiotherapy department once they have completed their 6 pool sessions. This could possibly be offered for CLBP patients to attend further group exercise sessions and provide advice as needed.

6.10.8 ***Mixed Methods Research***

The use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone. The paradigmatic world-view of research and the fact that quantitative and qualitative methods are based on different paradigms has been mentioned in **Chapter 3**. A pragmatic approach had been adopted in this study regardless of the philosophy. The method to achieve the best evidence has been used in this current study. Conducting the quantitative study first can provide options for enhancing the validity and reliability of qualitative findings as well as for exploring contradictory results found between the quantitative and qualitative data (Hesse-Biber, 2010). Qualitative designs are now regarded as of increasing importance in order to recognize patient perspectives and explore their experiences of health interventions (Richards and Hallberg, 2015). For example, attendance to both group programmes was described as a positive experience and met their expectations for managing CLBP. The supplementary qualitative method may build on what the core component provided and explain specific patterns in the quantitative data (Morgan, 2014). For example, in my study determine why the participants in the SRP might have had better outcomes than the BTFP group. The quantitative strand in this study had priority but the qualitative component provided an in-depth knowledge and understanding to explain these quantitative findings. The qualitative analysis aimed to confirm or contradict the quantitative data. Integrating the data from the RCT and focus groups in this current study had not helped to support the hypothesis or confirm the findings from the other method used. The hypothesis stated that the SRP is more effective than the BTFP for managing CLBP. Findings from the RCT suggested that statistically the SRP was not more effective than the BTFP for improving function and quality of life. Although in

the focus groups, participants attending the SRP found it more beneficial for managing their back pain. Individualised exercises and one-to-one attention provided within the SRP were described as being brilliant plus tailor made and increased motivation to self-manage participants' back pain. This may help explain that these components of the SRP were involved in the functional outcomes of this intervention and may provide a link between this programme and its effects. The circuit training or general exercise provided by the BTFP was described as providing a good gym work-out to strengthen the body but was more difficult to continue at home. Hence, the SRP may have provided more suitable exercises to continue with in the long-term to sustain any benefits achieved during and after the group programme as well as promote self-management. This hypothesis may be further strengthened by the fact that quality of life deteriorated in the BTFP group at six months. Although, there is moderate to strong evidence that education can improve pain and function in CLBP patients, this did not seem to apply to the BTFP. The group education was useful to participations but did not result in greater outcomes post programme compared to the SRP. However, there is no evidence to suggest that one-to-one input/education was more beneficial than group education. Participants indicated that group programmes should have both. The aim of any evaluation is to establish causality i.e. the link between the intervention and its effect. The mixed methods design may have provided a link between the individualized exercises and one-to-one attention which were components of the SRP and the outcomes achieved.

It was important for me to reflect on my own preconceptions and theories about the experimental intervention, in order to maintain reflexivity. I was careful in the data analysis to accurately represent the respondent's views in the focus groups and not my

own viewpoint or bias. I have an underlying positivistic view that there is an objective reality in which a given truth can be validated. I may be more comfortable using quantitative methods to test out hypotheses and make generalisations about this reality. However, during this research process I have learnt that in the qualitative approach subjective meaning is a critical component of knowledge building. I have developed the ability to recognise the importance of the subjective human creation of knowledge but at the same time not rejecting the notion of objectivity. In summary, the mixed methods approach used in this study provided a more comprehensive picture of the interventions but did not provide a correlation between quantitative findings and patient experiences. Both methods used together aimed to enhance the credibility of the research findings.

6.11 Implementation, Change and Leadership

Overall, very few primary studies demonstrate the superiority of one treatment over another (Pawson, 2013). Evidence-based practices are interventions for which there is consistent scientific evidence showing that they improve patient outcomes (Torrey et al., 2014). My thesis used a mixed methods design including qualitative strategies to inform the development and evaluation of an alternative group exercise programme. This attempted to identify any underlying mechanisms influencing outcomes. The intervention can only work as intended if the programme providers and participants go along with the programme theory and choose to use the resources as intended. The RCT provided the opportunity for non-English speaking participants to attend through the use of interpreters but only two participants for whom English was not their first language took part in the study. The programmes in the study offered up to 6 sessions but not all participants utilised all their allotted sessions. The SRP also offered the option of participants to receive manual therapy as part of their treatment but only 11% had "hands on treatment". This study has not provided sufficient evidence that the SRP may be an effective alternative for managing CLBP in a group setting. However, most effectiveness trials involve larger samples of 300-600 people (Zullig and Bosworth, 2015). Evaluation research had been described as a sequential multi-phase process. Sidani (2015) describes a five phase process of evaluating interventions. Phases 1 and 2 were conducted in this thesis. Phase 1 was the development of the intervention (SRP) to address the limitations of current group exercise programmes for managing CLBP. Phase 2 was the small scale implementation of the SRP and its evaluation. Phase 3 involves a larger RCT which aims to determine the efficacy of the intervention and demonstration of causal effects. Phase 4 determines the effectiveness of the intervention in day-to-day practice and

phase 5 involves the translation of the intervention into clinical practice. Thus, further multicentre trials with larger sample sizes may be required to evaluate the SRP before it is implemented widely into clinical practice. This may determine if the intervention can be used effectively in uncontrolled settings. Further evaluation studies can determine whether the intervention is sustainable in normal practice and can others reliably replicate this intervention plus maintain successful outcomes over the long-term (Sidani, 2015). Implementation fidelity is the extent to which an intervention is delivered as intended particularly in a clinical trial (Toomey et al., 2015). It is important that the outcomes found in this study are due to the effect of the intervention itself and not to variability in implementation. Complex interventions have been defined by the Medical Research Council (MRC) as interventions with several interacting components. All of these components have the potential to affect or influence outcomes separately which may make fidelity within a complex intervention more difficult to address (Craig et al., 2008). The SRP may be regarded as a complex group exercise intervention as it contains three major components; individualised exercise, one-to-one education and manual therapy. All of which could influence patient outcomes. In a review by Toomey et al. (2015) levels of implementation fidelity in self-management interventions for CLBP including an exercise and education component have been low. The five fidelity domains used in this review were: study design, training of providers, delivery of intervention, receipt of treatment and treatment enactment (monitoring how participants were applying their skills to daily life). Toomey et al. (2015) found that the most poorly reported aspect of fidelity was training of providers. This may not be applicable to the current study as all programme therapists were trained to deliver each group programme with one-to-one sessions including observation by the researcher of the session. All

programme therapists in this study were senior physiotherapists with extensive training in exercise and manual therapy.

Health service managers who commission and implement policy at a microlevel (my direct line-manager) are limited in their ability to use research evidence and perform appropriate evaluation. Research evidence has been reported to be just one influence among a range of factors that are considered in commissioning and implementing local policy. The decision to implement an intervention at a local level depends on its effectiveness and cost-effectiveness. Government policy and initiatives are among the greatest influences. Targets frame the commissioning context and can drive decisions at all levels (Evans et al., 2013). It may be difficult to translate evaluation results of this alternative programme particularly during political change. The re-design of the service during the thesis had affected the evaluation process itself. However, commissioners and service providers have a commitment to ensure patients with CLBP receive evidence-based treatments. Local change management resulting in the implementation of alternative group programme was also a product of this thesis. Local change management relates to not only the implementation of the alternative programme but also to the change of clinical practice pertaining to CLBP management in a group setting.

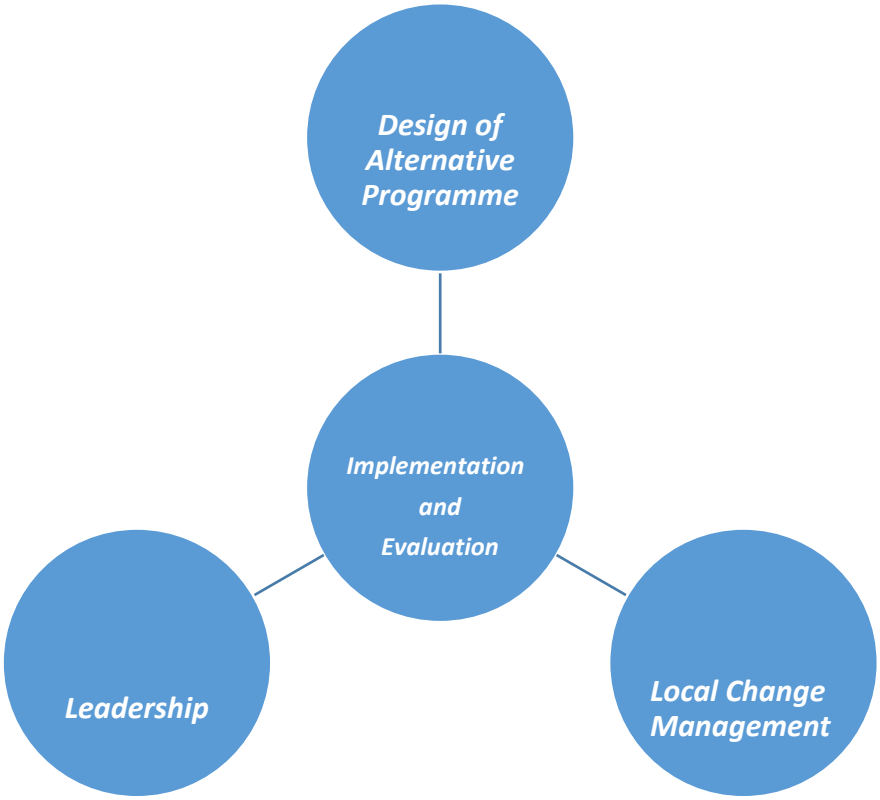

Figure 6.1: Alternative Group Programme Implementation Model

Figure 6.1 shows the implementation model of the alternative programme which resulted from a combination of my leadership and local change management initiatives.

One of the objectives of this thesis was to develop as a clinical leader by facilitating evidenced-based practice, innovation and influencing change leading to an improvement in the management of CLBP at a local level. The overall success of this project and the publication of my research suggested I had achieved this objective of developing into a clinical leader. The literature in **Chapter 2** highlighted the two distinct types of leadership style relevant to this thesis: Transactional and Transformational. Transactional leadership is based more on exchanges between the leader and the follower in which followers are rewarded for meeting specific goals or

performance criteria. This type of leadership is more practical in nature as has emphasis on targets or objectives but focuses more on extrinsic motivation for performance of job tasks. Transformative leaders inspire and motivate followers and may work better in closer supervisory relationships. This is similar to the researcher and programme therapist relationship in **stage 2** of this study. A transformational leader style creates a vision and inspires the acceptance of innovation through the development of enthusiasm, trust and openness. A leader may exhibit varying degrees of both transformational and transactional. A combination of both may enhance effective leadership and the best leaders tend to exhibit both leadership traits (Aarons, 2006; Bass, 1999). Leadership effectiveness depends upon the extent to which people follow and give legitimacy termed as internal validation. As well as the extent to which the organisation succeeds or survives termed external validation (Storey and Barbuto, 2011). My own leadership style was predominantly transformational. I inspired physiotherapists to adopt my goals and methods of practice in the management of CLBP. I challenged the standard way of conducting group exercise programmes. My leadership had influenced the adoption of an alternative innovation which was evidence-based. My leadership skills had shown the ability to engage with others, to provide a compelling voice and a strong set of values as well as an adaptive capacity. My objective of this thesis was to turn knowledge into action by bridging the gap between knowledge created regarding the alternative intervention and its implementation into a healthcare system. The alternative programme implementation model in **figure 6.1** highlights the contribution of my leadership in the implementation process. This new knowledge regarding the alternative programme is likely to change how physiotherapists manage CLBP in a group setting. However, a leader can become totally invested in their own vision. Their own perspective can

become limited and may lead to visions that are not effective for the organisation or that lag behind. Isolated leader visions often focus on personal aims (completing a doctorate) when a leader spends their time, energy and resources trying to get them off the ground. In this case the vision is owned by the leader and not the organisation. Organisational visions must emerge in part from the organisation itself through collaboration and input from organisational stakeholders at a number of levels (Aarons and Sommerfield, 2012). The alternative group programme was designed and implemented in collaboration with the manager as well as the therapists. Further development of the programme will be initiated from patient feedback in the focus groups. Hence, this demonstrates an organisational collaboration of a vision from idea to implementation. I had demonstrated some transactional leadership or managerial skills by focusing on procedures of the study recruitment, monitoring the group programmes, and setting tasks for the programme therapists to record and input outcome measures. However, unlike a transactional leadership style there are no rewards for the follower based on their performance (Farrell, 2000). Likewise, there was no disciplinary action if followers decided not to take part in the study or record outcomes. I am a researcher and clinician but have no official managerial role within my NHS organisation. Leadership is not restricted to higher levels of management. Distributed leadership across teams and networks is required for organisational change. However, I had to have a firm grasp on leadership culture within my organisation (how leadership works around here) in order to conduct and complete my research. Within an organisation there are official and informal systems of leadership. The official system relates to the ethos, power distribution and the effect of hierarchy on leadership. The shadow side or informal may include unwritten rules, politics and friendships. The official or informal systems can both have positive or negative

effects on the individual (Tate, 2010). For example, I needed to challenge the local system on how back pain was being managed and for the organisation at an official level to agree for me to proceed with my study. My role as an Extended Scope Practitioner (ESP) is to provide clinical leadership and act as a source of expertise in the management of MSK conditions. My influence as a respected clinician within the department allowed me to drive the project forward. Thus, these leadership systems (official and informal) combined may be more powerful than any individual's skill, behaviour or personality. As mentioned in the literature (**Chapter 2**), this suggests that a more systemic model of leadership is required beyond the individual and looks at improving the system rather than individuals. In summary, it was a testimony of my clinical leadership skills developed during this thesis that with limited resources and the current political climate in the NHS, I was able to drive the implementation of this alternate group programme into clinical practice and evaluate it. This was particularly difficult having the dual pressures of conducting a major study as well as continuing a full clinical caseload in a busy NHS musculoskeletal outpatient department with waiting list pressures.

6.12 Limitations of Study- Stage 2

Limitations refer to limiting conditions or restrictive weaknesses which are unavoidably present in the study's design (Punch, 2006). There may have been intervening factors between the pre and post-test measures that did not form part of the treatment which can affect the results leading to a type I error (Hicks, 2009). For example, subjects may have been participating in extra physical activities or exercise which may have influenced improvements seen in the study. A stringent exclusion criterion was used in this study to help eliminate any of these factors such as participation in previous exercise programmes which could have affected outcome.

There was an overall dropout rate of 33% which together with the small numbers of subjects used in the study and short follow-up time may have resulted in type II errors. The small sample size was due to recruiting difficulties described previously which was one of the weaknesses of this study. There was a lack of a long-term follow-up (>6/12) and is not known whether the subjects in the study sustained the improvements made or had any recurrences of their symptoms at one year. It was decided not to follow-up at one year as there had been only a 41% response rate at 6 months and this would likely have decreased further. A sample size calculation was performed (see **Chapter 3**) although this was a small RCT for a back pain intervention. This calculation was based on a predicted mean difference of 10% between the treatment groups when only a 4.0% adjusted mean difference was found (between group analysis). However, based on other similar studies it may have been unrealistic to expect much greater differences between the two groups. The low recruitment and poor attendance may have resulted in a reduction of statistical power to estimate the difference between the two group programmes. No cost analysis

evaluation was performed in this study. Cost analysis is usually performed in Phase 5 of the intervention evaluation process (Sidani, 2015). There was no extra cost running the SRP. Similar to the BTFP, a physiotherapist and assistant physiotherapist were required to run the programme. Both programmes were able to accommodate non-English speaking patients with the aid of interpreters. Only one interpreter in each treatment group was booked in this study. No additional equipment or capacity was required. Therefore, the cost to run the SRP would be comparable to the BTFP. A full economic evaluation would be required for a larger multicentre trial.

Both groups in the quantitative study had six one hour sessions over a three-month period. The objective as far as possible was to ensure all participants received the same amount of treatment so as not to influence the results i.e. dose-response relationship. All participants were instructed not to participate in any other form of exercise therapy during the study. However, their weekly quota of physical activity such as walking or house chores was not recorded. The average number of sessions attended by participants was similar in both groups (5.4 and 5.2 in the SRP and BTFP respectively). The SRP had a manual therapy option whereas the BTFP did not. Only 11% (n= 3/28) of participants received manual therapy and this additional treatment is unlikely to have greatly influenced the overall outcomes. It was not possible to quantity the individual one-to-one advice or input participants received in the experimental group (SRP). Also, participants in the standard group reported that they were not able to do all their exercises at home. These two factors may have contributed to the outcomes in the SRP and is a limitation with this study. Toomey et al. (2015) concluded in their systematic review that there is a lack of assessment of self-management behaviours in interventions for CLBP and it is not usually

determined whether self-management of their condition actually happened after the intervention. The group exercise programmes including education used in this study were essentially physiotherapist-led self-management programmes for people with CLBP. An assessment of self-management behaviour, skills and knowledge was not part of this mixed method study. However, participants in the focus groups reported that they understood CLBP was an on-going thing and would need to be constantly addressed which may have indicated self-management behaviours had occurred after the intervention. It is also not known whether any other factors post programme such as further treatment/advice influenced the outcomes at six months.

The limitations of the focus group interviews have been mentioned elsewhere. These include the difficulty of generalising from qualitative research, self-selection of participants and the interviews being conducted by the researcher. The experiences or views of a small group can never represent the 'truth' and it is not possible to generalise to the wider population of CLBP patients. Further research including focus groups is required to confirm my current findings. To what extent are the perceptions reported in the current study present in other sub-groups of CLBP patients may need to be determined. Participants were invited to take part in the focus groups and therefore not randomly selected. This self-selection of participants is a possible limitation as the views of other particular individuals particularly those who dropped out were not recorded. The fact that the researcher was taking the interviews may have potentially affected the outcome. However, this did not prevent negative viewpoints about the group programmes being disclosed. The participants in this study presented a wide range of views some of which have been recorded in other studies. It was decided to conduct the focus groups once participant recruitment had

been completed and participants had completed their group programmes. A six-month follow-up had not been completed for some of the focus group participants. This may have affected the quantitative assessment as the focus group itself could have been a co-intervention. I made a decision to conduct the focus groups at this time to ensure good attendance rates. It has been suggested that mixed methods research should be performed by quantitative and qualitative researchers in collaboration as well as the researchers being competent in doing these studies (Mengshoel, 2012). Although, I am a novice researcher, I have previous experience of quantitative research in my published pilot study and used focus groups in the development of the physiotherapy questionnaire used in **Stage 1**.

Finally, it may have been useful to explore the experiences by interview of those therapists running the group programmes. This may have added more information about the programmes and assisted with the evaluation. This was not possible in the current study due to a number of reasons. These included service requirements and one of the programme therapists had left the Trust.

6.13 Conclusion of Stage 2

There were no statistically significant differences between groups in outcome scores and apart from the EQ-5D at six months, the associated effect sizes were small. The within group analysis revealed significantly lower FRI scores post-programme compared to pre-programme in both groups (paired t-test, t = -4.02, df = 27, ***p*= 0.0004**, SRP and paired t-test, t = -2.53, df = 25, ***p*= 0.02**, BTFP). In contrast this analysis revealed significantly higher EQ-5D scores post-programme compared to pre-programme in the alternative group exercise programme but not the standard programme (paired t-test, t = 2.49, df = 27, ***p*= 0.02**, SRP and paired t-test, t = 1.51, df = 25, ***p*= 0.14**, BTFP). Quality of life deteriorated in the BTFP at 6-months. The within group analysis also revealed significantly lower pain scores post-programme compared to pre-programme in both groups (paired t-test, t = -2.16, df = 27, ***p*=0.04**, SRP and paired t-test, t = -2.59, df = 25, ***p*= 0.02**, BTFP). The relatively large confidence intervals found in the statistical analysis provided a less precise estimate of the outcome means. This was due to the study's small sample size and group variability. Participants in the focus groups had indicated that the individualised exercises and one-to-one input within the SRP had been useful to them as well as significantly reducing their pain. Participants in both programmes indicated that group education as well as individual input combined would be preferred. The Null Hypothesis stated that the alternative group physiotherapy programme is not more effective than a standard group programme in the management of non-specific CLBP for improving function and quality of life. Based on the statistical results of this small scale preliminary study the null hypothesis was accepted. There is a lack of statistical evidence of the SRP's superiority to the BTFP. There was a high drop-out rate and lost to follow-up from this study. High drop-out rates may provide an inaccurate

estimation of the treatment effect and increased type I error. A Type I error can make a false positive claim that the intervention is effective but in fact it is not. Not all patients benefit from these group exercise programmes. Many group exercise programmes have been designed and implemented but seem to have similar effects despite distinct differences between them (Slade et al., 2009a). We can't say for sure if the SRP has been effective or not due to the high number of drop-outs in this study. There may be a biased estimation of the treatment effects and problems concerning the generalisability of the results obtained. This has implications for implementing the SRP into clinic practice, as there is a lack of evidence for its effectiveness. The SRP may be a suitable alternative group programme for managing CLBP as it aims to direct patients in self-managing their pain by incorporating individualised exercise and increased physical activity levels into their weekly routine. This is likely to give patients more confidence in their ability to perform tasks as well as overcome any barriers to changing their exercise habits.

6.14 Recommendations from Stage 2

This small scale study indicates that the SRP may be a suitable alternative to current group programmes used in physiotherapy practice and may address the limitations with previous programmes. Implementation of this programme across the whole Trust or even at a regional level is recommended including an additional analysis related to cost. Based on the findings of the current study, modifications to the SRP are required but the overall design of the SRP should remain. These modifications include a more structured induction of new participants to the programme. Participants identified in the focus groups that the SRP seemed disorganised at first and this needs to be addressed. A group education component as well as one-to-one input should be included in the SRP. The group education would be similar to that used in the standard programme detailed in Appendix 9. All participants in addition to their exercises during the programme should be encouraged to increase their physical activity levels in accordance with the physical activity guidelines set by the Chief Medical Officer and NICE guidelines (DOH, 2011b; NICE, 2013). Future evaluation studies could record participants reported average weekly activity levels which was not done in the current study. Provision of information regarding local exercise and leisure facilities is recommended. I don't agree participants should be given information on Internet sites such as YouTube, unless these sites have been endorsed by the CSP or other professional bodies. Participants also mentioned in the focus groups that they would like a follow-up. A follow-up programme is also recommended to previous attendees and could be available to them for a small fee. This would be run outside clinical hours and any patients requiring further physiotherapy treatment would be advised to obtain a new referral from their GP. A similar idea has been used in the NHS for hydrotherapy classes particularly for

patients suffering from ankylosing spondylitis (an inflammatory condition of the spine). Therapists should also encourage more patients for whom English is not their first language to attend the SRP. This will ensure that more patients with CLBP who meet the inclusion criteria can attend this programme and not be excluded. However, in future studies, the provision of interpreters would need to be included in the economic evaluation. It is recommended the SRP be further evaluated using a mixed method design which should consist of a multicentre randomised control trial and supplementary qualitative component.

6.15 Summary and Epilogue of Thesis

This thesis has been a journey from the beginnings of an idea to improve the management of CLBP in a group setting to designing, implementing and evaluating an alternative group programme. The Doctorate Programme has allowed me to develop as an academic researcher and clinical leader as well as promote my physiotherapy profession. This has led on to publications in an International Journal, professional magazine and even a book (History of Exercise Therapy: From Ancient to Modern Times). Overall this has been a successful programme of study both professionally and personally. This journey has not been an easy one. Conducting research in clinical practice is difficult particularly having to overcome organisational changes in the NHS, the varying agendas of stakeholders and a full clinical caseload. Collaboration between all stakeholders within an organisation like the NHS including service users is important for larger research projects to succeed. Such projects are beyond the scope of a single clinician. This programme has laid down the foundations for me to develop further as a clinical researcher. The alternative group exercise programme as an end product of this programme may provide a useful addition to the management of CLBP and influence physiotherapy practice.

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8.0 Appendix

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Appendix 1
Peer Review Article

A physiotherapy survey to investigate the use of exercise therapy and group exercise programmes for management of non-specific chronic low back pain

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Objectives: To establish exercise prescription by individual therapists as well as the type and content of group exercise programmes used in clinical practice for management of chronic low back pain (CLBP).
Introduction: Group exercise programmes are a cost-effective treatment for managing CLBP but lack individualized exercise and education specific to the patient. Those patients for whom English is not their first language may be excluded from attending these programmes.
Methods: One hundred and fifty-four questionnaires were sent to 15 physiotherapy departments using convenience sampling within the Greater London area including 2 in independent practice. Closed questions and free response spaces provided were used to obtain information on exercise prescription and the content of group exercise programmes.
Results: There was a 63% response rate. Stretching, core stability, and lumbar stabilization were the most frequently used exercise types by individual therapists. Ninety seven percent of respondents utilized group programmes. Only 47% of all respondents were able to refer non-English speaking patients to the group programmes. The most frequently used group exercise was the Back to Fitness Programme. Group programmes generally lacked individualized exercises and education given on an individual basis. None of the group programmes offered manual therapy.
Conclusions: An alternative group physiotherapy programme should be considered alongside current programmes consisting of an individualized multimodal exercise programme carried over from the referring therapist. This group programme would consist of individual education sessions and manual therapy if appropriate. This would allow interpreters to be arranged for patients for whom English is not their first language.

Keywords: Chronic low back pain, Exercise programme, Core stability, Lumbar stabilization, Multimodal

Introduction

Low back pain is very common in the general population with an estimated lifetime prevalence of up to 80% and 1 year prevalence rates of 50 and 76%.[1,2] Chronic low back pain (CLBP) is defined as pain and discomfort localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain which has persisted for at least 12 weeks.[3] Approximately 10–15% will develop CLBP and it is responsible for at least 80% of the total costs of low back pain management.[4,5] The estimated cost of physiotherapy management for CLBP in the UK is 24–36 million pounds annually.[6] Exercise therapy for CLBP has been shown to be more beneficial than passive treatments.[7] There is no evidence that any other treatment is better than those interventions which use exercise therapy as the basis of treatment.[8] Previous surveys have supported the use of advice and exercise therapy for CLBP.[9,10] Core stability and lumbar stabilization were the most commonly used types of exercise therapy. Few studies showed that therapists provided supervised exercise programmes despite clinical guidelines supporting the use of group exercise classes for managing CLBP.[11,12] These surveys generally do not provide details of the amount or types of exercises used or show that the treatment provided by the therapists is supported by the current evidence base.[11,13]

Group exercise programmes are a cost-effective treatment for managing CLBP.[14] Many randomized controlled trials (RCTs) investigating group exercise

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for management of CLBP have used single mode exercise types such as Pilates, core stability, aerobic, or strengthening without being individualized.[4,15] Effective exercises for managing CLBP found in the literature are those that are specific, individualized, and regularly supervised.[16] Patients with CLBP tend to avoid physical activity due to pain and fear avoidance behaviour. They become de-conditioned due to their low activity levels, which results in decreased muscle power and cardiac capacity.[17] CLBP patients may benefit from a programme that consists of combined exercise types such as strengthening, mobility, and aerobic exercise.[18] Several types of group programmes have been described in the literature and vary greatly in content as well as duration.[19,20] To date, there have been no descriptive surveys investigating physiotherapy management of CLBP using group programmes.

The most widely used group programmes for management of CLBP in the literature are the back school, Back to Fitness Programme (BTFP), motor control/stabilization, and Pilates. The back school has been a common management strategy for back pain modelled on the Swedish Programme originating in the 1960s and contains a standard programme of exercises and education, which is supervised but not individualized.[21] The BTFP consists of circuit-based exercises for back pain patients.[22] Exercises in this programme are generally of a higher intensity and non-specific. This programme does not offer individual attention and may not promote long-term adherence to exercise.[23] Previous research has shown that individuals with CLBP have impaired control and delayed recruitment of the deep trunk muscles that are responsible for maintaining the stability of the spine.[24,25] Motor control or lumbar stabilization exercises have been delivered previously in a group format or used as part of a group programme. Motor control exercises are superior to a minimal intervention for treating CLBP but no more effective than other forms of exercise therapy.[26] Pilates has become a popular form of mind-body exercise for back pain patients.[27] It focuses on controlled movement, posture, and breathing along with activation of the deep trunk muscles.[28] Pilates exercises are not very functional as they are non-weight bearing and mostly performed on mats. They have a strong flexion bias which may not benefit patients with flexion-mediated low back and leg pain.[29] There are several other group exercise programmes described in the literature, but no one group exercise programme seems to be superior to any other and only have moderate effects on CLBP. There are no recommendations given for the specific type of exercise to be used and there does not seem to be any consensus on the most effective programme design to maintain any exercise benefits achieved.[30,31] The literature suggests that group programmes such as the back school do not have good long-term outcomes.[20] Group programme dropout rates have been quoted as up to 30%.[32] The high dropout rate of group programmes may be largely attributable to long waiting lists and inflexible appointment times.[33] There may be a need for an alternative group programme to address these limitations.

A physiotherapy survey was administered to investigate the use of exercise therapy and group exercise programmes for management of non-specific CLBP in clinical practice. The survey aimed to provide data on the exercises used by therapists for managing CLBP, referral rates to group exercise programmes, and the type and content of these programmes. The null hypotheses to be tested in this study were that group programmes use single mode exercise regimens; exercises given by therapists are different from those in the programme; group programmes lack individual attention and a manual therapy component; education provided is general and not specific to the patient.

Methodology

Questionnaire design

A cross-sectional self-report postal questionnaire was used to survey a population of physiotherapists involved in the management of CLBP. The questionnaire was developed following a literature review of previous studies, which have investigated how physiotherapists manage CLBP.[2,11] Content validity of the questionnaire was enhanced by using a similar structure and topic.[12] The questionnaire design had involved consultation with academic supervisors and those with previous survey experience at a Masters level of academic qualification and above. The draft questionnaire was first pre-tested with physiotherapists to obtain further feedback. This process had highlighted some changes to produce the final draft version of the questionnaire. This questionnaire was further pre-tested before distribution using a focus group consisting of physiotherapists, musculoskeletal (MSK) general practitioner (GP) physicians, and survey experts within the local NHS Trust. A focus group is a good method for identifying problems with questionnaire items and can enhance both the validity and reliability of the questionnaire.[34–36] This questionnaire was revised in response to the feedback received from the focus group, which further established the questionnaires content validity.[37]

The final questionnaire contained 25 questions divided into two sections. The questionnaire was predominated by close-ended questions with the use of a nominal, ranked, or descriptive answer format.[38] This format increases question specificity and facilitates quantitative analysis allowing direct comparisons

between respondents to be made.[34] Closed questions may lead to increased errors if they suggest an answer that a respondent may not have otherwise provided and may not be sufficiently comprehensive.[39] This was addressed in the design of the questionnaire by including an unspecified option, i.e. other (specify) category for some of the questions and a free response space at the end of the questionnaire to allow the respondent to write down their comments. A 'Don't know' category was also added to some of the questions. This ensured that if the respondents were not sure of the right answer they would choose the 'Don't know' option rather than guess. Assurances of confidentiality and anonymity were given to minimize the influence of social desirability. The first section included clinical details about the responding physiotherapist and asked to provide information regarding their referral of patients to group programmes for management of CLBP as well as the exercises they prescribe. The second section asked those physiotherapists involved in running group programmes to provide specific details regarding the content of these programmes including the type of exercises and education provided.

Ethics and Research and Development approval

Ethical approval was not required for this survey as this did not involve patients. Permission to administer the questionnaire to the physiotherapy departments was granted by their Research and Development Departments.

Distribution

Convenience sampling was used for this self-report questionnaire but the aim was to survey NHS Trusts within the greater London area. The majority of similar previous surveys have been conducted in regional areas. To my knowledge, there have been no surveys of this type conducted in the London area. London is the most ethnically diverse area in England and Wales with a rising number of minority ethnic groups being identified. The white British population in London is 45%.[40] The population of CLBP patients presenting to London physiotherapy departments is becoming increasingly diverse with English not being the first language for many of these people.[41] This may have an effect on how group programmes are utilized in this area. All potential physiotherapy departments were contacted prior to the study to determine whether they wished to participate. The questionnaire was sent out to 13 NHS MSK outpatient departments within 7 NHS Trusts or Integrated Care Organizations in the greater London area who had all agreed to take part. This included eight departments within secondary care and five in primary care. Two independent practices also took part in the survey. MSK outpatient physiotherapists, who manage CLBP patients, completed the questionnaire. Before distribution, the departments were contacted to confirm how many questionnaires they could or were willing to accept. This was a strategy for improving questionnaire response rate. This ranged from 1 to 23. In total, 154 questionnaires were distributed. Questionnaires sent to each physiotherapy department were given a unique identification code to monitor the response rate accurately. The questionnaire package contained a hand-signed covering letter, the questionnaire with cover sheet explaining the study, and postage-paid pre-printed return envelopes with each questionnaire. Three weeks after the initial distribution of the questionnaires an e-mail reminder was sent out to all departments. Respondents were also given the option to return the questionnaire by e-mail. At 8 weeks post-distribution, a final reminder by e-mail was sent to low responders.[10] Data collection took place over a 4-month period from March 2013 to June 2013 in line with the previous self-report questionnaire surveys.[2]

Questionnaire data analysis

All questionnaires were sent back to the researcher for analysis. Descriptive analysis of the questionnaire was mostly used utilizing figures, tables, and charts to visually represent the data collected. The quantitative data produced in the questionnaire using closed questions was nominal and was not normally distributed.[42] Non-parametric tests were used for the analysis where appropriate using the Statistical Package Stata version 12.1. The Kruskal–Wallis test was used when different groups of participants gave a single score on a rating scale with a level of significance set at $P < 0.05$. Ratings are an example of an ordinal scale of measurement with the data not being suitable for parametric testing.[43] For example, to determine whether there was an association between physiotherapy banding and the percentage of actual referrals to group programmes.[44]

Results

Respondents

There was a 63% response rate ($n = 97/154$). Fifty-six percent ($n = 54/97$) were employed in primary care, 28% in secondary care ($n = 27/97$), and 16% in independent practice ($n = 16/97$). Twenty-three percent of respondents were Band 8 ($n = 22/96$), 33% at Band 7 ($n = 32/96$), 31% at Band 6 ($n = 30/96$), 5% at Band 5 ($n = 5/96$), and 7% classified as other ($n = 7/96$). Others included those in independent practice and three MSK GP physicians. Clinical banding of the respondents is presented in Fig. 1.

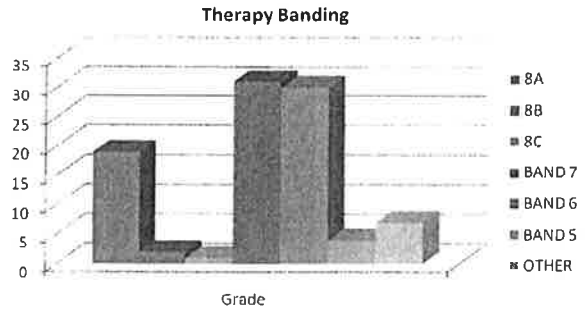

Figure 1 Banding of respondents.

Exercise therapy

Ninety percent ($n = 86/96$) of respondents prescribed up to six exercises to their CLBP patients, but only 44% ($n = 42/96$) reported that these exercises were the same or similar to those given in the group programmes. The respondents were asked what exercises they prescribed to their CLBP patients as part of back pain management. All the respondents prescribed exercises. Stretching exercises were most frequently used with core stability ranked second and lumbar stabilization exercises ranked third. The type of exercises prescribed less frequently were upper limb strengthening followed by balance and direction-specific exercises (McKenzie). Fig. 2 shows the frequency of the different exercises prescribed for CLBP by all respondents.

The most frequent exercises used by Band 8 respondents were aerobic, ranked first followed by stretches and functional. For Band 7, stretches ranked first, followed by core stability and lumbar stabilization exercises. In Bands 6 and 5, the most frequent exercises used were core stability, followed by stretches and lumbar stabilization. These differences are highlighted in Figs. 3–5. Core stability was ranked first, followed by stretches and lumbar stabilization for respondents in independent practice. The frequency of exercises prescribed in independent practice is shown in Fig. 6.

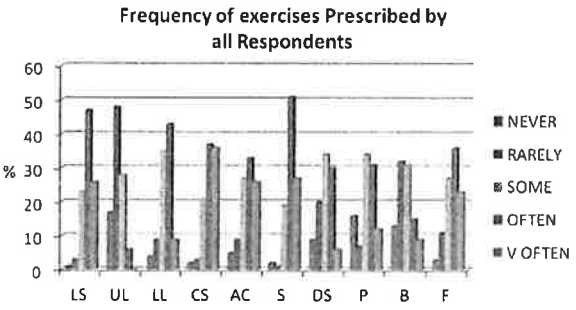

Figure 2 Frequency of exercises prescribed by all respondents. (LS = Lumbar stabilization; UL = Upper limb; LL = Lower limb; CS = Core stability; AC = Aerobic/ cardiovascular; S = Stretches; DS = Directional specific/ Mckenzie; P = Postural; B = Balance; F = Functional)

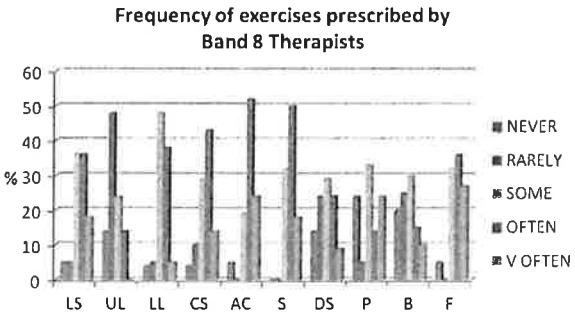

Figure 3 Frequency of exercises prescribed by Band 8 therapists.

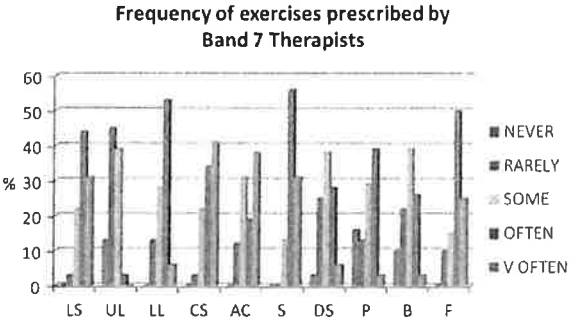

Figure 4 Frequency of exercises prescribed by Band 7 therapists.

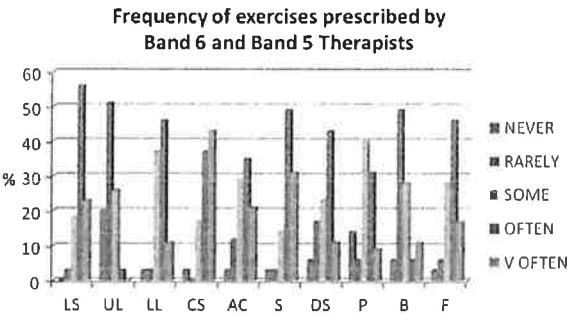

Figure 5 Frequency of exercises prescribed by Bands 6 and 5 therapists.

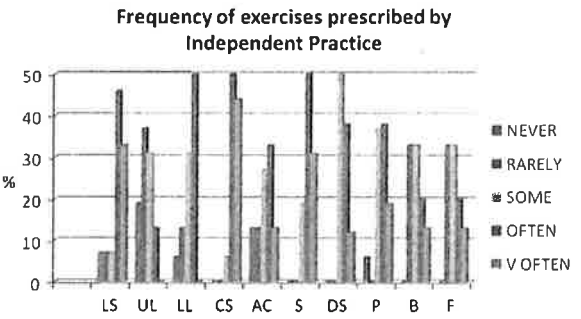

Figure 6 Frequency of exercises prescribed by independent practice.

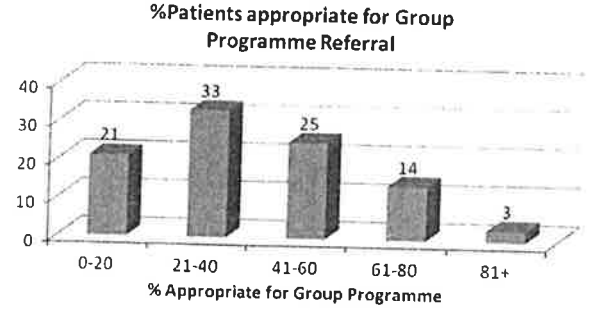

Figure 7 Percentage of CLBP patients appropriate for group programme referral.

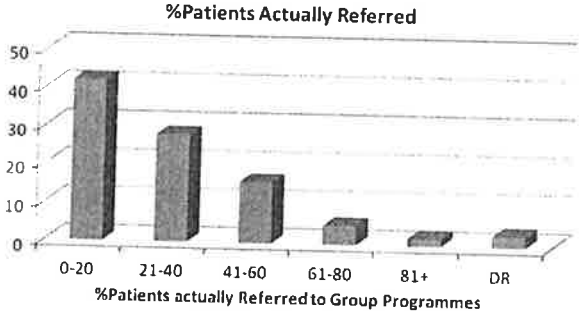

Figure 8 Percentage of CLBP patients actually referred to the group programmes.

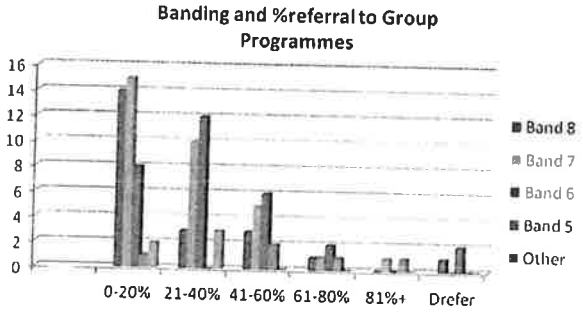

Figure 9 Therapist banding and percentage of actual referral to the group programmes.

Group programme referrals

Respondents were asked approximately what percentage of their CLBP patients would be appropriate for group programme referral and approximately what percentage of these patients they actually referred. The results show generally that there was a greater percentage of patients that would be appropriate for group referral than those who were actually referred. This difference is demonstrated in Figs. 7 and 8.

Seventy-seven percent of all respondents reported that >21% ($n = 74/96$) of their CLBP patients would be appropriate for group programme referral, but only 53% ($n = 51/96$) referred >21% of their CLBP patients to the group programmes. Three percent ($n = 3/96$) for all respondents did not refer to group programmes. Fifty-five percent of Band 8 respondents reported that >21% of their patients would be appropriate for group programme referral compared with 81% Band 7, 87% Band 6, and 100% Band 5.

Those respondents with a lower banding (Bands 5 and 6) tended to refer more patients to group programmes than the other bands. Eighty percent ($n = 4/5$) of Band 5 respondents and sixty-seven percent ($n = 20/30$) of Band 6 respondents referred >21% of their patients to group programmes compared with 53% ($n = 17/32$) Band 7 and 32% ($n = 7/22$) Band 8. Fig. 9 shows the banding and referral to group programmes. Further analysis showed that there was a significant difference found between bands in terms of percentage of actual referrals ($P < 0.04$). Referrals were highest in Band 5/6 respondents with 36% of those referring 41% or more of their patients. This is highlighted in Table 1. Respondents in secondary care tended to refer more patients to group programmes than those in primary care and independent practice. The results suggested that there was no significant difference between locations in terms of percentage of appropriate referrals. However, there was a significant difference in terms of percentage of actual referrals ($P < 0.05$). Those in secondary care had the highest rate of referral, with 37% referring

Table 1 Summary of Kruskal–Wallis tests for % referral to group programmes by different banding

Variable	Category	Bands 5/6	Band 7 *N* (%)	Band 8 *N* (%)	Other *N* (%)	*P* value
Appropriate referral	0–20%	4 (11%)	6 (19%)	10 (45%)	2 (29%)	0.09
	21–40%	11 (31%)	15 (47%)	3 (14%)	3 (43%)	
	41–60%	11 (31%)	7 (22%)	7 (32%)	0 (0%)	
	61–80%	7 (20%)	3 (9%)	2 (9%)	2 (29%)	
	81 + %	2 (6%)	1 (3%)	0 (0%)	0 (0%)	
Actual referral	0–20%	9 (27%)	15 (47%)	14 (67%)	4 (57%)	0.04
	21–40%	12 (36%)	10 (31%)	3 (14%)	3 (43%)	
	41–60%	8 (24%)	5 (16%)	3 (14%)	0 (0%)	
	61–80%	3 (9%)	1 (3%)	1 (5%)	0 (0%)	
	81+%	1 (3%)	1 (3%)	0 (0%)	0 (0%)	

41+ % of their patients compared with only 23% in primary care and 7% in independent practice. This is highlighted in Table 2.

Section 2–group physiotherapy programmes

Section 2 of the questionnaire asked respondents involved in group programmes about the type and content of the group programmes they were involved in at their place of work. Some respondents had listed two group programmes on their questionnaire. The most frequently used group physiotherapy programme for non-specific CLBP was the BTFP (n = 14/38), followed by Pilates (n = 7), core stability/lumbar stabilization (n = 6), combined group programmes (n = 7), spinal hydrotherapy (n = 2), back class/school (n = 1), and yoga (n = 1). Fifty percent of the physiotherapy departments surveyed used the BTFP. Chart 1 shows the proportion of different group programmes. The combined group programmes included a mix of Pilates, core stability, circuit training, and functional exercises. These group programmes were generally combinations or variations of the standard programmes found in the literature.

General content of group programmes

The group programmes in this survey consisted mainly of general exercises, circuit-based exercises, and an education component. None of these group programmes offered manual therapy to patients. Only 33% (n = 11/33) of group programmes had individualized exercises for their patients. Fig. 10 shows the general content of these group programmes.

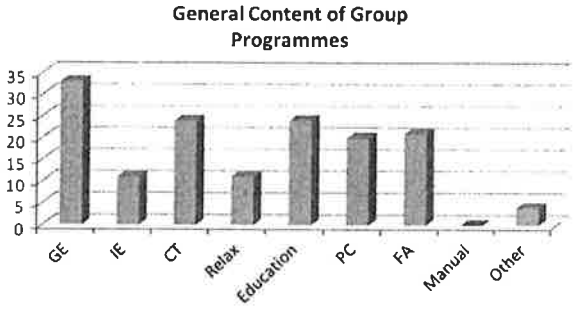

Figure 10 General content of the group programmes. (GE = Group exercises; IE = Individualized exercises; CT = Circuit training; Relax = Relaxation; PC = Postural correction; FA = Functional activities; Manual = Manual therapy)

Education

Seventy percent (n = 23/33) of the programmes in this survey provided education regarding CLBP management in a group setting with only 18% (n = 6/33) given on an individual basis. Written information regarding back care was given in 30% (n = 10/33) of the programmes. Some physiotherapy departments

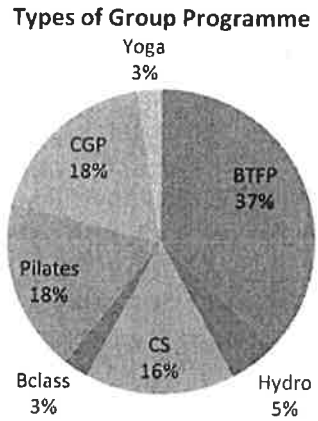

Chart 1 Types of group programmes in clinical practice

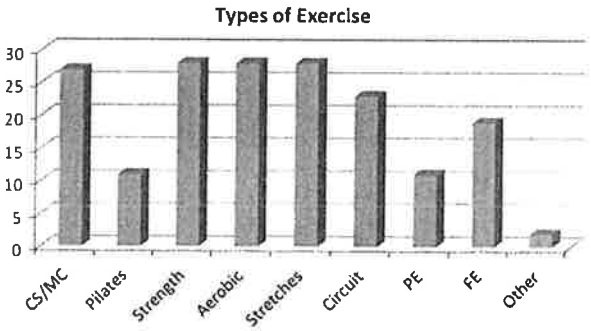

Figure 11 Types of exercises used in the group programmes. (CS/MC = Core stability/Motor control; PE = Postural exercises; FE = Functional exercises)

Table 2 Summary of Kruskal–Wallis tests for % referral to group programmes by primary care, secondary care, and independent practice

Variable	Category	Primary *N* (%)	Secondary *N* (%)	Independent *N* (%)	*P* value
Appropriate referral	0–20%	15 (28%)	3 (11%)	4 (25%)	0.16
	21–40%	19 (36%)	8 (30%)	5 (31%)	
	41–60%	10 (19%)	11 (41%)	4 (25%)	
	61–80%	8 (15%)	3 (11%)	3 (19%)	
	81 + %	1 (2%)	2 (7%)	0 (0%)	
Actual referral	0–20%	28 (54%)	7 (26%)	7 (50%)	0.05
	21–40%	12 (23%)	10 (37%)	6 (43%)	
	41–60%	8 (15%)	7 (26%)	1 (7%)	
	61–80%	3 (6%)	2 (7%)	0 (0%)	
	81 + %	1 (2%)	1 (4%)	0 (0%)	

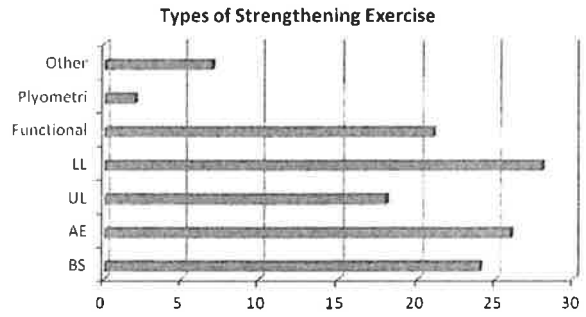

Figure 12 Types of strengthening exercise used in the group programmes. (BS = Back strengthening; AE = Abdominal exercises; Plyometri = Plyometrics)

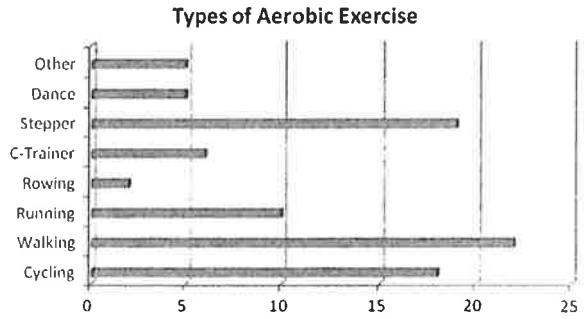

Figure 13 Types of aerobic exercise used in the group programmes.

had developed their own education booklet ($n = 5$). Only five group programmes had used published education booklets such as the ARC: Back Pain information booklet ($n = 5$). Generally, the Pilates group programmes provided no written information regarding back care.

Content of group programmes

Thirty percent ($n = 10/33$) had 9–10 exercises in their programmes and 55% (18/33) had >10 exercises. The most frequent types of exercises used in group programmes were stretches, strengthening, and aerobic. The types of exercises are shown in Fig. 11. The respondents were asked to state which type of strengthening exercise they used in their group programmes. This is shown in Fig. 12. The most frequently used strengthening exercises were lower limb, abdominal strengthening, and back strengthening. The respondents were also asked to state which type of aerobic exercise they used in their group programmes. This is shown in Fig. 13. Walking was the most frequently used aerobic exercise followed by stepper/step-ups and cycling.

Programme intensity and duration

Forty-two percent ($n = 14/33$) of group programmes consisted of low-intensity exercises only and 48% ($n = 16/33$) were a mixture of high and low intensity. There were no high-intensity exercise programmes. Twenty-five percent of the group programmes were of 4 weeks or less duration ($n = 9/36$), 47% were 6 weeks duration ($n = 17/36$), and 19% between 7 and 8 weeks duration. All programmes were held once a week on consecutive weeks. One independent practice was able to provide Pilates classes with no time limit as the clients were paying.

Referral for non-English speaking patients

Forty-seven percent ($n = 45/96$) of all respondents were able to refer non-English speaking patients to the group programmes run at their department. Many respondents used the free space provided to quote problems with interpreters and the fact that it was not appropriate to have interpreters in their classes.

Discussion

Exercise therapy

The majority of therapists provided up to six exercises for their patients and only in 44% were these similar to those in the group programmes. There was a discrepancy between the number of exercises prescribed by individual therapists (up to 6) and those offered in the group programme (9–10). It has been recommended that adults should improve their muscle strength by exercising all the major muscle groups on at least 2 days a week in accordance with the physical activity guidelines set by the Chief Medical Officer and National Institute for Health and Care Excellence (NICE) guidelines.[45,46] It has been suggested that CLBP patients are de-conditioned due to their low physical activity levels.[17,47] This de-conditioning leads to a lower level of physical fitness. Physical fitness has a combination of physical parameters such as muscle strength, muscle endurance, flexibility, cardiovascular capacity, motor control, and body composition, all of which may be affected by physical de-conditioning.[48] CLBP patients should be given multimodal exercises including strengthening to address their de-conditioning. Six exercises may be insufficient for a comprehensive conditioning programme and more than 10 may reduce compliance.

This is the first survey to provide the details of the types of exercises prescribed for CLBP patients and compare with different grades. The most frequent exercises prescribed by the respondents are stretches, core stability, and lumbar stabilization. Previous physiotherapy surveys have found that core stability and lumbar stabilization exercises were the most frequently used regardless of the therapist's grade.[10–11] Lumbar stabilization exercises specific to deep abdominal muscles are frequently prescribed, but these exercises are difficult for patients to transfer to functional or sporting activities in the long term.[49] Band 8 therapists tended to prescribe aerobic and functional exercises more frequently than the other bands. Previous

surveys have found that the use of functional exercises for managing LBP was generally found to be low at 27%.[9,50] Functional exercises may be more beneficial for CLBP patients in the long-term. A recent survey by Fidvi and May[2] found that aerobic exercises were not prescribed to their CLBP patients. Promoting aerobic exercise or physical activity at a moderate intensity is in line with the guidelines set by the Chief Medical Officer for adults between 19 and 65 years.[45] Upper limb strengthening exercises were not often prescribed by the respondents. The anatomical core has been defined as the axial skeleton consisting of both the pelvic and shoulder girdles and all the soft tissues including muscle with a proximal attachment to the axial skeleton.[51] This would include both upper and lower extremities. Training the upper limbs also stimulates the spinal stabilizers.[51] A resistance training programme for CLBP that stressed the large muscle groups of the whole body, including the upper quadrant, showed significant improvements in pain and disability.[15] It was found that McKenzie exercises are not widely used by the therapists in this survey. A previous survey had found the McKenzie approach as the second most popular management strategy for CLBP.[11] Exercise therapy by the McKenzie method has been a popular treatment strategy for LBP among physiotherapists.[31] However, to date, there have been no good quality RCTs published to support the effectiveness of this method. McKenzie exercises may be less effective for CLBP and no longer frequently used due to the lack of evidence for their effectiveness. A recent RCT comparing back school with McKenzie exercises in patients with CLBP found the McKenzie approach no more effective in the long-term for reducing pain and disability.[52]

Group programme referral

The results show that the majority of therapists except for 3% refer their CLBP patients to group programmes. Those therapists working in secondary care tended to refer far more often than those in primary care and independent practice. This may be explained by the fact that the group programmes are more likely to take place on site in secondary care making it easier to refer and for patients to attend. In primary care, a number of therapists work in smaller departments, satellite, or GP clinics which do not always have the facility for group programmes and are often held at a different location. It may be more difficult for patients to attend these sites and discourage referral. Although group programmes were available in independent practice, therapists tended to refer less, probably because patients are expecting more 'hands on' treatment. Bands 5 and 6 therapists tended to refer more of their CLBP caseload to group programmes than the higher bandings. Both Bands 7 and 8 therapists may see more complex CLBP patients whereby a group exercise programme is not necessarily an appropriate management strategy.

Only 47% of all respondents were able to refer non-English speaking patients to the group programmes run at their department, which may account partly for the difference between those appropriate for group referral and those actually referred. This may be an issue as the population of CLBP patients presenting to London physiotherapy departments is becoming increasingly diverse with English not being the first language for many of these people.[41]

Group physiotherapy programmes

This survey found that most popular group exercise programmes such as Pilates, BTFP, lumbar stability/motor control, and yoga quoted in the literature are being used in clinical practice as part of back pain management. The most widely used group physiotherapy programme was the BTFP. The BTFP is a standardized model of group exercise which can be applied easily into clinical practice.[53] It was interesting that the traditional back school widely quoted in the literature was used by only one physiotherapy department in this survey. However, some of the combined group programmes had included exercise and education components which could be classed as back school. All these group programmes tended to use multimodal exercises with a combination of strengthening, stretches, and aerobic, but underutilized upper limb strengthening. Walking was the most frequently used aerobic exercise in the group programmes. This type of exercise is low impact and can be continued post-programme as well as go towards achieving the weekly physical activity guidelines. Functional exercises were also used in these programmes, which may be more relevant to patients and promote adherence. However, a circuit-based format was often used which does not allow patients to perform their exercises at their own pace and exercises are generally not individualized to the patient. This would make it difficult for patients to carry on with exercise therapy in the long-term, especially if they do not have access to gyms or external exercise classes. None of the group programmes offered high-intensity exercise, which does not cater to those patients able to exercise at a higher level. Education was provided in these group programmes but usually in a group format. The information provided in the group education sessions may not be relevant to all patients. To date, there has been no clinically important effect found of group education programmes for CLBP.[54] Only a small number of the group programmes provided published written information (30%) regarding CLBP self-management. In some cases, only exercise sheets were given out. Information booklets have been developed

in the past to help healthcare providers in educating their patients. Educational booklets such as the back book based on the biopsychosocial model of back pain have been shown to increase patient's knowledge and modify their beliefs.[55] Manual therapy was not offered at all in these programmes. Twenty-five percent of the group programmes were of 4 weeks or less duration with 6 weeks being most common which is quoted in the literature. However, all group programmes were run on consecutive weeks. This type of format does not allow patients to join the group at any time and will generally have to wait until the current group programme has finished.

Limitations

A major disadvantage with postal questionnaires and in this study was non-response. This reduces the effective sample size and may introduce bias.[56] This may also threaten the validity of the research as non-responders may differ significantly from responders. Non-response bias may also limit the generalizability of these current findings to all outpatient physiotherapists treating CLBP.[11] It was not possible in this study to contact individual non-respondents directly to determine why they did not respond. The Health and Social Care Act which came into force on 1 April 2013 brings major reforms to the NHS. Many NHS Trusts and departments are going through re-organization.[57] This is a busy time for some physiotherapy departments, which may have affected response rates particularly as this was during the data collection period. In general, at an organizational level such as the NHS, there have been a number of reasons examined for non-response. These included being too busy, not considered relevant, and not having an address to return the questionnaire, but up to a quarter did not provide any clear reasons for not responding.[58] This study recorded self-reported behaviour such as types of exercise prescribed for CLBP and referral rates to group exercise programmes. However, this study may not have captured real clinical practice, which is difficult to measure. Inferences were made on the data provided in the survey but issues such as the barriers to group programme referral were not established. One of the reasons quoted for patients not joining a group programme was logistics and patient preference. The questionnaire in this survey did provide a free response space to give respondents the opportunity to add any other comments. This free response space was utilized by some but not by the majority of respondents.

Conclusion

This survey found that physiotherapy group exercise programmes are utilized by the majority of therapists as a management strategy for CLBP. There is a discrepancy between those who would be appropriate for group referral and those actually referred. Ethnic groups for whom English is not their first language are generally unsuitable for group programme referral due to the difficulty with interpreters. Those therapists working in secondary care tended to refer more to group programmes. Therapists at a lower banding tended to refer more than the higher bands. Three of the four null hypotheses regarding group programmes were rejected. Generally, exercises given by therapists were different from those in the programme, these programmes lacked individual attention and a manual therapy component, and education provided was general and not specific to the patient. However, the null hypothesis that group programmes do not use single mode exercise regimens was accepted. These programmes do use a combination of stretches, strengthening, aerobic, and functional exercises mostly in a circuit based format.

Recommendations for clinical practice

It is recommended that therapists should prescribe between 8 and 10 multimodal individualized exercises for CLBP patients in order to improve their physical fitness. This should include core stability, lower limb, and upper limb strengthening where appropriate, stretches/spinal mobility, functional, and aerobic exercises as recommended by the American College of Sports Medicine. This exercise programme should be modified according to the individual's physical function and health status.[59] It is proposed that there should be a shift away from lumbar stabilization exercises to more functional types of exercise and those that reflect the NICE 2013 physical activity guidelines. Group exercise programmes should be used as a treatment strategy for CLBP patients. It is proposed that there is a place for an alternative group physiotherapy programme to address the limitations of the current programmes. This would consist of an individualized multimodal exercise programme carried over from the referring therapist. The exercise component of the group programme should allow patients to perform their exercises at their own pace and not be circuit-based. These exercises can be supervised and progressed as necessary. Patients should be encouraged to perform their 8–10 individualized exercises outside the programme sessions as well as increasing their physical activity to meet the NICE 2013 guidelines. This programme should include an aerobic component such as walking or step-ups. Patients would have a minimum of six group sessions but not consecutive weeks. A rolling programme would allow patients to join the group at any week and reduce waiting times to attend. The group programme would also consist of a one-to-one session with the therapist. This would consist of individual education sessions and

manual therapy if appropriate. Patients should also be provided with a published information booklet, which is a comprehensive up to date guide on back pain and how it can be managed. For patients for whom English is not their first language, interpreters can be arranged and this would not disrupt the group. The plan is to implement this alternative programme in clinical practice at Ealing Hospital NHS Trust and compare it with a standard group programme.

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Appendix 2
Physiotherapy Questionnaire /Survey

31385

Ealing Hospital NHS
NHS Trust

PHYSIOTHERAPY SURVEY

EXERCISE THERAPY AND GROUP EXERCISE PROGRAMMES FOR THE MANAGEMENT OF NON-SPECIFIC CHRONIC LOW BACK PAIN

I am writing to invite you to take part in a survey to determine the use and content of group exercise programmes for the management of chronic low back pain (CLBP). Before deciding whether or not to take part, please take 5 minutes to read the information below so that you understand why the research is being done and what is involved. This research project is for educational purposes as part of a postgraduate qualification in Health. This study has been reviewed and given a favourable opinion by Middlesex University and your Trust's Research and Development Department where applicable.

The study aims to survey physiotherapists who manage and treat patients with CLBP in the Greater London area, at all grades and experience levels. More research into spinal rehabilitation is required to establish the most effective and inexpensive form of treatment for CLBP. ***CLBP is defined for this survey as current symptoms lasting greater than 3 months.***

You are asked to complete the following questionnaire which asks you to answer questions about your work location and banding, types of exercises you give for back pain, referral rates to group exercise programmes you have available at your place of work and follow-up. Section 2 of the questionnaire is regarding the content of these group programmes with particular focus on the types of exercise therapy used. Data concerning the frequency and duration of these programmes is also requested. This questionnaire should take approximately 10-15 minutes to complete. ***Section one of this questionnaire should only be completed if you are a Chartered Physiotherapist or Specialist Clinician who treats back pain patients. Section 2 can be completed by therapists involved in the running of these group programmes. You have been identified as someone who may meet this criterion.***

It is your right not to complete this questionnaire. Completing this questionnaire will not lead you to any benefits. All information will be entirely anonymous and all the data you provide in the questionnaire will be kept strictly confidential. *The final results of this survey will be used to complete a postgraduate dissertation and may be published in a journal. All those departments or clinics that have taken part in this survey will be sent a summary of the findings. Please note if you require further information about the research project or any advice regarding the completion of the questionnaire, you can telephone me on* ***0203 313 8875*** *or contact me by email below.*

After completing the questionnaire please return it either by email to alex.daulat@nhs.net or fax on 020 8383 8850 or post to:

Alex Daulat, MSK Extended Scope Practitioner
Greenford Green Clinic
Wadham Gardens
Middlesex, UB6 0BP.

Alex Daulat MSc MCSP
MSK Extended Scope Practitioner
Thank you for your co-operation

Please answer all of the following questions. If not applicable to you go to section 2 on page 5.

The first 4 questions ask you about your current role.

1. Please tick in the boxes provided the answer which relates most clearly to your current post. Service you work within:	
a) Primary care	
b) Secondary care	
c) Integrated care organisation	
d) Other (please give details)	
2. What Agenda for Change band are you? Please tick the answer which relates most appropriately to your current post.	
a) 8a | | 8b | | 8c	
b) 7	
c) 6	
d) 5	
e) Other (please give details)	
3. Do you have a speciality in your current post? Please tick the most appropriate answer.	
Yes | | No	
If yes, please indicate which of the following areas you have specialised in. Please tick as many options as appropriate.	
a) Upper Limb	
b) Lower Limb	
c) Spinal Conditions	
d) Rheumatology	
e) Pain Management	
f) Triage	
g) Other (please specify)	
4. In your post approximately what percentage of your patient caseload presents with a current episode of chronic low back pain lasting more than 3 months? Please tick the percentage.	
a) 0-20%	
b) 21-40%	
c) 41-60%	
d) 61-80%	
e) 81%+	
f) Don't know	

The following questions refer to your referral to group exercise programmes and exercises you prescribe patients. For the purposes of this questionnaire, this relates to patients with chronic non-specific mechanical low back pain. **This does not include the group of patients presenting with widespread sensory hypersensitivity mediated by central pain mechanisms who are best suited for multimodal pain management or chronic pain programmes.** Any of your patients who are not appropriate for or capable of participating in a graded exercise programme due to either severe physical or psychological impairment should also be excluded.

5. What are the percentages of your back pain patients that would be appropriate for referral to group programmes? Please tick the percentage.	
a) 0-20%	
b) 21-40%	
c) 41-60%	
d) 61-80%	
e) 81%+	
6. What percentage of your back pain patients do you actually refer to group programmes? Please tick the percentage.	
a) 0-20%	
b) 21-40%	
c) 41-60%	
d) 61-80%	
e) 81%+	
f) Don't refer (Please state below why you don't refer)	
7. On average how many sessions do you have with your patients before you refer them to a group programme?	
a) 1-2	
b) 3-4	
c) 5-6	
d) >6	
e) Not applicable	

8a. Do you give your patients any home exercises as part of their back pain management? Please tick.	
Yes ☐ ☐ No	
8b. If yes to 8a how many exercises on average are prescribed? Please tick.	
a) 1-2	
b) 3-4	
c) 5-6	
d) 7-8	
e) 9-10	
f) >10	

9. The next question refers to the types of exercises that you give to patients as a part of their back pain management? Please tick the box that matches how often you use the type of exercise listed.

Type of Exercise	Never	Rarely	Sometimes	Often	Very Often
Lumbar stabilisation/Motor control					
Upper limb strengthening					
Lower limb strengthening					
Core stability					
Aerobic/Cardiovascular					
Stretches					
Directional Specific (Mckenzie)					
Postural (e.g.Alexander Technique)					
Balance (Proprioception)					
Functional (Exercises that mimic work or home activities)					
Other (Please specify):					

10. Are your exercises the same as those given out in the group programmes at your place of work? Please tick	
Yes ☐ ☐ No ☐ ☐ Don't Know	
11. Do you routinely follow-up your patients post group programme? Please tick.	
a) Yes	
b) No	
c) Not applicable	
12. Are you able to refer all patients suitable for group programmes whom English is not their first language?	
Yes ☐ ☐ No ☐ ☐ Don't know	
If no please state the reason why.	

Section 2: If not applicable go to page 7.	
Only to be completed by those therapists who are actively or recently (last 12 months) involved in the running or management of group programmes. The final set of questions relate specifically to group programmes run at your place of work such as back school, back to fitness or Pilates used for the management of chronic low back pain. You may run more than one type of group programme at your place of work. Please could you complete questions 13-25 for the programme that you are or have been involved in and specify the type of programme.	
Group Programme (Please specify below):	
13. Can you indicate the content of the group programme that you are involved in. Please tick as many options as appropriate.	
a) Group exercises	
b) Individualised exercises	
c) Circuit training	
d) Relaxation	
e) Education	
f) Postural correction	
g) Functional Activities	
h) Manual therapy (please give details):	
i) Other (please give details):	
j) Don't know	
14a. If any education is provided in your programme please tick whether it is provided as a group or individually. If not applicable go to question 15.	
Group ☐ Individual ☐ Don't know	
14b. Are patients provided with any written information for education purposes? Please tick.	
Yes ☐ No ☐ Don't know	
14c. If answered yes to 14b, please tick the type of written information provided.	
a) The Back Book	
b) ARC: Back pain information booklet	
c) Back pain: Arthritis Research UK booklet	
d) Your own (please give details):	
e) Other (please give details)	

15. Does your programme consist of a warm-up and/or warm-down? Please tick	
Yes ☐ No ☐ Don't know	
15b. If answered yes to question 15a please tick the time in minutes allocated to the warm-up/warm down.	
a) <5	
b) 5-10	
c) 10-15	
d) 15 or more	
16. Can you indicate the types of exercise therapy used in your group programme if applicable? Please tick as many options as appropriate.	
a) Core stability/Motor control	
b) Pilates only	
c) Strengthening	
d) Aerobic	
e) Stretches	
f) Circuit training	
g) Postural exercises such as Alexander technique	
h) Functional exercises (please give details):	
i) Other (please give details):	
j) Don't know	
17. How many exercises are given on average in the group programme? Please tick	
<4 ☐ 4-6 ☐ 7-8 ☐ 9-10 ☐ >10 ☐ Don't Know	
Questions 18-20 refer to the types of strengthening and aerobic exercise used in your group programme.	
18. What types of strengthening exercises do you include in your group programme? Please tick as many options as appropriate. If not applicable go to Question 19.	
a) Back strengthening i.e. Back extensors	
b) Abdominal exercises i.e. rectus abdominus	
c) Upper Limb strengthening	
d) Lower Limb strengthening	
e) Functional (please give details):	
f) Plyometric training	
g) Other (please give details)	
h) Don't know	
19) What types of aerobic exercise do you include in your group programme? Please tick as many options as appropriate. If not applicable go to Question 21.	
a) Cycling	
b) Walking	
c) Running	
d) Rowing	
e) Cross-trainer	
f) Stepper/step-ups	
g) Dance	
h) Other (please give details):	
i) Don't know	

20) Please indicate the intensity of the aerobic exercise in your group programme. Please tick as many options as appropriate.	
a) High Intensity	
b) Low Intensity	
c) Mixture of high and low Intensity	
d) Don't Know	
21) What is the duration of your group programme? Please tick the appropriate duration.	
a) 4 weeks or less	
b) 5 weeks	
c) 6 weeks	
d) 7 weeks	
e) 8 weeks	
f) > 8 weeks (Please Specify):	
g) Don't know	
22) Is your group programme run consecutive weeks? Please tick.	
Yes | | No | | Don't know	
23) If your answered No to question 22) please state why below.	
24) What is the frequency of your group programme? Please tick the appropriate frequency.	
a) Once a week	
b) Twice a week	
c) > Twice a week	
d) Other (please specify):	
25) What outcome measures do you use for your group programme? Please list below:	

If you have other comments that are not included in the questionnaire, please list them below.

Thank you very much for taking your time in completing this questionnaire.

Appendix 3
Sample size calculation formula and common standard values for α and β error

Numerical outcomes

- Used to compare a normally distributed numerical outcome between two groups.

$$n = \frac{2s^2 . (c_\alpha + c_\beta)^2}{(m_2 - m_1)^2}$$

Where:

n = number required in each group

m_1 = mean in group 1
m_2 = mean in group 2
S = standard deviation

c_α = constant for significance level (α)
c_β = constant for power ($1-\beta$)

Constant values

- Constants used in power calculations depend on the choice of significance level and power used in calculation.

- Common values:

c_α = 1.96 for 5% significance level
= 2.58 for 1% significance level

c_β = 0.84 for 80% power
= 1.28 for 90% power

Appendix 4
Consent Form RCT

Ealing Hospital NHS
NHS Trust

Participant Identification Number:

CONSENT FORM

Title of Project: An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care.

Name of Researcher: Alex Daulat
Please read below and sign at the bottom of the form if you agree with the statements below.

Please initial box

1. I confirm that I have read and understand the information sheet (Version 4 dated 11/12/2013) for the above study and have had the opportunity to consider the information, to 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 and without my medical care or legal rights being affected. ☐

3. I understand that sections of any of my physiotherapy notes may be looked at by the researcher and responsible individuals from Middlesex University or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP and physiotherapy department being informed of the outcome of the treatment upon its completion. ☐

5. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Appendix 5
Checklist Form (RCT)

Group Programmes: SRP ☐ BTFP ☐ In Study ☐
Checklist and Goals

Name..... RiO No.....

The following table to be completed by the patient and therapist

	Exclusion Criteria	√
1.	Do you have a history of cardiac, respiratory, kidney, blood pressure or blood circulatory problems that may prevent participation in strenuous exercise programme	
2.	Do you have a fracture or recent trauma?	
3.	Do you have inflammatory or infectious diseases of the spine?	
4.	Do you have metabolic or bone disease?	
5.	Do you have neurological signs or symptoms?	
6.	Do you have advanced Rheumatoid arthritis or uncontrolled diabetes?	
7.	Are you pregnant or attempting to become pregnant?	
8.	Can you take part in a graded exercise programme or tolerate manual therapy?	
9.	Do you agree to participate in a group or mixed gender programme?	

Do you need an interpreter?.....
If yes, which language?.....

Goals:

1. .....
2. .....
3. .....

For SRP only:

Manual Therapy indicated Yes ☐ No ☐

If yes, please state technique.....

SBT Category: Low ☐ Medium ☐ High ☐

To book a place on the programme, please call 020 8967 5487 between 09.00 and 16.00 weekdays.

Appendix 6
Validated questionnaires, Permissions and Scoring

Start Back Tool and Scoring

The Keele STarT Back Screening Tool

Patient name: _____ Date: _____

Thinking about the **last 2 weeks** tick your response to the following questions:

		Disagree 0	**Agree** 1
1	My back pain has **spread down my leg(s)** at some time in the last 2 weeks	☐	☐
2	I have had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
3	I have only **walked short distances** because of my back pain	☐	☐
4	In the last 2 weeks, I have **dressed more slowly** than usual because of back pain	☐	☐
5	It's not really safe for a person with a condition like mine to be physically active	☐	☐
6	**Worrying thoughts** have been going through my mind a lot of the time	☐	☐
7	I feel that **my back pain is terrible** and **it's never going to get any better**	☐	☐
8	In general I have **not enjoyed** all the things I used to enjoy	☐	☐

9. Overall, how **bothersome** has your back pain been in the **last 2 weeks**?

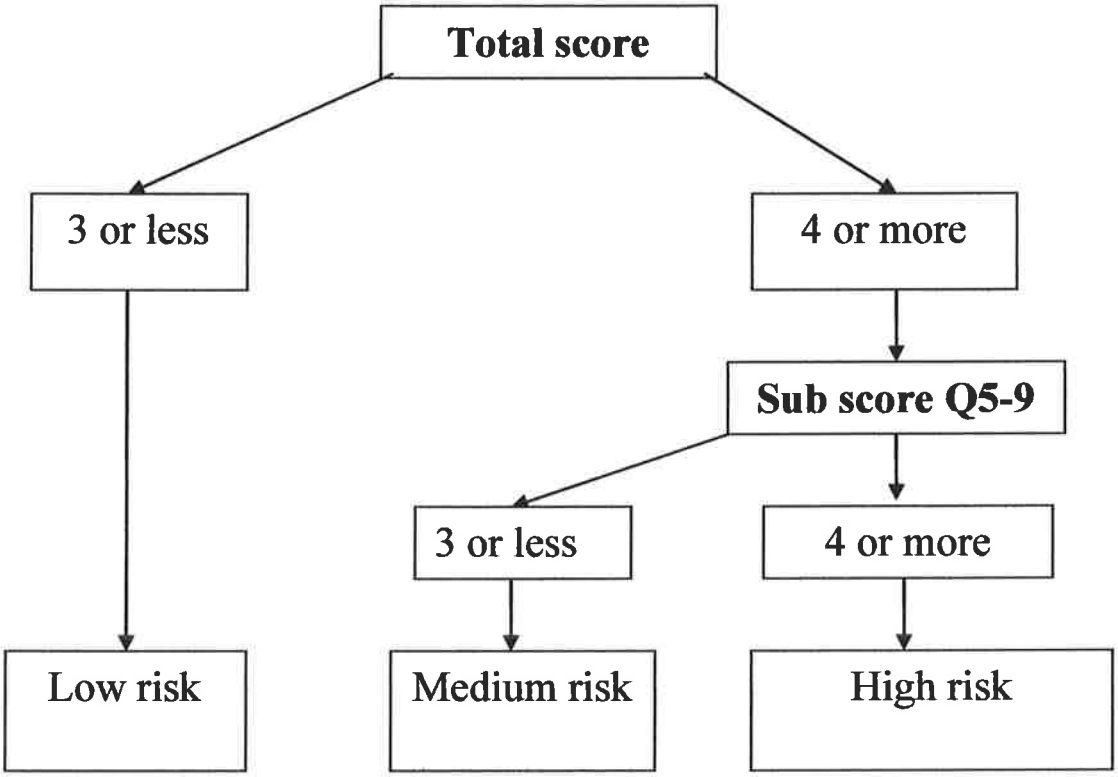
Not at all	Slightly	Moderately	Very much	Extremely
☐	☐	☐	☐	☐
0	0	0	1	1

Total score (all 9): _____ **Sub Score (Q5-9):**_____

01/08/07

Funded by Arthritis Research UK

The STarT Back Tool Scoring System



01/08/07

Funded by Arthritis Research UK

Functional Rating Index
Questionnaire, scoring and Permission

Rio Number: Pre-treatment: ☐ Post-treatment: ☐ Date:

Functional Rating Index

In order to properly assess your condition, we must understand how much your problem(s) have affected your ability to manage everyday activities. For each item below, please circle the number which most closely describes your condition right now.

1. Intensity of problem

0	1	2	3	4
None	Mild	Moderate	Severe	Worst possible

2. Sleeping

0	1	2	3	4
Perfect sleep	Mildly disturbed sleep	Moderately disturbed sleep	Greatly disturbed sleep	Totally disturbed sleep

3. Personal Care (washing, dressing, etc...)

0	1	2	3	4
No Pain/ no restrictions	Mild Pain/ no restrictions	Moderate Pain/ need to go slowly	Moderate Pain/ need some assistance	Severe Pain/ need 100% ssistance

4. Travel (driving, etc..)

0	1	2	3	4
No pain on long trips	Mild pain on long trips	Moderate pain on long trips	Moderate pain on short trips	Severe pain on short trips

5. Work

0	1	2	3	4
Can do usual work plus unlimited extra work	Can do usual work/ no extra work	Can do 50% of usual work	Can do 25% of usual work	Cannot work

6. Recreation

0	1	2	3	4
Can do all activities	Can do most activities	Can do some activities	Can do a few activities	Cannot do any activities

7. Frequency of pain

0	1	2	3	4
No pain	Occasional pain/ 25% of the day	Intermittent pain/ 50% of the day	Frequent pain/ 75% of the day	Constant pain/ 100% of the day

8. Lifting

0	1	2	3	4
No pain with heavy weight	Increased pain with heavy weight	Increased pain with moderate weight	Increased pain with light weight	Increased pain with any weight

9. Walking

0	1	2	3	4
No pain any distance	Increased pain after 1 mile	Increased pain after ½ mile	Increased pain after ¼ mile	Increased pain with all walking

10. Standing

0	1	2	3	4
No pain after several hours	Increased pain after several hours	Increased pain after after 1 hour	Increased pain after ½ hour	Increased pain with any standing

TOTAL SCORE:_____

INSTITUTE OF EVIDENCE-BASED CHIROPRACTIC

Functional Rating Index (FRI) Scoring Protocols

Scoring: The ten items of the FRI may be used to profile the nature of the dysfunction and pain, or they may be totaled. The index score is achieved by simply summing up the equally weighted scores, dividing by the total number of possible points, and multiplying by one hundred percent. The range of scores is zero percent (no disability) to one hundred percent (severe disability). The higher the number, the higher the perceived dysfunction and pain; the lower the number, the lower the perceived dysfunction and pain. Following is a calculation example:

1) When all 10 items are completed, the FRI score is calculated as follows: (total score / 40) x 100%
2) When only 9 sections are completed, the FRI score is calculated as follows: (total score / 36) x 100%

Absolute value change in score is a better indicator of outcome than the relative value change. Delta FRI = (pre-FRI% - post-FRI%)

To accommodate for scoring irregularities, the following decision rules have been established: 1) when a subject marks two responses on the same item, the responses are averaged; and 2) when a subject marks in between two response numbers, the response is the average of the two response numbers.

Application: It is recommended that for chronic conditions the FRI be used at baseline and every 2 weeks or 6 visits thereafter. If the score does not improve by at least 10% (absolute change) in any two successive two-week periods, you should pursue a change in management.

It is recommended that for acute and subacute conditions the FRI be used at baseline and every 1 week or 3 visits thereafter. If the score does not improve by at least 10% (absolute change) in any two successive one-week periods, you should pursue a change in management.

A 10% absolute change is estimated to represent a minimally clinically important change.
FRI Scale Estimates of Disability
0 - 20% = minimal disability
21 - 40% = moderate disability
41 - 60% = severe disability
61% + = very severe disability

Help

Reply | Reply to All | Forward

Re: functional rating index

Ron Feise [rjf@chiroevidence.com]

Sent: 13 March 2012 19:38

To: Daulat Alex (EALING PCT)

Hi Alex,

If your study is Ethics Board approved your have our permission. Do you have our scoring protocols? Good luck.

Cheers,
Ron

Ron Feise, D.C.
Institute of Evidence-Based Chiropractic
7047 East Greenway Parkway
Suite 250
Scottsdale, AZ 85254
(888)-809-4649
fax (888)-809-4648

The illiterate of the 21st century will not be those who cannot read and write
but those who cannot learn, unlearn and relearn. Alvin Toffler

EQ-5D-5L and EQ-VAS
Questionnaires and Permission

Health Questionnaire

English version for the UK

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

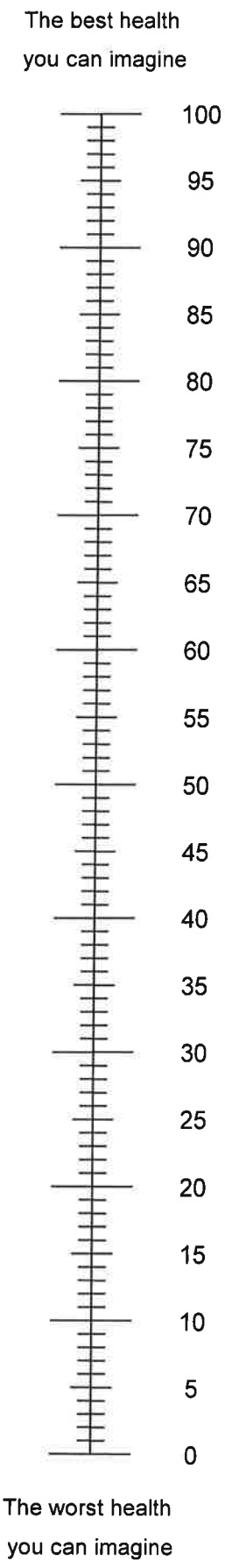
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



EQ-5D

Mandy Oemar [oemar@euroqol.org]

Sent: 13 March 2012 14:05

To: Daulat Alex (EALING PCT)

Attachments: UK (English) EQ-5D-5L.doc (70 KB) [Open as Web Page]

Dear Ms/Mr. Daulat,

Thank you for registering your research at the EuroQol Group's website.

As the study you registered at the EuroQol website involves low patient numbers (200) and is not funded by a pharmaceutical company/medical device manufacturer, or any other profit-making stakeholders, you may use the EQ-5D-5L instrument free of charge. If this is not the case, or the situation changes, please inform us as the EuroQol Group Foundation has a specific policy for large academic studies and/or studies funded by profit making bodies.

Please find attached the UK English EQ-5D-5L version (word format). A brief user guide is downloadable from the homepage of the EuroQol website (www.euroqol.org).

Please note that currently we do not have value sets associated with the EQ-5D-5L system. Pilot studies to elicit values for the EQ-5D-5L are just beginning in a number of countries. In the meantime, the EuroQol Group has developed a "crosswalk" between the EQ-5D-3L value sets and the new EQ-5D-5L descriptive system, resulting in interim value sets for the new EQ-5D-5L descriptive system. Please find all information about the crosswalk from EQ-5D-5L data to the EQ-5D-3L value sets online at the EuroQol website (http://www.euroqol.org/eq-5d/valuation-of-eq-5d/eq-5d-5l-crosswalk-value-sets.html).

Please also note that permission granted above only relates to the paper version of EQ-5D-5L. Requests to use digital representations of EQ-5D (e.g. web, tablet, PDA) should be made separately to userinformationservice@euroqol.org attaching your initial registration.

Best regards,

Mandy Oemar
Communication Officer
EuroQol Group Foundation

NPRS

Patient Name _____ Date _____

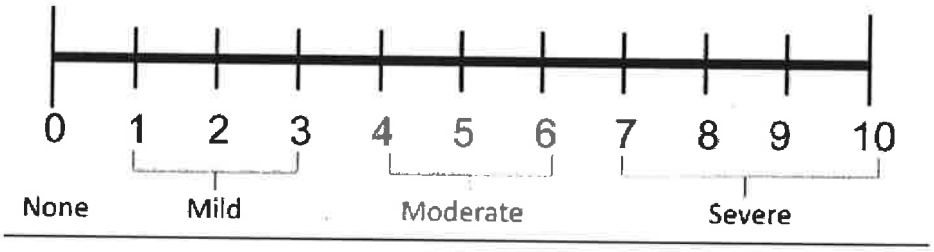
The Numeric Pain Rating Scale

Please indicate your level of pain over the last 24 hours on a scale of 0 – 10.
(0 representing "no pain"; 10 representing "excruciating pain")

Instructions: On the scale below…

1. Mark the letter "C" over the number which describes your CURRENT pain level.
2. Mark the letter "L" over the number which describes your LOWEST pain level in the last 24 hours.
3. Mark the letter "H" over the number which describes your HIGHEST pain level in the last 24 hours.

Patient Instructions (adopted from (McCaffery, Beebe et al. 1989):
"Please indicate the intensity of current, best, and worst pain levels over the past 24 hours on a scale of 0 (no pain) to 10 (worst pain imaginable)"



Reference:
McCaffery, M., Beebe, A., et al. (1989). Pain: Clinical manual for nursing practice, Mosby St. Louis, MO.

PSRS
Questionnaire and Permission

Participant Satisfaction Reporting Scale (PSRS)

Centre: ---------- **RIO Number: ----------**

Number of attended sessions: ---------

Learning from patients is vital to the improvement of our services. We would be grateful if would complete the 5 questions in this questionnaire about your treatment with us, which is completely confidential and anonymous.

For each question please circle the number that most closely responds to your experience

e.g. Almost completely satisfied with my treatment

5 (4) 3 2 1 0

Completely satisfied **Not satisfied at all**

---

1. How well was your back problem **explained** to you during treatment?

5 4 3 2 1 0

Completely explained No explanation given

2. Did you **agree** with the types of treatments and recommendations that you received?

5 4 3 2 1 0

Completely agreed/approved Disagreed/disapproved

3. How **satisfied** were you with the care that you received in the Group Programme?

5 4 3 2 1 0

Completely satisfied Completely dissatisfied

4. Rate your overall **improvement** since starting treatment:

5 4 3 2 1 0

Complete improvement No improvement

5. Rate your level of **satisfaction with your improvement** since starting treatment:

5 4 3 2 1 0

Completely satisfied Completely dissatisfied

Please write any further comments you have below:

Help

Reply | Reply to All | Forward

RE: Participant Satisfaction Reporting...

Hirsh, Adam Todd [athirsh@iupui.edu]

Sent: 16 March 2012 14:22

To: Daulat Alex (EALING PCT)

Alex,
Permission to use this scale is not required; you may use it in your studies as long as it is appropriately cited. All the best in your studies.
Cheers,
Adam

From: Daulat Alex (EALING PCT) [alex.daulat@nhs.net]
Sent: Tuesday, March 13, 2012 5:07 AM
To: Hirsh, Adam Todd
Subject: Participant Satisfaction Reporting Scale

Dear Dr Hirsh

I am a researcher-practitioner working in the UK. I have read one of your earlier papers (2005) concerning patient satisfaction with treatment for chronic pain. I was particularly interested in using the Participant satisfaction reporting scale in my PhD study with chronic back pain patients.

I would like to know how to obtain permission to use this scale in my research if it is indeed yourself or any other contact details.

Thank you very much for your help.

Kind Regards

Alex Daulat

Appendix 7
Randomisation Chart

Random Allocation to Experimental and Control Group once consent has been provided

Locate the last date entry in bold. The column adjacent to this or the next row will be the next group allocation for your patient (Letter above the date). Please date this column, add the patient Rio number, bold and save. The patient can then be referred to this programme.

Example: Group A is the Spinal Rehabilitation Programme (SRP) and Group B is the Back to Fitness (BTF) programme.

B	B	A	B	A	A	B	B	A	A
Date 5/7/13 Rio No 123433	**Date 9/7/13 Rio No 123456**	**Date 12/7/13 Rio No 123444**	Date	Date	Date	Date	Date	Date	Date

The last date entry was **12/7/13**. The adjacent column will allocate your patient to group B the BTF programme. Proceed to date, add patient Rio number, bold and save ready for the next patient group allocation. Please refer to the next page for the randomisation chart.

Randomisation Chart

A	A	B	B	B	B	A	A	A	B
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	B	A	B	A	A	B	A	B	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	B	B	A	A	A	B	A	B	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
A	B	A	B	B	B	B	A	A	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	A	B	A	B	A	B	A	B	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
A	A	B	B	B	B	A	A	A	B
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
A	B	A	B	B	A	B	A	A	B
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
A	B	B	A	B	A	B	A	A	B
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	B	A	A	B	B	A	A	B	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	A	A	B	A	B	A	B	B	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	A	B	A	B	B	A	B	A	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
B	B	A	A	B	B	A	A	B	A
Date	Date	Date	Date	Date	Date	Date	Date	Date	Date

Appendix 8
SRP Guide and Protocol

Spinal Rehabilitation Programme: Guidelines for Programme Therapists relating to patients taking part in the study (RCT)

Pre-Programme

Programme assistant to check all programme referrals and whether interpreters have been booked one week prior to attendance. All participant consent forms and subsequent outcome measure forms of participants will be stored in the Programme Study File- Marked SRP. This will always be stored securely in the filing cabinet after use.

About the Programme

- Up to a maximum of 6 sessions per patient but not necessarily consecutive. This allows for more extended rehabilitation or for patients unable to attend weekly.

- All patients should complete the program within 3/12. Patients must attend at least two sessions per month. Those patients who cancel must re-book within 3/52 or they will be discharged.

- Maximum of 10 patients per session.

- No group education component.

- Programme consists of individualised exercises initially given by the referring therapist and progressed. There will be six exercise stations which can accommodate up to three patients at a time and a one to one station. Patients are encouraged to do their exercises at home.

- Patients should bring their home exercise programme with them. These exercises can be found in their RIO notes, if the patient does not have a copy.

The five exercise stations are

Upper quadrant

Lower quadrant

Core strengthening

Stretches/Lumbar mobility

Aerobic

- One to one sessions are used for education, advice or techniques on how to manage back pain. These can also be used for manual therapy techniques if indicated but this programme is predominately exercise based.

- One to one station. The referrer indicates programme goals with may also be educational i.e. lifting technique. The referrer also indicates on the **Checklist Form** whether manual therapy is indicated and what has been done previously. Manual therapy if appropriate can be applied during the one to one station by the programme therapist. Not every patient in the class would necessarily require manual therapy.

- Assistant to run exercise components/stations and therapist to run one to one station.

- If programme therapist is ill, class can still be run by cancelling another available therapists' patients at that time rather than cancelling all ten patients in the class.

If no one to cover then the class will have to be cancelled. Also if the assistant is ill then cover must be provided or the programme will not run. The programme must be run by a minimum of two people.

Programme Structure

Week 1: All study participants should bring their individualised exercises with attached checklist form. If they have not brought this with them, details can be checked on their RIO notes. Induct all new patients to programme and complete outcome measures. Any patients deemed not to be appropriate for the programme or decide not to continue taking part in the study may be sent back to the referring therapist. In this case, please contact the Chief Investigator.

Outcome Measures: All outcome measure forms can be found in the study file

Programme goals set by referrer

Functional Rating Index, NPRS and EQ-5D-5L

Programme Format:

Pre-programme warm-up performed by assistant which will last 5 minutes.

Individualised exercises with different exercise stations set up. Assistant to supervise and progress exercises as appropriate.

One to one station managed by programme therapist who also oversees the exercise component.

Warm-down performed by assistant which will last 5 minutes.

Patients book their next appointment at reception but can not book block sessions.

Programme therapist completes attendance sheet and SOAP notes as required. Forms are available on the shared drive under Class Info. and should be stored in the study file

Week 2-5

Pre-programme warm-up.

Individualised exercises with different exercise stations.

One to one station.

Warm-down.

Patients book their next appointment at reception but can not book block sessions.

Week 6

Pre-programme warm-up

Individualised exercises with different exercise stations.

One to one station

Warm-down.

Complete outcomes and record on discharge letter. –These are % achievement of goals, FRI, NPRS and the EQ-5D-5L. The Participant Satisfaction Reporting Scale (PSRS) will also be completed by patients. All outcome measure forms will be stored in the SRP study file.

- Discharge is done by the programme therapist with standard programme discharge form on RIO.
- Programme therapists should discuss any problem patients with the Chief Investigator-Alex Daulat at EDTC or by e-mail.

There may be some circumstances when the patient may decide to withdraw from the study without giving a reason. In this situation, they will still be offered treatment within the group programmes. If there is a significant deterioration to their symptoms, that patient might be removed from the study and referred back to the referring physiotherapist for further assessment and appropriate management. Once the patient has completed their group programmes, they will be discharged by the programme therapist. The chief Investigator will contact all participates by letter regarding participation in the focus groups.

Appendix 9
BTFP Guide and Protocol

Back to Fitness Programme: Guidelines for Programme Therapist relating to patients taking part in the study

Pre-Programme

Programme assistant to check all programme referrals and whether interpreters have been booked one week prior to attendance. All participant consent forms and subsequent outcome measure forms of participants will be stored in the Programme Study File- Marked BTFP. A GP information leaflet regarding the patients' participation in the study will need to be completed and sent to the relevant GP practice but only if the patient consents to this. Blank outcome measures, patient information and GP information leaflets can be found in the Study File. The study file will always be locked securely after use in the filing cabinet.

About the Programme

- Up to a maximum of 6 sessions per patient but not necessarily consecutive. This allows for more extended rehabilitation or for patients unable to attend weekly.

- All patients should complete the program within 3/12. Patients must attend at least two sessions per month. Those patients who cancel must re-book within 3/52 or they will be discharged.

- Maximum of 10 patients per session. Class is run by physiotherapist and an assistant physiotherapist (To set up exercise stations).

- Group education component in the form of tips of the day. All participants will be provided with the Arthritis Research UK, Back Pain Booklet on their first attendance. This is a rolling programme.

- Programme consists of circuit based exercises and an education component (See BTFP crib sheet).

- There will be twelve exercise stations. The exercise sheet can be found on the shared drive-classes and Alex's research folder which patients can do at home.

- The programme starts with a warm-up. Then each patient will spend 1 ½ minutes at each station (stopwatch required). Once all stations have been completed the exercise class ends with a warm-down.

- At the end of the exercise session the therapist will give tips of the day on a weekly cycle (5-10 minutes). There is also an opportunity for patients to ask questions. There are not any one to one sessions in this programme.

Topics to be covered for tips of the day.

1st week of every month: Spine structure and Posture.

2nd week of every month: Goal Setting.

3rd week of every month: Acute versus Chronic pain.

4th week of every month: Flare-up and correct lifting advice.

- If programme therapist is ill, class can still be run by cancelling another available therapists' patients at that time rather than cancelling all ten patients in the class.

If no one to cover then the class will have to be cancelled. Also if the assistant is ill then cover must be provided or the programme will not run. The programme must be run by a minimum of two people.

Programme Structure

Week 1: Induct all new patients to class and complete outcome measures. Any patients deemed not to be appropriate for the programme or decide not to continue taking part in the study may be sent back to the referring therapist. In this case, please contact the Chief Investigator.

Outcome Measures:

Programme goals set by referrer

Functional Rating Index, NPRS and EQ-5D-5L.

Class Format:

Pre-programme warm-up performed by assistant for 5 minutes

Circuit training

Warm-down for 5 minutes

Tips of the day and questions.

Patients book their next appointment at reception but can not book block sessions.

Class therapist completes attendance sheet and SOAP notes. Forms are available on the shared drive under Class Info and should be stored in the study file.

Week 2-5

Pre-programme warm-up.

Circuit training

Warm-down

Tips of the day and questions.

Patients book their next appointment at reception but can not book block sessions.

Week 6

Pre-programme warm-up.

Circuit training.

Warm-down.

Tips of the day and questions.

Complete outcomes and record on discharge letter. –These are % achievement of goals, FRI, NPRS and the EQ-5D-5L. The Participant Satisfaction Reporting Scale (PSRS) will also be completed by patients. All outcome measure forms will be stored in the study file.

- Discharge is done by the programme therapist with standard programme discharge form on RIO.
- Programme therapists should discuss any problem patients with the Chief Investigator-Alex Daulat at EDTC.

There may be some circumstances when the patient may decide to withdraw from the study without giving a reason. In this situation, they will still be offered treatment within the group programmes or individual physiotherapy as appropriate. If participants experience any adverse reactions or change to their clinical status; they should be monitored by the programme therapist and provided with appropriate treatment as necessary.

If there is a significant deterioration to their symptoms, that patient might be removed from the study and referred back to the referring physiotherapist for further assessment and appropriate management.

Once the patient has completed their group programmes, they will be discharged by the programme therapist. The chief Investigator will contact all participants by letter regarding participation in the focus groups.

Contact for the chief investigator for advice or further information

For further information or if you have any questions I am happy to discuss it with you:

Alex Daulat
Extended Scope Practitioner
Integrated Musculoskeletal Service
Community Musculoskeletal Specialist Team
Clayponds Hospital
Sterling Way
South Ealing
London W5 4RN
Tel: 020 8232 3393
Email: alex.daulat@nhs.net

BTFP CRIB Sheets

BACK TO FITNESS CRIB SHEETS

1. Welcome to the "Back-to-Fitness" Class (to do on induction)
2. Making sense of medical jargon: spinal anatomy & pathology
3. Why does pain persist?
4. How to increase your activity & exercise tolerance: goal setting & pacing?
5. Posture: How important is it really?
6. What can I do if my back flares up again?
7. Relaxation Vs Exercise Discussion Vs Thoughts & feelings – to decide.

1. WELCOME TO THE BACK TO FITNESS CLASS:

POINTS TO DISCUSS:

- **Why am I here?**
- **What will I be doing?**
- **Will the exercises increase my pain?**

Why am I here?
Explain principles of class: i.e. designed for those that have persistent or recurrent lower back pain episodes.
Discuss expectations: i.e. no simple cure. But does not mean nothing can be done. Aim of this class will be to teach how you can manage condition in order to improve health of back.
Describe medical vs. self-management model. E.g. you could discuss management of other incurable conditions such as diabetes & how emphasis for these is on self-management in order to optimise condition. Explain how similar to back pain management.
Discuss prognosis: i.e. variable – dependent on number of factors (e.g. length of time had symptoms, current activity levels, level of pain, etc.) Reinforce that for many we are not anticipating complete resolution by end of class or that can we guarantee that they will never have back pain again.
So, this programme is to "kick start" things – expectation will be for them to continue with the principles taught upon completion in order to get best results.
What will I be doing?
Discussion re: structure of the class – i.e. 6 week programme. Each week 45 minutes of exercise, followed by 15 minutes of us teaching back care advice.
However, not only expected to be doing these sessions once a week – expectation that should be doing this activity at home. Reinforcing the "the more they put into it the more they'll get out of it", etc.
Will it increase my pain?
Explaining that our aim is to ensure they're able to perform the exercises comfortably without increasing pain levels. For that reason, it's important they go at their own pace with the exercises. However, if finding difficult to let therapist know ASAP.
Also, if finding it too easy… again let a therapist know!
Discuss that normal to feel some discomfort post-exercise as "doing activity that not done in a while", etc.
Safety / Housekeeping
Ask patient's to tell you if there are any changes to their medical conditions or if they have any conditions that they need to inform us of before exercising.
Tell them may need to bring own water, towel if necessary as don't have these on site.

2. MAKING SENSE OF MEDICAL JARGON!?!

POINTS TO DISCUSS:

- **What is the back made of?**
- **What conditions could cause pain in the back?**
- **Why is it difficult to diagnose back pain?**

Why are we talking about this?
Question: what do they already know? What structures make up the back?
Structures to list: vertebrae, facet joints, discs, nerves, muscles, ligaments, etc...
Then discuss each area in a little more detail, along with discussing different pathologies.
For example,

1) Bones:
- **Question:** do bones continue to change after you stop growing?
- Discussion why activity & loading is good for bone health, etc.

Pathology:
- **Question:** What is a condition that affects the health of bony tissue?
- Discuss osteoporosis (what it is, what causes it, how to reduce risk of it, etc.)

2) Joints:
- **Question:** can anyone list the different structures of a joint (could draw one on board)
- Explain role of cartilage and how movement can assist with nourishment, etc.

Pathology:
- **Question:** Can anyone tell me the name of a condition which affects joints?
- Osteoarthritis (AKA – spondylosis, degenerative disc disease, etc.) – reinforcing all terms describing the same thing! Explain what happens to joint with OA.

3) Discs:
- **Question:** what is the function of the disc?
- Discuss the layers of a disc.

Pathology:
- **Question:** What is a condition which affects the disc?
- A) Degenerative disc disease – discuss what this means & discuss why possibly a negative term & how describes normal age-related changes, etc.
- B) A prolapsed disc – discuss pathology.

"So, lots of things that can cause pain, so how can we find out what's wrong?"
- Difficult! Discuss statistics related to non-specific back pain (i.e for 80-90% people with back pain can't get a diagnosis!)
- Why is it non-specific? Discuss the limitations of imaging – how "normal" backs can even show the above pathologies (bulging discs, etc.) and have no pain!
- "So if we don't know what's wrong how do we know how to treat it?" Discuss how regardless of source that the treatment for mechanical back pain is the same…. i.e. what they doing at the moment in the class – exercise and learning how to look after their backs!

3. WHY DOES PAIN PERSIST?

- **What is the difference between acute & chronic pain?**
- **Why does pain persist even after things have healed?**
- **How does stress contribute?**

Discuss how in persistent pain there is a weak correlation between pain & damage – aim of session to show why!
Discuss differences between acute & chronic pain (i.e. short-term vs long term, healing vs healed, useful vs useless).
Discuss neurophysiology acute pain – input=output.
Discuss neurophysiology of chronic pain.
- Could discuss sensitisation at dorsal horn & pain amplification – showing how there is a mechanism where pain changes without any change to input, etc.

What things can make this worse? Talk about stress and impact on neurophysiology.
"So, if this is what's going on in my body, how do I fix it?" Discuss the multi-dimensional influences of pain – biopsychosocial model. Therefore, need to address all factors: e.g. improve local biology (with exercise, etc.),

as well as general well-being (relaxation, etc.). How evidence shown just focusing on one of these dimensions is less effective!
Explain how the back-to fitness programme is helping to address the multi-dimensional aspects of pain!

4. HOW TO ACHIEVE YOUR GOALS: GOAL SETTING & PACING

- **What's the point in setting goals?**
- **How to set good goals?**
- **How can I help myself achieve that goal?**

Question: Why do we set goals = motivation!
Discuss why important for them to write their goals down. Discuss reality of how compliance dips, etc. & goal setting is a way of ensuring motivation maintained!
How do we set goals?

Show recognition that goal setting within pain can be difficult as influences multiple aspects of back pain (activity, relationships, mood levels, social life, work life, etc. etc.)

So rather than focusing on everything – focus on one area. If they are having difficulty coming up with goals, consider these questions:

- What would you rather be doing with your time?
- If you woke up tomorrow & could manage your pain easier what would you like to do?
- Where do you see yourself in 1-2 years' time?

Once come up with an area to focus on need to make it a good goal. **Question:** What makes a good goal?
Discuss SMART – discuss each of the areas and give examples for each.
Question: does anyone have a goal at present that they'd like to be able to achieve? Discuss how to achieve the goal – best way to achieve goal is to practice it!!
Discuss pacing – if possible try to use examples given by the group. Include

- How to set a baseline?
- How to increase activity – how much to increase increments by, etc.?
- Recognition that may not be able to complete task pain-free but by doing these activities it'll ensure that they are increasing how much they can do, despite the pain, etc. etc.

Encourage everyone to have a goal written by next week & discuss if any difficulty with setting one!

5. POSTURE – HOW IMPORTANT IS IT REALLY?

- **Does the shape of our spine influence whether we have back pain?**
- **Do I really need to be sitting up all the time?**
- **How can I lift items safely?**

Question: How important is posture? What does posture mean?

1) Some people when they discuss posture are referring to spinal curvature or rather the shape of your spine.

Question: Has anyone been told their spine is shaped in a certain way?
Discuss the different types of spinal curvature: i.e. flat back, lordotic, etc.
Question: what causes the spine to take these shapes? Lifestyle and genetics!
Then reinforce that no evidence to show that none of these spinal types are at more at risk of back pain than any other. So, spinal curvature is NOT a significant risk factor for back. Variation is NORMAL, etc.

2) Or posture could mean how well someone sits.

Question: what's good posture / what's a bad posture? Why is it a bad posture?
Discuss how sitting in a slumped position is a normal… we all do it!

So why is it considered to be so bad? Discussing how it's not so much the position.... It the length of time you're in that position for! Advice re: variable positioning & how we need to change position regularly (every 20-30 mins). Could talk about reduction of blood flow / ischaemia with static positioning and how basis behind postural lower back pain.

3) Spinal posture & movement.

Here you could discuss bending forwards. **Question:** Is bending forwards bad? Again, No. Back designed to do this!
However, if lifting a certain load = recommendations of using legs, etc.

6. WHAT DO I DO IF MY BACK FLARES-UP AGAIN?

- **What is a flare-up?**
- **What can I do to recover from a flare-up more quickly?**

Question: What is a flare-up?
Question: How long do they last?
Question: What symptoms are normal to experience?
Question: Why do I get flare-ups?

- Inactivity/overactivity
- Stress
- Cold/flu
- No reason!

Question: Have I damaged myself?
Question: Suggested strategies for flare-up management?

- Don't panic
- Challenge unhelpful thoughts
- Pacing/planning day
- Use heat/ice
- Stretch
- Rest Vs. Gradual increase of movement

Session 7 ideas:

- Thoughts and Feelings discussion
- Relaxation.
- Exercise discussion – why good / barriers to exercise & exercise options in community.

BTFP Exercise Sheets

Complete this form as you do each exercise. Write which level you completed and the number of repetitions of that exercise you achieved in at each station. Please ask the physiotherapist if you have any questions. Try to increase your repetitions or exercise level each week.

Station number	Exercise	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6	
		level	Reps.	level	Reps.	level	Reps.	level	Reps.	level	Reps.	level	Reps.
1	Step ups												
2	Sit up												
3	Lunge												
4	Push up												
5	Hip abduction												
6	Superman												
Station number	Exercise	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6	
		level	Reps.	level	Reps.	level	Reps.	level	Reps.	level	Reps.	level	Reps.
7	Squat												
8	Gym ball balance – Knee ext												

9	Sit-stand														
10	Bridging														
11	Side lunges														
12	Star excursion 														

Appendix 10
Focus Group Question Guide

Draft Focus Group Question Guide
(Based on the format suggested by Halcomb et al, 2007 and Liamputtong, 2011)

Introductory Question	**Can you please tell us about your experience of attending the group programme?**
Transition Question	**Can you tell us about what in the programme has helped with your chronic back pain?**
Key Focus Questions: **1**	**What were your expectations of the group programme?**
2	**Do you think education regarding back pain should be provided in a group or individually?**
3	**What are the barriers to participating in this programme and regular exercise afterwards?**
Summarising Question	**Think back on your experiences and this discussion today and tell us what else we can do to improve the management of chronic low back pain.**
Concluding Question	**Is there anything else that anyone feels that we should have discussed today?**

Appendix 11
Participant Information Leaflets

Ealing Hospital NHS
NHS Trust

Integrated Musculoskeletal Service
Community Musculoskeletal Specialist Team
Clayponds Hospital
Sterling Place
South Ealing W5 4RN
Tel: 020 8232 3393

Participant Information Sheet

Research Study title:

An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care.

Researcher: Alex Daulat

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve? Please take time to read the following information carefully and discuss with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

Low back Pain

Low back pain is pain, muscle tension, or stiffness, localised between the ribs and above the buttock, with or without leg pain and is defined as chronic when pain persists for greater than 12 weeks.

Physiotherapy

Many people are referred to a physiotherapist for their back pain. Physiotherapists can give expert advice on pain relief and exercise therapy. They can also reduce spinal pain and improve movement with manipulation, mobilisation and stretches. Both manipulation/mobilisation are techniques by which the physiotherapist can safely move the spine in ways you could not do yourself. Spinal manipulation can be described as the use of hands applied to the patient incorporating the use of instructions and manoeuvres to achieve maximal painless movement.

What is the purpose of the study?

More research into spinal rehabilitation is required to establish the most effective and inexpensive form of treatment for chronic low back pain. The alternative group physiotherapy programme may promote long-term self-management of back pain. This study may go towards improving management for chronic low back pain.

The study will last for two years and will compare one group programme with another.

Why have I been chosen?

You have been chosen because you have been referred by your GP to see a physiotherapist to treat your back pain. There will be one hundred and twenty patients in this study.

Do I have to take part?

It is up to you to decide whether or not to take part. However, you do not have to take part in this study. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Your GP will be informed of your participation in the study only if you consent to this.

A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. You can still be referred to the group programmes even if you decide not to take part in the study.

What will happen to me if I take part?

You will be randomised to either one of two group programmes. You will then be asked to attend your assigned group programme and take with you your individualised exercise programme given to you by your physiotherapist after the initial assessments. Your physiotherapist will also set three goals prior to starting these programmes. During the first session of the programme you will be asked to fill in two outcome measures questionnaires. These questionnaires are: The Functional Rating Index which will measure function and the EQ-5D-5L which will measure quality of life. The two group programmes which you may be assigned to are the Spinal Rehabilitation Programme (SRP) and the Back to Fitness Programme (BTFP).

In the SRP, you will then start with your exercises which will be supervised by one of the therapists. You will then have a one to one session with the therapist every programme session who will offer you manual therapy which consists of 'hands on' treatment if this is clinically appropriate. In this session you will also be given advice on your condition. You will then be offered up to six sessions in the programme which you can book at the end of each

session. You do not have to attend weekly but you must attend at least two sessions per month.

The BTFP is a circuit based group exercise class. This programme does not offer manual therapy but will provide advice on how to manage your back pain. As with the SRP, you will be offered up to six sessions which you can book at the end of each session. You do not have to attend weekly but you must attend at least two sessions per month.

After completion of the SRP or the BTFP you will be asked to fill in the outcome measure questionnaires again to indicate whether the physiotherapy treatment has been effective. Your three set goals will be reviewed to determine if you achieved them. You will also be required to complete a patient satisfaction questionnaire regarding your treatment within the programme and a community patient experience questionnaire regarding your views on the programmes.

All participants are expected to do their exercises at home in between sessions as instructed and should not participate in any form of exercise therapy which may affect the results. However, you are advised to increase your physical activity levels to a least two and half hours of moderate intensity exercise per week if possible. This would include activities such as brisk walking or swimming.

What do I have to do?

We will ask you to attend all booked sessions in your assigned group programme and follow your exercise regimen within the respective programmes. At home the individualised exercise programme can take approximately 45 minutes and should be performed 3 times a week in addition to the programme sessions. You will also be asked to complete the 2 outcome measure questionnaires at the initial programme session, at completion of the programme together with the set goals. As well as patient satisfaction and experience questionnaires. These outcome measure questionnaires will also need to be completed 6 and 12 months post programme to assess the long-term effectiveness of the treatment. This will be done via telephone by one of our therapists and therefore you will not be required to come to the department to complete these questionnaires. All participants will be invited to take part in focus group interviews to discuss and share their experiences of the group programmes. You will be invited to take part by letter in due course. The focus group interviews will take place in 2015.

You are asked not to receive any other therapy or treatment whilst you attend physiotherapy.

You are asked not to undertake any other form of exercise therapy during the programme period. Examples of exercise therapy that should not be undertaken include any form of exercise class such as Pilates, aerobics or yoga or any personal training sessions.

There are no other lifestyle restrictions. If you were to become pregnant during the study this would affect your treatment and you must inform your physiotherapist or programme therapist.

What are the alternatives for diagnosis or treatment?

Your back pain will be treated conservatively by physiotherapy. If you were not benefiting from the treatment your physiotherapist can arrange further review or referral to a Specialist if indicated.

What are the side effects of any treatment received when taking part?

You may experience some post-exercise muscle soreness post session or slight discomfort following your 'hands on' treatment. We will take this into account and adjust your treatment accordingly. You will be also given advice on how to manage your pain at home as well as relief from any post-treatment discomfort.

If you are in any way concerned about any discomfort or anything else during the treatment then you can contact the researcher: Alex Daulat on 020 3313 8875.

What are the possible disadvantages and risks of taking part?

Pregnant women in their first trimester are advised not to undertake any new physiotherapy exercises as part of their standard care and therefore they will be excluded from taking part in the study. Pregnant women must not therefore take part in this study and neither should women who plan to become pregnant during the study. Any woman who finds that she has become pregnant while taking part in the study should immediately inform the researcher and her GP.

It is possible that you may not benefit from physiotherapy but there are minimal risks to the treatment as you would have been screened thoroughly prior to your inclusion into the study. In the event of you not benefiting from physiotherapy, other treatment options will then be discussed with you.

What are the possible benefits of taking part?

You will receive physiotherapy treatment based on the best available evidence for the treatment of back pain and by experienced physiotherapists.

We hope that these programmes will help you so that you can manage your back pain better. However, this cannot be guaranteed. The information we get from this study may help us to treat future participants with back pain more successfully.

Will my taking part in this study be kept confidential?

The information we collect about you will be part of a standard physiotherapy assessment and kept in your patient notes. This information will be stored securely and analysed by the researcher.

All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you which is used will have your name and address removed so that you cannot be recognised from it. In the unlikely event of a loss of capacity, the research team will retain your personal data collected and continue to use it confidentially in connection with the purposes of the study. This may include further research after this current study has ended.

What will happen to the results of the research study?

The final results will be used to complete a postgraduate dissertation and may be published in a journal. No data collected from you will be identifiable. Recommendations will be made once the analysis has been made. A summary sheet of the findings and recommendations of this study will be sent to all participants. This summary will also provide details of where the results of the study can be accessed.

Who has reviewed the study?

All research conducted in the NHS will be reviewed by the National Research Ethics Service. They will protect your rights, safety and wellbeing.

If you have any complaints or comments on the service received?

Please contact:

Patient Advice and Liaison Service
NHS Ealing Primary Care Trust
119 Uxbridge Road
Hanwell
London W7 3ST.

Tel: 0800 641120 (Free phone)

Contact for further information

For further information or if you have any questions I am happy to discuss it with you:

Alex Daulat
Extended Scope Practitioner
Integrated Musculoskeletal Service
Community Musculoskeletal Specialist Team
Clayponds Hospital
Sterling Way
South Ealing
London W5 4RN
Tel: 020 8232 3393
Email: alex.daulat@nhs.net

Dr Catherine M. KERR,
School of Health and Social Science,
MIDDLESEX UNIVERSITY,
The Burroughs,
Hendon,
LONDON.
NW4 4BT
Tele no 0208 411 4595
c.kerr@mdx.ac.uk

Thank you for reading this information sheet and considering taking part in this study

All participants will each be given a copy of this information sheet and a signed consent form to keep.

Stronger Together

London North West Healthcare NHS
NHS Trust

Focus Group information/invitation

Integrated Musculoskeletal Service
Community Musculoskeletal Specialist Team
Clayponds Hospital
Sterling Place
South Ealing W5 4RN
Tel: 020 8232 3393

Research Study title:

An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care.

Researcher: Alex Daulat

I would like to invite you to attend a focus group interview to discuss and share your experiences of the group programme that you attended as part of your treatment. These focus group interviews will take place on Wednesday 10th June 2015 at 10.00am and 2.00pm at **Ealing Day Treatment Centre, Britton Drive, Southall, Middlesex, UB1 2SH. Tel. 8571 1143.** There is free parking available at this site. Refreshments will be provided. On your arrival to the centre please check in at reception.

Before you decide to attend the focus group interviews it is important for you to understand why these are being done and what it will involve? Please take time to read the following information carefully and discuss with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you still wish to take part.

If you do decide to take part; please contact me **Alex Daulat** on **07951119709** and leave a message if not answered. Please indicate if you would like to attend the 10.00am session or the 2.00pm session and quote your ID number.

You will then be sent a confirmation of the time by post with a map enclosed.

Thank you for reading this.

What are the possible benefits of taking part?

You will have the opportunity to discuss your experiences of your physiotherapy treatment with us. The information you provide may help to improve our service and provision of group physiotherapy programmes for managing chronic low back pain. This may have implications for yourself if your back pain reoccurs and you require further treatment with us.

Will my taking part in the focus groups be kept confidential?

The information we collect during the focus group interviews will be stored securely and analysed by the researcher.

Any information that is collected about you during the course of the interviews will be kept strictly confidential. Any information about you which is used will have your name and address removed so that you cannot be recognised from it. In the unlikely event of a loss of capacity, the research team will retain your personal data collected and continue to use it confidentially in connection with the purposes of the study. This may include further research after this current study has ended.

What will happen to the information obtained from the focus group interviews?

Data on audio-tape obtained from the focus groups will be transcribed, the content analysed to code and categorised into themes and sub-themes. An independent researcher not involved in the study will review the transcripts for reliability of the identified codes and themes. These themes will then subject to further analysis and interpretation. Once the audio-tapes have been transcribed, they will be destroyed. The final results from these interviews will be used to complete a postgraduate dissertation and may be published in a journal. No data collected from you will be identifiable. Direct quotations from respondents may be published from the focus group interviews but only if the respondent has consented to this. Direct quotations may provide a more accurate account of the participant's experience of the group programme they attended. Recommendations will be made once the analysis has been made. A summary sheet of the findings and recommendations of the whole study will be sent to all participants. This summary will also provide details of where the results of the study can be accessed.

Who has reviewed the study?

All research conducted in the NHS will be reviewed by the National Research Ethics Service. They will protect your rights, safety and wellbeing.

If you have any complaints or comments on the service received?

Focus Groups

Focus groups are often used in back pain research to explore participants' experiences of a treatment programme or service. Focus group interviews enable individual members of a group to interact with each other which can eventually lead to a discussion regarding a certain topic. This has the advantage over one to one interviews as this can enhance the breath and depth of the information produced. This method may provide further insights in to how patients regard their treatment and may go to improving our service as well as the management for chronic low back pain.

The focus group session will last up to two hours.

Why have I been chosen?

You have been chosen because you have taken part in one of our group exercise programmes at the Trust as part of a research study for your back pain treatment. There will be 4-8 participants in each focus group.

Do I have to take part?

It is up to you to decide whether or not to take part. However, you do not have to take part in these focus group interviews. If you do decide to take part you will be given this invitation letter to keep and be asked to sign a consent form. Your participation is voluntary. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What will this involve and what do I have to do?

You will attend one focus group at the physiotherapy department. The session will be led by the researcher. Another independent researcher will be present as the note taker. Participants in these focus groups will be given the opportunity to discuss their experiences with the aim of exploring the impact of the group programme on them as individuals. Prompts will be used to facilitate further discussion. There will be a check list of topics such as participant expectations, benefits of the group programmes to them and barriers to participation in the relevant programme. Each focus group will be allocated up to two hours and will be moderated by the researcher. The group meeting will be minuted and recorded by audio-tape.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks of taking part in the focus group interviews.

Please contact:

Patient Advice and Liaison Service (PALS)
Ealing Hospital NHS Trust
PALS centre is located on level 2 within Ealing Hospital
The centre is open Monday to Friday 9.30am until 4.00pm (no appointment required).

Also available by:

Free phone: 0800 641120
E-mail at PALS@eht.nhs.uk
Website at www.ealinghospital.nhs.uk
Direct Line: 020 8967 5653

Contact for further information

For further information or if you have any questions I am happy to discuss it with you:

Alex Daulat
Extended Scope Practitioner
Integrated Musculoskeletal Service
Community Musculoskeletal Specialist Team
Clayponds Hospital
Sterling Way
South Ealing
London W5 4RN
Tel: 020 8232 3393
Email: alex.daulat@nhs.net

Dr Catherine M. KERR,
School of Health and Social Science,
MIDDLESEX UNIVERSITY,
The Burroughs,
Hendon,
LONDON.
NW4 4BT
Tele no 0208 411 4595
c.kerr@mdx.ac.uk

Thank you for reading this information sheet and considering taking part in the focus group interviews

All participants will each be given a copy of this information sheet and a signed consent form to keep.

Appendix 12
Risk Assessment Form

INDEPENDENT FIELD/LOCATION WORK RISK ASSESSMENT FRA1

This proforma is applicable to, and must be completed in advance for, the following field/location work situations:

1. *All field/location work undertaken independently by individual students, either in the UK or overseas, including in connection with proposition module or dissertations. Supervisor to complete with student(s).*
2. *All field/location work undertaken by postgraduate students. Supervisors to complete with student(s).*
3. *Field/location work undertaken by research students. Student to complete with supervisor.*
4. *Field/location work/visits by research staff. Researcher to complete with Research Centre Head.*
5. *Essential information for students travelling abroad can be found on www.fco.gov.uk*

FIELD/LOCATION WORK DETAILS

Name ALEX DAULBY

Student No: MOO386281

Research Centre (staff only).....

Supervisor Dr Catherine KERR.

Degree course: Doctorate in Professional Studies (Health).....

Telephone numbers and name of next of kin who may be contacted in the event of an accident	**NEXT OF KIN** **Name** Barbara Lawler..... **Phone** 020 8504 1529
Physical or psychological limitations to carrying out the proposed field/location work	None.....
Any health problems (full details) Which may be relevant to proposed field/location work activity in case of emergencies.	None.....
Locality (Country and Region)	United Kingdom.....
Travel Arrangements	N/A.....
NB: Comprehensive travel and health insurance must always be obtained for independent overseas field/location work.	N/A.....
Dates of Travel and Field/location work	N/A.....

PLEASE READ THE FOLLOWING INFORMATION VERY CAREFULLY

Hazard Identification and Risk Assessment

List the localities to be visited or specify routes to be followed (**Col. 1**). For each locality, enter the potential hazards that may be identified beyond those accepted in everyday life. Add details giving cause for concern (**Col. 2**).

Examples of Potential Hazards :
Adverse weather: exposure (heat, sunburn, lightening, wind, hypothermia)
Terrain: rugged, unstable, fall, slip, trip, debris, and remoteness. Traffic: pollution.
Demolition/building sites, assault, getting lost, animals, disease.
Working on/near water: drowning, swept away, disease (weils disease, hepatitis, malaria, etc), parasites', flooding, tides and range.
Lone working: difficult to summon help, alone or in isolation, lone interviews.
Dealing with the public: personal attack, causing offence/intrusion, misinterpreted, political, ethnic, cultural, socio-economic differences/problems. Known or suspected criminal offenders.
Safety Standards (other work organisations, transport, hotels, etc), working at night, areas of high crime.
Ill health: personal considerations or vulnerabilities, pre-determined medical conditions (asthma, allergies, fitting) general fitness, disabilities, persons suited to task.
Articles and equipment: inappropriate type and/or use, failure of equipment, insufficient training for use and repair, injury.
Substances (chemicals, plants, bio- hazards, waste): ill health - poisoning, infection, irritation, burns, cuts, eye-damage.
Manual handling: lifting, carrying, moving large or heavy items, physical unsuitability for task

If no hazard can be identified beyond those of everyday life, enter 'NONE'.

1. LOCALITY/ROUTE	2. POTENTIAL HAZARDS
Physiotherapy Department **Ealing Day Treatment Centre** **Britten Drive** **Southall** **UB1 2SH**	**None**

The University Field/location work code of Practice booklet provides practical advice that should be followed in planning and conducting field/location work.

Risk Minimisation/Control Measures

PLEASE READ VERY CAREFULLY

For each hazard identified (**Col 2**), list the precautions/control measures in place or that will be taken (**Col 3**) to "**reduce the risk to acceptable levels**", and the safety equipment (**Col 5**) that will be employed.

Assuming the safety precautions/control methods that will be adopted (**Col. 3**), categorise the field/location work risk for each location/route as negligible, low, moderate or high (**Col. 4**).
Risk increases with both the increasing likelihood of an accident and the increasing severity of the consequences of an accident.

An acceptable level of risk is: a risk which can be safely controlled by person taking part in the activity using the precautions and control measures noted including the necessary instructions, information and training relevant to that risk. The resultant risk should not be significantly higher than that encountered in everyday life.
Examples of control measures/precautions:
Providing adequate training, information & instructions on field/location work tasks and the safe and correct use of any equipment, substances and personal protective equipment. Inspection and safety check of any equipment prior to use. Assessing individuals fitness and suitability to environment and tasks involved. Appropriate clothing, environmental information consulted and advice followed

(weather conditions, tide times etc.). Seek advice on harmful plants, animals & substances that may be encountered, including information and instruction on safe procedures for handling hazardous substances. First aid provisions, inoculations, individual medical requirements, logging of location, route and expected return times of lone workers. Establish emergency procedures (means of raising an alarm, back up arrangements). Working with colleagues (pairs). **Lone working is not permitted where the risk of physical or verbal violence is a realistic possibility.** Training in interview techniques and avoiding /defusing conflict, following advice from local organisations, wearing of clothing unlikely to cause offence or unwanted attention. Interviews in neutral locations. Checks on Health and Safety standards & welfare facilities of travel, accommodation and outside organisations. Seek information on social/cultural/political status of field/location work area.

Examples of Safety Equipment: Hardhats, goggles, gloves, harness, waders, whistles, boots, mobile phone, ear protectors, bright fluorescent clothing (for roadside work), dust mask, etc.

If a proposed locality has not been visited previously, give your authority for the risk assessment stated or indicate that your visit will be preceded by a thorough risk assessment.

3. PRECAUTIONS/CONTROL MEASURES	4. RISK ASSESSMENT (low, moderate, high)	5. SAFETY/EQUIPMENT
Patients involved in the physiotherapy treatment may experience some post-exercise muscle soreness post session or slight discomfort following their 'hands on' treatment. The treating physiotherapist will take this into account and adjust any treatment accordingly. Patients will be also given advice on how to manage their pain at home as well as relief from any post-treatment discomfort. All those physiotherapists in the treatment of patients during the study are fully trained. All have up to date health and safely training. This is an annual mandatory requirement.	Low	N/A

PLEASE READ THE FOLLOWING INFORMATION AND SIGN AS APPROPRIATE

DECLARATION: The undersigned have assessed the activity and the associated risks and declare that there is no significant risk or that the risk will be controlled by the method(s) listed above/over. Those participating in the work have read the assessment and will put in place precautions/control measures identified.

NB: Risk should be constantly reassessed during the field/location work period and additional precautions taken or field/location work discontinued if the risk is seen to be unacceptable.

Signature of Field/location worker (Student/Staff) ..... S.A Deacon ..... **Date** 6th August 2012

Signature of Student Supervisor ..... **Date** 27th July 2012

APPROVAL: (ONE ONLY)

Signature of Director of Programmes (undergraduate students only) ..... **Date** .....

Signature of Research Degree Co-ordinator or Director of Programmes (Postgraduate) ..... **Date** .....

Signature of Research Centre

Head (for staff field/location workers) ..... **Date** .....

FIELD/LOCATION WORK CHECK LIST

1. Ensure that **all members** of the field party possess the following attributes (where relevant) at a level appropriate to the proposed activity and likely field conditions:

- [x] Safety knowledge and training?
- [x] Awareness of cultural, social and political differences?
- [x] Physical and psychological fitness and disease immunity, protection and awareness?
- [x] Personal clothing and safety equipment?
- [x] Suitability of field/location workers to proposed tasks?

2. Have all the necessary arrangements been made and information/instruction gained, and have the relevant authorities been consulted or informed with regard to:

- [x] Visa, permits?
- [x] Legal access to sites and/or persons?
- [x] Political or military sensitivity of the proposed topic, its method or location?
- [x] Weather conditions, tide times and ranges?
- [x] Vaccinations and other health precautions?
- [x] Civil unrest and terrorism?
- [x] Arrival times after journeys?
- [x] Safety equipment and protective clothing?
- [x] Financial and insurance implications?
- [x] Crime risk?
- [x] Health insurance arrangements?
- [x] Emergency procedures?
- [x] Transport use?
- [x] Travel and accommodation arrangements?

Important information for retaining evidence of completed risk assessments:

Once the risk assessment is completed and approval gained the **supervisor** should retain this form and issue a copy of it to the field/location worker participating on the field course/work. In addition the **approver** must keep a copy of this risk assessment in an appropriate Health and Safety file.

Appendix 13
Focus Group Consent Form

Stronger Together

London North West Healthcare NHS
NHS Trust

Participant Identification Number:

CONSENT FORM FOR FOCUS GROUP INTERVIEWS

Title of Project: An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care.

Name of Researcher: Alex Daulat

Please read below and sign at the bottom of the form if you agree with the statements below.

Please initial box

1. I confirm that I have read and understand the cover letter and information sheet (Version 5 dated 14/01/2015) regarding the focus group interviews and have had the opportunity to consider the information, to 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 and without my legal rights being affected. ☐

3. I understand that the researcher will use the recording of this session by audio-tape or dictaphone for research purposes. The researcher is responsible for the secure storage of this recording. Once the recording has been transcribed it will be destroyed or deleted. ☐

4. I understand that, I have the right to withdraw my permission to make this recording at any time before, during or after the session and that I can ask the researcher to stop the recording at any time. ☐

5. I give consent for the researcher to make recordings of this interview session. ☐

6. I give permission for the researcher to publish any direct quotations that I I have made during the focus group interview. ☐

Name of participant	Date	Signature
Name of person taking consent (if different from researcher)	Date	Signature
Researcher	Date	Signature

Appendix 14
R&D Approval Letters

Imperial College

Imperial College Healthcare NHS
NHS Trust
Joint Research Compliance Office
Academic Health Science Centre
Imperial College London and
Imperial College Healthcare NHS Trust
Room 5L10A, 5th Floor, Lab Block
Charing Cross Hospital
Fulham Palace Road
London W6 8RF
Tel: +44 (0)20 3311 0206
Fax: +44 (0)20 3311 0203
c.buicke@imperial.ac.uk/
www.ic.ac.uk/clinicalresearchgovernanceoffice

Christine Buicke
Research Governance Manager

17/04/2013

Mr J A Daulat
Extended Scope Practitioner in Physiotherapy
Ealing NHS Trust
Community Musculoskeletal Specialist Team
Clayponds Hospital
Sterling Place
South Ealing
W5 4RN

Dear Mr Daulat,

RE: JRCO Study Approval

Project Title: Developing an alternative group physiotherapy programme for the management of chronic low back pain in Primary Care.

Short Title: Developing an alternative group programme for chronic back pain

Joint Research Compliance Office Reference number: 13SM0526

Ethics reference number: n/a – study involving staff only **Principal Investigator:** Mr Alex Daulat

I confirm that this project has now been approved by the Joint Research Compliance Office. The project may now start at Imperial College Healthcare NHS Trust sites. Please note that the start date of the project is the date of this letter and the duration is the same as that provided in your application form.

The list of documents reviewed and approved by the Joint Research Compliance Office under requirements of the Research Governance Framework are as follows:

Document	Version	Date
NHS REC (IRAS) application form, version 3.4	109185/377785/1/608	26th November 2012
NHS R&D (IRAS) application form, version 3.4	109185/421130/14/964	05th March 2013
Research Study Protocol	Student No : MOO386281	07th September 2012
Physiotherapy Survey	Version 04	08th October 2012
Sponsors Agreement Letter from Middlesex University, London.	Student Number: 386281	29th November 2012
Chief Investigators CV: John Alexander Daulat		
Middlesex University of London – Planning	IPL4016	08th October

Imperial College

Imperial College Healthcare NHS
NHS Trust

a Practitioner Research & Development Programme		2012
Physiotherapy Survey	Version 05	18th February 2013
NHS Ealing Hospital NHS Trust, R&D Department Approval Letter	(RDE12/021)34	07th February 2013

Before you commence your research, please note that you must be aware of your obligations to comply with the minimum requirements for compliance with the Research Governance indicators 17 (Data Protection); 25 (Health and Safety) and 22 (Financial Probity). Details of the requirements to be met can be found in the Research Governance Framework available on www.dh.gov.uk.

Under the Research Governance regulations, Serious Adverse Event Reports, and amendments to the protocol or other supporting documents must be forwarded to the Joint Research Compliance Office. In accordance with the Research Governance Framework, research projects carried out in the Trust may be randomly chosen by the Joint Research Compliance Office for auditing.

I wish you well in your research.

Yours sincerely,

Ms Christine Buicke
Research Governance Manager

South London Healthcare NHS
NHS Trust

Queen Elizabeth, Woolwich
Research & Development
Stadium Road
Woolwich
London
SE18 4QH

Tel: 020 8836 5911
Fax: 020 8836 6744
SLH-TR.ResearchAndDevelopment@nhs.net
www.SLH.nhs.uk

Mr Alex Daulat
25 Broadmead Rd
Woodford Green
Essex
IG8 0AX

Dear Mr Daulat

Tuesday 26th February 2013

STUDY TITLE: Developing an alternative group programme for chronic back pain

REC REF: N/A Staff Survey

R&D REFERENCE NUMBER: SLHT/2013/PHYSIO/210

I am pleased to inform you that the above study has been granted NHS Permission at South London Healthcare NHS Trust. NHS Permission is granted on the understanding and provision that you adhere to the following conditions:

- The research is conducted in line with the Department of Health Research Governance Framework for Health and Social Care (Second Edition April 2005), The Data Protection Act 1998, the Human Tissue Act 2004 and ICH Good Clinical Practice guidelines.
- The research is conducted to the approved protocol and in accordance with Trust policies and procedures.
- Any amendments to the approved protocol must be provided to the R&D department for approval.
- Please also ensure that the office is notified of any changes in status to the project, for example if the site should close before the stated end date and any urgent safety measures enacted.
- You must notify the R&D department of the actual commencement and completion date of the study.
- Copies and details of the dissemination of results e.g. publication in peer reviewed journal, presentation of abstract at meetings etc are sent to the R&D department..

Yours sincerely

Victoria Simpson
Research & Development Administrator
cc to: Paul Knight – Clinical Pathway Lead: Low Back Pain, SLHT

The North West London Hospitals NHS
NHS Trust

R&D Office
Rooms 7N 014, Level 7, Maternity Block
Northwick Park Hospital
Watford Road, Harrow HA1 3UJ
Tel: 020 8869 2011
Fax: 020 8869 5081
E-mail: alan.warnes@nhs.net
Website: www.nwlh.nhs.uk/research

NHS Management Permission Letter for Research (for studies not requiring formal Ethics Approval)

To: Alex Daulat

From: Dr Alan Warnes (R&D Manager)

Date: 26/02/2013

R&D Ref: RD12/109

Project Title: Developing an Alternative group physiotherapy programme for the management of chronic low back pain in primary care.

I understand that you are going to undertake PHASE 1 of the above research which does not require formal ethical approval but requires local R&D approval. A condition that you do not undertake research in an NHS organisation until relevant NHS Management Permission or Approval has been received, applies in this case. I am therefore writing on behalf of the North West London Hospitals NHS Trust to inform you that the project has been approved by the Trust and you may now proceed.

NHS Permission for the above referenced research has been granted on the basis described in the relevant documents and supporting documentation. If the study goes onto PHASE 2 then a further R&D approval will be required. Approved working documents to be used at the Trust are listed on the following page.

To maintain this approval, the following conditions must be met:

1. All staff involved in the running of this study must adhere to the Research Governance Framework requirements, ICH GCP (if applicable), Trust organisational policies, SOPs and any other relevant legislation or regulatory standards, these include but are not limited to:
    - The Data Protection Act 1998
    - The Human Tissue Act 2004
    - The Mental Capacity Act 2005

    (see www.nwlh.nhs.uk/research for web links).

2. As Chief/Principal Investigator you are required to formally advise the R&D Office of **ANY** changes to the project including:
    - Any changes to the status of the project, e.g. abandoned, completed etc
    - Any changes to the protocol – however minor.

- Any changes to the funding arrangements.

3. The Chief Investigator is also required to:
   - Notify the R&D Office, in a timely fashion, of any Serious Adverse Events relating to the Research and the appropriate urgent safety measures taken in line with ICH GCP requirements.
   - Ensure that the R&D Office has copies of all annual, safety (if applicable) and final progress reports.
   - Ensure all researchers involved in the project hold the necessary expertise required to undertake the work and have Honorary Contracts or letters of access should they be required or if they are needed.
   - Ensure adequate and accurate reporting and monitoring of said project.
   - Co-operate with all internal Trust oversight and auditing procedures.
   - Provide bi annual reports on recruitment and screen failures where applicable, when requested.

4. Non-compliance with these conditions and any other further conditions, which may have been earlier stated, invalidates this Trust approval.

5. This approval will automatically lapse if no annual report on this study is received at the R&D office, 14 months from the date of this letter. Guidance on Annual reporting is available from the R&D Office.

6. All studies sponsored by the Trust are covered under the NHS Indemnity Scheme for Clinical Negligence (*NHS Indemnity Arrangements for clinical negligence claims in the NHS*, issued under cover of HSG 96/48).

Yours sincerely,

Dr Alan Warnes

Attachments:

1. Non-CT_ResearchEssentialDocumentsV1.0_05Oct2007.

(All document templates and Trust SOPs are located at www.nwlh.nhs.uk/research in the document Library)

Approved Working Documents (For R&D Office Reference)

Document Type	Version	Date
Investigator CV (Alex Daulat)		
Protocol IPL4016		07/09/2012
Letter from Middlesex University		08/10/2012
Sponsor's letter		29/11/2012
Final survey questionnaire		11/02/2013

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Research and Development Support Office

Alex Daulat
MSK Extended Scope Practitioner
Greenford Green Clinic
Wadham Gardens
Middlesex, UB6 0BP

21/02/2013

Dear Alex Daulat

R&D Number: C&W13/011
Study Title: Developing an alternative group physiotherapy programme for the management of chronic low back pain in Primary Care

I am pleased to inform you that the R&D review of the above project is now complete, and the project has been formally approved to be undertaken at Chelsea and Westminster Hospital NHS Foundation Trust. The documents reviewed are as follows:

Document	Version	Date
Protocol	Stage 1 – survey only	07/09/2012
Pilot Questionnaire and Information Sheet	Version 5.0	18/02/2013
Letter of Confirmation of Sponsorship (Middlesex University)		29/11/2012
CV for Alex Daulat		08/02/2013

Permission is granted on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and applicable NHS Trust policies and procedures. R&D standard operating procedures are available to download from the intranet or can be requested by emailing research.development@chelwest.nhs.uk.

The R&D approval applies for the duration of the research except where action is taken to suspend or terminate the approval early. Where the duration of the study is to be extended beyond the period specified in the Site Specific Information (SSI) form, you must notify the R&D Support Office prior to the extension. Also please be reminded that you must notify us of any amendments and the study closure.

Please note that the NHS organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research.

I wish you well in your research. Please do not hesitate to contact us should you need any guidance or assistance.

Yours sincerely

Donna McLean
Research Operations Manager

Ealing Hospital NHS
NHS Trust

Research and Development Office
R&D Office
Level 1
Ealing Hospital
Uxbridge Road,
Southall
Middlesex
UB1 3HW
Direct line : 0208 967 5000 ext 3468
Fax 0208 967 5215

07th February 2013

Mr Alex Daulat
Ealing Hospital
Uxbridge Road
Southall
Middlesex

Dear Alex

Research Project: Developing an alternative group physiotherapy programme for management of chronic low back pain in primary care. (RDE12/021)

Thank you for the documentation with details of the above project you are requesting to carry out at Ealing Hospital NHS Trust.

I have looked at the protocol and note that this project is deemed a cross over between service evaluation and research not requiring ethical approval.

Under paragraph 2.3.13 of GAfREC, review by a REC within the UK Health Departments" Research Ethics Service is not normally required for research involving healthcare or social care staff recruited as research participants by virtue of their professional role providing the research does not raise any material ethical issues. As questionnaires will be completely anonymised and participation is voluntary and no specific cases e.g. involving vulnerable adults/children will be disclosed this should not raise any material ethical issues.

I believe you have discussed the implications of the project with others whose services the project may have an impact upon and *that any relevant costs incurred by distribution of the questionnaire will be borne by the MSK Community Team.* If this no longer the case then please notify the R&D Office. I am happy to give permission to be carried out at Ealing Hospital NHS Trust.

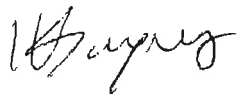
On a minor note it is recommended that the word 'draft' on the top of the physiotherapy staff survey is removed.

Your project details will be passed onto Dr Alan Warnes, R&D Manager, who will log them on our database and, if appropriate, include our participation in the study in any returns requested by the Department of Health or one of its agents.

I would like to take this opportunity to remind you that Ealing Hospital NHS Trust manages all research in accordance with the requirements of the Research Governance Framework. As a researcher working in the Trust you must comply with all reporting requirements, systems and duties of action put in place by the Trust to deliver research governance and any other applicable legislation such the Data Protection Act 1998 and Caldicott Principles.

If the R&D Office can be of any further assistance please do not hesitate to contact myself or Dr Alan Warnes (R&D Manager) on the above number.

Yours sincerely,



Kevin Baynes
R&D Director

Cc- Ms Stephanie Griffths, Consultant Physiotherapist, Ealing Community Services

Approved Working Documents (For R&D Office Reference)

Document Type	Version	Date
Protocol	Assignment 2	07/09/2012
Physiotherapy Staff Survey	Version 04	08/10/2012

West London Primary Care Research Consortium

NHS Brent

Wembley Centre for Health & Care
116 Chaplin Road
Wembley
Middlesex
HA0 4UZ

Tel: 020 8795 6730/5
Fax: 020 8795 6737

Email: ricky.banarsee@brentpct.nhs.uk

Mr Alexander Daulat
Ealing Hospital NHS Trust (Community Services)
Clayponds Hospital
Sterling Place, South Ealing
London W5 4RN

20th February 2013

Dear Alex

Project Title:	Developing an alternative group physiotherapy programme for the management of chronic low back pain in Primary Care
REC	Not required for Stage 1
Sponsor	Middlesex University IRAS 109185

The West London Primary Care Consortium (for Research and Innovation) is the lead Research Governance (RG) office for North West London Independent Contractors/practices and the Central London Community Healthcare NHS Trust.

NHS RG assurance for the above research has been given on the basis described in the application form and supporting documentation for Stage 1 of the above study; subject to the conditions listed below and overleaf. Assurance is given on the understanding that the study is conducted in accordance with the Research Governance Framework and NHS Trust policies and procedures.

This permission covers any independent contractor within the above trust(s) but we request that you inform us of all the independent contractors/ practices taking part in the study within those trust(s).

Please note that the ultimate decision as to whether to take part in a study lies with the Independent Contractor, even if the study has received our assurance.

Please note that this does not commit the trusts to ongoing financial support for any intervention trialled. The trusts do not indemnify the research site, the host organisation or the participants in relation to the conduct or management of the research; the responsibility for indemnity arrangements rests with the study sponsor.

Please do not hesitate to contact Sylvia Westrup, (s.westrup@imperial.ac.uk) if you require further assistance.

With kind regards

Ricky Banarsee
Director WeLReN/Applied Research Unit at Brent PCT

Sent via email
alex.daulat@nhs.net;
stephaniegriffiths@nhs.net; kay@prphysio.co.uk; rcphysiocentre@gmail.com

West London
Primary Care
Research Consortium

The above study is approved subject to the following conditions:

There will be no call upon NHS resources other than any mentioned in the application and agreed with the site.

The research sponsor or the CI or the local PI at the research site may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The Research Office should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D office should be notified within the same time frame as the REC and any other regulatory bodies.

The Sponsor organisation must have in place procedures for detecting and dealing with misconduct and fraud. All researchers must be aware of these procedures and any instances must be reported to us. Alternatively suspected incidents may be reported, in confidence, directly to us.

Unless the Study Team requests otherwise, we will include details of this project on our database.

We will ask the Study Team to send us a copy of the final report and/or a summary of the findings.

Only members of the clinical care team can access patient identifiable information without the patient's consent. Researchers are not part of the clinical care team and therefore require a patient's consent for access to their confidential data.

You must comply with current information governance (IG) requirements.

GP indemnity for routine clinical practice is covered by GP Medical Defence Union arrangements. If the PI is a GP, s/he must have notified her/his Medical Defence Union to inform them that s/he is conducting a clinical trial.

For a clinical trial, the PI must have attended a Good Clinical Practice study day within the past 2 years.

Ealing Hospital NHS
NHS Trust

Research and Development Office
R&D Office
Level 1
Ealing Hospital
Uxbridge Road,
Southall
Middlesex
UB1 3HW
Direct line : 0208 967 5000 ext 3468
Fax 0208 967 5215

31/01/2014

Alex Daulat
Extended Scope Practitioner
Ealing Hospital
Uxbridge Road
Southall
Middlesex

Dear Alex

Research Project: An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care (stage 2 to original study) R&D Ref: RDE13/015

Thank you for the documentation with details of the above project you are requesting to carry out at Ealing Hospital NHS Trust.

I have looked at the protocol and note that you have discussed the implications of the project with others whose services the project may have an impact upon. I am happy to give the project approval to be carried out at Ealing Hospital NHS Trust. *It is recommended that any physiotherapist obtaining informed consent for the purposes of the study should be appropriately trained, experienced and recorded in a study delegation log.*

Your project details will be passed onto Dr Alan Warnes, R&D Manager, who will log them on our database and, if appropriate, include our participation in the study in any returns requested by the Department of Health or one of its agents.

I would like to take this opportunity to remind you that Ealing Hospital NHS Trust manages all research in accordance with the requirements of the Research Governance Framework. As a researcher working in the Trust you must comply with all reporting requirements, systems and duties of action put in place by the Trust to deliver research governance.

If the R&D Office can be of any further assistance please do not hesitate to contact myself or Dr Alan Warnes (R&D Manager) on the above number.

Yours sincerely,

Dr Kevin Baynes
R&D Director

Cc- Dr Gordon Weller, Middlesex University (Sponsor)

Appendix 15
SOMM Conference Abstract

THE SOCIETY OF MUSCULOSKELETAL MEDICINE

putting theory into practice

This is certify that

Alex Daulat

Was an author of a

POSTER PRESENTATION

of the abstract entitled

A physiotherapy survey to investigate the use of exercise therapy and group exercise programmes for management of non-specific chronic low back pain

at the SOMM Conference held on 15 March 2014 at the Radisson Blu Portman Hotel, London.

Appendix 16
Ethics: Study Approval Letter

NHS
Health Research Authority
NRES Committee London - Riverside
Bristol Research Ethics Committee Centre
Level 3 Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT

Telephone: 01173421339
Facsimile: 01173420445

10 December 2013

Mr John Alexander Daulat
Extended Scope Practitioner in Physiotherapy
Ealing Hospital NHS Trust
Community Musculoskeletal Specialist Service
Clayponds Hospital
Sterling Place, South Ealing
W5 4RN

Dear Mr Daulat

Study title:	**An alternative group physiotherapy programme for the management of chronic low back pain in Primary Care**
REC reference:	**13/LO/1776**
Protocol number:	**n/a**
IRAS project ID:	**134763**

The Research Ethics Committee reviewed the above application at the meeting held on 02 December 2013. Thank you to yourself and Dr Margaret Volante for attending to discuss the application.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Miss Tina Cavaliere, nrescommittee.london-riverside@nhs.net.

Ethical opinion

1. The Committee asked you to explain the results of the physiotherapy survey conducted in phase 1 of the study.

You explained that 15 physiotherapy departments were surveyed and the results revealed that 33% gave visual exercises and none of the groups received manual therapy. The Back to Fit

programme used by 50% of the departments showed a low success rate.

2. The Committee asked how you designed your physiotherapy programme.

You explained that you used your own clinical experience and had researched similar types of programmes. You added that the results of the physiotherapy survey also helped you in designing the programme.

3. The Committee asked you to explain how a pregnant women's unborn child may be affected if she takes part in the study.

You replied that pregnant women who are in their first trimester are advised not to take part in physiotherapy exercises and this is standard procedure.

4. The Committee responded to say that the PIS should be re-worded under the section heading "What are the possible disadvantages and risks of taking part?" so that it states clearly that pregnant women in their first trimester are advised not to undertake any physiotherapy exercises and therefore they will be excluded from taking part in the study. The Committee felt that the current wording might be alarming to someone who becomes pregnant during the course of the study.

You agreed to amend the PIS accordingly.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1) **Changes to the Participant Information Sheet (PIS):**

a) Please state in the PIS that pregnant women in their first trimester are advised not to undertake any physiotherapy exercises as part of their standard care and therefore they will be excluded from taking part in the study. Remove the sentence about physiotherapy causing harm to the unborn child.

The Committee nominated the REC Manager to be the point of contact should further clarification be sought from the application upon receipt of the decision letter.

You must notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/LO/1776	**Please quote this number on all correspondence**

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

Yours sincerely

pp.

Dr Sabita Uthaya
Chair

Email: nrescommittee.london-riverside@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Dr Gordon Weller*
MR SIMON LEWIS, Ealing Hospital NHS Trust

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering Letter		02 November 2013
Evidence of insurance or indemnity	Indemnity Insurance Cover - Zurich	12 September 2013
Evidence of insurance or indemnity	Indeminity Insurance Cover - Middlesex Univeristy	01 July 2013
GP/Consultant Information Sheets	GP information sheet. Version 3	07 July 2013
Investigator CV	Mr Alex Daulat. Version 4	08 October 2013
Investigator CV	Dr Volante	25 October 2012
Investigator CV	Dr Kerr	
Letter from Sponsor	Sponsor"s letter	28 October 2013
Letter from Statistician		12 September 2013
Letter of invitation to participant	2 - Focus Groups	07 July 2013
Other: Risk Assessment Form	1	06 August 2012
Other: Patient Experience Survey	3	08 October 2013
Other: Consent form for focus groups	2	07 July 2013
Other: RCT: Referrers' guide	1	07 July 2013
Other: Group Programmes - checklist	1	07 July 2013
Other: Functional Rating Index Scoring Protocols		
Other: Functional Rating Index - email to Mr Daulat		13 March 2012
Other: Back to fitness crib sheets		11 October 2012
Other: Medical and Professional Liability - Graybrook		
Other: EQ-5D email to Mr Daulat		13 March 2012

Other: BTFP: Therapists' Guide	1	07 July 2013
Other: SRP:Therapists' Guide	1	07 July 2013
Other: Randomisation Chart	1	07 July 2013
Other: Draft focus group questions	1	08 September 2013
Other: EQ-5D-5L Scoring		
Other: PSRS - Partcipant Satisfaction Reporting Scale		
Other: PSRS - Scoring		
Other: PSRS - email to Mr Daulat		16 March 2012
Other: Keele Start Back Screening Tool		
Other: Keele Start Back Scoring System		
Other: Email from Mr Daulat to Mr Hill		24 December 2012
Other: Exercise Sheet		11 October 2012
Other: Riverside REC Unfavourable Opinion Letter		18 January 2013
Participant Consent Form: Patient Consent form	3	07 July 2013
Participant Information Sheet	3	07 July 2013
Protocol	3	14 September 2013
Questionnaire: Validated questionnaire - Functional Rating Index		
Questionnaire: EQ-5D -5L Health Questionnaire	2	
REC application	3.5	30 October 2013
Referees or other scientific critique report	Programme Approval Summary	08 October 2013

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

There were no declarations of interest.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments

NRES Committee London - Riverside

Attendance at Committee meeting on 02 December 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Mark Atkins	Microbiologist	Yes	
Ms Anna Bischler	Pharmacist	Yes	
Mr John Clifford	Lawyer	Yes	
Dr Julian Collinson	Consultant Cardiologist	Yes	
Ms Stephanie Ellis	Former Civil Servant	Yes	
Dr Matthew Hyde	Research Scientist	No	
Dr Margaret Jones	General Practitioner	Yes	
Ms Alexandra Mancini	Modern Matron	No	
Ms Fanny Mitchell	Retired	Yes	
Dr Karen Phekoo	Researcher	No	
Mr Kamen Shoylev	Lawyer	No	
Ms Fiona Slomovic	Advocacy and Mediation Consultant	No	
Mrs Dinah Smith	Head Teacher	Yes	
Dr Sabita Uthaya	Consultant Neonatologist	Yes	
Ms Julia Williams	Senior Producer	No	
Dr Daniel Wood	Clinical Psychologist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Tina Cavaliere	Coordinator

Written comments received from:

Name	*Position*
Ms Fanny Mitchell	Retired
Ms Julia Williams	Senior Producer

Appendix 17
RCT Referrers Guide

Randomised Controlled Study
Guidelines for Referring Therapist

A randomised control study is being conducted in our service which aims to compare an alternative group physiotherapy programme (Spinal Rehabilitation Programme- SRP) with a standard group programme (Back to Fitness- BTFP) used at the Trust. Participants will be recruited over a one year period and randomised to each group.

Patient Selection, consent and randomisation

Step 1

Following the initial assessment to decide whether your patient is appropriate for the study please check the inclusion and exclusion criteria on pages 1-3.

Inclusion criteria:

1. Male and female subjects between ages of 20-75 years. This is a standard adult age range used in CLBP studies investigating the effect of exercise and /or manual therapy (Bronfort et al, 2011; Lewis et al, 2008).
2. CLBP for >3/12 (Airaksinen et al., 2004).
3. Motivated and willing to attend both the physiotherapy programmes.

Exclusion criteria:

1. Cardiac, respiratory, kidney, blood pressure or blood circulatory problems which may prevent participation in any strenuous exercise programme (Geisser et al, 2005).
2. Recent spinal surgery within one year which may affect the ability to participate in group exercise programmes. These patients are usually excluded from CLBP studies (Harts et al, 2008; Kell and Asmundson, 2009).
3. Acute fracture or recent trauma require specialist management and would not be suitable for group rehabilitation programmes (Luk et al, 2010).
4. Inflammatory or infectious diseases of the spine.
5. Metabolic or bone disease such as osteoporosis.

Both 4 and 5 conditions are a contraindication to physiotherapy and would require further investigation and onward referral (Ferreira et al, 2007).

6. Neurological signs or symptoms such as sensation loss in a specific dermatome, myotomal muscle weakness or abnormal reflexes. These neurological deficits may require further investigation or monitoring and would not be appropriate for an extensive exercise programme or manual therapy (Bronfort et al, 2011; Cecchi et al, 2010).
7. Advanced rheumatoid arthritis or uncontrolled diabetes. These conditions are contraindicated to manual therapy and exercise programmes (Maitland, 1999). These conditions would also require specialist review.
8. Subjects who were pregnant or attempting to become pregnant (Mannion et al, 2001).
9. Chronic pain syndrome patients with severe physical or psychological impairment (Dufour et al, 2010). This includes the group of patients

presenting with widespread sensory hypersensitivity mediated by central pain mechanisms. These patients are unlikely to respond to exercise and/or manual therapy and may need to be referred for multimodal pain management programmes or pain clinic (Schafer et al, 2009).

10. Participated in a regular exercise programme or had previous physiotherapy or any other treatment within the last six months.
11. Any spinal condition requiring further investigation or on-ward referral and not likely to respond to conservative treatment.

Step 2

Provide the patient with a participant information leaflet (Located on the shared drive under, MSK then classes and Alex's research folder) regarding the study and allow them a minimum of seven days to decide whether they wish to participate in the study. If they do not wish to participate then they will continue with their physiotherapy treatment as appropriate. Patients not participating in the study can still be referred to either the SRP or BTFP.

Step 3

If the patient has agreed to participate in the study, then they must read and sign the consent form (Located on the shared drive under classes and Alex's research folder). They will keep a copy and the other copy will be sent by internal mail to the researcher, Alex Daulat at Greenford Green clinic, Wadham Gardens, UB6 0BP. **Consent to participating in the study must also be recorded in the patient's RIO notes.**

Step 4

Administer the Start Back Screening Tool (SBT) to all participants prior to randomization (Located on the shared drive under classes and Alex's research folder). Record from the SBT on RIO notes and on the checklist form whether low, medium or high risk.

Step 5

Randomly allocate the patient to the experimental (SRP) and Control Group (BTFP). Please refer to the randomisation chart located on the shared drive under classes and Alex's research folder.

Process after Randomisation

If the patient is randomised to the SRP, please refer to the guidelines on page 4 below. If the patient is referred to the BTFP, please refer to the guidelines on page 5. Indicate on the checklist form using the box provided which group programme the participant has been randomised to. **Remember both group programmes in this study will take place at Ealing Hospital only.**

Group A: SRP

1) For the SRP, prescribe an individualised programme and home exercises from the list on the shared drive. This exercise programme should be multimodal and functional where possible containing four categories of exercise which are evidence based. These are:

Upper quadrant (Upper limb strengthening)

Lower quadrant (Lower limb strengthening)

Core strengthening (Trunk muscles)

Stretches/Lumbar mobility

Therapists should prescribe between 8-10 exercises and at least one exercise from each category should be prescribed. For all exercises assess which level is appropriate for the patient to start with and this will be progressed in the programme. Each exercise has a code which can be recorded in the patient's RIO notes.

2) Decide if the patient requires manual therapy and start this either at the first session or on your next follow-up session. You will see the patient up to two times including the

initial assessment and then refer on to the programme. Document on the checklist form if manual therapy is indicated and identify which technique.

3) Complete the checklist form and write down up to three programme goals on this form. The checklist form should be attached to the front of the exercise sheets. Patients should also be given the patient information leaflet for the SRP located on the shared drive under classes and Alex's research folder.

Group B: BTFP

1) Provide the patient with the Back to Fitness Exercise Sheet (found on the shared drive under Alex's research folder).
2) Complete the checklist form and write down up to three programme goals on this form. The checklist form should be attached to the front of the Back to Fitness exercise sheets. Patients should also be given the patient information leaflet for the BTFP located on the shared drive under classes and Alex's research folder.

All patients participating in the study should be encouraged to continue with their prescribed exercises after their treatment.

Patients not participating in the study can still be referred to either programme. Generally, those patients requiring less one to one input and in the low or medium Start Back category may be more appropriate for the BTFP.

ELECTRONIC RECORDS PROCEDURE FOR BOTH PROGRAMMES

1. Discharge the patient from your clinic and inform GP/referrer by discharge letter
2. The patient then must phone to make an appointment. If they do not contact to make an appointment within 3 weeks, they will be discharged.

Step by Step guide to Creating referral for Group Programmes for therapist or admin teams

Entry exit from first ICON in RIO diary

↓↓

Fill in patient RIO no which you want to refer

↓↓

In the bottom of that Screen you can find Create New Referral

↓↓

Click on create new Referral

↓↓

Referral date time: fill the date

↓↓

Speciality: Physiotherapy

↓↓

Care setting: Community and clinic

↓↓

Referral Source: Physiotherapy

↓↓

Referrer: Type your name

↓↓

Referral Reason: Rehab

↓↓

Team Referred to:
EH Spinal Rehab Programme or
EH Back to Fitness Programme

↓↓

HCP Referred to: None

↓↓

Referral Urgency: 0-1

↓↓

Administrative: NHS patients including overseas visitors

↓↓

Referral comment: If required

↓↓

Received Date:

↓↓

Accepted Date:

↓↓

Save Referral

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3. Give patient their exercise leaflet with the checklist form and programme goals attached to the front. All exercises **must** be recorded in clinical electronic records for the SRP. Ensure that goals are added to the checklist. **NB** This process will replace the need for a referral form to the programmes. Therefore, the patient **must** be told to bring the checklist with their exercises and the referrer **must** list the chosen exercises and goals in the electronic notes, in case the patient forgets to bring the exercise leaflet to the class (NOT REQUIRED FOR THE BTFP). Please also tick if an interpreter is needed, with the language.
4. Email the admin team at Ealing Hospital with the RiO number and confirmation of the programme (NB the referral must be discharged before this can be completed) so that they can create the referral to the programme on RiO. **Ensure** that you inform the admin team if an **interpreter** is required as this information needs to be added to the comment against the patient's name in the Interactive Worksheet. The subject heading should be ***'Date' Programme Referral Interpreter required.*** Only add Interpreter required if that is the case. The admin team should create referrals within two days of email receipt, where possible, hence the need for the date to be in the subject.

NB The email address for the admin team at Ealing Hospital is ehn-tr.ersadmin@nhs.net

There may be some circumstances when the patient may decide to withdraw from the study without giving a reason. In this situation, they will still be offered treatment within the group programmes or individual physiotherapy as appropriate.

If participants experience any adverse reactions or change to their clinical status; they should be monitored and provided with appropriate treatment as necessary. If there is a significant deterioration to their symptoms, that patient might be removed from the study and referred back to the referring physiotherapist for further assessment and appropriate management.

Once the patient has completed their group programmes, they will be discharged by the programme therapist. The chief Investigator will contact all participants by letter regarding participation in the focus groups.

Contact for the chief investigator for advice or further information

For further information or if you have any questions I am happy to discuss it with you:

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Appendix 18
Certificate of Attendance

Middlesex University London

Certificate of attendance

Alex Daulat

Has attended the

Research Student Summer Conference 2015

Prof Hemda Garelick, Conference Chair

Hemda Garelick